



# 廣東東陽光藥業股份有限公司

SUNSHINE LAKE PHARMA CO., LTD.

(A joint stock company incorporated in the People's Republic of China with limited liability)

STOCK CODE: 6887



## LISTING BY WAY OF INTRODUCTION

Sole Sponsor



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## IMPORTANT

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**IMPORTANT: If you are in any doubt about any of the contents of this Listing Document, you should obtain independent professional advice.**



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**廣東東陽光藥業股份有限公司**

*(A joint stock company incorporated in the People's Republic of China with limited liability)*

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**LISTING BY WAY OF INTRODUCTION OF H SHARES OF  
SUNSHINE LAKE PHARMA CO., LTD.  
ON THE MAIN BOARD OF  
THE STOCK EXCHANGE OF HONG KONG LIMITED**

**Nominal Value RMB1.00 each**

*Sole Sponsor*



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This Listing Document is published in connection with the Introduction on the Main Board of the Stock Exchange and contains particulars given in compliance with the Securities and Futures (Stock Market Listing) Rules (Chapter 571V of the Laws of Hong Kong) and the Listing Rules solely for the purpose of giving information with regard to the Company and its subsidiaries.

**This Listing Document does not constitute an offer of, nor is it calculated to invite offers for, shares or other securities of the Company, nor have any such shares or other securities been allotted with a view to any of them being offered for sale to or subscription by the public.**

Your attention is drawn to the section headed "Risk Factors" of this Listing Document.

Information regarding the proposed arrangements for the listing and registration of, and for dealings and settlement of dealings in, the H Shares following the Introduction is set out in the section headed "Information about this Listing Document and the Introduction" of this Listing Document.

The H Shares have not been and will not be registered under the U.S. Securities Act or any state securities laws of the United States and will be issued in reliance on the exemption from the registration requirements of the U.S. Securities Act, and in reliance on applicable exemptions under U.S. state securities laws.

June 30, 2025

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## EXPECTED TIMETABLE

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Latest time for lodging transfers of HEC CJ Pharm

H Shares in order to be entitled to attend and

vote at the HEC CJ Pharm EGM and the HEC

CJ Pharm H Shareholders' Class Meeting . . . . . 4:30 p.m. on  
Thursday, July 17, 2025

Closure of registers for transfers of HEC CJ

Pharm Shares for determination of the HEC CJ

Pharm Shareholders entitled to attend and vote

at the HEC CJ Pharm EGM and the HEC CJ

Pharm H Shareholders' Class Meeting . . . . . Friday, July 18, 2025 to  
Monday, July 21, 2025  
(both dates inclusive)

Latest time for lodging forms of proxy in respect of the:

HEC CJ Pharm EGM . . . . . 9:00 a.m. on  
Sunday, July 20, 2025

HEC CJ Pharm H Shareholders' Class Meeting . . . . . 9:30 a.m. on  
Sunday, July 20, 2025

Record date for HEC CJ Pharm Shareholders for

the HEC CJ Pharm EGM and the HEC CJ Pharm

H Shareholders for the HEC CJ Pharm H Shareholders'

Class Meeting . . . . . Monday, July 21, 2025

HEC CJ Pharm EGM . . . . . 9:00 a.m. on  
Monday, July 21, 2025

HEC CJ Pharm H Shareholders' Class Meeting . . . . . 9:30 a.m. on  
Monday, July 21, 2025  
or immediately after the conclusion of  
the HEC CJ Pharm EGM  
or any adjournment  
thereof on Monday, July 21, 2025

Announcement of the results of the HEC

CJ Pharm EGM and the HEC CJ Pharm

H Shareholders' Class Meeting published

on the Stock Exchange's website and HEC

CJ Pharm's website . . . . . by 7:00 p.m. on  
Monday, July 21, 2025

Expected date for all Conditions to

effectiveness to be satisfied<sup>(3)</sup> . . . . . Monday, July 21, 2025

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## EXPECTED TIMETABLE

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Announcement of the satisfaction of all Conditions to effectiveness, last day for dealings in HEC CJ Pharm H Shares and expected date of withdrawal of listing of HEC CJ Pharm H Shares <sup>(3)</sup>	Monday, July 21, 2025
Resumption of registers for transfer of HEC CJ Pharm Shares	Tuesday, July 22, 2025
Each of the Company and HEC CJ Pharm notifies its creditors and makes a public announcement of the Merger pursuant to the PRC Company Law	within 10 days (for notice to creditors) and 30 days (for the announcement) following the HEC CJ Pharm EGM and the HEC CJ Pharm H Shareholders' Class Meeting
Expected latest time for dealings in HEC CJ Pharm H Shares on the Stock Exchange	4:10 p.m. on Tuesday, July 29, 2025
Latest time for lodging transfers of HEC CJ Pharm H Shares in order to be entitled to receive H Shares	4:30 p.m. on Friday, August 1, 2025
Closure of registers of members of HEC CJ Pharm	from Monday, August 4, 2025 onwards
Share Exchange Record Date	Monday, August 4, 2025
Expected date and time of withdrawal of listing of HEC CJ Pharm H Shares	4:00 p.m. on Tuesday, August 5, 2025
H Shares certificates to be dispatched on <sup>(3)</sup>	Wednesday, August 6, 2025
Announcement that all Conditions to implementation are satisfied (or waived, as applicable) <sup>(4)</sup>	Thursday, August 7, 2025

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## EXPECTED TIMETABLE

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Latest date for the Share Exchange .....Thursday, August 7, 2025

Dealings in the H Shares on the Stock

Exchange expected to commence at .....9:00 a.m. on  
Thursday, August 7, 2025

End of the period during which creditors may  
request the Company and HEC CJ Pharm to  
pay off their respective indebtedness or provide  
guarantees .....

within 30 days after the  
receipt of notice by creditors  
or 45 days after the issue of  
announcement to creditors  
if the aforesaid notice has  
not been received by creditors  
(whichever is the latest)

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*Notes:*

- (1) The timetable may be subject to change. Further announcement(s) will be made in the event that there is any change.
- (2) Unless otherwise expressly stated, all references in this Listing Document to times and dates are references to Hong Kong times and dates.
- (3) The H Share certificates are expected to be despatched to Share Exchange Shareholders on Wednesday, August 6, 2025 after the Stock Exchange grants its approval for the Listing. The H Share certificates will not become valid unless the formal letter of approval for the Listing is obtained, and the Introduction has become effective. In the event that the approval for the Listing is not obtained on Monday, August 4, 2025, the H Share certificates will not be despatched on Wednesday, August 6, 2025, dealings in the H Shares on the Stock Exchange will not commence on Thursday, August 7, 2025 and the listing of the HEC CJ Pharm H Shares will also not be withdrawn on Tuesday, August 5, 2025. In such event, we will make an announcement of the above and of a revised timetable as soon as practicable. Investors who trade in the H Shares prior to the receipt of the H Share certificates or prior to the H Share certificates becoming valid do so entirely at their own risk.
- (4) The Company and HEC CJ Pharm will jointly publish announcement(s) when or as soon as reasonably practicable after all Conditions to effectiveness of the Merger Agreement have been satisfied and the Conditions to implementation of the Merger have been satisfied or waived, as appropriate.

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*This Listing Document is issued by our Company solely in connection with the Introduction and does not constitute an offer to sell or a solicitation of an offer to subscribe for or buy any security. This Listing Document may not be used for the purpose of, and does not constitute, an offer to sell or a solicitation of an offer to subscribe for or buy any security in any other jurisdiction or in any other circumstances. No action has been taken to permit a public offering of our Shares or the distribution of this Listing Document in any jurisdiction other than Hong Kong.*

*You should rely only on the information contained in this Listing Document, the Composite Document and the public filings made by us and/or HEC CJ Pharm in relation to the Introduction and the Privatization to make your investment decision. We have not authorized anyone to provide you with information that is different from what is contained therein. Any information or representation not included in this Listing Document must not be relied on by you as having been authorized by us, the Sole Sponsor, any of our or their respective directors or advisors, or any other person or party involved in the Introduction and the Privatization. Information contained on our website, located at [www.hecpharm.com](http://www.hecpharm.com), does not form part of this Listing Document.*

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## SUMMARY

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*This summary aims to give you an overview of the information contained in this Listing Document. As it is a summary, it does not contain all the information that may be important to you and all content of such information is subject to the full text of this Listing Document. It should be read in conjunction with the full text of this Listing Document. You should read this Listing Document in its entirety before you decide to invest in our Shares.*

*There are risks associated with any investment. Some of the particular risks in investing in our Shares are set out in “Risk Factors” beginning on page 65 of this Listing Document. You should read that section carefully before you decide to invest in our Shares.*

## OVERVIEW

We are a vertically integrated pharmaceutical company engaging in research and development, production and commercialization of pharmaceutical products. We strategically focus on therapeutic areas of infectious diseases, chronic diseases and oncology. For the years ended December 31, 2022, 2023 and 2024, our revenue from sales of anti-infective drugs was RMB3,242.5 million, RMB5,745.8 million and RMB2,797.6 million, respectively, accounting for 85.0%, 90.0% and 69.6% of our total revenue for the same periods, respectively. We also generated revenue from sales of chronic disease treatment drugs in the amount of RMB517.3 million, RMB580.7 million and RMB1,067.7 million for the years ended December 31, 2022, 2023 and 2024, respectively, accounting for 13.6%, 9.1%, 26.6% of our total revenue for the same period, respectively. As of the Latest Practicable Date, our oncology drug candidates were still at various clinical trial stages.

During the Track Record Period, we manufactured and mainly sold our drugs in China. As of the Latest Practicable Date, we had sold 48 drugs in China and 23 drugs in overseas markets. In 2022, 2023 and 2024, our revenue from the PRC was RMB3,753.2 million, RMB6,335.9 million and RMB3,880.5 million, respectively, representing 98.4%, 99.2% and 96.6% of our total revenue, respectively. During the Track Record Period, we also conducted R&D collaboration projects with overseas partners. In 2022, 2023 and 2024, our overseas revenue from sales of drugs and license fee generated from overseas R&D collaboration projects was RMB60.4 million, RMB49.7 million and RMB138.4 million, respectively, representing 1.6%, 0.8% and 3.4% of our total revenue, respectively. Please see “Business — Research and Development — Collaboration and Licensing Agreements” for further details.



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## SUMMARY

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### **Our Major Drugs**

#### ***Infectious Diseases***

Our existing anti-infective product portfolio mainly includes (i) our top-selling product, Kewei (oseltamivir phosphate), for the treatment of influenza (in particular, Type A and Type B influenza viruses), (ii) one innovative drug developed in-house, Dongweien (emitasvir phosphate), for the treatment of hepatitis C, and (iii) three generic drugs for the treatment of infections caused by sensitive bacteria, namely Clarithromycin, Levofloxacin and Moxifloxacin Hydrochloride.

In 2022, 2023 and 2024, our oseltamivir phosphate drugs, including Kewei, our top-selling product, accounted for 81.2%, 86.9% and 64.2% of our revenue for the years ended December 31, 2022, 2023 and 2024, respectively. Our revenue fluctuated during the Track Record Period due to the fluctuation of revenue generated from the sales of oseltamivir phosphate drugs during the Track Record Period. Please see “— Summary Financial Information — Revenue” for more details. We were among the first few PRC pharmaceutical companies to secure the right to use key patents relating to the oseltamivir phosphate, granting us a first-mover advantage in the manufacturing and selling Oseltamivir Phosphate Capsules in the PRC. Our licenses under the Oseltamivir Phosphate Licensing Agreement cover several key patents relating to oseltamivir phosphate compound and oseltamivir phosphate synthetic process for manufacturing oseltamivir phosphate API and oseltamivir phosphate capsules. The key patents relating to oseltamivir phosphate compound began to expire in August 2017, with the final patent relating to oseltamivir phosphate synthetic process which is used in the manufacturing of oseltamivir phosphate products having expired in March 2024. Since 2017, other pharmaceutical companies have been producing and selling oseltamivir phosphate capsule products by using different oseltamivir phosphate manufacturing process. As a result, our oseltamivir phosphate capsule drug has been competing with other oseltamivir phosphate producers since 2017.

We believe the expiry of the oseltamivir phosphate patents starting from 2017 has no material impact on our business, as the average selling prices for both oseltamivir phosphate granules and capsules remained stable during the period from 2016 to 2019 (which is the period from one year before to two years after the year when the patents in connection with oseltamivir phosphate started to expire (2017)). We believe that the patent expiry in March 2024 doesn't have a major impact on the competitive landscape for oseltamivir phosphate capsule as it is not a patent necessary for the other oseltamivir phosphate producers to produce oseltamivir phosphate and the number of oseltamivir phosphate producers in the PRC remained stable before and after the expiry of such patent in March 2024. Please see “Business — Our Productions and Product Candidates — Infectious Disease — Influenza — Commercialized Product — Kewei (Oseltamivir Phosphate Granules/Capsules) 可威® (磷酸奥司他韦颗粒/胶囊)” for details. Our Kewei also faces increasingly intense competition from other types of anti-influenza drugs and other oseltamivir phosphate manufacturers and such competition had negatively affected our revenue generated from oseltamivir phosphate products in 2024 as compared to 2023. Please see “Risk Factors — Risks Relating to Our Business and Industries

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## SUMMARY

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— We operate in a highly-competitive environment, and we may not be able to compete effectively against our competitors selling competing drugs, which could subject us to the pressure of price reduction and adversely affect our operations, revenue and business prospects” for details.

### *Chronic Diseases*

Our commercialized chronic disease treatment drugs primarily focuses on the treatment of diabetes, hyperuricemia, hypertension and stomach acid related disease, including five insulin products and four major generic drugs. In 2022, 2023 and 2024, our revenue generated from sales of chronic disease treatment drugs was RMB517.3 million, RMB580.7 million and RMB1,067.7 million, accounting for 13.6%, 9.1% and 26.6% of our total revenue for the same periods, respectively. For details of our five insulin products, please see “Business — Diabetes — Commercialized Products — Insulins in China.” For details of the four major generic drugs, namely Benzbromarone, Telmisartan, Olmesartan Medoxomil and Esomeprazole Magnesium, for the treatment of hyperuricemia, hypertension and stomach acid related disease in the therapeutic areas of chronic diseases that we sold during the Track Record Period, please see “Business — Other Commercialized Products for Chronic Diseases.”

### **Research and Development**

With over two decades of experience since our inception in 2003, we have built independent research and development platforms. We have developed comprehensive and integrated in-house research and development capabilities. We have more than 1,100 research and development personnels which consist of scientists with work experience gained in multinational pharmaceutical companies and pharmaceutical talents with rich experience in research and development. Core members of the team, including Dr. Zhang Yingjun (張英俊博士), Dr. Gu Baohua (谷保華博士), Dr. Ye Qunrui (葉群瑞博士) and Dr. Cai Xiaoli (蔡曉莉醫學博士), have industry insights and drug research and development experience. Our research and development platforms cover the full cycle of the development of chemical drugs and biologics. We also possess advanced technologies such as small nucleic acid, ADC, PROTAC and specific antibody. Our strong in-house research and development capabilities have translated into a diverse and robust drug pipeline, and enable us to efficiently advance our drugs under development to commercialization. In particular, we are approved by the Ministry of Science and Technology of the PRC to establish a State Key Laboratory of Anti-Infective Drug Development due to our extensive pipeline of anti-infective drugs. As of the Latest Practicable Date, we had successfully launched three Class I innovative drugs, applied for launching one Class I innovative drug through our in-house research and development. In addition, we also collaborated with our business partners to fully develop the commercial potential of our drug candidates. For example, we entered into an exclusive license and commercialization agreement for HEC88473 with Apollo Therapeutics Group Limited in November 2024. Please see “Business — Research and Development — Collaboration and Licensing Agreements — Licensing Agreement with Apollo” for details. Our research and

## SUMMARY

development costs amounted to RMB791.6 million, RMB827.4 million, and RMB887.7 million for the years ended December 31, 2022, 2023 and 2024, accounting for 20.8%, 13.0%, and 22.1% of our total revenue, respectively.

### Sales, Marketing and Distribution

Our approach to generating demand for our products is based on two central strategies: promotional activities and strengthening and optimizing our distribution network. We promote our drugs primarily through our in-house sales and marketing team, which interacts with KOLs as well as other healthcare professionals through educational promotion activities. We believe our educational promotion activities enhance healthcare professionals' knowledge about the relevant therapeutic areas, as well as their understanding of the usage, clinical efficacy and other features of our products.

We sell our products primarily to GSP-certified third-party offline distributors, which distribute our products to hospitals, other medical institutions and pharmacies in the PRC. As of December 31, 2024, we have 1,884 employees engaged in our marketing and educational promotion activities, covering 32 provinces, cities and autonomous regions and nearly 300 prefecture-level cities in the PRC. As of December 31, 2024, we had 610 third-party distributors conducting sales, marketing and distribution activities within the PRC. Our GSP-certified third-party distributors are located throughout the PRC, which enables us to deepen our market penetration and expand our coverage of hospitals, pharmacies and other medical institutions throughout the PRC. We believe that this approach optimizes the allocation of our sales, marketing and distribution resources in an effective manner. Please see “Business — Sales, Marketing and Distribution” for details.

We have two types of distributors, namely (i) general distributors which are mainly responsible for distributing our products to hospitals and other medical institutions and, to a lesser extent, distributing our products other than Kewei to pharmacies in the geographic areas stipulated in the relevant distributorship agreements and (ii) our Kewei pharmacy distributors, which are mainly responsible for marketing and distributing our top-selling product, Kewei, to pharmacies in the PRC.

The table below sets forth a breakdown of our distribution revenue by each type of distributor during the Track Record Period:

	Year ended December 31,					
	2022		2023		2024	
	<i>RMB'000</i>	<i>% of total</i>	<i>RMB'000</i>	<i>% of total</i>	<i>RMB'000</i>	<i>% of total</i>
General Distributors . . . .	3,114,039	83.6	4,939,412	78.6	3,278,198	85.3
Kewei Pharmacy						
Distributors . . . . .	608,668	16.4	1,347,025	21.4	565,054	14.7
<b>Total . . . . .</b>	<b>3,722,707</b>	<b>100.0</b>	<b>6,286,437</b>	<b>100.0</b>	<b>3,843,252</b>	<b>100.0</b>

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## SUMMARY

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### Manufacturing

We have obtained GMP certifications from China, the United States and Europe for the production of our current drugs. Our Songshan Lake base has obtained GMP certifications from the United States, the European Union and China, including recently passing EU GMP audit conducted by National Office for Health and Social Affairs of Germany in November 2023, GMP inspection by the U.S. FDA in March 2024, and a GMP compliance check by the Guangdong Provincial Drug Administration in January 2025. Our Yidu production base obtained PRC GMP certification, and recently passed the inspection conducted by the U.S. FDA in May 2024.

Our production facilities are located in Dongguan and Yidu in China. We currently have four production facilities for the manufacturing of our drugs, including one in Songshan Lake Park, Dongguan and three in Yidu (which also has API workshops). As of the Latest Practicable Date, our production facilities had a total GFA of approximately 301,160 square meters across 16 main production workshops, certain of which were still under construction.

Our Yidu Factory No. 1 is our primary production facility and currently produces our top-selling product, Kewei. The fluctuations in utilization rates generally reflect the fluctuations in our production volumes in line with the level of market demand for the corresponding products. For our Yidu Factory No. 1, the utilization rate for granules was 25.4%, 97.8%, 54.0% for 2022, 2023 and 2024, respectively and the utilization rate for capsules was 2.9%, 4.4% and 4.3% for 2022, 2023 and 2024, respectively. Please see “Business — Manufacturing — Production facilities” for details.

We own all of our production facilities and production lines in our production workshops. We have obtained all necessary governmental approvals, permits and licences, including GMP certifications for all of our production workshops and production lines in respect of the products that we currently produce. We also conduct regular inspection, repairs and maintenance to ensure that we comply with the GMP and relevant regulations. Please see “Business — Manufacturing” for details on our production facilities.

### OUR COMPETITIVE STRENGTHS

We believe that we have the following competitive strengths:

- We are a pharmaceutical company with vertically integrated capabilities in research and development, production and commercialization of pharmaceuticals, ranking first in the PRC in terms of the sales revenue of antiviral drugs for the past five years
- We have established a diverse and robust pipeline of innovative drug candidates with commercialization potential
- We have built comprehensive in-house research and development capabilities and have created comprehensive research and development platforms and technologies that cover the entire drug development cycle for both chemical drugs and biologics

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## SUMMARY

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- We have a strong nationwide sales and distribution network, and we work closely with our strategic partners worldwide to gradually increase our market penetration and brand influence in overseas markets
- We have an advanced production and supply chain system in China, and our production bases fully comply with international GMP standards
- We have an experienced team with a proven track record, which enables our business to grow in the future

### OUR STRATEGIES

We plan to implement the following strategies:

- We will focus on upgrading our key research and development platforms and further strengthening our diverse and robust drug pipeline in order to achieve sustainable growth
- With internationalization being our key development strategy, we plan to accelerate our expansion into global markets and strive to become an international pharmaceutical company
- We plan to strengthen our brand recognition and accelerate the commercialization of our approved pharmaceutical products
- We plan to attract and develop global pharmaceutical talents by establishing a human resources system that facilitates and incentivizes career development
- We plan to actively seek and work with global strategic partners

### OUR PRODUCTS AND PRODUCT CANDIDATES

#### Our Existing Product Portfolio

Driven by our in-house research and development, we have developed a diverse and robust product portfolio. As of the Latest Practicable Date, we had 150 approved drugs in various countries and regions, including China, the United States and Europe. As of the Latest Practicable Date, we had sold 48 drugs in the PRC and 23 drugs in overseas markets. Our existing product portfolio focuses on therapeutic areas of infectious diseases and chronic diseases, mainly comprising the following major products: (i) five major anti-infective drugs, including our top-selling product, Kewei (oseltamivir phosphate), one Class I innovative drug developed in-house, Dongweien (emtasvir phosphate), and three other major anti-infective generic drugs, and (ii) nine major products for the treatment of chronic diseases, including five insulin products and four other major chronic disease treatment generic drugs. Sales of our major products accounted for 92.6%, 95.3% and 84.9% of our total revenue for the years ended December 31, 2022, 2023 and 2024, respectively.

## SUMMARY

The following table sets forth the selected information of our major products in major dosage forms, which contributed an important portion of our revenue during the Track Record Period or was expected to contribute to our future growth, as of the Latest Practicable Date.

Therapeutic Area	Major Product	Classification	Indication	Major Dosage Form	Year of First Inclusion in NRDL <sup>(2)</sup>	Inclusion in National Essential Drug List (2018 Version) <sup>(3)</sup>			VBP Scheme <sup>(4)</sup>	In-house R&D/License-in Patents
						Yes	No <sup>(6)</sup>			
Infectious diseases . . . . .	Kewei (Osetamivir Phosphate Capsules/Granules)	Capsules: Class VI active chemical drug <sup>(1)</sup>	Influenza	Capsules: 75 mg per capsule	2006, Part B	Yes	No <sup>(6)</sup>			Licensed-in patents until the expiry of the relevant patents in March 2024
	可威® (磷酸奥司他韦胶囊/颗粒)	Granules: Class V active chemical drug <sup>(1)</sup>		Granules: 15 mg per sachet	2008, Part B	Yes		Provincial <sup>(7)</sup>		Licensing-in patents until the expiry of the patents in April 2026
	Dongwei'en (Emitasvir Phosphate Capsules) 東衛恩® (磷酸依米他韋膠囊)	Class I chemical drug – innovative drug	Hepatitis C	0.1g per capsule	2022, Part B	No	No			In-house R&D
	Clarithromycin Tablets (克拉霉素片) <sup>(5)</sup>	Class IV chemical drug – generic drug	Infections caused by clarithromycin-sensitive bacteria	250 mg/500 mg per tablet	2004, Part B	Yes		National: 2020-2023 Provincial <sup>(7)</sup>		In-house R&D
								2024: four provinces		
								2025: four provinces		

SUMMARY

Therapeutic Area	Major Product	Classification	Indication	Major Dosage Form	Year of First Inclusion in NRDL <sup>(2)</sup>	Inclusion in National Essential Drug List (2018 Version) <sup>(3)</sup>	VBP Scheme <sup>(4)</sup>	In-house R&D/License-in Patents
Chronic diseases . . . . .	Levofloxacin Tablets (左氧氟沙星片) <sup>(5)</sup>	Class IV chemical drug – generic drug	Infections caused by sensitive bacteria	250 mg/500 mg per tablet	2018, Part A	Yes	National: 2021-2024 Provincial <sup>(7)</sup> 2025: 17 provinces	In-house R&D
	Moxifloxacin Hydrochloride Tablets (鹽酸莫西沙星片) <sup>(5)</sup>	Class IV chemical drug – generic drug	Infections caused by sensitive bacteria	400 mg per tablet	2018, Part B	Yes	National: 2020-2023 Provincial <sup>(7)</sup> 2023: four provinces 2024: 20 provinces 2025: 20 provinces	In-house R&D
	Human Insulin Injection (Yibilin R) (人胰島素注射液 (宜必霖R))	Class III biological drug – biosimilar drug	Diabetes	3 ml: 300 IU (prefilled pen-type)	2020, Part A	Yes	National: 2021-2024; 2024-2027	In-house R&D
	Mixed Protamine Human Insulin Injection (30R) (Yibilin 30) (精蛋白人胰島素混合注射液(30R)(宜必霖30®))	Class III biological drug – biosimilar drug	Diabetes	3 ml: 300 IU (prefilled pen-type)	2023, Part A	Yes	National: 2024-2027	In-house R&D
	Insulin Glargine Injection (Yibigan) (甘精胰島素注射液(宜必甘®))	Class III biological drug – biosimilar drug	Diabetes	3 ml: 300 IU (prefilled pen-type)	2021, Part B	Yes	National: 2021-2024; 2024-2027	In-house R&D

## SUMMARY

Therapeutic Area	Major Product	Classification	Indication	Major Dosage Form	Year of First Inclusion in NRDL <sup>(2)</sup>	Inclusion in National Essential Drug List (2018 Version) <sup>(3)</sup>	VBP Scheme <sup>(4)</sup>	In-house R&D/License-in Patents
	Insulin Aspart Injection (門冬胰島素注射液)	Class III biological drug – biosimilar drug	Diabetes	3 ml: 300 IU (prefilled pen-type)	2022, Part B	No	National: 2024-2027	In-house R&D
	Insulin Aspart 30 Injection (門冬胰島素30注射液)	Class III biological drug – biosimilar drug	Diabetes	3 ml: 300 IU (prefilled pen-type)	2022, Part B	No	National: 2024-2027	In-house R&D
	Ertongshu (Benzbromarone Tablets) 爾同舒® (苯溴馬隆片)	Class IV active chemical drug <sup>(1)</sup>	Hyperuricemia	25 mg/50 mg per tablet	2004, Part B	Yes	Provincial <sup>(7)</sup> 2025: two provinces	In-house R&D
	Oumeining (Telmisartan Tablets) 歐美寧® (替米沙坦片)	Class II active chemical drug <sup>(1)</sup>	Hypertension	40 mg/80 mg per tablet	2004, Part B	No	National: 2021-2024 Provincial <sup>(7)</sup> 2025: eight provinces	In-house R&D
	Esomeprazole Magnesium Enteric-Coated Capsules (艾司奧美拉唑鎂腸溶膠囊)	Class III chemical drug – generic drug	Stomach acid related diseases	20 mg per capsule	2020, Part B	No	National: 2021-2024 Provincial <sup>(7)</sup> 2025: 17 provinces	In-house R&D
	Olmesartan Medoxomil Tablets (奧美沙坦酯片) <sup>(5)</sup>	Class IV chemical drug – generic drug	Hypertension	20 mg/40 mg per tablet	2019, Part B	No	National: 2020-2023 Provincial <sup>(7)</sup> 2023: four provinces 2024: 22 provinces 2025: 22 provinces	In-house R&D



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## SUMMARY

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*Notes:*

- (1) This drug was registered before the implementation of the new registration classification of chemical drugs and its classification remains the same upon its re-registration.
- (2) The NRDL comprises Part A and Part B. Patients purchasing pharmaceuticals included in Part A of the NRDL are entitled to reimbursement of the entire amount of the purchase price, while patients purchasing pharmaceuticals included in Part B of the NRDL are required to pay a deductible amount and obtain reimbursement for the remainder of the purchase price. The amount of the deductible differs from region to region in the PRC. The market demand for our drugs is sensitive to the coverage of the NRDL. Please see “Risk Factors — Risks Relating to Our Business and Industries — If our products are removed or excluded from national, provincial or other government sponsored medical insurance programs or the National Essential Drug List, our operation, revenue and business prospects in relation to the affected products could be materially and adversely affected.”
- (3) The current version of National Essential Drug List is promulgated by the NHC and National Administration of Traditional Chinese Medicine pursuant to the Notice on the Issuance of National Essential Drug List (2018 Version) (關於印發《國家基本藥物目錄(2018 年版)》的通知) on September 30, 2018, which became effective on November 1, 2018. The National Essential Drug List is a list of essential medicines designated by the Chinese government to ensure equitable access to healthcare at fair prices. The market demand for our drugs is also sensitive to the coverage of the National Essential Drug List. Please see “Risk Factors — Risks Relating to Our Business and Industries — If our products are removed or excluded from national, provincial or other government sponsored medical insurance programs or the National Essential Drug List, our operation, revenue and business prospects in relation to the affected products could be materially and adversely affected.”
- (4) The VBP scheme aims to achieve a lower price of pharmaceuticals and medical devices center on medical products with mature, high-volume clinical usage and sufficient market competition through a competitive bidding process for large-volume procurement. The VBP scheme has been rolled out at both national and provincial levels. For details of the differences of the national and provincial VBP schemes, see “Regulatory Environment — Principal Regulatory Provisions — Laws and Regulations on Drug Supply — VBP of Drugs in “4+7 Cities” and Nationwide.”
- (5) This drug has also been sold overseas. For details of our sales overseas, see “Business — Sales, Marketing and Distribution — Sales Outside the PRC.”
- (6) We also sell oseltamivir phosphate capsules in 75 mg doses under the brand Yangjiantai (陽健泰®). Yangjiantai was approved for sale in China in 2022 and was included in the NRDL (Part B) and the National Essential Drug List in the same year. It was also included in the national VBP scheme in 2022 and the cycle is expected to end in 2025. We intend to submit bids for Yangjiantai to be included in the provincial VBP scheme after 2025. During the Track Record Period, Kewei accounted for 99.9%, 99.4% and 96.5% and Yangjiantai accounted for 0.1%, 0.5% and 3.4% of our total sales of oseltamivir phosphate for 2022, 2023 and 2024, respectively. We also sold a small amount of dry suspension form of oseltamivir phosphate and 30 mg and 45 mg unbranded oseltamivir phosphate capsules which in aggregate accounted for nil, 0.1% and 0.1% of our total sales of oseltamivir phosphate for 2022, 2023 and 2024, respectively. Given the relatively small revenue contribution from Yangjiantai and the fact that we do not plan to conduct large-scale marketing to promote the brand, we do not expect our overall financial and business performance will be significantly impacted by whether Yangjiantai is included in the national VBP scheme or not.
- (7) Represents the number of provinces that implemented the provincial VBP scheme on our products in the corresponding year, with the figure for 2025 reflecting the status as of the Latest Practicable Date.

## SUMMARY

The following table sets forth the sales of our major products, which contributed an important portion of our revenue during the Track Record Period or are expected to contribute to our future growth, in absolute amounts and as percentages of our total revenue for the periods indicated:

			Year ended December 31,					
Therapeutic area	Major products	Indication	2022		2023		2024	
(RMB in thousands, except for percentages)								
Anti-infective drugs . . . . .	Oseltamivir Phosphate <sup>(1)</sup>	Influenza	3,097,403	81.2%	5,546,118	86.9%	2,580,704	64.2%
	Clarithromycin	Infections caused by clarithromycin sensitive bacteria	52,293	1.4%	41,875	0.7%	43,146	1.1%
	Moxifloxacin Hydrochloride Tablets	Infections caused by sensitive bacteria	33,434	0.9%	47,516	0.7%	48,214	1.2%
	Emitasvir Phosphate Capsules	Hepatitis C	10,816	0.3%	40,665	0.6%	89,486	2.2%
	Levofloxacin Tablets	Infections caused by sensitive bacteria	25,771	0.7%	29,778	0.5%	27,566	0.7%
	Subtotal <sup>(3)</sup>		3,219,718	84.4%	5,705,952	89.4%	2,789,116	69.4%
Chronic disease treatment drugs . . . . .	Benzbromarone Tablets	Hyperuricemia	98,424	2.6%	94,968	1.5%	109,534	2.7%
	Esomeprazole Magnesium Enteric-Coated Capsules	Stomach acid related diseases	89,734	2.4%	92,274	1.5%	206,187	5.1%
	Telmisartan Tablets	Hypertension	62,922	1.6%	77,980	1.2%	110,281	2.7%
	Insulin Injections <sup>(2)</sup>	Diabetes	12,420	0.3%	69,449	1.1%	136,688	3.4%
	Olmesartan Medoxomil Tablets	Hypertension	44,433	1.2%	42,540	0.7%	59,405	1.5%
	Subtotal <sup>(4)</sup>		307,933	8.1%	377,211	5.9%	622,095	15.5%
Total major products			3,527,650	92.6%	6,083,163	95.4%	3,411,211	84.9%

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## SUMMARY

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*Note:*

- (1) Our oseltamivir phosphate products mainly include Kewei granule, Kewei capsule, Yangjiantai capsule products. For revenue generated by our main oseltamivir phosphate products, please refer to “Business — Sales, Marketing and Distribution — Our Oseltamivir Phosphate Products and the Reasons for the Fluctuation of the Sales of Our Oseltamivir Phosphate Products during the Track Record Period” for detail. During the Track Record Period, we also generated small amount of revenue from (i) the sales of dry suspension form of oseltamivir phosphate in the amount of nil, RMB6.0 million and RMB3.5 million for 2022, 2023 and 2024, respectively and (ii) the sales of 30 mg and 45 mg unbranded oseltamivir phosphate capsules which in aggregate generated revenue in the amount of nil, RMB763.5 thousands, RMB33.1 thousands for 2022, 2023 and 2024, respectively. The dry suspension form of oseltamivir phosphate and 30 mg and 45 mg unbranded oseltamivir phosphate capsules in aggregate accounted for nil, 0.1% and 0.1% of our total sales of oseltamivir phosphate for 2022, 2023 and 2024, respectively.
- (2) Our insulin products include (i) Human Insulin Injection, (ii) Mixed Protamine Human Insulin Injection (30R), (iii) Insulin Glargine Injection, (iv) Insulin Aspart Injection, and (v) Insulin Aspart 30 Injection. Mixed Protamine Human Insulin Injection (30R) was approved for sale in 2023 and we started generating revenue from its sales in 2024. For details of our five insulin products, please see “Business — Our Products and Product Candidates — Chronic Diseases — Diabetes — Commercialized Products — Insulins in China.”
- (3) In 2022, 2023 and 2024, our five major anti-infective products (Oseltamivir Phosphate, Clarithromycin, Moxifloxacin Hydrochloride Tablets, Emitasvir Phosphate Capsules and Levofloxacin Tablets) contributed 99.3%, 99.3% and 99.7% of our revenue from sales of anti-infective products for the same periods, respectively. The remaining revenue from sales of anti-infective products in 2022, 2023 and 2024 was contributed by six, four and six other anti-infective products, respectively.
- (4) In 2022, 2023 and 2024, our nine major chronic disease treatment products (namely Benzbromarone Tablets, Esomeprazole Magnesium Enteric-Coated Capsules, Telmisartan Tablets, five Insulin Injections and Olmesartan Medoxomil Tablets) contributed 59.5%, 65.0% and 58.3% of our revenue from sales of chronic disease treatment products for the same periods, respectively. The remaining revenue from sales of chronic disease treatment products in 2022, 2023 and 2024 was contributed by 20, 22 and 27 other chronic disease treatment products, respectively.

### **Competitive Landscape for our Oseltamivir Phosphate Products**

The size of the anti-influenza drug market in China was RMB6.7 billion in 2024, of which the sales value of oseltamivir phosphate was RMB4.7 billion, accounting for 70.3% of the total market share for 2024. The other two major drug competitors for oseltamivir phosphate are peramivir and baloxavir marboxil. In 2024, the sales value of peramivir was RMB830.7 million, accounting for 12.4% of the total anti-influenza drug market and the sales value of baloxavir marboxil was RMB726.0 million, accounting for 10.8% of the total anti-influenza drug market. The anti-influenza drug market in China is highly competitive, with over 120 pharmaceutical companies producing influenza medications. In particular, the three leading companies, including us, collectively held 56.9% of the market share of the anti-influenza drug market in China in terms of revenue in 2024. In 2024, the sales of our oseltamivir phosphate products, including our top-selling product, Kewei, reached RMB2.6 billion and accounted for 38.5% of the anti-influenza drug market in China.

There are currently more than 70 pharmaceutical companies in China producing oseltamivir phosphate. We are one of the main producers with well-established production and commercialization scale. In 2024, sales of our oseltamivir phosphate products, including our top-selling product, Kewei, accounted for 54.8% of the entire oseltamivir phosphate market in

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## SUMMARY

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China. We are also a market leader in the oseltamivir phosphate granules market in China in terms of sales volume of and revenue derived from oseltamivir phosphate granules. Sales of Kewei granules accounted for over 99% of the oseltamivir phosphate granules market in China during the Track Record Period.

The provincial VBP schemes had been implemented on Kewei granules since 2023 and 20 provinces have implemented VBP schemes on Kewei granules as of 2024. We mainly sell Kewei granules through provincial VBP schemes to public hospitals. We also sell Kewei granules to public hospitals located in provinces where the VBP has not been implemented, and to pharmacies and other medical institutions outside of VBP schemes. Our dominant market position in Kewei granules has enabled us to face less pricing pressures when bidding to have it included in provincial volume-based schemes. As a result our dominant market position on granules, whether the provincial VBP schemes had been implemented and the number of provinces which implemented provincial VBP on Kewei granules have no material impact on the aggregate sales volume of Kewei granule for both VBP and non-VBP sales. Please see “Industry Overview — Overview of the Anti-influenza Drug Market in China — Competitive Landscape of the Anti-infective Drug Market in China” for details.

### Product Pricing

The PRC government regulates the prices at which pharmaceutical manufacturers sell drugs to the public hospitals mainly through VBP schemes. All drugs used by public hospitals must be procured via the centralized drug procurement platforms or the public procurement platforms established by provincial-level healthcare security administrations (collectively, the “**government’s platforms**”). A pharmaceutical manufacturer is required to declare its products, including the price at which the pharmaceutical companies sell the drug to the public hospitals, on the government’s platforms before such products are allowed to be sold to public hospitals. For the drugs that win the bids during the centralized tender process and are included in the VBP schemes, their bidding prices are displayed on the government’s platforms. As for the other non-centralized procured drugs or drugs which are not included in the VBP schemes, the drug prices on the government’s platforms are those declared by the relevant pharmaceutical manufacturers and officially vetted by the relevant authority, with such prices being subject to routine monitoring by the provincial healthcare security administration. Please see “Regulatory Environment — Principal Regulatory Provisions — Laws and Regulations on Drug Supply” for more details on VBP schemes and drug price regulation in the PRC.

Our Kewei granules are included in the provincial VBP schemes, and our Yangjiantai capsules are included in national VBP schemes. Kewei granules and Yangjiantai capsules are required to declare their bidding prices on the government’s platforms, and they are sold to public hospitals at such prices. Our Kewei capsules has not been included in any national or provincial VBP schemes. Like many other drugs, Kewei capsules must comply with the above government’s platforms pricing policies on non-centralized procured drugs or drugs which are not included in the VBP schemes, in order for public hospitals to purchase it through such government’s platforms.

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## SUMMARY

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### Our Product Pipeline

As of the Latest Practicable Date, we had two innovative drugs for the treatment of Hepatitis C, namely Dong’antai (Netanasvir Phosphate) and Dong’anqiang (Encofosbuvir), approved for marketing in the PRC by the NMPA. In addition, we had more than 100 drugs in the pipeline, including 49 Class I innovative drug candidates in China. Our major innovative drug candidates mainly comprise (i) one Class I innovative drug candidate for the treatment of Diabetes, namely Dongjiantang (Olorigliflozin), for which we have submitted the NDA to the NMPA, and (ii) four Class I innovative drug candidates in Phase III clinical trials, namely Dong’andi (Morphothiadine Mesylate) for the treatment of Hepatitis B, Dongjiandi (Yinfenidone Hydrochloride) for the treatment of IPF, Dongningchun (Clifutinib Besylate) for the treatment of AML and Dongningguan (Larotinib Mesylate) for the treatment of esophageal squamous cell carcinoma. We have a diverse and robust product pipeline in our strategically focused therapeutic areas, including infectious diseases, chronic diseases, and oncology. For details, see “Business — Our Products and Product Candidates — Our Product Pipeline.”

### OUR SUPPLIERS

Our suppliers mainly include (i) equipment and construction service providers, (ii) suppliers of raw materials for the manufacturing of our drugs (such as APIs) and packaging materials, (iii) suppliers of raw materials and consumables for our research and development, (iv) CROs, which provide third-party contracting services for research and development, (v) suppliers of production and research and development equipment and (vi) marketing and advertising service providers. Majority of our purchases are acquired within the PRC. We made 97.5%, 96.8% and 94.5% of our purchases in the PRC for the years ended December 31, 2022, 2023 and 2024, respectively. Other countries from which we made purchases are mainly India, Switzerland and the United Kingdom. For the years ended December 31, 2022, 2023 and 2024, our purchases from our five largest suppliers in each year during the Track Record Period were RMB430.0 million, RMB431.1 million and RMB572.4 million, respectively, representing 27.0%, 22.0% and 27.1% of our total purchases for the respective years. Purchases attributable to our largest supplier in each of the years ended December 31, 2022, 2023 and 2024 amounted to RMB245.6 million, RMB248.8 million and RMB305.0 million, respectively, representing 15.4%, 12.7% and 14.5% of our total purchases for the respective years.

### OUR CUSTOMERS

Our five largest customers in each of the years ended December 31, 2022, 2023 and 2024 were in the PRC and mainly included pharmaceutical companies who are our third-party distributors. Revenue from our five largest customers in each of the years ended December 31, 2022, 2023 and 2024 amounted to RMB2,504.0 million, RMB4,176.6 million and RMB2,514.4 million, respectively, which accounted for 65.7%, 65.4% and 62.6% of our total revenue for the respective years. None of our five largest customers in each year during the Track Record Period was also our supplier and vice versa. Revenue generated from sales to our largest

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## SUMMARY

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customer in each of the years ended December 31, 2022, 2023 and 2024 were RMB993.9 million, RMB1,469.3 million and RMB1,010.0 million, respectively, representing 26.1%, 23.0% and 25.1% of our revenue for the respective years.

### RISK FACTORS

Our business faces risks including those set out in the section headed “Risk Factors.” In particular, the sales of our top-selling product, Kewei, is susceptible to various factors including (i) fluctuations of flu incidence, (ii) expiries of patents relating to oseltamivir phosphate compound in 2017 and synthetic process in March 2024, which resulted in increased competition for our oseltamivir phosphate capsule products and (iii) the patent expiry for our oseltamivir phosphate granule products in April 2026 which will bring more competition for our oseltamivir phosphate granule products. As different investors may have different interpretations and criteria when determining the significance of a risk, you should read the “Risk Factors” section in its entirety before you decide to invest in our Shares. Some of the major risks that we face include:

- Our revenue and business prospects currently depend on Kewei (oseltamivir phosphate). If we are unable to maintain the sales volumes, pricing levels and profit margins of Kewei, our revenue and business prospects could be materially and adversely affected.
- We operate in a highly-competitive environment, and we may not be able to compete effectively against our competitors selling competing drugs, which could subject us to the pressure of price reduction and adversely affect our operations, revenue and business prospects.
- We rely substantially on the success of our drug candidates, some of which are in pre-clinical or clinical development stage, as well as our ability to identify additional drug candidates. If we are unable to successfully identify new drug candidates, complete clinical development, obtain regulatory approval and commercialize our drug candidates, or experience significant delays in doing so, our business will be materially harmed.
- If we fail to maintain an effective distribution network for our pharmaceutical products, our business may be adversely affected.
- We incurred losses in certain years during the Track Record Period and recorded significant revenue drop for the first quarter of 2025 as compared with the first quarter of 2024, and there may be uncertainty about the business prospects in the future.

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## SUMMARY

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### OUR CONTROLLING SHAREHOLDERS

As of the Latest Practicable Date, Yichang HEC Research, Shenzhen HEC Industrial, Guangdong HEC Technology, Yidu Junjiafang and Yidu Shuaixinwei directly held in aggregate approximately 62.12% of the total issued share capital of our Company.

Yichang HEC Research is owned as to 86.74% by Dongguan HEC Research, which is owned as to 73.64% by Linzhi HEC Pharmaceutical Research, 2.11% by Shenzhen HEC Industrial and 6.93% by Ruyuan HEC Industrial, a non wholly-owned subsidiary of Shenzhen HEC Industrial. Linzhi HEC Pharmaceutical Research is owned as to 82.72% by Shenzhen HEC Pharmaceutical, which is wholly owned by Shenzhen HEC Industrial, 9.19% by Yidu HEC Industrial and 2.98% by Yichang HEC Medicine, each a non wholly-owned subsidiary of Shenzhen HEC Industrial, and 5.11% by Ruyuan Yuneng Electric. Yichang HEC Medicine is owned as to 53.73% by Zhejiang HEC Health and 5.75% by Dongguan HEC Industrial, each a wholly-owned subsidiary of Shenzhen HEC Industrial. Guangdong HEC Technology is owned as to 52.69% in aggregate directly or indirectly by Shenzhen HEC Industrial and its parties acting in concert, namely, Yichang HEC Medicine, Ruyuan Yangzhiguang Aluminum, Ruyuan HEC Enterprise Management, Shenzhen NewFoxon and Suzhou Fenghe. Shenzhen HEC Industrial is held as to 42.34%, 27.01% and 30.66% by Ruyuan Yuneng Electric, Shaoguan Xinyuneng Industrial and Ruyuan Xinjing Technology, respectively, while Shaoguan Xinyuneng Industrial is owned as to 58% and 42% by Ruyuan Yuneng Electric and Ruyuan Xinjing Technology, respectively. Ruyuan Yuneng Electric is owned as to 71.75% by Ms. Guo, 27.45% by Mr. Zhang and 0.5% by Ruyuan Shuaicai Investment, a limited partnership where Mr. Zhang acts as the general partner thereof and holds 90% interest therein. Ruyuan Xinjing Technology is ultimately controlled by Ms. Guo and Mr. Zhang. Furthermore, Mr. Zhang is also the sole general partner of Yidu Shuaixinwei and Yidu Junjiafang.

Upon the completion of the Introduction and the Privatization, Mr. Zhang and Ms. Guo will continue to indirectly hold in aggregate 50.98% of the total issued share capital of our Company through entities controlled by them. Accordingly, and by virtue of the family relationship of Mr. Zhang and Ms. Guo, Mr. Zhang, Ms. Guo and the entities controlled by them, namely Guangdong HEC Technology, Yichang HEC Research, Dongguan HEC Research, Linzhi HEC Pharmaceutical Research, Ruyuan HEC Industrial, Yidu HEC Industrial, Yichang HEC Medicine, Shenzhen HEC Pharmaceutical, Shenzhen HEC Industrial, Dongguan HEC Industrial, Zhejiang HEC Health, Ruyuan Yuneng Electric, Ruyuan Shuaicai Investment, Shaoguan Xinyuneng Industrial, Ruyuan Xinjing Technology, Yidu Junjiafang and Yidu Shuaixinwei, will become a group of our Controlling Shareholders after the Listing.

### CONNECTED TRANSACTIONS

We have entered into certain transactions with Shenzhen HEC Industrial (being one of our Controlling Shareholders), and following the Listing, the transactions contemplated thereunder will continue and constitute continuing connected transactions under Chapter 14A of the Listing Rules. We have applied to the Stock Exchange for, and the Stock Exchange has granted



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## SUMMARY

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to us, a waiver from strict compliance with the announcement requirement under Chapter 14A of the Listing Rules in respect of such continuing connected transactions. Please see “Connected Transactions” for further details.

### STRUCTURE OF THE INTRODUCTION AND THE PRIVATIZATION

Our Company has made the Privatization Proposal to privatize HEC CJ Pharm by way of merger by absorption in accordance with the PRC Company Law, other applicable PRC laws, Hong Kong laws, the Takeovers Code and the Listing Rules and pursuant to which, subject to the fulfillment (or waiver, as applicable) of the Pre-Conditions and all the Conditions (being the Conditions to effectiveness and the Conditions to implementation), our Company will issue H Shares to all Share Exchange Shareholders according to the Share Exchange Ratio as the consideration for the Share Exchange. Accordingly, our Company has made an application to the Stock Exchange for our listing of the H Shares by way of introduction. According to the Share Exchange Ratio, for every Share Exchange HEC CJ Pharm H Share canceled under the Privatization Proposal, 0.263614 H Shares will be issued.

Following the fulfillment (or waiver, as applicable) of the Pre-Conditions and the Conditions under the Merger Agreement and the completion of the Share Exchange:

- (a) the listing of HEC CJ Pharm H Shares on the Stock Exchange will be withdrawn;
- (b) our H Shares will be listed on the Stock Exchange by way of introduction;
- (c) the Share Exchange Shareholders will become our Shareholders;
- (d) our Company will assume all assets, liabilities, interests, businesses, employees, contracts and all other rights and obligations of HEC CJ Pharm from the Implementation Date; and
- (e) HEC CJ Pharm will be eventually deregistered in the PRC.

The Privatization and the Listing will not proceed if the Merger is not approved or lapses or does not become unconditional for any reason, and the Merger is conditional upon obtaining the necessary approvals and/or having made the necessary filings for the listing (by way of introduction) of, and permission to deal in, our H Shares on the Stock Exchange pursuant to the Listing. For the status of obtaining of approvals and/or completion of filings for the Listing, please refer to “History, Development and Corporate Structure — Structure of the Introduction and the Privatization”.

For further information, please refer to “History, Development and Corporate Structure — Structure of the Introduction and the Privatization”.



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### **BENEFITS OF THE INTRODUCTION AND THE PRIVATIZATION**

Our Directors believe that the completion of the Merger and the Listing benefits both Share Exchange Shareholders and the Company and marks a significant milestone in the development of the Company. The Merger and the Listing represent an opportunity for Share Exchange Shareholders to become shareholders of the Enlarged SLP Group, and will benefit the Company and Share Exchange Shareholders in the following aspects:

Benefits of the Merger and the Listing to the Company include:

- Through the Merger, the Enlarged SLP Group will become an integrated pharmaceutical company engaging in R&D, production and commercialization of pharmaceutical products, and consolidate its position as a comprehensive pharmaceutical company
- Integrating domestic and overseas sales channels to build a global pharmaceutical company
- Improving overall corporate efficiency for long-term sustainable and resilient growth

Benefits of the Merger and the Listing to the Share Exchange Shareholders include:

- Our integrated in-house R&D system and our R&D platform that covers the complete drug development cycle to achieve long-term value creation
- Eliminating connected transactions, improving operational efficiency and expanding economies of scale
- Enhancing overall performance in the capital market

### **APPLICATION FOR LISTING ON THE STOCK EXCHANGE**

We are applying for the Listing under Rule 8.05(3) of the Listing Rules and satisfy the market capitalization/revenue test, with reference to, among other things, (i) our revenue for the financial year ended December 31, 2024, being RMB4,018.9 million, which is over HK\$500 million as required by Rule 8.05(3) of the Listing Rules; and (ii) our expected market capitalisation would exceed the market capitalisation requirements under Rules 8.05(3) on the basis that: (1) the estimated value of the Company (being in the range of RMB28,944.6 million to RMB32,902.5 million, as concluded in the valuation report appended to the 3.5 Announcement) far exceeds the market capitalisation requirements; (2) the latest market capitalisation of HEC CJ Pharm (based on the average closing price of its H shares as stated in the Stock Exchange's daily quotations sheets for the five business days up to and including the Latest Practicable Date) (being HK\$12.63 billion) which exceeds the market capitalisation requirements under Rules 8.05(3) on its own and taking into account the fact that (x) based on

## SUMMARY

the valuation report appended to the 3.5 Announcement, the valuation of HEC CJ Pharm only makes up 23.2% of the total valuation of the Group and (y) the business performance of the Group (save as disclosed below in the section “— Recent Development — Update on Our Financial Performance for the First Quarter of 2025”) has not had any material adverse changes.

### SUMMARY FINANCIAL INFORMATION

The following tables set forth summary financial data from our consolidated financial information for the Track Record Period, extracted from the Accountants’ Report set out in Appendix I to this Listing Document.

#### Summary of Consolidated Statements of Profit or Loss

	Year ended December 31,		
	2022	2023	2024
	RMB'000	RMB'000	RMB'000
<b>Revenue</b> . . . . .	3,813,566	6,385,616	4,018,905
Cost of sales . . . . .	(891,377)	(1,308,568)	(960,274)
<b>Gross profit</b> . . . . .	2,922,189	5,077,048	3,058,631
Other (losses)/income . . . . .	(1,294,012)	(422,669)	89,743
Distribution costs . . . . .	(1,244,177)	(1,577,083)	(1,197,046)
Administrative expenses . . . . .	(387,872)	(480,720)	(557,116)
Research and development costs . . . . .	(791,642)	(827,415)	(887,653)
Reversals/(recognition) of impairment loss on trade and other receivables . . . . .	2,575	(3,079)	(126,011)
<b>(Loss)/profit from operations</b> . . . . .	(792,939)	1,766,082	380,548
Finance costs . . . . .	(686,884)	(380,591)	(239,787)
Share of (loss)/profit of an associate . . . . .	—	(29)	293
<b>(Loss)/profit before taxation</b> . . . . .	(1,479,823)	1,385,462	141,054
Income tax . . . . .	63,908	(371,584)	(116,251)
<b>(Loss)/profit for the year</b> . . . . .	<u>(1,415,915)</u>	<u>1,013,878</u>	<u>24,803</u>
<b>(Loss)/profit for the year attributable to:</b>			
Equity shareholders of the Company . . . . .	(1,209,205)	184,924	(207,434)
Non-controlling interests . . . . .	(206,710)	828,954	232,237
<b>(Loss)/profit for the year</b> . . . . .	<u>(1,415,915)</u>	<u>1,013,878</u>	<u>24,803</u>
<b>(Loss)/earnings per share</b>			
Basic and diluted (in RMB). . . . .	<u>(3.29)</u>	<u>0.44</u>	<u>(0.47)</u>

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## SUMMARY

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### **Non-IFRS Measure**

To supplement our consolidated statements of profit or loss and other comprehensive expenses which are presented in accordance with IFRS, we also use adjusted net (loss)/profit as a non-IFRS measure, which is not required by, or presented in accordance with, IFRS. We believe that the presentation of the non-IFRS measure when shown in conjunction with the corresponding IFRS measures provides useful information to management and investors in facilitating a comparison of our operating performance from year to year. In particular, the non-IFRS measure eliminates impact of certain expenses, including fair value change on derivative financial instruments embedded in convertible bonds, equity-settled share-based payment expenses, interest on financial instruments with preferential rights issued to investors and listing and privatisation expenses. Such non-IFRS measure allows investors to consider metrics used by our management in evaluating our performance.

We define adjusted net (loss)/profit (measure) as (loss)/profit for the year adjusted by adding back loss from fair value change on derivative financial instruments embedded in convertible bonds, equity-settled share-based payment expenses, interest on financial instruments with preferential rights issued to investors and listing and privatisation expenses. Fair value change on derivative financial instruments embedded in convertible bonds are expenses arising from fair value change on the derivative component of our convertible bonds issued due to exchange rate and share price fluctuations. We no longer recognize such liabilities as of July 31, 2023, because we had fully repurchased the outstanding portion of our convertible bonds issued by HEC CJ Pharm in July 2023. Equity-settled share-based payment expenses are expenses arising from granting restricted shares to selected employees, senior management, and directors, the amount of which is non-cash in nature. Interest on financial instruments with preferential rights issued to investors represents the interest on the redemption amount pursuant to a series of investment agreements and equity transfer agreements entered into with our Pre-Listing Investors from July 2020. We no longer recognize such liabilities as of March 31, 2022, because each of our then Pre-Listing Investors provided a confirmation to our Company and our subsidiaries that are subject to the redemption rights in March 2022, pursuant to which our Pre-Listing Investors confirmed in writing that they had waived their redemption rights against our Company and the involved subsidiaries, and as a result of which such rights were terminated on the same date. Listing and privatisation expenses are the expenses arising from activities in relation to the proposed Listing and Privatisation and are excluded from our (loss)/profit for the year.

The use of the non-IFRS measure has limitations as an analytical tool, and you should not consider it in isolation from, or as a substitute for, or superior to, analysis of our results of operations or financial condition as reported under IFRS. In addition, the non-IFRS financial measure may be defined differently from similar terms used by other companies and therefore may not be comparable to similar measures presented by other companies.

## SUMMARY

The following table shows reconciliation from our (loss)/profit for the years to our adjusted net (loss)/profit (non-IFRS measure) for the year indicated:

	Year ended December 31,		
	2022	2023	2024
	RMB'000	RMB'000	RMB'000
<b>(Loss)/profit for the year . . . . .</b>	<u>(1,415,915)</u>	<u>1,013,878</u>	<u>24,803</u>
<i>Adjusted for:</i>			
Equity-settled share-based payment expenses . . . . .	–	130,278	266,545
Interest on financial instruments with preferential rights issued to investors . . . . .	172,715	–	–
Fair value change on derivative financial instruments embedded in convertible bonds . . . . .	859,569	79,796	–
Listing and privatisation expenses . . . . .	<u>–</u>	<u>3,000</u>	<u>17,191</u>
<b>Adjusted net (loss)/profit for the year (Non-IFRS measure). . . . .</b>	<u>(383,631)</u>	<u>1,226,952</u>	<u>308,539</u>

Our adjusted net loss or profit for the year (non-IFRS measure) generally fluctuated in line with our revenue. In particular, we recorded adjusted net loss for the year (non-IFRS measure) of RMB383.6 million in 2022, primarily due to (i) our loss for the year of RMB1,415.9 million as a result of the lower than usual sales volume of Kewei (oseltamivir phosphate) in 2022 due to travel restrictions, social-distancing measures and business closures which significantly reduced the movement of people and increased widespread preventive measures against influenza, which resulted in a significant decline in the incidence of respiratory diseases such as influenza, (ii) non-recurring items including (a) interest on convertible bonds issued by HEC CJ Pharm of RMB257.3 million, which were fully repurchased in July 2023, (b) net foreign exchange loss of RMB239.8 million arising from the translation of convertible bonds issued by HEC CJ Pharm denominated in US dollars, (c) impairment loss of RMB43.0 million on intangible assets in connection with the combination treatment regimen of Emitasvir Phosphate and Furaprevir for the treatment of hepatitis C (the “**Combination Therapy**”), which was impaired due to delayed development timelines in 2022 and (d) impairment loss of RMB75.9 million on goodwill in connection with the acquisition of Dongguan HEC Medical for the R&D, production and sales of the Combination Therapy; the goodwill was fully impaired in 2023 due to delays in the development of the Combination Therapy and increased market competition and (iii) recurring impairment loss on generic drugs intellectual property rights of RMB147.4 million in 2022 due to certain under-performing generic drugs as a result of lower-than-expected sales or delayed development timelines in 2022, including Clarithromycin Tablets, Olanzapine Tablets, Azithromycin Tablets and Esomeprazole Magnesium Enteric-Coated Capsules.

## SUMMARY

### (Loss)/profit for the Year Attributable to Non-controlling Interests

During the Track Record Period and up to the Latest Practicable Date, we held approximately 51.4% equity interest in HEC CJ Pharm. Accordingly, non-controlling interests accounted for approximately 48.6% of HEC CJ Pharm's profits or losses. From 2022 to 2024, the share of profits and losses attributable to non-controlling interests experienced fluctuations, primarily reflecting changes in HEC CJ Pharm's financial performance. These changes were largely driven by sales volume movements of the top-selling product Kewei (oseltamivir phosphate).

### Revenue

The table below sets forth a breakdown of our revenue derived from our major product lines for the years indicated:

	Year ended December 31,					
	2022		2023		2024	
	<i>RMB'000</i>	<i>% of total</i>	<i>RMB'000</i>	<i>% of total</i>	<i>RMB'000</i>	<i>% of total</i>
Anti-infective drugs . . . .	3,242,508	85.0	5,745,811	90.0	2,797,632	69.6
Chronic disease treatment drugs . . . . .	517,258	13.6	580,743	9.1	1,067,707	26.6
Others <sup>(1)</sup> . . . . .	53,800	1.4	59,062	0.9	153,566	3.8
<b>Total</b> . . . . .	<u>3,813,566</u>	<u>100.0</u>	<u>6,385,616</u>	<u>100.0</u>	<u>4,018,905</u>	<u>100.0</u>

*Note:*

- (1) Others comprise (i) revenue from sales of drugs that were not anti-infective drugs or chronic disease treatment drugs, mainly including tadalafil and sildenafil, (ii) transfer and license fee we received pursuant to the HEC88473 Agreement with Apollo, and to a lesser extent, (iii) rental revenue generated from the leasing of fixed assets and (iv) revenue from the disposal of surplus construction materials.

The table below sets forth a breakdown of the revenue derived from our oseltamivir phosphate products by dosage form for the years indicated:

	Year ended December 31,					
	2022		2023		2024	
	<i>RMB'000</i>	<i>% of total</i>	<i>RMB'000</i>	<i>% of total</i>	<i>RMB'000</i>	<i>% of total</i>
Oseltamivir phosphate (capsule) . . . . .	512,252	16.5	715,576	12.9	395,676	15.3
Oseltamivir phosphate (granule) . . . . .	2,585,151	83.5	4,824,592	87.0	2,181,509	84.6
Oseltamivir phosphate (dry suspension) . . . . .	—	—	5,950	0.1	3,520	0.1
<b>Total</b> . . . . .	<u>3,097,403</u>	<u>100</u>	<u>5,546,118</u>	<u>100</u>	<u>2,580,704</u>	<u>100</u>

## SUMMARY

The table below sets forth, for the years indicated, a breakdown of our revenue by geographical location:

	Year ended December 31,					
	2022		2023		2024	
	<i>RMB'000</i>	<i>% of total</i>	<i>RMB'000</i>	<i>% of total</i>	<i>RMB'000</i>	<i>% of total</i>
The PRC .....	3,753,159	98.4	6,335,896	99.2	3,880,476	96.6
Overseas <sup>(1)</sup> .....	60,407	1.6	49,720	0.8	138,429	3.4
<b>Total</b> .....	<u>3,813,566</u>	<u>100.0</u>	<u>6,385,616</u>	<u>100.0</u>	<u>4,018,905</u>	<u>100.0</u>

*Note:*

- (1) Overseas countries comprise the United States, Germany, the United Kingdom, Malaysia, Algeria, South Africa and the United Arab Emirates. Our overseas revenue increased significantly in 2024, primarily due to license fee generated pursuant to the HEC88473 Agreement with Apollo.

During the Track Record Period, most of our revenue was derived from sales of oseltamivir phosphate products, a large portion of which is attributable to the sales of Kewei (oseltamivir phosphate), with a smaller portion contributed by oseltamivir phosphate capsules under the brand Yangjiantai, which was included in the national VBP scheme in 2022. During the Track Record Period, Kewei accounted for 99.9%, 99.4% and 96.5% and Yangjiantai accounted for 0.1%, 0.5% and 3.4% of our total sales of oseltamivir phosphate for 2022, 2023 and 2024, respectively.

We report our revenue by our major product lines, which include anti-infective drugs, chronic disease treatment drugs and others. Our revenue increased by 67.4% from RMB3,813.6 million in 2022 to RMB6,385.6 million in 2023, primarily attributable to the respective increases in revenue derived from sales of (i) anti-infective drugs driven by higher demand for Kewei (oseltamivir phosphate) due to increased flu incidence in 2023 and greater societal awareness of respiratory infectious diseases; there were 2.5 million and 12.5 million new influenza cases reported in China in 2022 and 2023, respectively, based on the Statistical Report on China's Healthcare Development and according to Frost & Sullivan, the PRC's anti-influenza drug market increased by 150.0% from RMB4.4 billion in 2022 to RMB11.0 billion in 2023 due to the significant influenza outbreaks in 2023 and (ii) chronic disease treatment drugs due to enhanced marketing efforts and expanded distribution channels for our insulin series. During the Track Record Period, our revenue generated from the sales of oseltamivir phosphate products fluctuated with flu incidence in China and our revenue fluctuation was generally in line with our competitors during the Track Record Period. Our revenue decreased by 37.1% from RMB6,385.6 million in 2023 to RMB4,018.9 million in 2024, primarily attributable to a decrease in total sales of oseltamivir phosphate mainly due to (i) lower incidence of seasonal flu outbreaks in China in 2024 as compared to 2023, which was evidenced by the fact that there were 12.5 million and 8.6 million new influenza cases reported in China in 2023 and 2024, respectively, based on the Statistical Report on China's Healthcare Development which caused the drop in sales for both Kewei granules and capsules; (ii) the

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## SUMMARY

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reduced sales of our Kewei capsule in 2024 as public hospitals reduced the purchase of Kewei capsules outside of their VBP schemes in 2024; (iii) the decrease of average selling price of our Kewei granules and Kewei capsules by 7.8% and 20.1%, respectively, in 2024 as compared with those in 2023; and (iv) increasingly intense competition our oseltamivir phosphate is facing from other types of anti-influenza drugs and other oseltamivir phosphate manufacturers which caused (i) the market share of oseltamivir phosphate as a percentage of total anti-influenza drug market decreased from 78.0% in 2023 to 70.3% in 2024 and (ii) the market share of our oseltamivir phosphate products as a percentage of total PRC oseltamivir phosphate market decreased from 64.8% in 2023 to 54.8% in 2024. For details, please see “Business — Sales, Marketing and Distribution — Our Oseltamivir Phosphate Products and the Reasons for the Fluctuation of the Sales of Our Oseltamivir Phosphate Products during the Track Record Period.”

### Gross Profit and Gross Profit Margin

Our gross profit increased from RMB2,922.2 million in 2022 to RMB5,077.0 million in 2023, and our gross profit margin increased from 76.6% in 2022 to 79.5% in 2023. Such increases were primarily attributable to a significant increase in the revenue from our anti-infective drugs, as well as decreases in the cost of raw materials and unit manufacturing costs for Kewei (oseltamivir phosphate) as we benefited from economies of scale attained from ramping up our production to meet market demand. In 2024, our gross profit decreased to RMB3,058.6 million and our gross profit margin decreased to 76.1%. The decreases were primarily attributable to a decrease in revenue from our anti-infective drugs as a result of lower sales volume of Kewei (oseltamivir phosphate), a high margin product, due to lower incidence of seasonal flu outbreaks in 2024.

The table below sets forth, for the years indicated, the gross profit margins of our major product lines.

	Year ended December 31,		
	2022	2023	2024
Anti-infective drugs . . . . .	81.8%	84.2%	82.5%
Chronic disease treatment drugs . . . . .	48.0%	39.8%	62.1%
Others . . . . .	40.0%	16.3%	56.6%
<b>Total</b> . . . . .	<u>76.6%</u>	<u>79.5%</u>	<u>76.1%</u>

### (Loss)/Profit for the Year

Our profit for the year changed from a loss for the year of RMB1,415.9 million in 2022 to a profit for the year of RMB1,013.9 million in 2023, primarily attributable to the respective increases in revenue derived from sales of (i) anti-infective drugs and (ii) chronic disease treatment drugs. Our profit for the year decreased to RMB24.8 million in 2024, primarily attributable to a decrease in revenue derived from the sales of anti-infective drugs.



## SUMMARY

### Summary of Consolidated Statements of Financial Position Items

The following table sets forth selected information from our consolidated statements of financial position as of the dates indicated:

	As of December 31,		
	2022	2023	2024
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Total current assets . . . . .	4,150,648	6,412,476	4,978,760
Total non-current assets . . . . .	6,538,335	6,245,623	6,952,754
Total current liabilities . . . . .	8,958,309	6,178,491	4,814,251
Total non-current liabilities . . . . .	2,604,609	2,304,289	2,649,763
Total assets . . . . .	10,688,983	12,658,099	11,931,514
Net current (liabilities)/assets . . . . .	(4,807,661)	233,985	164,509
Total assets less current liabilities . . . . .	1,730,674	6,479,608	7,117,263
Net (liabilities)/assets . . . . .	(873,935)	4,175,319	4,467,500
(Net deficit)/total equity attributable to equity shareholders of the Company . . . . .	(3,688,684)	327,921	344,149
Non-controlling interests . . . . .	2,814,749	3,847,398	4,123,351

Our net liabilities changed from RMB873.9 million as of December 31, 2022 to net assets of RMB4,175.3 million as of December 31, 2023, primarily due to (i) profit of year of RMB1,013.9 million, (ii) capital contribution from shareholders of RMB1,616.1 million and (iii) deemed contribution from a shareholder of RMB2,312.3 million. Our net assets then increased to RMB4,467.5 million as of December 31, 2024, primarily due to (i) profit for the year of RMB24.8 million and (ii) equity-settled share-based payment of RMB266.5 million.

Our net current assets decreased from RMB234.0 million as of December 31, 2023 to RMB164.5 million as of December 31, 2024 and such decrease was primarily due to (i) a decrease in our restricted cash and (ii) a decrease in cash and cash equivalents.

We recorded net current liabilities of RMB4,807.7 million as of December 31, 2022 and net current assets of RMB234.0 million as of December 31, 2023 and such improvement was primarily due to (i) an increase in our restricted cash and our cash and cash equivalents, (ii) a decrease in our trade and other payables and (iii) a decrease in our current interest-bearing borrowings because we had fully repurchased the outstanding portion of our convertible bonds issued by HEC CJ Pharm in July 2023, which was offset by an increase in our current bank loans and other borrowings.



## SUMMARY

### Summary of Consolidated Statements of Cash Flows Items

	Year ended December 31,		
	2022	2023	2024
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Net cash generated from operating activities . . . . .	1,160,966	1,318,106	500,532
Net cash (used in)/generated from investing activities . . . . .	(1,109,599)	(1,682,992)	29,794
Net cash (used in)/generated from financing activities . . . . .	(313,575)	1,314,291	(970,666)
Net (decrease)/increase in cash and cash equivalents . . . . .	(262,208)	949,405	(440,340)
Cash and cash equivalents at January 1 .	1,232,268	971,510	1,920,158
Effect of foreign exchange rate changes . . . . .	1,450	(757)	992
<b>Cash and cash equivalents at 31 December . . . . .</b>	<u>971,510</u>	<u>1,920,158</u>	<u>1,480,810</u>

We had net cash generated from operating activities of RMB500.5 million in 2024, resulting from our profit before taxation of RMB141.1 million, adjustments for non-cash items of RMB903.3 million, changes in working capital of RMB296.2 million and corporate income tax paid of RMB247.6 million. Adjustments for non-cash items primarily included the adding back of (i) depreciation of RMB284.7 million, (ii) finance costs of RMB239.8 million and (iii) equity-settled share-based payment expenses of RMB266.5 million. Changes in working capital primarily included (i) an increase in inventories of RMB208.8 million and (ii) a decrease in trade and other payables of RMB88.8 million. Please see “Financial Information — Liquidity and Capital Resources — Cash Flows” for details of our cash flows.

### FUTURE PLANS AND PROSPECTS

During the Track Record Period, we had built a comprehensive R&D platform, production facilities that meet international standards and an extensive sales network. We plan to take the following integration initiatives after completion of the Merger and the Listing, so as to accelerate the integration of our business.

Our strategic plans include:

- Clarify the direction of future development to become a comprehensive pharmaceutical enterprise integrating research, production and sales
- Increase capital efficiency and expedite product innovation, continuously upgrading product technology to enhance market dominance

## SUMMARY

- Reduce the competition and connected transactions between HEC CJ Pharm and SLP as well as enhance operational efficiency
- Establish presence in the global capital market and enhance our corporate image

Our future development and integration initiatives include:

- Facilitate the integration and development of research and development platforms and product pipelines to consistently strengthen competitiveness
- Enhance our renowned brand image and establish an efficient distribution network
- Optimize our overall production system and enhance systematic operational efficiency
- Consolidate structure and reduce governance costs

## KEY FINANCIAL RATIOS

The table below sets forth, as of the dates or for the years indicated, certain financial ratios.

		Year ended December 31,/As of December 31,		
	Notes	2022	2023	2024
<b>Liquidity ratios</b>				
Current ratio (times) . . . . .	(1)	0.7	1.0	1.0
Quick ratio (times) . . . . .	(2)	0.6	1.0	0.9
<b>Profitability ratios</b>				
Gross profit margin % . . . . .	(3)	76.6	79.5	76.1
Net profit margin % . . . . .	(4)	N/A	15.9	0.6
Adjusted net profit margin (non-IFRS measure) % . . . . .	(5)	N/A	19.2	7.7
<b>Solvency ratio</b>				
Gearing ratio % . . . . .	(6)	N/A	128.2	103.5

*Notes:*

- (1) Current ratio represents current assets as of a record date divided by current liabilities as of the same record date.
- (2) Quick ratio represents current assets excluding inventories as of a record date divided by current liabilities as of the same record date.
- (3) Gross profit margin represents the revenue for a period minus the cost of sales for such period divided by the revenue for such period.

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## SUMMARY

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- (4) Net profit margin represents the profit for a period divided by the revenue for such period. Negative figures are marked as N/A.
- (5) Adjusted net profit margin (non-IFRS measure) represents the adjusted net profit (non-IFRS measure) for a period divided by the revenue for such period. For details of adjusted net profit (non-IFRS measure), see “Financial Information — Non-IFRS Measure”. Negative figures are marked as N/A.
- (6) Gearing ratio represents total indebtedness (being bank loans and other borrowings, lease liabilities and interest-bearing borrowings) divided by total equity as of the dates indicated. Negative figures are marked as N/A.

### IMPACTS OF THE COVID-19 OUTBREAK

The outbreak of the COVID-19 pandemic since early 2020 has materially and adversely affected the global economy. As of the Latest Practicable Date, we had not experienced material disruptions in our research and development activities as a result of the COVID-19 pandemic. Although we encountered temporary slow-down in subject enrollment for certain clinical trials in China, since 2023, we have resumed normal business operations and our business has gradually recovered from the impacts of the COVID-19 pandemic. We have since considered COVID-19 to have minimal negative impact on our financial results.

During the Track Record Period, the market demand for our anti-infective drugs, especially Kewei, was affected by the COVID-19 pandemic due to travel restrictions, social-distancing measures and business closures. The decrease was primarily attributed to the fact that at the beginning of the COVID-19 pandemic outbreak, the mobility of China’s domestic population declined, and the number of medical activities, prescriptions and sales volume of drugs in hospitals also decreased accordingly. Our top-selling product, Kewei, is a prescription medicine sold primarily at tiered hospitals, and the sales volume of this product also declined due to the impact of the COVID-19 pandemic.

Although the COVID-19 pandemic prevention and control in China had largely stabilized by 2022, our business operations and financial results still experienced some residual negative impacts during the year. Our revenue derived from sales of anti-infective drugs amounted to RMB3,242.5 million in 2022, which was primarily attributed to the fact that the COVID-19 pandemic prevention and control in China had generally stabilized, the flow of people and daily social activities had gradually returned to normal, and the overall flow of people, the number of diagnosis and treatment activities and the volume of prescriptions in terminal medical institutions have recovered significantly in 2022. In addition, many southern provinces in China issued flu warnings and the number of patients of fever clinics surged in 2022. Meanwhile, comparing with the early stage of the COVID-19 pandemic, the sales activities of Kewei returned to a normal and reasonable level in 2022. Therefore, with the gradual recovery of the flow of people and the number of flu cases and the normalization of our sales activities, Kewei, our top-selling product, showed a very good trend of recovery in its sales volume leveraging on its brand advantages accumulated in the field of flu treatment for years and its advantages in efficacy and safety.

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## SUMMARY

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Our revenue derived from sales of anti-infective drugs increased by RMB2,503.3 million, or 77.2%, from RMB3,242.5 million in 2022 to RMB5,745.8 million in 2023. The increase was primarily attributed to a greater incidence of influenza in 2023 as compared with that of 2022 upon the complete removal of travel restrictions and social-distancing measures in early 2023. In addition, as result of the COVID-19 pandemic, there has been an increased societal awareness and focus on respiratory infectious diseases and antiviral treatments. Kewei is a key drug for the treatment of influenza, within the markets in which we operate. We believe our ability to maintain our market share in an increasingly competitive environment was primarily due to our ability to ramp up our oseltamivir phosphate production scale to respond to changing market demands in a timely manner, our coverage of various sales and distribution channels and our brand reputation.

### **DIVIDEND POLICY**

During the Track Record Period, we did not declare dividends.

Our Board is responsible for submitting proposals in respect of dividend payments, if any, to the Shareholders' general meeting for approval. Our Board may declare dividends in the future after taking into account our distributable profits, financial condition, cash flow, expected future capital expenditure, return to our Shareholders, capital requirements, finance costs, the external financing environment and any other factors that the Directors may deem relevant. Any declaration and payment, as well as the amount of, dividends will be subject to the requirements of our constitutional documents and the PRC Company Law. Under the PRC Company Law and our Articles of Association, dividends are distributed to our Shareholders in proportion to their shareholdings. As of the Latest Practicable Date, we did not have a formal dividend policy or a fixed pay-out ratio for future cash dividends. The payment of dividends may also be limited by legal restrictions and by financing agreements that we may enter into from time to time.

### **LISTING AND PRIVATIZATION EXPENSES**

The estimated total listing and privatization expenses, which are non-recurring in nature, are RMB81.9 million. The expenses consist of (i) fees paid and payable to legal advisors and Reporting Accountants of RMB36.9 million and (ii) other fees and expenses of RMB45.0 million. Among the estimated aggregate amount of our listing and privatization expenses, (i) RMB38.2 million was or is expected to be charged to our consolidated statements of profit or loss, of which RMB3.0 million was recognized as our profit or loss for the year ended December 31, 2023, RMB17.2 million was recognized as our profit or loss for the year ended December 31, 2024 and RMB18.0 million is expected to be recognized as our profit or loss for year ending December 31, 2025, and (ii) RMB43.7 million is directly attributable to the issuance of new Shares and is expected to be accounted for as a deduction from equity upon the Listing.

## SUMMARY

### UNAUDITED PRO FORMA STATEMENT OF ADJUSTED NET TANGIBLE ASSETS

The following unaudited pro forma statement of adjusted net tangible assets of the Group is prepared in accordance with Rule 4.29 of the Listing Rules and is set out below to illustrate the effect of the Introduction and the Privatisation on the consolidated net tangible liabilities attributable to equity shareholders of the Company as of 31 December 2024 as if the Introduction and the Privatisation had taken place at 31 December 2024.

The unaudited pro forma statement of adjusted net tangible assets has been prepared for illustrative purposes only and because of its hypothetical nature, it may not give a true picture of the financial position of the Group had the Introduction and the Privatisation been completed as of 31 December 2024 or at any future date.

Consolidated net tangible liabilities attributable to equity shareholders of the Company as of 31 December 2024	Effect of the Introduction and the Privatisation	Unaudited pro forma adjusted consolidated net tangible assets attributable to equity shareholders of the Company	Unaudited pro forma adjusted consolidated net tangible assets attributable to equity shareholders of the Company per Share	
<i>RMB'000</i> <i>(Note 1)</i>	<i>RMB'000</i> <i>(Note 2)</i>	<i>RMB'000</i>	<i>RMB</i> <i>(Note 3)</i>	<i>HK\$</i> <i>(Note 4)</i>
<u>(464,765)</u>	<u>3,307,917</u>	<u>2,843,152</u>	<u>5.13</u>	<u>5.55</u>

*Notes:*

- (1) The consolidated net tangible liabilities attributable to equity shareholders of the Company as of 31 December 2024 is arrived at after (i) deducting intangible assets of RMB1,573,456,000; and (ii) adjusting the share of intangible assets attributable to non-controlling interests of RMB764,542,000 from the consolidated total equity attributable to equity shareholders of the Company of RMB344,149,000 as of 31 December 2024 which is extracted from the Accountants' Report set out in Appendix I to the listing document.
- (2) The adjustment represents the derecognition of the carrying amount of non-controlling interests in HEC CJ Pharm upon the completion of the Introduction and the Privatisation as at 31 December 2024, and the corresponding change in consolidated net tangible liabilities attributable to equity shareholders of the Company, after deduction of listing and privatisation expenses paid or payable by the Company of RMB61,672,000 (excluding the related expenses charged to profit or loss during the Track Record Period).
- (3) The unaudited pro forma adjusted consolidated net tangible assets attributable to equity shareholders of the Company per Share is arrived at after the adjustments referred to in the preceding paragraphs and on the basis that a total of 553,700,263 Shares were in issue (being the outstanding 463,943,215 domestic shares in issue immediately before the Introduction and the Privatisation and 112,712,832 H shares to be issued pursuant to the Introduction and the Privatisation, excluding the 22,955,784 shares under the 2023 Restricted Share Scheme) assuming that the Introduction and the Privatisation had been completed on 31 December 2024.
- (4) The unaudited pro forma adjusted consolidated net tangible assets attributable to equity shareholders of the Company per Share amount in Renminbi is converted into Hong Kong dollars with an exchange rate of HK\$1.00 to RMB0.9253. No representation is made that the Renminbi amount has been, could have been or may be converted into Hong Kong dollars, or vice versa, at that rate or at any other rates.

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## SUMMARY

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- (5) No adjustment has been made to reflect any trading results or other transactions of the Group entered into subsequent to 31 December 2024, including but not limited to the Special Dividend to be declared by HEC CJ Pharm to the shareholders whose names appear on the register of members of HEC CJ Pharm on the Share Exchange Record Date (other than the Company or its subsidiaries, if any). The Directors of the Company preliminarily estimated that the Special Dividend would amount to approximately RMB593.4 million, based on the total number of 427,567,700 HEC CJ Pharm Shares held by the aforementioned shareholders as of 31 December 2024 and the proposed Special Dividend of HK\$1.50 per HEC CJ Pharm Shares. The Special Dividend payable is converted from Hong Kong dollars at an exchange rate of HK\$1.00 to RMB0.9253. No representation is made that the Hong Kong dollar amount has been, could have been or may be converted into Renminbi, or vice versa, at that rate or at any other rates. Had the Special Dividend been declared on 31 December 2024, the unaudited pro forma adjusted net tangible assets would have decreased by RMB593.4 million and the unaudited pro forma adjusted net tangible assets per Share would have decreased by RMB1.07 (equivalent to HK\$1.16).

## RECENT DEVELOPMENT

### Update on Our Financial Performance for the First Quarter of 2025

Our revenue for the first quarter of 2025 decreased by 40.7% as compared with the first quarter of 2024 which in turn had a greater adverse impact on our profitability in the first quarter of 2025. Such greater adverse impact on our profitability was primarily due to the fact that in the first quarter of 2025 as compared with the same period in 2024, (i) our gross profit margin remained relatively stable; and (ii) our operating expenses decreased at a slower pace than our revenue. The decrease of the revenue for the first quarter of 2025 was primarily because (i) our revenue for the first quarter of 2024 was relatively high as there was a large-scale outbreak of flu season at the end of 2023 which prompted our distributors to substantially increase the purchase of the oseltamivir phosphate in the first quarter of 2024; and (ii) due to an outbreak of flu season at the end of 2024, our distributors increased purchase of oseltamivir phosphate at the end of 2024 to prepare for the flu season ahead of the Chinese New Year holiday in January 2025. However, as the actual severity of the flu outbreak was less and the duration of the flu season was shorter than originally expected, the distributors reduced the purchase of new oseltamivir phosphate from us in the first quarter of 2025.

### Special Dividend

Subject to the fulfillment (or waiver, as applicable) of all the Pre-Conditions and the Conditions, HEC CJ Pharm will pay a Special Dividend to HEC CJ Pharm Shareholders whose names appear on the register of members of HEC CJ Pharm on the Special Dividend Record Date other than our Company and our subsidiaries (if applicable). The Special Dividend payable is based on HK\$1.50 per share for a total number of 427,567,700 HEC CJ Pharm Shares held by the aforementioned shareholders. We estimate that the total Special Dividend payable would amount to approximately RMB593.4 million which will be settled by the cash owned by HEC CJ Pharm.

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## SUMMARY

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### **Key Regulatory Approvals for Our Product Candidates**

We submitted the BLAs to the NMPA in January and June 2025, respectively, for two insulin analogs, namely Guangjianda (Insulin Degludec Injection) and Guangjianshu (Insulin Degludec/Insulin Aspart Injection). In addition, our two Class I innovative anti-HCV drugs, namely Netanasvir Phosphate Capsules and Encofosbuvir Tablets, were approved by the NMPA for launching in China in February 2025 and March 2025, respectively. We are currently scaling up production and finalizing our market launch preparations, with sales expected to begin in July 2025 in the PRC. In parallel, we are preparing to initiate negotiations with national medical insurance authorities in December 2025, and we anticipate that our products will be included in the NRDL starting in January 2026.

### **MATERIAL ADVERSE CHANGE**

Our Directors confirm that, up to the date of this Listing Document, except as disclosed above in the section “— Recent Development — Update on Our Financial Performance for the First Quarter of 2025”, there has been no material adverse change in our financial, operational, or trading position or prospects since December 31, 2024, which is the end date of the periods reported on in the Accountants’ Report included in Appendix I to this Listing Document, and there has been no event since December 31, 2024 that would materially affect the information as set out in the Accountants’ Report included in Appendix I to this Listing Document. Please see “Risk Factors — A. Risks Relating to Our Business and Industries — We incurred losses in certain years during the Track Record Period and recorded significant revenue drop for the first quarter of 2025 as compared with the first quarter of 2024, and there may be uncertainty about the business prospects in the future” for details.

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## DEFINITIONS

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*In this Listing Document, unless the context otherwise requires, the following terms and expressions have the meanings set forth below. Certain other terms are explained in the section entitled “Glossary of Technical Terms” in this Listing Document.*

“3.5 Announcement”	the joint announcement issued by our Company and HEC CJ Pharm on May 10, 2024 regarding the Privatization Proposal
“Accountants’ Report”	the accountants’ report for our Group, the text of which is set out in Appendix I to this Listing Document
“affiliate(s)”	with respect to any specified person, any other person, directly or indirectly, controlling or controlled by or under direct or indirect common control with such specified person
“AI”	artificial intelligence
“AIDD”	AI-driven Drug Design, drug development method using AI technology at any point during the drug development process. The technology leverages the power of machine learning algorithms to identify potential targets and design molecules that can interact with those targets
“Articles” or “Articles of Association”	the articles of association of our Company, as amended, supplemented or otherwise modified from time to time, conditionally adopted on December 11, 2024 with effect from the Listing Date, a summary of which is set out in Appendix V to this Listing Document
“B2C”	business-to-consumer
“BLA”	biologics license applications, applications by which a pharmaceutical company applies to a drug regulatory agency to bring a new drug to market
“Board” or “Board of Directors”	the board of Directors of our Company
“Board of Supervisors”	the board of Supervisors of our Company
“business day”	a day on which the Stock Exchange is open for the transaction of business



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## DEFINITIONS

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“CAGR”	compound annual growth rate
“CCASS”	the Central Clearing and Settlement System established and operated by HKSCC
“China,” “PRC” or “mainland China”	the People’s Republic of China which for the purpose of this Listing Document does not include Hong Kong, Macau and Taiwan unless the context otherwise specifies
“Companies Ordinance”	the Companies Ordinance (Chapter 622 of the Laws of Hong Kong), as amended, supplemented or otherwise modified from time to time
“Companies (Winding up and Miscellaneous Provisions) Ordinance”	the Companies (Winding up and Miscellaneous Provisions) Ordinance (Chapter 32 of the Laws of Hong Kong), as amended, supplemented or otherwise modified from time to time
“Company,” “our Company” or “SLP” or “Offeror”	Sunshine Lake Pharma Co., Ltd. (廣東東陽光藥業股份有限公司), (formerly known as Sunshine Lake Pharma Limited* (廣東東陽光藥業有限公司)), a company established under the laws of the PRC with limited liability on December 29, 2003, and subsequently converted into a joint stock company with limited liability on June 21, 2023
“Company Law” or “PRC Company Law”	the Company Law of the PRC (中華人民共和國公司法), as amended, supplemented or otherwise modified from time to time
“Composite Document”	the document to be issued by or on behalf of our Company and HEC CJ Pharm to all HEC CJ Pharm Shareholders in accordance with the Takeovers Code containing, among others, details of the Merger, as may be revised or supplemented as appropriate, which is required under the Takeovers Code to be despatched no later than 7 days after the fulfilment of all Pre-Conditions (the last of which, as at the Latest Practicable Date, is the approval for the Listing of the Listing Committee) and will be available on display on the Company’s website from the date of its despatch

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## DEFINITIONS

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“Conditions”	has the meaning given to it in the section headed “History, Development and Corporate Structure — Structure of the Introduction and the Privatization” in this Listing Document
“Conditions to effectiveness”	has the meaning given to it in the section headed “History, Development and Corporate Structure — Structure of the Introduction and the Privatization” in this Listing Document
“Conditions to implementation”	has the meaning given to it in the section headed “History, Development and Corporate Structure — Structure of the Introduction and the Privatization” in this Listing Document
“Controlling Shareholders”	has the meaning ascribed to it under the Listing Rules and unless the context otherwise requires, refers to Mr. Zhang, Ms. Guo, Guangdong HEC Technology, Yichang HEC Research, Dongguan HEC Research, Linzhi HEC Pharmaceutical Research, Ruyuan HEC Industrial, Yidu HEC Industrial, Yichang HEC Medicine, Shenzhen HEC Pharmaceutical, Shenzhen HEC Industrial, Dongguan HEC Industrial, Zhejiang HEC Health, Ruyuan Yuneng Electric, Ruyuan Shuaicai Investment, Shaoguan Xinyuneng Industrial, Ruyuan Xinjing Technology, Yidu Junjiafang and Yidu Shuaixinwei, for further details of which, please refer to “Relationship with our Controlling Shareholders” in this Listing Document
“CSDCC”	China Securities Depository and Clearing Corporation Limited (中國證券登記結算有限責任公司)
“CSRC”	China Securities Regulatory Commission (中國證券監督管理委員會)
“Delisting Date”	the date on which the listing of HEC CJ Pharm on the Stock Exchange has been withdrawn
“Director(s)”	the director(s) of our Company or any one of them

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## DEFINITIONS

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“Dissenting Shareholder”	an HEC CJ Pharm H Shareholder who has validly voted against the resolutions in respect of the Merger Agreement, the Merger and the relevant arrangements at the HEC CJ Pharm EGM and the HEC CJ Pharm H Shareholders’ Class Meeting
“Domestic Share(s)”	ordinary share(s) in the share capital of our Company with a nominal value of RMB1.00 each, which are subscribed for or credited as paid up in Renminbi and are unlisted Shares which are currently not listed or traded on any stock exchange
“Dongguan HEC Biopharmaceutical”	Dongguan HEC Biopharmaceutical R&D Co., Ltd.* (東莞市東陽光生物藥研發有限公司), a company established in the PRC with limited liability on March 21, 2019 and a direct wholly-owned subsidiary of our Company
“Dongguan HEC Generic Drug”	Dongguan HEC Generic Drug R&D Co., Ltd.* (東莞市東陽光仿製藥研發有限公司), a company established in the PRC with limited liability on March 21, 2019 and a direct wholly-owned subsidiary of our Company
“Dongguan HEC Industrial”	Dongguan HEC Industrial Development Co., Ltd.* (東莞市東陽光實業發展有限公司), a company established in the PRC with limited liability on December 17, 2004, a wholly-owned subsidiary of Shenzhen HEC Industrial and one of our Controlling Shareholders
“Dongguan HEC Medical”	Dongguan HEC Medical Co., Ltd.* (東莞東陽光醫藥有限公司), formerly known as Dongguan HEC TaiGen Pharmaceutical R&D Co., Ltd.* (東莞東陽光太景醫藥研發有限責任公司), a company established in the PRC with limited liability on January 10, 2017 and an indirect non-wholly owned subsidiary of our Company
“Dongguan HEC Medicine”	Dongguan HEC Medicine R&D Co., Ltd.* (東莞市東陽光新藥研發有限公司), a company established in the PRC with limited liability on March 21, 2019 and a direct wholly-owned subsidiary of our Company
“Dongguan HEC Pharmaceutical”	Dongguan HEC Pharmaceutical Co., Ltd.* (東莞東陽光製藥有限公司), a company established in the PRC with limited liability on July 16, 2019 and a direct wholly-owned subsidiary of our Company

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## DEFINITIONS

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“Dongguan HEC Research”	Dongguan HEC Research Co., Ltd.* (東莞東陽光藥物研發有限公司), a company established in the PRC with limited liability on August 23, 2002 and one of our Controlling Shareholders
“Dongguan Yangzhikang”	Dongguan Yangzhikang Pharmaceutical Co., Ltd.* (東莞市陽之康醫藥有限責任公司), a company established in the PRC with limited liability on August 24, 2018 and an indirect non-wholly owned subsidiary of our Company
“EIT Law”	Enterprise Income Tax Law of the PRC (中華人民共和國企業所得稅法), as amended, supplemented or otherwise modified from time to time
“Enlarged SLP Group”	our Group together with the privatized HEC CJ Pharm
“Employee Incentive Scheme”	the employee incentive scheme as adopted on June 18, 2023, the principal terms of which are summarized in “Appendix VI — Statutory and General Information — D. Employee Incentive Scheme”
“EUR”	Euro, the lawful currency of member states of the European Union
“Executive”	the Executive Director of the Corporate Finance Division of the SFC or any delegate of the Executive Director
“Frost & Sullivan”	Frost & Sullivan (Beijing) Inc., Shanghai Branch Co., an independent global market research and consulting company
“Frost & Sullivan Report”	the independent industry report prepared by Frost & Sullivan as commissioned by us
“General Rules of HKSCC”	General Rules of HKSCC published by the Stock Exchange and as amended from time to time
“Germany HEC”	HEC Pharm GmbH, a company incorporated in Germany with limited liability on December 22, 2009 and a direct non-wholly owned subsidiary of our Company
“Greater China Region”	for the purpose of this Listing Document, the PRC, Hong Kong, Macau and Taiwan

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## DEFINITIONS

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“Group,” “our Group,” “we” or “us”	our Company and its subsidiaries from time to time or, where the context so requires, in respect of the period prior to our Company becoming the holding company of its present subsidiaries, such subsidiaries as if they were subsidiaries of our Company at the relevant time
“Guangdong HEC Biopharmaceutical”	Guangdong HEC Biopharmaceutical Co., Ltd* (廣東東陽光生物製劑有限公司), a company established in the PRC with limited liability on February 10, 2017 and an indirect non-wholly owned subsidiary of our Company
“Guangdong HEC Technology”	Guangdong HEC Technology Holding Co., Ltd.* (廣東東陽光科技控股股份有限公司), a company established in the PRC on October 24, 1996, whose shares are listed on the Shanghai Stock Exchange (stock code: 600673), and one of our Controlling Shareholders
“Guide for New Listing Applicants”	the Guide for New Listing Applicants published by the Stock Exchange effective from January 1, 2024 (as amended from time to time)
“HEC Biochemical Pharma”	Yichang HEC Biochemical Pharmaceutical Co., Ltd* (宜昌東陽光生化製藥有限公司), a company established in the PRC on November 29, 2018 and indirectly controlled by Ms. Guo and Mr. Zhang
“HEC CJ Pharm”	Yichang HEC ChangJiang Pharmaceutical Co., Ltd. (宜昌東陽光長江藥業股份有限公司) (formerly known as Yidu HEC Pharmaceutical Company Limited* (宜都東陽光製藥有限公司) and Yichang Changjiang Pharmaceutical Company Limited* (宜昌長江藥業有限公司)), the shares of which are listed on the Stock Exchange (stock code: 1558), a direct non-wholly owned subsidiary of our Company
“HEC CJ Pharm EGM”	the extraordinary general meeting of HEC CJ Pharm to be convened, or any adjournment thereof, to consider and, if thought fit, approve the Merger Agreement, the Merger and the relevant arrangements

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## DEFINITIONS

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“HEC CJ Pharm H Share(s)”	the ordinary shares issued by HEC CJ Pharm, with a RMB denominated par value of RMB1.00 each, which are subscribed for and paid up in Hong Kong dollars and are listed and traded on the Stock Exchange, representing approximately 74.29% of the issued share capital of HEC CJ Pharm as of the date of the 3.5 Announcement
“HEC CJ Pharm H Shareholder(s)”	the holder(s) of the HEC CJ Pharm H Share(s)
“HEC CJ Pharm H Shareholders’ Class Meeting”	class meeting of HEC CJ Pharm to be convened for HEC CJ Pharm H Shareholders, or any adjournment thereof, to consider and, if thought fit, approve the Merger Agreement, the Merger and the relevant arrangements
“HEC CJ Pharm Share(s)”	ordinary share(s) with a nominal value of RMB1.00 each in the share capital of HEC CJ Pharm
“HEC CJ Pharm Shareholder(s)”	the registered holder(s) of the HEC CJ Pharm Share(s)
“HKD,” “HK\$” or “HK dollars”	Hong Kong dollars and cents, respectively, the lawful currency of Hong Kong
“H Share(s)” or “SLP H Share(s)”	shares in the ordinary share capital of our Company, with a nominal value of RMB1.00 each, which are to be traded in HK\$ and listed on the Stock Exchange pursuant to the Listing
“H Share Registrar”	Computershare Hong Kong Investor Services Limited
“HKSCC”	Hong Kong Securities Clearing Company Limited, a wholly owned subsidiary of Hong Kong Exchanges and Clearing Limited
“HKSCC Nominees”	HKSCC Nominees Limited, a wholly owned subsidiary of HKSCC
“HKSCC Operational Procedures”	the operational procedures of HKSCC, containing the practices, procedures and administrative or other requirements relating to HKSCC’s services and the operations and functions of CCASS, FINI or any other platform, facility or system established, operated and/or otherwise provided by or through HKSCC, as from time to time in force

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## DEFINITIONS

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“Hong Kong” or “HK”	the Hong Kong Special Administrative Region of the PRC
“Hong Kong HEC”	HEC (Hong Kong) Sales Co., Limited (香港東陽光銷售有限公司), a company incorporated in Hong Kong with limited liability on August 25, 2020 and a direct wholly-owned subsidiary of our Company
“Hong Kong Listing Rules” or “Listing Rules”	the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited (as amended from time to time)
“Hong Kong Stock Exchange” or “Stock Exchange”	The Stock Exchange of Hong Kong Limited
“ICH”	International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH), an initiative that brings together the regulatory authorities and pharmaceutical industry to discuss scientific and technical aspects of pharmaceuticals and develop ICH guidelines
“IFRS”	IFRS Accounting Standards issued by the International Accounting Standards Board
“Implementation Date”	the implementation date of the Merger agreed between our Company and HEC CJ Pharm upon which our Company will assume all assets, liabilities, interests, businesses, qualifications, employees, contracts and all other rights and obligations of HEC CJ Pharm
“IND”	investigational new drug, an application and approval process required before drug candidates may commence clinical trials
“Independent Third Party(ies)”	a person or entity who is not a connected person of our Company within the meaning of the Hong Kong Listing Rules
“Independent HEC CJ Pharm H Shareholders”	HEC CJ Pharm H Shareholders other than SLP and SLP Concert Parties
“Independent HEC CJ Pharm Shareholders”	HEC CJ Pharm Shareholders other than SLP and SLP Concert Parties



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## DEFINITIONS

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“Introduction”	the proposed Listing of our Company by way of introduction on the Main Board of the Hong Kong Stock Exchange, which include the creation of listed equity consideration (in the form of H Shares) for the Privatization
“KOL(s)”	key opinion leader, a person or organization who has expert product knowledge and influence in a particular field, who is trusted by relevant interest groups and has significant effects on consumer behavior
“Latest Practicable Date”	June 20, 2025, being the latest practicable date for ascertaining certain information in this Listing Document prior to its publication
“Linzhi HEC Pharmaceutical Research”	Linzhi HEC Pharmaceutical Research Co., Ltd.* (林芝東陽光藥業研發有限公司), a company established in the PRC with limited liability on December 20, 2016 and one of our Controlling Shareholders
“Listing”	the listing (by way of introduction) of, and permission to deal in, the H Shares on the Main Board of the Stock Exchange
“Listing Committee”	the Listing Committee of the Stock Exchange
“Listing Date”	the date, expected to be on or about Thursday, August 7, 2025, on which the H Shares are listed and on which dealings in the H Shares are first permitted to take place on the Stock Exchange
“Listing Document”	this listing document being issued by our Company in connection with the Introduction
“Long-stop Date”	the last date the Pre-Conditions, the Conditions to effectiveness and the Conditions to implementation can be fulfilled or waived, as applicable, being December 31, 2025 or such other date as agreed between our Company and HEC CJ Pharm with the consent of the Executive
“Macau”	the Macau Special Administrative Region of the PRC

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## DEFINITIONS

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“Main Board”	the stock exchange (excluding the option market) operated by the Stock Exchange which is independent from and operates in parallel with the GEM of the Stock Exchange
“Merger”	the proposed merger by absorption of HEC CJ Pharm by our Company in accordance with the PRC Company Law and other applicable PRC laws as contemplated under the Merger Agreement
“Merger Agreement”	the merger agreement entered into between our Company and HEC CJ Pharm on May 10, 2024 in relation to the Merger
“Ministry of Finance” or “MOF”	the Ministry of Finance of the PRC (中華人民共和國財政部) (or its local authority, as applicable)
“MIIT”	the Ministry of Industry and Information Technology of the PRC (中華人民共和國工業和信息化部) (or its local authority, as applicable)
“Mr. Zhang”	Mr. ZHANG Yushuai (張寓帥), the son of Ms. Guo and one of our Directors and Controlling Shareholders
“Ms. Guo”	Ms. GUO Meilan (郭梅蘭), the mother of Mr. Zhang and one of our Controlling Shareholders
“mu”	an area unit used in China, equals to approximately 667 square metres
“National Essential Drug List”	the National Essential Drug List (2018 version) (《國家基本藥物目錄(2018年版)》) promulgated by the NHC, as amended, supplemented or otherwise modified from time to time
“NCCN”	National Comprehensive Cancer Network
“NDA”	new drug application, a process required by a regulatory authority to approve a new drug for sale and marketing
“NDRC”	the National Development and Reform Commission of the PRC (中華人民共和國國家發展和改革委員會) (or its local authority, as applicable)

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## DEFINITIONS

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“NHC”	National Health Commission of the PRC (中華人民共和國國家衛生健康委員會), formerly known as National Health and Family Planning Commission of the PRC (“ <b>NHFPC</b> ”) (中華人民共和國國家衛生和計劃生育委員會); references to NHC include NHFPC
“NMPA”	the National Medical Products Administration (國家藥品監督管理局), formerly known as China Food and Drug Administration (“ <b>CFDA</b> ”) (國家食品藥品監督管理總局) or State Food and Drug Administration (“ <b>SFDA</b> ”) (國家食品藥品監督管理局) or China’s Drug administration (“ <b>CDA</b> ”) (國家藥品監督管理局); references to NMPA include CFDA, SFDA and CDA
“North & South Brother (HK)”	North & South Brother International Investment H.K. Co. Limited (香港南北兄弟國際投資有限公司), a company established in Hong Kong on October 31, 1997 and an Independent Third Party
“North & South Brother Pharma”	North & South Brother Pharmacy Investment Company Limited (南北兄弟藥業投資有限公司), a company established in Hong Kong on October 31, 2006 and an Independent Third Party
“NPC”	the National People’s Congress of the PRC (中華人民共和國全國人民代表大會)
“NRDL”	China’s National Reimbursement Drug List, also known as Drugs Catalog for the National Basic Medical Insurance, Work-related Injury Insurance and Maternity Insurance (《國家基本醫療保險、工傷保險和生育保險藥品目錄》), which was published by MOHRSS, as amended, supplemented or otherwise modified from time to time
“Oseltamivir Phosphate Licensor”	F. Hoffmann-La Roche Ltd, an international pharmaceutical company based in Switzerland that holds the rights to certain patents relating to oseltamivir phosphate, an Independent Third Party
“OTC”	over the counter, drugs sold directly to a consumer without a prescription, as opposed to prescription drugs

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## DEFINITIONS

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“PBOC”	People’s Bank of China (中國人民銀行), the central bank of the PRC
“PCT”	the Patent Cooperation Treaty, an international patent law treaty, concluded in 1970. It provides a unified procedure for filing patent applications to protect inventions in each of its contracting states. A patent application filed under the PCT is called an international application, or PCT application
“Poisons and Drugs Research Office”	Poisons and Drugs Research Office of the Medical Science Academy of the PRC People’s Liberation Army (中國人民解放軍軍事醫學科學院毒物藥物研究所)
“PRC GAAP”	generally accepted accounting principles of PRC
“Pre-Listing Investment”	investment made by the Pre-Listing Investors
“Pre-Listing Investors”	the investors as set out in the section headed “History, Development and Corporate Structure — Pre-Listing Investment — 5. Information about the Pre-Listing Investors” in this Listing Document
“PRC Laws”	any and all laws, regulations, statutes, rules, decrees, notices, and supreme court’s judicial interpretations as may be in force and publicly available in the PRC from time to time
“PRC Legal Advisor”	Jia Yuan Law Offices, our legal advisor as to PRC laws
“Pre-Conditions”	has the meaning given to it in the section headed “History, Development and Corporate Structure — Structure of the Introduction and the Privatization” in this Listing Document
“Privatization”	the privatization of HEC CJ Pharm by our Company by way of merger by absorption in accordance with the PRC Company Law and other applicable PRC laws as contemplated under the Merger Agreement and the voluntary withdrawal of the listing of the HEC CJ Pharm H Shares from the Stock Exchange pursuant to Rule 6.15(2) of the Listing Rules
“Privatization Proposal”	the proposal for the Privatization

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## DEFINITIONS

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“province”	a province or, where the context requires, a provincial level autonomous region or municipality, under the direct supervision of the central government of the PRC
“R&D”	research and development
“RMB” or “Renminbi”	Renminbi, the lawful currency of the PRC
“Ruyuan HEC Enterprise Management”	Ruyuan Yao Autonomous County HEC Enterprise Management Co., Ltd.* (乳源瑤族自治縣東陽光企業管理有限公司), a company established in the PRC with limited liability on September 2, 2010
“Ruyuan HEC Industrial”	Ruyuan Yao Autonomous County HEC Industrial Development Co., Ltd.* (乳源瑤族自治縣東陽光實業發展有限公司), a company established in the PRC with limited liability on May 28, 2004 and one of our Controlling Shareholders
“Ruyuan HEC Pharma”	Ruyuan HEC Pharmaceutical Co., Ltd.* (乳源東陽光藥業有限公司), a company established in the PRC with limited liability on March 5, 2010 and indirectly controlled by Ms. Guo and Mr. Zhang
“Ruyuan Shuaicai Investment”	Ruyuan Yao Autonomous County Shuaicai Investment Service Partnership (L.P.)* (乳源瑤族自治縣帥才投資服務合夥企業(有限合夥)), a limited partnership established in the PRC on February 4, 2024 of which Mr. Zhang is the sole general partner and owns 90% interest therein and one of our Controlling Shareholders
“Ruyuan Xinjing Technology”	Ruyuan Yao Autonomous County Xinjing Technology Development Co., Ltd.* (乳源瑤族自治縣新京科技發展有限公司), a company established in the PRC with limited liability on June 26, 2001 and one of our Controlling Shareholders
“Ruyuan Yangzhiguang Aluminum”	Ruyuan Yangzhiguang Aluminum Development Co., Ltd.* (乳源陽之光鋁業發展有限公司), a company established in the PRC with limited liability on June 25, 1998

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## DEFINITIONS

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“Ruyuan Yuneng Electric”	Ruyuan Yao Autonomous County Yuneng Electric Industrial Co., Ltd.* (乳源瑤族自治縣寓能電子實業有限公司), a company established in the PRC with limited liability on June 26, 2001 and one of our Controlling Shareholders
“SAFE”	State Administration of Foreign Exchange of the PRC (中華人民共和國國家外匯管理局)
“SAMR”	State Administration for Market Regulation of the PRC (中華人民共和國國家市場監督管理總局)
“SASAC”	the State-owned Assets Supervision and Administration Commission of the State Council (國務院國有資產監督管理委員會)
“SAT”	the State Taxation Administration of the PRC (中華人民共和國國家稅務總局)
“Securities and Futures Ordinance” or “SFO”	the Securities and Futures Ordinance (Chapter 571 of the Laws of Hong Kong) (as revised, supplemented or otherwise modified from time to time)
“SFC”	the Securities and Futures Commission of Hong Kong
“Shaoguan Xinyuneng Industrial”	Shaoguan Xinyuneng Industrial Investment Co., Ltd.* (韶關新寓能實業投資有限公司), a company established in the PRC with limited liability on November 9, 2016 and one of our Controlling Shareholders
“Share(s)”	ordinary share(s) in the share capital of our Company with a nominal value of RMB1.00 each, comprising Domestic Shares and H Shares
“Shareholder(s)”	holder(s) of our Share(s)
“Share Exchange”	exchange of the HEC CJ Pharm H Shares held by the Share Exchange Shareholders into the H Shares according to the Share Exchange Ratio and the terms of the Merger Agreement

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## DEFINITIONS

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“Share Exchange HEC CJ Pharm H Share(s)”	the HEC CJ Pharm H Shares held by the Share Exchange Shareholders which will be exchanged into the H Shares according to the Share Exchange Ratio pursuant to the Share Exchange
“Share Exchange Ratio”	one HEC CJ Pharm H Share to exchange for 0.263614 H Share, meaning that our Company will issue 0.263614 H Share to exchange for one HEC CJ Pharm H Share
“Share Exchange Record Date”	the trading day of the Stock Exchange, expected to be on or about Monday, August 4, 2025, on which a list of the Share Exchange Shareholders who are eligible to participate in the Share Exchange and the number of HEC CJ Pharm H Shares held by such Share Exchange Shareholders will be confirmed
“Share Exchange Shareholder(s)”	the HEC CJ Pharm Shareholders who are registered on the register of members of HEC CJ Pharm on the Share Exchange Record Date (other than our Company or our subsidiaries (if any)) including the HEC CJ Pharm Shareholders who, on the Share Exchange Record Date, do not declare, only partially declare, are ineligible to declare or invalidly declare to exercise the right of the Dissenting Shareholders and any third party designated by HEC CJ Pharm which has acquired HEC CJ Pharm Shares held by the Dissenting Shareholder(s) (if any)
“Shenzhen HEC Industrial”	Shenzhen HEC Industrial Development Co., Ltd.* (深圳市東陽光實業發展有限公司), a company established in the PRC with limited liability on January 27, 1997 and one of our Controlling Shareholders
“Shenzhen HEC Industrial Group”	Shenzhen HEC Industrial and its subsidiaries (other than our Group)
“Shenzhen HEC Pharmaceutical”	Shenzhen HEC Pharmaceutical Co., Ltd.* (深圳市東陽光藥業有限公司), a company established in the PRC with limited liability on March 14, 2016 and one of our Controlling Shareholders
“Shenzhen HEC Testing”	Shenzhen HEC Testing Technology Co., Ltd.* (深圳市東陽光檢測技術有限公司), a company established in the PRC with limited liability on February 28, 2014 and a direct wholly-owned subsidiary of our Company



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## DEFINITIONS

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“Shenzhen NewFoxon”	NewFoxon Xuebao No. 3 Private Securities Investment Fund* (紐富斯雪寶3號私募證券投資基金), a fund managed by Shenzhen NewFoxon Investment Co., Ltd.* (深圳紐富斯投資管理有限公司)
“SLP Concert Parties”	parties acting in concert with us in relation to HEC CJ Pharm under the Takeovers Code
“Sole Sponsor”	China International Capital Corporation Hong Kong Securities Limited
“Special Dividend”	subject to, the fulfillment (or waiver, as applicable) of all the Pre-Conditions and the Conditions, the proposed special dividend of HK\$1.50 per HEC CJ Pharm Share to be declared by HEC CJ Pharm payable in cash to HEC CJ Pharm Shareholders whose names appear on the register of members of HEC CJ Pharm on the Special Dividend Record Date other than our Company and our subsidiaries (if applicable)
“Special Dividend Record Date”	the record date for determining the entitlements of HEC CJ Pharm Shareholders to the proposed Special Dividend, which will be decided by the board of HEC CJ Pharm and announced by HEC CJ Pharm
“State Council”	State Council of the PRC (中華人民共和國國務院)
“subsidiary(ies)”	has the meaning ascribed to it in section 15 of the Companies Ordinance
“Supervisor(s)”	the supervisor(s) of our Company
“Suzhou Fenghe”	Suzhou Fenghe Yinghui Corporate Management Partnership (L.P.)* (蘇州豐禾盈輝企業管理合夥企業(有限合夥)), a limited partnership established in the PRC on December 20, 2024
“Takeovers Code”	the Code on Takeovers and Mergers issued by the SFC, as amended, supplemented or otherwise modified from time to time
“Track Record Period”	the three financial years ended December 31, 2022, 2023 and 2024

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## DEFINITIONS

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“United States” or the “U.S.”	the United States of America, its territories and possessions, any State of the United States and the District of Columbia
“U.S. Securities Act”	The United States Securities Act of 1933, as amended
“US\$” or “US dollars” or “USD”	United States dollars, the lawful currency of the United States
“US HEC”	HEC Pharm USA, Inc., a corporation incorporated in the State of New Jersey on November 1, 2011 and an indirect wholly-owned subsidiary of our Company
“Yichang HEC Medical Technology”	Yichang HEC Medical Technology Promotion Service Co., Ltd.* (宜昌東陽光醫藥科技推廣服務有限公司), a company established in the PRC with limited liability on September 10, 2019 and an indirect non-wholly owned subsidiary of our Company
“Yichang HEC Medical”	Yichang HEC Medical Co., Ltd.* (宜昌東陽光醫藥有限公司), a company established in the PRC with limited liability on July 8, 2005 and an indirect non-wholly owned subsidiary of our Company
“Yichang HEC Medicine”	Yichang HEC Medicine Co., Ltd.* (宜昌東陽光藥業股份有限公司), a company established in the PRC with limited liability on January 12, 2004, a non wholly-owned subsidiary of Shenzhen HEC Industrial and one of our Controlling Shareholders
“Yichang HEC Pharmaceutical”	Yichang HEC Pharmaceutical Co., Ltd.* (宜昌東陽光製藥有限公司), a company established in the PRC with limited liability on February 28, 2018 and an indirect non-wholly owned subsidiary of our Company
“Yichang HEC Research”	Yichang HEC Research Co., Ltd.* (宜昌東陽光藥研發有限公司), a company established in the PRC with limited liability on December 12, 2014 and one of our Controlling Shareholders

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## DEFINITIONS

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“Yidu HEC Industrial”	Yidu HEC Industrial Development Co., Ltd.* (宜都市東陽光實業發展有限公司), a company established in the PRC with limited liability on February 10, 2004, a non wholly-owned subsidiary of Shenzhen HEC Industrial and one of our Controlling Shareholders
“Yidu Fangwenwen”	Yidu Fangwenwen Equity Investment Limited (L.P.)* (宜都芳文文股權投資合夥企業(有限合夥)), a limited liability partnership established in the PRC on February 5, 2021 of which Dr. Zhang Yingjun is the sole general partner, and one of our employee incentive platforms
“Yidu Junjiafang”	Yidu Junjiafang Equity Investment Limited (L.P.)* (宜都俊佳芳股權投資合夥企業(有限合夥)), a limited liability partnership established in the PRC on October 30, 2020 of which Mr. Zhang is the sole general partner, and one of our Controlling Shareholders
“Yidu Shuaixinwei”	Yidu Shuaixinwei Equity Investment Limited (L.P.)* (宜都帥新偉股權投資合夥企業(有限合夥)), a limited liability partnership established in the PRC on October 30, 2020 of which Mr. Zhang is the sole general partner, and one of our Controlling Shareholders
“Yidu Yingwenfang”	Yidu Yingwenfang Equity Investment Limited (L.P.)* (宜都英文芳股權投資合夥企業(有限合夥)), a limited liability partnership established in the PRC on February 9, 2021 of which Dr. Zhang Yingjun is the sole general partner, and one of our employee incentive platforms
“Zhejiang HEC Health”	Zhejiang HEC Health Pharmaceutical Co. Ltd.* (浙江東陽光健康藥業有限公司), a company established in the PRC with limited liability on September 15, 2009, a wholly-owned subsidiary of Shenzhen HEC Industrial and one of our Controlling Shareholders
“%”	per cent

In this Listing Document, the terms “associate”, “close associate”, “connected person”, “core connected person”, “connected transaction”, “controlling shareholder” and “substantial shareholder” shall have the meanings given to such terms in the Hong Kong Listing Rules, unless the context otherwise requires.

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## DEFINITIONS

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Certain amounts and percentage figures included in this Listing Document have been subject to rounding. Accordingly, figures shown as totals in certain tables may not be an arithmetic aggregation of the figures preceding them. Any discrepancies in any table or chart between the total shown and the sum of the amounts listed are due to rounding.

For ease of reference, in this Listing Document, “\*” denotes translation of certain PRC established companies or entities, laws or regulations into English for identification purposes only. In the event of any inconsistency, the Chinese versions shall prevail.

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## GLOSSARY OF TECHNICAL TERMS

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*This glossary of technical terms contains terms used in this Listing Document as they relate to our business. As such, these terms and their meanings may not always correspond to standard industry meaning or usage of these terms.*

“antibiotic(s)”	a substance produced by or derived from certain fungi, bacteria and other microorganisms, or produced by chemical processes that can destroy or inhibit the growth of other microorganisms; widely used in the prevention and treatment of infectious diseases
“acute myeloid leukemia” or “AML”	a cancer caused by an over-proliferation of myeloid blood cells, characterized by the rapid growth of large numbers of abnormal cells in the bone marrow and blood, which interfere with blood production
“AD” or “Alzheimer’s disease”	caused by the accumulation of abnormal protein structures in the brain, which leads to the death of brain cells and the shrinking of brain tissue, affecting patients’ memory and thinking skills
“ADC”	antibody drug conjugate, a class of biopharmaceutical drugs that comprise an antibody conjugated to a payload molecule, typically a cytotoxic agent, via a chemical linker
“API(s)”	active pharmaceutical ingredient (API) (or drug substance), any substance or mixture of substances intended to be used in the manufacture of a drug (medicinal) product and that, when used in the production of a drug, becomes an active ingredient of the drug product.
“bioequivalence”	the relationship between two preparations of the same drug in the same dosage form that have a similar bioavailability (rate and extent of availability)
“biosimilar”	a therapeutic biological product that is similar in quality, safety and efficacy to a reference drug approved for registration

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## GLOSSARY OF TECHNICAL TERMS

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“blood glucose”	also referred to as blood sugar, the concentration of glucose in your blood, an indicator of diabetes monitoring
“Class I innovative (chemical/biological) drug” or “innovative (chemical/biological) drug”	innovative drug that has never been marketed worldwide, being API and its preparation that contain new compounds with clearly defined structure and pharmacological effects which is defined by Reform Plan for Registration Category of Chemical Medicine (《化學藥品註冊分類改革工作方案》) issued by NMPA on March 4, 2016; in other jurisdictions, this type of drug may be classified differently, such as new drug or other classifications, based on their respective regulatory frameworks
“Class II modified new (chemical) drug”	modified new drug that has never been marketed worldwide, being drugs that optimize their structure, dosage form, prescription process, administration route, and indication on the basis of known active ingredients which is defined by Reform Plan for Registration Category of Chemical Medicine (《化學藥品註冊分類改革工作方案》) issued by NMPA on March 4, 2016
“Class III chemical drug”	drugs produced domestically that mimic in-house research and development drugs already listed overseas but not yet listed domestically, having the same active ingredients, dosage forms, specifications, indications, administration routes, and dosage as reference preparations which is defined by Reform Plan for Registration Category of Chemical Medicine (《化學藥品註冊分類改革工作方案》) issued by NMPA on March 4, 2016
“Class III biological drug”	biological products that have been marketed in or outside China which is defined by Requirements for Registration Classification and Application Dossiers of Biological Products (《生物製品註冊分類及申報資料要求》) issued by NMPA on June 29, 2020

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## GLOSSARY OF TECHNICAL TERMS

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“Class IV chemical drug”	drugs produced domestically that mimic domestically listed in-house research and development drugs, having the same active ingredients, dosage forms, specifications, indications, administration routes, and dosage as the reference formulation which is defined by Reform Plan for Registration Category of Chemical Medicine (《化學藥品註冊分類改革工作方案》) issued by NMPA on March 4, 2016
“cccDNA”	covalently closed circular DNA, a special DNA structure that arises during the propagation of some viruses in the cell nucleus and may remain permanently there
“chemotherapy”	treatment of non-specific usage of intracellular poisons to inhibit mitosis (cell division) or induce DNA damage
“CIA”	chemotherapy-induced anemia, a side effect of chemotherapy that can occur when chemotherapy drugs damage cells in the bone marrow that produce red blood cell
“cirrhosis”	a chronic disease of the liver marked by degeneration of cells, inflammation and fibrous thickening of tissue
“Class I hospital” or “primary hospital”	township or community hospitals designated as Class I hospitals by the hospital classification system of the National Health and Family Planning Commission (currently known as National Health Commission of the PRC (中華人民共和國國家衛生健康委員會)), whose primary focus is on preventive care, minimal health services, and rehabilitation
“Class II hospital” or “secondary hospital”	regional hospitals designated as Class II hospitals by the hospital classification system of the National Health and Family Planning Commission (currently known as the NHC), typically providing multiple communities with integrated healthcare services and undertaking certain academic and scientific research missions

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## GLOSSARY OF TECHNICAL TERMS

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“Class III hospital” or “tertiary hospital”	largest regional hospitals with the highest standard in China designated as Class III hospitals by the hospital classification system of the National Health and Family Planning Commission (currently known as the NHC), typically providing high-quality professional healthcare services covering a wide geographic area and undertaking higher academic and scientific research initiatives
“CMC”	chemistry, manufacturing, and controls
“COPD”	chronic obstructive pulmonary disease, a progressive and often preventable lung disease characterized by long-term breathing problems and poor airflow due to conditions like chronic bronchitis and emphysema
“CR”	complete remission, the disappearance of all signs and symptoms of a disease, usually after treatment, indicating that the disease is no longer detectable
“CRc”	composite complete remission
“CRh”	complete remission with partial hematologic recovery
“CRO”	contract research organization, a contract research organization, who provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contractual basis
“DAA”	direct-acting antiviral agent(s) or drug(s), drugs used to treat viral infections, especially hepatitis C, by directly targeting the virus and inhibiting its replication, significantly improving treatment effectiveness and shortening treatment duration
“DDP (Incoterms 2010)”	Delivered Duty Paid under the 2010 version of the Incoterms, an international trade term where the seller assumes responsibility for all costs, risks and obligations involved in delivering goods to the buyer’s designated location, including customs duties, taxes, and transport costs, until delivery is completed



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## GLOSSARY OF TECHNICAL TERMS

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“DPP-4”	dipeptidyl peptidase-4, also known as adenosine deaminase complexing protein 2 or CD26 (cluster of differentiation 26) is a protein that, in humans, is encoded by the DPP4 gene
“diabetes”	a chronic disease marked by high blood sugar that occurs either when the pancreas does not produce enough insulin or when the body cannot effectively use the insulin it produces
“DNA”	deoxyribonucleic acid, a molecule that carries most of the genetic instructions used in the development, functioning and reproduction of all known living organisms and many viruses
“drug-drug interaction”	means the cumulative changes in a drug’s effect on the body when the drug is taken together with another drug. Drug-drug interaction can delay, decrease, or enhance absorption of either drug
“druggability”	the ability of a target to be therapeutically modulated by medicines
“Encofosbuvir” or “Encofosbuvir Tablets”	a Class I innovative anti-HCV drug candidate, previously known as “Yiqibuvir”
“ESCC” or “esophageal squamous cell carcinoma”	a high-mortality cancer with complex etiology and progression involving both genetic and environmental factors
“exposure-response (E-R) models”	exposure-response analysis refers to developing empirical models to characterize the relationship between drug exposure vs. drug response. Drug response can refer to biomarker changes, safety events, and clinical responses
“FGF21”	fibroblast growth factor 21, is a metabolic hormone primarily expressed in the liver. It acts on adipose, liver and pancreatic tissues to regulate glucose and lipid homeostasis as well as other metabolic processes

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## GLOSSARY OF TECHNICAL TERMS

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“FLT3”	a transmembrane ligand-activated receptor tyrosine kinase that is normally expressed by hematopoietic stem or progenitor cells and plays an important role in the early stages of both myeloid and lymphoid lineage development
“FLT3 inhibitor”	a type of tyrosine kinase inhibitors, which inhibit the phosphorylation of FLT3 protein through the ATP binding site of the active region of the kinase, and then inhibit the relevant downstream growth signaling pathway, and play a therapeutic role
“FLT3-ITD”	FLT3 internal tandem duplication, a common mutation in AML and correlates with a poor prognosis and higher risk of relapse of AML patients. ITDs are in-frame mutations caused by duplication of various in length fragments encoding the JM domain of FLT3 receptor. The length of ITD insert can influence the clinical outcome in AML patients
“fusion protein”	proteins created through the joining of two or more genes by molecular engineering
“generic drug”	a drug that contains the same active ingredients as an original formulation and is comparable in dosage form, strength, quality, performance and intended use
“GCG”	glucagon, a peptide hormone produced by the alpha cells of the pancreas. It raises blood glucose by promoting glycogen breakdown and new glucose synthesis in the liver
“GCP”	good clinical practice, an international ethical and scientific quality standard for the performance of a clinical trial on medicinal products involving humans
“GIP”	dependent insulinotropic polypeptide. Secreted by intestinal K-cells upon food intake, especially carbs. It stimulates insulin release in a glucose-dependent way and affects lipid metabolism

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## GLOSSARY OF TECHNICAL TERMS

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“GLP”	good laboratory practice, a quality system of management controls for research laboratories and organizations to try to ensure the uniformity, consistency, reliability, reproducibility, quality and integrity of chemical and pharmaceuticals non-clinical safety tests
“GLP-1”	glucagon-like peptide-1, an incretin hormone secreted by L-cells in the distal intestinal ileum and colon after eating
“GMP”	good manufacturing practice, a quality system enforced by relevant regulatory authorities to ensure that the products produced meet specific requirements for identity, strength, quality and purity
“granules”	a form in which medicines may be delivered for oral ingestion, produced by mixing extracted active medicinal ingredients with supplemental materials or powdered medicines which are formed into dry granules
“GSP”	good supply practice, guidelines and regulations from time to time issued pursuant to the Drug Administration Law of the PRC (《中華人民共和國藥品管理法》) to provide quality assurance and ensure that pharmaceutical distribution enterprises distribute pharmaceutical products in compliance with the guidelines and regulations
“head-to-head”	a trial designed to evaluate an investigational medicine compared to an existing standard of care
“HIF-PHD”	hypoxia inducible factors – prolyl hydroxylase domain proteins. Hypoxia inducible factors (HIFs) are central transcription factors in the hypoxia response and drive the expression of a vast number of survival genes in cancer cells and in cells in the tumor microenvironment. HIFs are tightly controlled by a class of oxygen sensors, the HIF-prolyl hydroxylase domain proteins (PHDs), which hydroxylate HIFs, thereby marking them for proteasomal degradation

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## GLOSSARY OF TECHNICAL TERMS

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“HbA1c”	glycosylated hemoglobin, a form of hemoglobin that is chemically linked to a sugar. Most monosaccharides, including glucose, galactose and fructose, spontaneously bond with hemoglobin, when present in the bloodstream of humans
“HBcrAg”	hepatitis B core-related antigen, a soluble antigen that circulates in the blood
“HBsAg”	HBV surface antigens, a protein found on the surface of HBV
“hepatitis B”	an infectious disease affecting the liver, caused by the hepatitis B virus (HBV)
“hepatitis C”	an infectious disease affecting primarily the liver, caused by the hepatitis C virus (HCV)
“hERG”	hERG codes for a protein known as Kv11.1, the alpha subunit of a potassium ion channel. This ion channel is best known for its contribution to the electrical activity of the heart; the hERG channel mediates the repolarizing IKr current in the cardiac action potential, which helps coordinate the heart’s beating
“heuristic search”	a type of problem-solving algorithm that uses heuristic functions to guide the exploration of possible solutions. A heuristic function is an approximation or estimation used as a way to find better, more efficient solutions faster than exhaustive searches through all possible combinations
“hypertension”	a long-term medical condition in which blood pressure is persistently elevated
“hyperuricemia”	a level of uric acid in the blood that is abnormally high
“hypoglycemic”	a condition in which the blood sugar (glucose) level is lower than the standard range

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## GLOSSARY OF TECHNICAL TERMS

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“in vitro”	Latin for “in glass” (usually performed in experimental glassware); studies in vitro are conducted using components of an organism that have been isolated from their usual biological surroundings, such as microorganisms, cells or biological molecules
“in vivo”	Latin for “within the living”; studies in vivo are those in which the effects of various biological entities are tested on whole, living organisms as opposed to a partial or dead organism
“IPF” or “idiopathic pulmonary fibrosis”	a chronic, progressive lung disease. This condition causes scar tissue (fibrosis) to build up in the lungs, which makes the lungs unable to transport oxygen into the bloodstream effectively
“inhibitor”	also known as retarding agent, a substance used to block or reduce the rate of chemical reaction, the same effect as a negative catalyst
“insulin”	a substance that the human body makes and uses to turn sugar into energy
“License in/License out”	the introduction or licensing of products or technologies
“mechanism of action”	the specific biochemical interaction through which a drug substance produces its pharmacological effect
“molecule”	an electrically neutral group of two or more atoms held together by chemical bonds
“monotherapy”	treatment of a condition by means of a single drug
“NASH”	non-alcoholic steatohepatitis, severe form of nonalcoholic fatty liver disease characterized by inflammation of the liver and damage to liver cells, which can lead to fibrosis (scarring) or cirrhosis
“Netanasvir Phosphate” or “Netanasvir Phosphate Capsules”	a Class I innovative anti-HCV drug candidate, previously known as “Antaitasvir Phosphate”

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## GLOSSARY OF TECHNICAL TERMS

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“NS5A”	non-structural protein 5A, a zinc-binding and proline-rich hydrophilic phosphoprotein that plays a key role in HCV RNA replication
“NS5B”	non-structural protein 5B, an RNA polymerase
“NS3/4A”	a protease that plays an essential role in translation and polyprotein processing during the HCV viral replication process
“Ologliflozin” or “Ologliflozin Capsules”	a Class I innovative antidiabetic medication drug candidate, previously known as “Rongliflozin Pyroglutamate”
“orphan drug designation”	a designation granted by the FDA to a drug or biological product which prevents, diagnoses or treats a rare disease or condition, qualifying the sponsors for certain incentives
“pan-genotypic”	anti-viral activity against all genotypes; for hepatitis C, a pan-genotypic drug would effectively target genotypes 1 to 6
“pharmacology”	the science that deals with the origin, nature, chemistry, effects, and uses of drugs, including pharmacognosy, pharmacokinetics, pharmacodynamics, pharmacotherapeutics and toxicology
“Phase I clinical trial(s)”	phase I clinical trials aim to test the safety of a new drug candidate
“Phase II clinical trial(s)”	phase II clinical trials test the new drug candidate on a larger group of patients, to gather information about whether it works and how well it works in the short-term
“Phase III clinical trial(s)”	phase III clinical trials are for a new drug candidate that has already passed phases I and II which test the new drug candidate in larger groups of patients, and compare the new drug candidate against an existing treatment or a placebo to see if it works better in practice and if it has important side effects

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## GLOSSARY OF TECHNICAL TERMS

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“placebo”	a substance or treatment with no active therapeutic effect, commonly used in clinical trials as the administered substance for the control group
“pneumonia”	an infection of one or more lungs which is usually caused by bacteria, viruses or fungi
“PPI”	proton pump inhibitors, a substance used to treat certain disorders of the stomach and intestines, such as heartburn and ulcers. Proton pump inhibitors block the actions of an enzyme in the stomach and reduce the amount of acid made in the stomach
“pre-clinical studies”	pre-clinical studies testing a drug candidate on nonhuman subjects, to gather efficacy, toxicity, pharmacokinetic and safety information and to decide whether a drug candidate is ready for clinical trials
“primary endpoint”	the main clinical event or result that is measured at a specified time of the study to see if the investigational treatment is effective
“PROTAC”	proteolysis targeting chimera, a molecule that induces selective intracellular proteolysis
“proteolysis”	the breakdown of proteins or peptides into amino acids by the action of enzymes
“QT interval”	the duration of ventricular electrical systole, a measurement made on an electrocardiogram used to assess some of the electrical properties of the heart
“receptor”	a protein molecule usually found on the surface of a cell that receives chemical signals from outside the cell
“ribavirin”	an anti-viral medication used to treat respiratory syncytial virus infection, hepatitis C and viral hemorrhagic fevers
“RLD”	reference listed drug, the approved drug product that the proposed generic drug is intended to duplicate

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## GLOSSARY OF TECHNICAL TERMS

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“RNA”	ribonucleic acid, a polymeric molecule essential in various biological roles in coding, decoding, regulation and expression of genes
“SGLT-2”	sodium-glucose Cotransporter-2, a protein that facilitates glucose reabsorption in the kidney
“sildenafil”	a medication used to treat erectile dysfunction and pulmonary arterial hypertension
“SVR12”	sustained virologic response 12 weeks after treatment completion
“synthesis”	the production of chemical compounds by reaction from simpler materials
“tadalafil”	a medication used to treat erectile dysfunction, benign prostatic hyperplasia, and pulmonary arterial hypertension
“type 2 diabetes”	a form of diabetes characterized by high blood sugar, insulin resistance and relative lack of insulin
“TKD”	tyrosine kinase domain, a specific region within a protein that has the enzymatic activity to phosphorylate tyrosine residues on other proteins, playing a crucial role in cell signaling pathways that regulate various cellular processes such as growth, differentiation, and survival
“TLR8 agonist”	a type of molecule that activates Toll-like receptor 8 (TLR8), a protein mainly expressed in myeloid cells such as monocytes, macrophages, and neutrophils in the human body
“U.S. FDA” or “FDA”	the Food and Drugs Administration of the United States
“VBP” or “volume-based procurement”	a set of drug and medical device procurement regulations implemented in China which primarily regulate the drug and medical device procurements of public hospitals in China. The VBP aims to achieve a lower price of pharmaceuticals and medical devices center on medical products with mature, high-volume clinical usage and sufficient market competition through a competitive centralized bidding process for large-volume procurement. VBP has been rolled out at both national and provincial levels



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## FORWARD-LOOKING STATEMENTS

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This Listing Document includes forward-looking statements. All statements other than statements of historical facts contained in this Listing Document, including, without limitation, those regarding our future financial position, our strategy, plans, objectives, goals, targets and future developments in the markets where we participate or are seeking to participate, and any statements preceded by, followed by or that include the words “believe,” “expect,” “estimate,” “predict,” “aim,” “intend,” “will,” “may,” “plan,” “consider,” “anticipate,” “seek,” “should,” “could,” “would,” “continue,” or similar expressions or the negative thereof, are forward-looking statements. These forward-looking statements involve known and unknown risks, uncertainties and other factors, some of which are beyond our control, which may cause our actual results, performance or achievements, or industry results, to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. These forward-looking statements are based on numerous assumptions regarding our present and future business strategies and the environment in which we will operate in the future. Important factors that could cause our actual performance or achievements to differ materially from those in the forward-looking statements include, among others, the following:

- our business strategies and plans to achieve these strategies;
- future developments, trends and conditions in and competitive environment for the industries and markets in which we operate;
- general economic, political and business conditions in locations where we operate;
- our financial condition and performance;
- our capital expenditure plans;
- changes to the regulatory environment, policies, operating conditions of and general outlook in the industries and markets in which we operate;
- our expectations with respect to our ability to acquire and maintain regulatory licenses or permits;
- the amount and nature of, and potential for, future development of our business;
- the actions of and developments affecting our competitors; and
- the actions of and developments affecting our major customers and suppliers.

Additional factors that could cause actual performance or achievements to differ materially include, but are not limited to, those discussed under the section headed “Risk Factors” and elsewhere in this Listing Document. We caution you not to place undue reliance on these forward-looking statements, which reflect our management’s view only as at the date of this Listing Document. We undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. Considering these risks, uncertainties and assumptions, the forward-looking events discussed in this Listing Document might not occur. All forward-looking statements contained in this Listing Document are qualified by reference to the cautionary statements set out in this section.

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## RISK FACTORS

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You should carefully consider all of the information in this Listing Document, including the following risk factors before making any investment decision in relation to the H Shares. Our business, financial condition or results of operations could be materially and adversely affected by any of these risks. The market price of the H Shares could fall significantly due to any of these risks, and you may lose all or part of your investment.

We believe that there are certain risks involved in our operations, many of which are beyond our control. We have categorized these risks and uncertainties into: (i) risks relating to our business and industries; and (ii) risks relating to the Listing. Additional risks and uncertainties that are presently not known to us or not expressed or implied below or that we currently deem immaterial could also harm our business, financial condition and operating results. You should consider our business and prospects in light of the challenges we face, including the ones discussed in this section.

### A. RISKS RELATING TO OUR BUSINESS AND INDUSTRIES

**Our revenue and business prospects currently depend on Kewei (oseltamivir phosphate). If we are unable to maintain the sales volumes, pricing levels and profit margins of Kewei, our revenue and business prospects could be materially and adversely affected.**

During the Track Record Period, sales of oseltamivir phosphate accounted for 81.2%, 86.9% and 64.2% of our revenue for the years ended December 31, 2022, 2023 and 2024, respectively. Most of the oseltamivir phosphate revenue was generated from Kewei (oseltamivir phosphate), our top-selling product. As our revenue has been, and we expect in the short to medium term will continue to be, concentrated on Kewei, our business will be susceptible to factors that may adversely affect Kewei, including incidence of seasonal flu outbreaks, seasonality of sales of Kewei, competition from other manufacturers of anti-viral drugs, prolonged outbreak of an epidemic illness, efficacy of Kewei, pricing level, sales volume, profit margin and production.

The sales of Kewei is significantly affected by flu incidence and pronounced seasonality patterns that may materially impact our financial performance and business operations. For example, our revenue decreased by 37.1% from RMB6,385.6 million in 2023 to RMB4,018.9 million in 2024 mainly due to the fact that our sales for Kewei decreased significantly in 2024 as compared to that of 2023. Such drop was in turn mainly caused by a decrease in flu incidence in China in 2024 as compared to the same period in 2023. In addition, Kewei is effective specifically against Type A and Type B influenza viruses, making it highly sought after during the winter-spring flu seasons in China (typically November through March), when influenza activity reaches its highest levels. Conversely, during periods of low influenza activity, particularly summer months (June through August), demand for Kewei experiences substantial declines, often resulting in significant reductions in our sales volume and revenue for this product. Kewei does not exhibit effectiveness against Types C and D influenza viruses,

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nor is its efficacy guaranteed for any new and potentially evolving influenza viruses that may emerge in the future. This limitation could impact the market position of Kewei, particularly if alternative drugs are proven to be more effective against such novel strains. The unpredictability of seasonal flu outbreaks in terms of timing, severity, duration, type, and geographic spread can vary significantly from year to year. A particularly mild flu season could result in substantially reduced demand for Kewei, potentially leaving us with excess inventory. As these factors are largely beyond our control and are difficult to predict with certainty, the potential fluctuations relating to Kewei's performance could materially impact our revenue and business prospects. In addition, any prolonged outbreak of epidemic illness may lead to large-scale travel restrictions, social-distancing measures and business closures which would significantly reduce the movement of people, resulting in a decline in the incidence of influenza which in turn could have a negative impact on our business. Furthermore, as oseltamivir phosphate is mostly effective when taken within 48 hours of the onset of flu symptoms, if a patient does not take oseltamivir phosphate during this period, the patient may choose to take other drugs instead of oseltamivir phosphate which may have a negative impact on the sales of our oseltamivir phosphate products.

In addition, the key patents relating to oseltamivir phosphate compound began to expire in August 2017, with the final key patent relating to oseltamivir phosphate synthetic process expired in March 2024. Since 2017, other pharmaceutical companies have been producing and selling oseltamivir phosphate capsule products by using different oseltamivir phosphate manufacturing processes. As a result, our oseltamivir phosphate capsule drug has been competing with other oseltamivir phosphate capsules produced by other pharmaceutical companies since 2017. We mainly sold two types of oseltamivir phosphate capsule products during the Track Record Period, namely (i) oseltamivir phosphate capsule under the brand Kewei with a revenue of RMB507.6 million, RMB684.9 million and RMB307.0 million for 2022, 2023 and 2024, respectively, representing 16.4%, 12.3% and 11.9% of our total revenue from oseltamivir phosphate products, respectively; and (ii) oseltamivir phosphate capsule under the brand Yangjiantai with a revenue of RMB4.7 million, RMB29.2 million and RMB87.7 million for 2022, 2023 and 2024, respectively, representing 0.1%, 0.5% and 3.4% of our total revenue from oseltamivir phosphate products, respectively. The patent relating to our oseltamivir phosphate granules will expire in April 2026, and there may be more competitors producing oseltamivir phosphate granules after the patent expiry. Our oseltamivir phosphate granule under the brand Kewei generated a revenue of RMB2,585.2 million, RMB4,824.6 million and RMB2,181.5 million for 2022, 2023 and 2024, respectively, representing 83.5%, 87.0% and 84.6% of our total revenue from oseltamivir phosphate products, respectively. The increased competition may have a negative impact on the sales of Kewei. Furthermore, the pricing of our oseltamivir phosphate products also has a significant impact on our financial performance. Our Kewei granules are included in provincial VBP schemes and Yangjiantai capsules are included in national VBP schemes. As a result, the relevant products included in the VBP schemes will be sold to the public medical institutions at the bid prices, which in part determine the prices at which we sell our products to our distributors. The centralized tender process can create pricing pressure among substitute products or products that are perceived to be substitute products. If there are more competitors participating in the centralized tender process, it will create pricing pressure on our Kewei granules. Our Kewei capsules has not been

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included in the provincial VBP. However, Kewei capsules, like many other drugs, must comply with the government's platforms approval and pricing policies stipulated by national and provincial-level healthcare security administrations to be eligible for the purchase by public hospitals through the government's platforms established by provincial-level healthcare security administrations. In addition, for our Kewei capsules, as there has not been any VBP schemes implemented on Kewei capsules, we cannot sell Kewei capsules to public hospitals through VBP schemes under normal situation and can only sell Kewei capsules to public hospitals outside of the VBP schemes. As a result, whether the public hospitals under or over purchase the amount of oseltamivir phosphate capsules they need in a given year will have a big impact on the sales of Kewei capsules. If there is no shortage of oseltamivir phosphate capsules in public hospitals, we will not be able to sell Kewei capsules to public hospitals which will have a material adverse impact on the sales of our Kewei capsules. Please see "Business — Product Pricing" for more details.

In addition to the above, changes in the price of APIs or other raw materials in the production of Kewei have affected and will continue to affect the profit margins of such products, which could cause our business, revenue and profitability to decline. For example, the gross margins of our anti-infective products in the Track Record Period were affected by cost of APIs. While we intend to continue to expand our product portfolio and diversify the sources of our revenue, there is no assurance that Kewei will not continue to contribute a significant portion of our revenue.

**We operate in a highly-competitive environment, and we may not be able to compete effectively against our competitors selling competing drugs, which could subject us to the pressure of price reduction and adversely affect our operations, revenue and business prospects.**

We operate in a highly-competitive environment, and we may not be able to compete effectively against competitors. Our inability to compete effectively could result in a decrease of our sales, reduction of the prices of our products and a loss of market share, any of which could have a material adverse effect on our results of operations and profit margins.

Our key competitors are large international and domestic manufacturers of pharmaceutical products. Our drugs primarily compete with drugs that are indicated for similar conditions as our drugs on the basis of efficacy, safety, price, brand, general market acceptance and recognition. Our competitors may be able to more quickly or more successfully discover, develop, acquire or market effective substitutes for our products.

In particular, as we were a market leader in terms of both sales volume and revenue derived from the sales of oseltamivir phosphate granules, holding over 99% of the market share of oseltamivir phosphate granules in China during the Track Record Period, we faced less pricing pressure (i) in the provinces where the provincial VBP schemes are implemented on Kewei granules, when submitting bids for provincial VBP schemes, or (ii) in the provinces where Kewei granules are not included in provincial VBP schemes, when obtaining price approvals from provincial-level healthcare security administrations at which our Kewei

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granules can be sold to the public hospitals in such provinces. However, the patent relating to our oseltamivir phosphate granules will expire in April 2026, and there may be more competitors producing oseltamivir phosphate granules after the patent expiry. If we fail to compete with our competitors and maintain a market-leading position for our Kewei granules, we may lose our bargaining power and face increased pricing pressure for our Kewei granules when we seek to have our Kewei granules included in provincial VBP schemes or obtaining pricing approval from provincial-level healthcare security administrations, which in turn, will have a material negative impact on our business performance and financial position.

In addition, our top-selling drug, Kewei, faces increasingly intense competition from other oseltamivir phosphate manufacturers and other types of anti-influenza drugs. The anti-influenza drug market in China is highly competitive, with over 120 pharmaceutical companies producing influenza medications. Increasingly intense competition from other types of anti-influenza drugs had negatively affected our revenue generated from oseltamivir phosphate products during the Track Record Period. According to Frost & Sullivan, peramivir and baloxavir marboxil, which accounted for 8.6% and 5.4% of the PRC's anti-influenza drug market in 2023, respectively, were able to increase their market shares to 12.4% and 10.8% in 2024, respectively while the market share of oseltamivir phosphate decreased from 78.0% to 70.3% in 2024. In addition, our competitors within the PRC oseltamivir phosphate market in China such as Company A and Company B also increased their market share from 16.3% and 3.9% in 2023 to 21.2% and 4.9% in 2024, respectively while the market share of our oseltamivir phosphate products decreased from 64.8% to 54.8%. If we failed to compete with other oseltamivir phosphate manufacturers and other types of anti-influenza drugs and maintain our market share, it will have a material negative impact on our business performance and financial position.

Furthermore, several pharmaceutical companies have commercialized flu vaccines and are devolving universal flu vaccines which may be more effective. The commercialization of such new vaccines with better efficacy may lower the flu incidence in future which may have a negative impact on the sales of our oseltamivir phosphate products.

**We rely substantially on the success of our drug candidates, some of which are in pre-clinical or clinical development stage, as well as our ability to identify additional drug candidates. If we are unable to successfully identify new drug candidates, complete clinical development, obtain regulatory approval and commercialize our drug candidates, or experience significant delays in doing so, our business will be materially harmed.**

Our business relies on the successful development, regulatory approval and commercialization of our pre-clinical or clinical stage drug candidates for the treatment of patients with cancer, diabetes, hepatitis or other targeted indications as well as new drug candidates we may identify and develop. We have invested a significant amount of effort and financial resources into the development of our existing drug candidates and into the research

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of new drug candidates. Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and clinical trials may not be predictive of future trial results. The success of our drug candidates depends on a number of factors, including:

- successful enrollment of patients in, and completion of, clinical trials, as well as completion of pre-clinical studies;
- obtaining sufficient supplies of any competing drug product that may be necessary for use in clinical trials for evaluation of our drug candidates;
- favorable safety and efficacy data from our clinical trials and other studies;
- successful identification of potential product candidates based on our research or business development methodology or search criteria and process;
- sufficient resources to acquire or discover additional drug candidates;
- receipt of regulatory approvals;
- establishing commercial manufacturing capabilities, either by building facilities ourselves or making arrangements with third-party manufacturers;
- in relation to CROs or other third parties, whether their performance of their duties to us is (i) compliant with our protocols and applicable laws and (ii) able to protect the integrity of all resulting data;
- obtaining and maintaining patent, trade secret and other intellectual property protections and regulatory exclusivity for our drug candidates;
- ensuring we do not infringe, misappropriate or otherwise violate the patents, trade secrets or other intellectual property rights of third parties;
- successfully launching commercial sales of our drug candidates, if and when approved;
- competition with other products; and
- maintaining an acceptable safety profile of our drug candidates following regulatory approval.

If we fail to achieve one or more of these factors in a timely manner or at all, we may experience significant delays in our ability to develop, obtain approval for and commercialize our drug candidates. Such delays could materially harm our business and our ability to generate sufficient revenue and cash flow to sustain our operations.



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**If we fail to maintain an effective distribution network for our pharmaceutical products, our business may be adversely affected.**

We sell our products primarily to GSP-certified third-party offline distributors. As at December 31, 2024, we had relationships with 610 third-party distributors within the PRC. Our ability to maintain and grow our business will depend on our ability to access a distribution network that timely delivers our products to the PRC and overseas markets. However, we only have limited control over our distributors and cannot guarantee that they will distribute our products in a manner that we deem satisfactory. In addition, our distributors may engage sub-distributors. We have limited control over these sub-distributors as we do not enter into contract with the sub-distributors. It is difficult to monitor their compliance with regulatory requirements and business practices. Non-compliance by any of our sub-distributors under applicable regulations may adversely affect the sales and distribution of our products.

Furthermore, we may be exposed to the risks of fraud or other misconduct committed by our distributors or sub-distributors, over whom we have no direct control. Fraud or other misconduct by our distributors or sub-distributors may involve engaging in kick-backs, bribery or other unlawful payments. In any such event, we could, as a result, incur liability to our downstream customers for fraud or misconduct committed by such distributor or sub-distributors. Any claims could subject us to costly litigation and impose a significant strain on our financial resources and attention of management personnel regardless of whether the claims have merit, any of which could result in complaints from our downstream customers, regulatory and legal liabilities, as well as serious harm to our reputation.

Moreover, we typically enter into distribution agreements with our general distributors for a term of one year and with our pharmacy distributors for a term of three years. We need to continually renew distribution agreements with our distributors in order to maintain our distribution network. Our distributors might elect not to renew their agreements with us or otherwise terminate their business relationship with us for different reasons, for example, if certain factors limit the profit margins that such distributors can obtain through the resale of our pharmaceutical product to hospitals, medical institutions and sub-distributors. Our business prospects may be adversely affected if we lose our relationships with our existing distributors or otherwise fail to maintain or expand our distribution network effectively.

In addition, as one of the measures of the PRC healthcare system reform, the State Council together with seven other central government departments (including the NHC and the NMPA) jointly issued the Circular on Issuing the Implementing Opinions on Carrying out the Two-invoice System for Drug Procurement among Public Medical Institutions (for Trial Implementation) (《印發關於在公立醫療機構藥品採購中推行「兩票制」的實施意見(試行)的通知》) (the “**Circular**”) on December 26, 2016. Please refer to the paragraphs headed “Regulatory Environment — Principal Regulatory Provisions — Laws and Regulations on Drug Supply — Two-invoice System.” The “Two-Invoice System” refers to one invoice between the pharmaceutical manufacturer and the pharmaceutical distributor, and one invoice between the pharmaceutical distributor and the hospital, and thereby only allows a single level of distributor for the sale of pharmaceutical products from the pharmaceutical manufacturer to

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the hospital. According to the Circular, two-invoice system will be promoted in pilot provinces (autonomous regions and municipalities directly under the Central Government) involved in the comprehensive medical reform program and pilot cities for public hospital reform on a priority basis, while other regions are encouraged to implement such system, so that such system can be promoted in full swing nationwide in 2018. To meet this requirement, many drug manufacturers have reduced the tiers of distributors, or converted drug distributors into contracted service organizations. As a result, the system significantly limits the options for companies like us to use multiple tiers of distributors to reach a larger geographic area. The reduction in distribution tiers resulted in a decrease in distribution mark-ups and an accompanying reduction in prices paid by public hospitals. The pharmaceutical manufacturers and pharmaceutical distributors who fail to comply with the requirements of the “two-invoice system”, may lose their qualification to participate in the bidding and procurement process of public hospitals as well as to win bids and distribute drugs to public hospitals. In addition, the relevant pharmaceutical manufacturers and pharmaceutical distributors will also have a bad record of drug sales. Alterations to this regulatory framework or its enforcement could lead to unforeseen challenges, such as increased compliance requirements or adjustments in our business processes.

**We incurred losses in certain years during the Track Record Period and recorded significant revenue drop for the first quarter of 2025 as compared with the first quarter of 2024, and there may be uncertainty about the business prospects in the future.**

We are a pharmaceutical company. Investment in pharmaceutical product development is highly speculative because it entails substantial upfront capital expenditure and significant risk that a drug candidate may fail to gain regulatory approval or become commercially viable. We will be susceptible to factors that may adversely affect our marketed products including sales volume, lower incidence of seasonal flu outbreaks, pricing level, profit margin and production. We have incurred and may continue to incur significant development and other expenses related to our ongoing operations. We reported loss for the year of RMB1,415.9 million, for the year ended December 31, 2022. Although our loss for the years decreased during the Track Record Period and we reported profit for the year of RMB1,013.9 million and RMB24.8 million for the year ended December 31, 2023 and 2024, there may be uncertainty about the business prospects in the future as we:

- continue our development and commence clinical trials of our drug candidates;
- seek regulatory approvals for our drug candidates throughout the research and development and clinical trial stages;
- commercialize any of our drug candidates for which we may obtain marketing approval;
- maintain and expand our manufacturing facilities;



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- continue to build up clinical, operational, financial, manufacturing and scientific personnel;
- establish and expand our sales, marketing and commercialization infrastructure and workforce and maintain our sales network for any products that obtain regulatory approval;
- seek to identify additional drug candidates;
- address any competing technological and marketing developments, including new products developed by competitors;
- obtain, maintain, expand and protect our intellectual property portfolio;
- may experience an increase in the amount of loss allowance in respect of our trade and bills receivables;
- enforce and defend intellectual property-related claims; and
- acquire or in-license other intellectual property, drug candidates and technologies.

The likelihood and size of our future net losses will depend, in part, on the rate of growth of our expenses and our ability to successfully commercialize and generate revenue from sales of our drug candidates, which will be adversely affected if any of our drug candidates fail, for any reason, before commercialization. To remain profitable, we must develop and eventually commercialize drug candidates with significant market potential. This will require us to succeed in a range of challenging activities, including completing pre-clinical testing and clinical trials of our drug candidates, obtaining regulatory (such as IND, NDA/BLA) and marketing approval for these drug candidates, manufacturing, marketing and selling those drug candidates and satisfying any post-marketing requirements. If we are unable to achieve sufficient market acceptance or favorable pricing for our drug candidates, it could impact our ability to generate revenue and become profitable as well as our prospects of generating sufficient cash to fund the development of our other pipeline projects.

We cannot guarantee that we will succeed in any or all of these activities and, even if we do, we may not generate sufficient revenue to break even or achieve profitability. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. Even if we remain profitable in the near future, we may not be able to sustain profitability in subsequent periods. In addition, our revenue for the first quarter of 2025 decreased by 40.7% as compared with the first quarter of 2024 which in turn had a greater adverse impact on our profitability in the first quarter of 2025. Such decrease in revenue may have a negative impact on our gross profit and net profit. Please see “Summary — Recent Development — Update on Our Financial Performance for the First Quarter of 2025”

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for details. Our failure to remain profitable may adversely affect the value of the Company and impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations.

**Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.**

We are highly dependent on the expertise of principal members of our management and scientific teams. See “*Directors, Supervisors and Senior Management*” in this Listing Document for further details of the expertise and experience of our key management. We do not maintain “key person” insurance for any of our executives or other employees.

Our success also depends on our continued ability to attract, retain and motivate highly qualified employees, in particular technical employees as well as manufacturing and sales personnel. We also engage consultants and advisors, including scientific and clinical advisors, to assist us in formulating our discovery, clinical development and commercialization strategies. The loss of the services of one or more of our key executives, senior management, technical, manufacturing and sales personnel or third-party consultants or advisors could delay or prevent the successful development and commercialization of our existing and future drug candidates and materially harm our ability to successfully implement our business strategies.

Furthermore, replacing executive officers, key employees or consultants may be difficult and take more time because the pool of qualified individuals is very small and the competition for them is fierce. We may be unable to hire, train, retain or motivate these key personnel or consultants on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel.

We may also face competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, our consultants and advisors may have commitments under consulting or advisory contracts with entities other than us that limit the scope of services they can provide to us.

**If we are unable to win bids through the centralized tender processes conducted by PRC authorities, we will lose market share and our revenue and profitability may be adversely affected.**

A number of the products we sell to our distributors are on-sold to public hospitals owned or controlled by government authorities in the PRC. For details on our major products which are included in the VBP scheme, please refer to “Summary — Our Products and Product Candidates — Our Existing Product Portfolio”. Each public medical institution owned by the government at the county level or higher or owned by state-owned enterprises, including state-controlled enterprises, must purchase substantially all their pharmaceutical products through a centralized tender process. We submit bids in a tender process to supply our products to these institutions at fixed prices. Our bids are generally considered on the basis of prices relative to substitute products and their clinical effectiveness, as well as the quality of our

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products. If we are successful in winning bids in a centralized tender process, the relevant products will be sold to public hospitals at bid prices, which will partly determine the prices at which we can sell our products to our distributors.

The centralized tender process can create pricing pressure among substitute products or products that are perceived to be substitute products. Our sales volumes and profitability depends on our ability to successfully differentiate our products and price our bids in a manner that enable us to succeed in the centralized tender processes at profitable levels. If we are unable to differentiate our products or are otherwise unsuccessful in winning future bids in the centralized tender processes at profitable levels, we will lose revenue that would have otherwise been realized through the sale of products to the relevant PRC public hospitals.

We may fail to win bids in a centralized tender process due to various factors, including reduced demand for the relevant product, uncompetitive bidding price, the relevant product being perceived to be less clinically effective than competing products, or our services or other aspects of our operations being perceived to be less competitive. If our products are not selected in the centralized tender processes in one or more regions, we will be unable to sell the relevant products to public hospitals in those regions. This could materially and adversely affect our market share, revenue and profitability.

**All material aspects of the research, development, manufacturing and commercialization of our drug candidates are heavily regulated and are subject to change, which may affect our operations, revenue and profitability or impose additional compliance burdens on us.**

All jurisdictions in which we intend to develop and commercialize our drug candidates regulate these activities in great depth and detail. The pharmaceutical and biopharmaceutical industries in these jurisdictions are subject to comprehensive government regulation and supervision, in particular, regulation of the development, approval, manufacturing, marketing, sales and distribution of products. However, there are differences in the regulatory regimes that make for a more complex and costly regulatory compliance burden for a company like us that plans to operate in each of these regions.

The process of obtaining regulatory approvals and maintaining compliance with appropriate laws and regulations requires the expenditure of substantial time and financial resources. Any recently enacted and future legislations may increase the difficulty and cost for us to obtain regulatory approval of, and commercialize, our drug candidates, and affect the prices we may obtain. Changes in government regulations or in practices relating to the pharmaceutical and biopharmaceutical industries, such as a relaxation in regulatory requirements or the introduction of simplified approval procedures which would lower the entry barrier for potential competitors, or an increase in regulatory requirements which may increase the difficulty for us to satisfy such requirements, may have a material adverse impact on our business, financial condition, results of operations, and prospects. In addition, we are subject to scheduled or unscheduled periodic inspections of our facilities to monitor our regulatory compliance. During the Track Record Period, we passed all the inspections and obtained clearance in relation to discovery and development of our drug candidates from the

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regulatory authorities in all material respects. However, we cannot assure you that we will be able to do so going forward. Assessment and ultimate decision regarding these regulatory approvals, clearance and inspection are subject to the discretion of the relevant authority, which means that even if we meet all necessary requirements, there is no guarantee that we will obtain or renew such approvals in a timely manner. Failure to obtain or maintain the regulatory approvals in the jurisdictions we operate or target to operate in the future at any time during the drug development process or approval process, or after approval, may subject us to administrative or judicial sanctions. These sanctions could include, but are not limited to, a regulator's refusal to approve pending applications, withdrawal of an approval, license revocation, a clinical hold, voluntary or mandatory product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. Any occurrence of the foregoing could therefore materially adversely affect our business, financial condition, results of operations and prospects.

For example, pursuant to the Opinions on Conducting the Consistency Evaluation for the Quality and Efficacy of Generic Drugs issued by the General Office of the State Council (《國務院辦公廳關於開展仿製藥質量 and 療效一致性評價的意見》) promulgated on February 6, 2016 and the Opinions of Relevant Matters Concerning Implementing the Opinions on Conducting the Consistency Evaluation for the Quality and Efficacy of Generic Drugs issued by the NMPA (《關於落實〈國務院辦公廳關於開展仿製藥質量 and 療效一致性評價的意見〉的有關事項的意見》), promulgated on May 25, 2016, generic drugs approved for marketing before the implementation of the new registration classification of chemical drugs, including domestic generic drugs, imported generic drugs and the indigenous varieties of the originally developed drugs, shall carry out consistency evaluation. In principle, the consistency evaluation should be completed before the end of 2018 for the oral solid preparations of generic chemicals approved for sale before October 1, 2007 listed in the National Essential Drug List (2012 version) (《國家基本藥物目錄(2012年版)》). For any other generic drugs approved for marketing before the implementation of the new classification of registration of chemical drugs, after a drug produced by a pharmaceutical enterprise passes the consistency evaluation, other pharmaceutical enterprises shall, in theory, complete the consistency evaluation for their identical drugs within three years; no registration will be granted in case of failure to do so as required within the prescribed time limit.

Pursuant to the Circular on Relevant Matters Concerning Consistency Evaluation for Quality and Curative Effect of Generic Drugs (《關於仿製藥質量 and 療效一致性評價有關事項的公告》) further promulgated by NMPA on December 28, 2018, the time limit for evaluation of the varieties included in the National Essential Drug List (2018 version) (《國家基本藥物目錄(2018年版)》) will no longer be set uniformly. For generic drugs, including essential drug varieties, approved for listing before the implementation of new registration and classification of chemical drugs, after the first variety has passed the consistency evaluation, the same variety of other drug manufacturers should, in theory, complete the consistency evaluation within three years. If it is not completed within the time limit, the enterprise may apply to the local

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provincial drug regulatory authority for an extension of the evaluation if it is deemed to be clinically necessary and in short supply in the market. If the registration is not completed within the prescribed time limit, it shall not be re-registered.

For example, several of our products have yet to pass the consistency evaluation. Substantial uncertainty persists regarding both the substantive and procedural requirements of the evaluation process. This includes ambiguities in the interpretation of the pertinent written requirements and procedures, as well as associated costs, particularly those incurred in conducting consistency evaluations. If we fail to complete the evaluation for our generic drugs, we may not be able to re-register such drugs for sale, or participate in the centralized tender process. If we fail to complete the bioequivalence test study, we may fail to obtain generic drugs approval, as a result of which, we cannot commence production and sale of the relevant drugs. All of these may materially and adversely affect our business, financial condition, results of operations and prospects. Please see “Regulatory Environment — Laws and Regulations on Drugs — Registration of Generic Drugs” for more details.

**Our failure to obtain or renew certain approvals, licences, permits and certificates required for our business may materially and adversely affect us.**

We are required to obtain and maintain various approvals, licences, permits and certificates from relevant authorities to operate our business. Please see “Business — Permits, Licenses and Certifications.” In addition, some of these approvals, permits, licences and certificates are subject to periodic renewal and/or reassessment by the relevant authorities, and the standards of such renewal and/or reassessment may change from time to time. We cannot assure you that we will be able to successfully procure such renewals and/or reassessment when due, and any failure to do so could severely disrupt our business.

Furthermore, if the interpretation or implementation of existing laws and regulations changes or new regulations come into effect requiring us to obtain any additional approvals, permits, licences or certificates that were previously not required to operate our existing businesses, we cannot assure you that we will successfully obtain them, which in turn could restrict our scope of permitted business activities and constrain our drug development and revenue generation capability.

**The market opportunities for our drug candidates in pipeline may be smaller than we anticipate, which could render some drug pipelines ultimately unprofitable even if commercialized.**

We estimate the incidence and prevalence of target patient populations for particular diseases based on various third-party sources, such as scientific literature, surveys of clinics, patient foundations or market research, as well as internally generated analysis, and we use such estimates in making decisions regarding our drug development strategy, including determining which pipelines to focus our limited resources on in pre-clinical or clinical trials. These estimates may be inaccurate or based on imprecise data. The addressable market opportunity will depend on, among other things, acceptance of the drug by the medical

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community, patient access, drug pricing and reimbursement. The number of patients in the addressable market may turn out to be lower than expected, patients may not be amenable to treatment with our drugs, or new patients may become increasingly difficult to identify.

Furthermore, new studies may change the estimated incidence or prevalence of the indications that are targeted by our drug pipelines, including but not limited to infectious diseases, oncology, NASH, diabetes, respiratory and neuropsychiatric diseases pipelines, and the number of addressable patients for our drug pipelines in any case may turn out to be lower than expected. In such cases, even if we obtain significant market share for our drug pipelines, given how small the potential target populations are, we may never achieve profitability without obtaining regulatory approval for additional indications. Any of the above unfavorable developments could have a material adverse effect on our business, financial condition and results of operations.

**We have entered into collaboration arrangements and licensing agreements for the development and commercialization of our product candidates, and may continue to form or seek such arrangement in the future, even though we may not realize the benefit of it. Disputes may arise between us and our partners, which could adversely affect our business operations and financial condition.**

As an important component of our research and development model, we have entered into collaboration and licensing arrangements with leading domestic and international pharmaceutical companies and biotechnology companies regarding our co-development, in-license and/or out-license initiatives. Please see “Business — Research and Development — Collaboration and Licensing Agreements” in this Listing Document for further information on those collaboration arrangements. We may form or seek strategic alliances, create joint ventures or collaborations, or enter into additional licensing arrangements with third parties whom we believe will complement or expand our development and commercialization efforts with respect to our drug candidates and any future drug candidates that we may develop. Any of these relationships may require us to incur non-recurring and other charges, increase our short- and long-term expenditure, issue securities that dilute existing shareholdings, or disrupt our management and business.

We have limited experience in developing new pharmaceutical products for overseas markets, including the United States, which can be significantly more costly and time consuming than for the PRC market. As a result, we have sought co-development partners to assist us with regulatory requirements and to share costs associated with clinical trials or other aspects of product development. For example, we and one of our business partners are carrying out research and development collaborations in relation to certain chronic diseases.

Our strategic collaboration with collaboration partners involves numerous risks. We may not achieve the revenue and cost synergies expected from the transaction. These synergies are inherently unpredictable, and are subject to significant business, economic and competitive uncertainties and contingencies, many of which are difficult to predict and are beyond our control. If we achieve the expected benefits, they may not be achieved within the anticipated



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time frame. In addition, the synergies from our collaboration with collaboration partners may be offset by other costs incurred in collaborating with collaboration partners, increases in other expenses, operating losses or problems in the business which are unrelated to our collaboration with collaboration partners. Disputes may arise between us and our current or future collaboration partners. For example, our collaboration partners may refuse to pay or may be unable to settle the licensing fee. Such disputes may cause delay or termination of the research, development or commercialization of our drug candidates, or may result in costly litigation or arbitration that diverts management attention and resources. As a result, there can be no assurance that these synergies will be achieved.

We face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our drug candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our drug candidates as having the requisite potential to demonstrate safety and efficacy or commercial viability. If and when we collaborate with a third party for development and commercialization of a drug candidate, we can expect to relinquish some or all of the control over the future success of that drug candidate to the third party. The milestone payments that we expect to receive under the collaboration and/or license agreement are usually contingent on the achievement of certain development or commercial milestones, and failure to achieve such milestones means that we will not be able to receive these payments. Milestone payments may account for a substantial part of the total amount of the payments that we expect to receive under these agreements.

**We face substantial competition, which may result in others discovering, developing or commercializing competing drugs before or more successfully than we do.**

The development and commercialization of new drugs is highly competitive. We face competition from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide who may have significantly greater financial resources and expertise as well as from small and early-stage companies who collaborate with large and established companies in research and development activities. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. A number of large pharmaceutical and biotechnology companies are currently marketing and selling drugs or pursuing the development of drugs for the treatment of infectious diseases, oncology, NASH, diabetes, respiratory and neuropsychiatric diseases for which we are commercializing our drugs or developing our drug candidates. We also face potential competitions from academic institutions, government agencies and other public and private research organizations who conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

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Our ability to commercialize our drug candidates could be materially harmed if our competitors develop and commercialize drugs that are safer, more effective, cheaper or have fewer or less severe side effects compared to our own drug candidates. If our competitors manage to obtain approval from the FDA, NMPA, EMA or other comparable regulatory authorities for their drugs and enter into the relevant market ahead of us, we may experience a second mover disadvantage or a delay in our regulatory approval.

Other pharmaceutical companies in the past manufactured and sold products which compete with some of our major products and may continue to do so in the future when the patents of those major products that we are licensed to or own expire. It may erode our market share in the PRC for our major products, which may materially and adversely affect our future sales revenue and profit of such products.

Our current and potential competitors also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

**We are subject to stringent privacy laws, information security policies and contractual obligations related to data privacy and security, and we may be exposed to risks related to our management of the medical data of subjects enrolled in our clinical trials and other personal or sensitive information.**

Data protection and privacy laws and regulations generally require clinical trial sponsors and operators and their personnel to protect the privacy of their enrolled subjects and prohibit unauthorized disclosure of personal information. If such institutions or personnel divulge the subjects' private or medical records without their consent, they will be held liable for damage caused thereby. We receive, collect, generate, store, process, transmit and maintain medical data treatment records and other clinical details of the subjects enrolled in our clinical trials. As such, we are subject to the relevant local, national and international data protection and privacy laws, directives regulations and standards that apply to the collection, use, retention, protection, disclosure, transfer and other processing of personal data in the various jurisdictions in which we operate and conduct our clinical trials, as well as contractual obligations. As of the Latest Practicable Date, we are primarily subject to numerous PRC laws, Hong Kong laws, EU laws and U.S. federal and state laws governing data protection and privacy.

In recent years, the PRC authorities have promulgated certain laws and regulations in respect of information security, data collection and privacy protection regulations in the PRC, including the Cybersecurity Law of the PRC (中華人民共和國網絡安全法), the Provisions on Protection of Personal Information of Telecommunication and Internet Users (電信和互聯網用戶個人信息保護規定), the Cybersecurity Review Measures (網絡安全審查辦法), the Data Security Law of the PRC (中華人民共和國數據安全法) which became effective from September 1, 2021, the Personal Information Protection Law of the PRC (中華人民共和國個人信息保護法) which became effective from November 1, 2021, and the Measures for the



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Security Assessment of Outbound Data Transfer (數據出境安全評估辦法) which became effective from September 1, 2022. Under the Personal Information Protection Law of the PRC, in case of any personal information processing, such individual prior consent shall be obtained, unless the Law indicates otherwise. Further, any data processing activities, that are in relation to the sensitive personal information such as biometrics, medical health and personal information of teenagers under fourteen years old, are not allowed, unless such activities have a specific purpose, are highly necessary and strictly protective measures have been taken. We are not a critical information infrastructure operator and are not an internet platform operator which holds the personal information of more than 1 million users. As of the Latest Practicable Date, we have not received any written or oral notification from the competent authorities or supervisory authorities which have determined that we constituted a critical information infrastructure operator, or that our business operations in all aspects (including but not limited to data processing activities) affect or may affect national security. In addition, the listing in Hong Kong does not fall within the context of “overseas” listing under the Cybersecurity Review Measures of the People’s Republic of China (中華人民共和國網路安全審查辦法). Based on the foregoing, and as advised by our PRC Legal Advisor, we do not fall under the circumstances requiring a cybersecurity review under the Cybersecurity Review Measures of the People’s Republic of China (中華人民共和國網路安全審查辦法).

In addition, certain industry-specific laws and regulations affect the collection and transfer of data in China. The Regulations on the Administration of Human Genetic Resources of the PRC (中華人民共和國人類遺傳資源管理條例), or the HGR Regulation, was promulgated by the State Council in May 2019 and came into effect in July 2019. It stipulates that Foreign Entities, individuals, and the entities established or actually controlled by Foreign Entities or individuals are forbidden to collect, preserve and export China’s human genetic resources. On May 26, 2023, the Ministry of Science and Technology of China promulgated the Implementation Rules for the Administrative Regulation on Human Genetic Resources (《人類遺傳資源管理條例實施細則》), or the Implementation Rules for HGR, which came into effect on July 1, 2023. The Implementation Rules for HGR further clarify the criteria to constitute a Foreign Entity, which shall include (i) any foreign organization or individual that holds directly or indirectly more than 50% of the shares, equity interests, voting rights, property shares or other interests in the institution, (ii) any foreign organization or individual that is able to dominate or have material effect on the decision-making or management of the institution through its voting right or other interests, although the shares, equity interests, voting rights, property share or other interests it directly or indirectly holds in the institution is less than 50%, (iii) any foreign organization or individual that is able to dominate or have material effect on the decision-making or management of the institution through investment relationship, contract or other arrangement; and (iv) other situations stipulated by laws, regulations and rules. Currently, we do not fall into the definition of the Foreign Entity under the Implementation Rules for HGR, but we cannot assure you that we will not be defined as a Foreign Entity in the future. We may only be permitted to utilize and be provided with China’s human genetic resources after satisfying all requirements under the HGR Regulation and other applicable laws if we were regarded as a Foreign Entity. This could potentially cause delays in our ability to access and utilize these resources in a timely manner.

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In October 2020, the SCNPC promulgated the Biosecurity Law of the PRC, which became effective in April 2021. The Biosecurity Law of the PRC (中華人民共和國生物安全法) reaffirms the regulatory requirements stipulated by the HGR Regulation while potentially increasing the administrative sanctions where China's human genetic resources are collected, preserved, exported or used in international cooperation in violation of applicable laws. As a result, we may be exposed to compliance risks under the HGR Regulation and the Biosecurity Law of the PRC. For more information regarding the PRC laws and regulations governing data protection and privacy, see "Regulatory Environment — Laws and Regulations of the PRC" in this Listing Document.

In addition, our clinical trials frequently also involve professionals from third-party institutions working on-site with our staff and enrolled subjects. We cannot ensure that such persons will always comply with our data privacy measures. We also cooperate with third parties including principal investigators, hospitals, CROs, CDMOs and other third-party contractors and consultants for our clinical trials and operations. Any leakage or abuse of patient data by our third-party partners may be perceived by the patients as our fault, negligence or a result of our failure. Furthermore, any change in such laws and regulations could affect our ability to use medical data and subject us to liability for the use of such data for previously permitted purposes. Any failure or perceived failure by us to prevent information security breaches or to comply with privacy policies or privacy-related legal obligations, or any compromise of information security that results in the unauthorized release or transfer of personally identifiable information or other patient data, could cause our customers to lose trust in us and could expose us to legal claims.

In addition, according to the relevant rules for the management of scientific data applicable in each jurisdiction, we may be required to obtain governmental approval before any scientific data can be transferred from one jurisdiction to another. As the assessment and ultimate decision regarding these approval(s) are subject to the discretion of the relevant authority, we cannot guarantee that we will always successfully obtain relevant approvals for sending scientific data (such as the results of our pre-clinical studies or clinical trials) to another jurisdiction. If we are unable to obtain necessary approvals in a timely manner, or at all, our research and development of drug candidates may be hindered, which may materially and adversely affect our business, results of operations, financial conditions and prospects.

**Mutations to viruses (including mutations that develop increases drug resistance) may affect the effectiveness of our anti-viral products.**

Anti-viral products are one of our key therapeutic areas. In particular, our Kewei product is used for the treatment and prevention of the anti-influenza virus (in particular, the influenza A virus and the influenza B virus). The effectiveness of our anti-viral products in relation to the treatment and prevention of viral infections may be adversely affected if the virus type for which our products target mutates or otherwise develops resistance against the relevant products (or the chemical compound associated with the relevant products). According to U.S. Centers for Disease Control, mutations of viruses may happen over time or suddenly. For example, as a virus replicates, small genetic changes in the viral genome may occur. As these

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changes accumulate over time, the virus may become genetically different from the original virus type. In other cases, a mutation may suddenly occur when two different viruses infect a host at the same time, which may lead to the two viruses combining and producing a new virus type.

The efficacy of our anti-viral products will be affected by mutated viruses or viruses that develop resistance against certain chemical compounds over time. If the effectiveness of our anti-viral products in respect of the treatment against the relevant virus type is diminished, it may reduce the demand for our anti-viral products and in turn, may adversely affect the revenue generated from such anti-viral products.

**Our drugs and any future approved drug candidates may fail to achieve the degree of market acceptance by physicians, patients and others in the medical community necessary for commercial success.**

Even if our future drug candidates receive regulatory approval, they may nonetheless fail to gain sufficient market acceptance by physicians and patients and others in the medical community. If our drug candidates do not achieve an adequate level of acceptance, we may not generate significant product sales revenue and we may not become profitable. The degree of market acceptance of our drug candidates, if approved for commercial sale, will depend on a number of factors, including, but not limited to:

- no adverse events caused by our drug candidates which could interrupt, delay or halt clinical trials;
- the clinical indications for which our drug candidates are approved;
- physicians, hospitals, medical treatment centers and patients considering our drug candidates as a safe and effective treatment;
- the potential and perceived advantages of our drug candidates over alternative treatments;
- the prevalence and severity of any side effects;
- product labeling or package insert requirements of regulatory authorities;
- limitations or warnings contained in the labeling approved by regulatory authorities;
- the timing of market introduction of our drug candidates as well as competitive drugs;
- the cost of treatment in relation to alternative treatments;

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- the availability of adequate coverage and reimbursement under the national and provincial reimbursement drug lists in the PRC, or from third-party payers and government authorities in other jurisdictions;
- price control or downward adjustment by the government authorities or other pricing pressure, including the price reduction during the negotiation for inclusion in the national reimbursement drug lists;
- the willingness of patients to pay out-of-pocket in the absence of coverage and reimbursement by third-party payers and government authorities;
- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; and
- the effectiveness of our sales and marketing efforts.

If any approved drug candidates that we commercialize fail to achieve market acceptance among physicians, patients, hospitals, medical treatment centers or others in the medical community, we will not be able to generate revenue. Even if our future approved drug candidates obtain market acceptance, we may not be able to maintain such market acceptance over time if new products or technologies are introduced that are more favorably received than our drug candidates, are more cost-effective or render our drug candidates obsolete. Our failure to achieve or maintain market acceptance for our future approved drug candidates would materially adversely affect our business, financial condition, results of operations and prospects.

**The regulatory approval processes of the NMPA, FDA and other comparable regulatory authorities are complex. If we are unable to obtain without undue delay any regulatory approval for our drug candidates in our targeted markets, our business may be materially and substantially affected.**

The regulatory approval processes of the NMPA, the FDA and other comparable regulatory authorities are often complex, and depend on numerous factors, including the substantial discretion of the regulatory authorities. Our drug candidates could fail to receive regulatory approval in a timely manner for many reasons, including but not limited to:

- failure to begin or complete clinical trials due to disagreements with regulatory authorities;
- failure to demonstrate that a drug candidate is safe and effective or, it is safe, pure, and potent for its proposed indication;
- failure of clinical trial results to meet the level of statistical significance required for approval;

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- data integrity issues related to our clinical trials;
- disagreement with our interpretation of data from preclinical studies or clinical trials;
- failure to conduct a clinical trial in accordance with regulatory requirements or our clinical trial protocols; and
- clinical sites, investigators or other participants in our clinical trials deviating from a trial protocol, failing to conduct the trial in accordance with regulatory requirements, or dropping out of a trial.

In addition, the NMPA, the FDA or a comparable regulatory authority may require more information, including additional analyses, reports, data, non-clinical studies and clinical trials, or questions regarding interpretations of data and results, to support approval, which may prolong, delay or prevent approval and our commercialization plans, or we may decide to abandon the development programs. Changes in regulatory requirements and guidance may also occur, and we may need to amend clinical trial protocols submitted to competent regulatory authorities to reflect these changes. Resubmission may impact the costs, timing or successful completion of a clinical trial. The policies of the NMPA, the FDA and other comparable regulatory authorities may also change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our drug candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may not obtain the regulatory approvals or may lose the approvals that we may have obtained and we may not achieve or sustain profitability.

Additionally, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval procedures vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking regulatory approvals in various jurisdictions could result in significant delays, difficulties and costs for us and may require additional preclinical studies or clinical trials which would be costly and time consuming. We cannot assure you that we will be able to meet regulatory requirements of different jurisdictions or that our drug candidates will be approved for sale in those jurisdictions. Additional time, effort and expense may be required to bring our drug candidates, upon regulatory approval, to the international markets in compliance with different regulatory processes.

If we experience delays in the completion of, or the termination of, a clinical trial of any of our drug candidates, the commercial prospects of that drug candidate will be harmed, and our ability to generate product sales revenues from any of those drug candidates will be compromised. Any delays in completing our clinical trials will increase our costs, slow down our drug candidate development and approval process, and jeopardize our ability to commence product sales and generate related revenues for that candidate. Any of these occurrences may

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harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our drug candidates.

**We rely on a limited number of suppliers for our raw materials and active pharmaceutical ingredients; if any of such suppliers fails to continue to supply us with raw materials at commercially acceptable prices, our sales volumes and margins for the relevant product could be adversely affected.**

We rely on a limited number of suppliers for the raw materials and active pharmaceutical ingredients necessary for the production of our drug products. We formulate our procurement requirements based on our sales plan. We enter into purchase agreements with our raw material suppliers for terms of less than a year or make purchase orders based on the procurement requirements. We cannot assure you that our suppliers will continue to sell products to us on commercially acceptable terms, or at all. We also cannot assure you that we will be able to establish new supplier relationships, or renew our agreements with our existing suppliers when they expire.

Moreover, we are exposed to the risk of inadequate supplies of raw materials and active pharmaceutical ingredients, as well as price increases. The availability and prices of raw materials and active pharmaceutical ingredients required for our production of pharmaceutical products may be impacted by factors such as general market conditions, including increased demand for such materials and ingredients from producers of substitute products or from alternative uses, weather conditions and the occurrence of natural disasters, many of which are outside of our control. In the event that any of our suppliers fails to continue to supply us with adequate quantities of raw materials at commercially reasonable prices, we may not be able to procure raw materials and active pharmaceutical ingredients from other sources on similar commercial terms.

In addition, certain of our raw materials are imported from overseas, and our suppliers may fail to obtain the permits and licences required for the importation of these raw materials. We may also be unable to respond to increases in the prices for raw materials and active pharmaceutical ingredients due to our reliance on a limited number of suppliers or for other reasons, and unable to pass on such price increases to our customers due to governmental price controls for pharmaceutical products in China or competitive conditions for our products. In the event of any disruption to our supply of the raw materials and active pharmaceutical ingredients necessary for the production of our pharmaceutical products at commercially acceptable prices, we may be forced to reduce, suspend or cease production or sale of certain of our pharmaceutical products, and our sales volumes for the relevant product could be adversely affected. Increases in the prices to the raw materials and active pharmaceutical ingredients necessary for the production of our pharmaceutical products could also adversely affect our margins for the relevant product.

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**We may rely on third parties to manufacture a portion of our clinical and commercial drug supplies. Our business could be harmed if those third parties fail to provide us with sufficient quantities of product or fail to do so at acceptable quality levels or prices.**

Although we intend to further develop and rely on our own manufacturing facilities, we may use third parties as part of our manufacturing process and for the clinical and commercial supply of our drug candidates, which is not expected to be a major undertaking in addition to owning and operating our in-house manufacturing facilities. Currently, we have agreements for the supply of drug materials with manufacturers or suppliers that we believe have sufficient capacity to meet our demands. We believe that adequate alternative sources for such supplies exist. However, there is a risk that, if supplies are interrupted, it would materially harm our business.

Reliance on third-party manufacturers would expose us to the following risks:

- we may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the NMPA, FDA, EMA or other comparable regulatory authorities must evaluate and/or approve any manufacturers as part of their regulatory oversight of our products and drug candidates. This evaluation would require new testing and cGMP-compliance inspections by NMPA, FDA, EMA or other comparable regulatory authorities;
- our third-party manufacturers might be unable to timely manufacture our products or drug candidates or produce the quantity and quality required to meet our clinical and commercial needs, if any;
- manufacturers are subject to ongoing periodic unannounced inspection by NMPA to ensure strict compliance with GMP and other government regulations and by other comparable regulatory authorities for corresponding non-PRC requirements. We do not have control over third-party manufacturers' compliance with these regulations and requirements;
- we may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our products and drug candidates;
- manufacturers may not properly obtain, protect, maintain, defend or enforce our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- manufacturers may infringe, misappropriate, or otherwise violate the patent, trade secret, or other intellectual property rights of third parties;



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- raw materials and components used in the manufacturing process, particularly those for which we have no other source or supplier, may not be available or may not be suitable or acceptable for use due to material or component defects; and
- our contract manufacturers and critical reagent suppliers may be subject to inclement weather, as well as natural or man-made disasters.

Each of these risks could delay or prevent the completion of our clinical trials or the approval of any of our drug candidates, result in higher costs or adversely impact commercialization of our future approved drug candidates. In addition, we will rely on third parties to perform certain specification tests on our drug candidates prior to delivery to patients. If these tests are not appropriately done and test data are not reliable, patients could be put at risk of serious harm and regulatory authorities could place significant restrictions on our Company until deficiencies are remedied.

**If our CROs fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.**

We and third parties, such as our CROs, are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. We cannot assure you that these third parties will comply with such laws and regulations as we have no ultimate control over their behavior, conduct and business practices. In addition, our construction projects can only be put into operation after certain regulatory procedures with the relevant administrative authorities in charge of environmental protection, health and safety have been completed. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

In addition, we may be required to incur substantial costs to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.



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**Failure to comply with regulatory requirements by our manufacturing facilities, or damage to, destruction of or interruption of production at such facilities, could delay our development plans or commercialization efforts.**

We have obtained international good manufacturing practice (GMP) accreditations for our manufacturing facilities based in the PRC, which will allow us to enter the global market. These facilities may encounter unanticipated delays and expenses due to a number of factors, including regulatory requirements. Cost overruns associated with maintaining our facilities could require us to raise additional funds from other sources.

Our manufacturing facilities will be subject to ongoing, periodic inspection by the NMPA, FDA, EMA or other comparable regulatory agencies to ensure compliance with GMP regulations. Our failure to follow and document our adherence to such GMP regulations or other regulatory requirements may lead to significant delays in the availability of products for clinical or, in the future, commercial use, may result in the termination of or a hold on a clinical trial, or may delay or prevent filing or approval of marketing applications for our drug candidates or the commercialization of our drugs, if approved. We also may encounter difficulties with the following:

- achieving adequate or clinical-grade materials that meet NMPA, FDA, EMA or other comparable regulatory agency standards or specifications with consistent and acceptable production yield and costs;
- shortages of qualified personnel, raw materials or key contractors; and
- ongoing compliance with GMP regulations and other requirements of the NMPA, FDA, EMA or other comparable regulatory agencies.

In addition, our quality control and quality assurance procedures may not be effective in consistently preventing and resolving deviations from our quality standards, which could render our products unsuitable for use, jeopardize any GMP certifications and/or harm our market reputation and relationship with business partners.

Failure to comply with applicable regulations could also result in sanctions being imposed on us, including fines, injunctions, civil penalties, a requirement to suspend or put on hold one or more of our clinical trials, failure of regulatory authorities to grant marketing approval of our drug candidates, delays, suspension or withdrawal of approvals, supply disruptions, license revocation, seizures or recalls of our drug candidates, operating restrictions and criminal prosecutions, any of which could harm our business.

Developing advanced manufacturing techniques and process controls is required to fully utilize our facilities. Advances in manufacturing techniques may render our facilities and equipment inadequate or obsolete.

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If our manufacturing facilities or equipment are damaged or destroyed, we may not be able to replace them quickly or inexpensively or at all. In the event of a temporary or protracted loss of the facilities or equipment, we may not be able to transfer manufacturing to a third party. Even if it were possible, the transfer may be expensive and time-consuming, particularly since the new facility would need to comply with the necessary regulatory requirements and we would need to obtain regulatory approval before selling any of our drug candidates manufactured at the third-party facility. As a result, our clinical trials may be delayed and our production and sales of our drug candidates may be reduced. Any interruption in manufacturing operations at our manufacturing facilities could adversely affect our ability to meet the demands of our clinical trials or commercialization and could materially harm our business, financial condition and operations.

**Our efforts to further expand our manufacturing capacity may not be successful, and we may not be able to precisely anticipate market demand.**

In anticipation of commercialization of more drug candidates, we aim to expand our manufacturing capacity even further. However, the success of these plans, particularly the timetable and progress of construction, are subject to significant uncertainty. In particular, such plans are capital-intensive and require significant upfront investment. Since we intend to finance the expansion through various channels, including with debt financing and expected cash flow from commercial sales of products which we have commenced or have yet to commence, we cannot guarantee that we will be able to timely obtain such financing, if at all.

Furthermore, there may be significant changes in the macroeconomics of the pharmaceutical industry, including, among other things, market demand, product and supply pricing trends and customer preferences. Any adverse trends in these respects could result in operational inefficiency and unused capacity in our facilities. We may also experience various unfavorable events in the course of developing our new manufacturing facilities, such as:

- unforeseen delays due to construction, land use rights or regulatory issues, which could result in loss of business opportunities;
- construction cost overruns, which may require diverting resources and management's attention from other projects; and
- difficulty finding sufficient numbers of trained and qualified staff.

The success of our business expansion also depends on our ability to advance drug candidates through the development, regulatory approval and commercialization stages. Any delay, suspension or termination in such respects would harm our ability to generate satisfactory returns on our investment in manufacturing expansion, if at all, which in turn could have a material adverse effect on our business, financial condition and results of operations.

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**Even after we obtain regulatory approval for the marketing and distribution of our drug candidates, our products will continue to remain subject to ongoing or additional regulatory obligations and continued regulatory review, which may result in significant additional expenses, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our future approved drugs.**

If any of our drug candidates is approved in the future, it will be subject to ongoing or additional regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies, and submission of safety, efficacy and other post-market information, including requirements of regulatory authorities in China, the U.S. and other jurisdictions. These requirements also include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with current Good Manufacture Practices, or the current good manufacturing practice (cMGP), and Good Clinical Practice, or the GCP, for any clinical trials that we conduct post-approval.

Any approvals that we receive for our drug candidates may be subject to limitations on the approved indicated uses for which the drug may be marketed or to the conditions of approval, which could adversely affect the drug's commercial potential or contain requirements for potentially costly post-marketing testing and surveillance to monitor the safety and efficacy of the drug candidates. The NMPA, FDA or a comparable regulatory authority may also require a REMS program as a condition of approval of our drug candidates or following approval.

Once a drug is approved by the NMPA, FDA or a comparable regulatory authority for marketing, it is possible that there could be a subsequent discovery of previously unknown problems with the drug, including problems with third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements. If any of the foregoing occurs with respect to our drug products, it may result in, among other things:

- restrictions on the marketing or manufacturing of the drug, withdrawal of the drug from the market, or voluntary or mandatory drug recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the NMPA, FDA or comparable regulatory authority to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of drug license approvals;
- drug seizure or detention, or refusal to permit the import or export of drugs; and
- injunctions or the imposition of civil, administrative or criminal penalties.

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In addition, we are subject to ongoing regulatory requirements for our day-to-day business operations. Accordingly, we and third parties we work with must continue to spend time, money and efforts in all areas of regulatory compliance, including manufacturing, production and quality control. We cannot predict the likelihood, nature or extent of governmental policies or regulations that may arise from future legislation or administrative actions in China, the U.S. or other jurisdictions, where the regulatory environment is constantly evolving. If we are unable to maintain regulatory compliance, or if we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, we may lose any regulatory approval that we have obtained, and we may not achieve or sustain profitability.

**Negative results from off-label use of our future marketed drug products could materially harm our business reputation, product brand and financial condition and expose us to liability.**

Products distributed or sold in the pharmaceutical market may be subject to off-label drug use. Off-label drug use is prescribing a product for an indication, dosage or in a dosage form that is not in accordance with regulatory approved usage and labeling. Even though the NMPA, FDA and other comparable regulatory authorities actively enforce the laws and regulations prohibiting the promotion of off-label use, there remains the risk that our product is subject to off-label drug use and is prescribed in a patient population, dosage or dosage form that has not been approved by competent authorities. This occurrence may render our products less effective or entirely ineffective and may cause adverse drug reactions or adverse events. Any of these occurrences can create negative publicity and materially and adversely affect our business reputation, product brand, commercial operations and financial condition, including our share price. These occurrences may also expose us to liability and cause a delay in the progress of our clinical trials and may ultimately result in failure to obtain regulatory approval for our drug candidates.

**We may be directly or indirectly subject to applicable anti-kickback, false claims laws, physician payment transparency laws, fraud and abuse laws or similar healthcare and security laws and regulations in China and other jurisdictions, which could, in the event of noncompliance, expose us to administrative sanctions, criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.**

Our business operations and current and future arrangements with clinical site investigators, healthcare professionals, consultants, third-party payors, patient organizations, and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we market, sell, and distribute our drug candidates, if approved. Such laws include the PRC Anti-Unfair Competition Law (中華人民共和國反不正當競爭法), the PRC Criminal Law (中華人民共和國刑法), the U.S. federal Anti-Kickback Statute, the U.S. federal False Claims Act, HIPAA, and the U.S. Physician Payments Sunshine Act.

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Efforts to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. Our business practices may be concluded as not compliant with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and if we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in governmental healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and have a significant impact on our businesses and results of operations. If any of the physicians or other providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government-funded healthcare programs, which may also adversely affect our business. Furthermore, defending against any such actions can be costly, time-consuming, and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

**We are subject to the risks of doing business globally, including risks relating to political and economic instability and changes in diplomatic and trade relationships, which may materially and adversely affect our business and results of operations.**

Our overseas sales network covers eight countries and regions such as the United States, Germany and the United Kingdom. In the future, we plan to expand our overseas sales network to Africa and Latin America and further increase the scope of our sales network in major developed countries and regions to enhance our global sales capabilities. Accordingly, our business and financial results in the future could be adversely affected due to a variety of factors, including:

- changes in a specific country's or region's political and cultural climate or economic condition;
- unexpected changes in laws and regulatory requirements in local jurisdictions;
- differences between national and local practice with respect to laws and regulatory requirements in a specific jurisdiction;
- difficulty of effective enforcement of contractual provisions in certain jurisdictions;
- efforts to develop an international sales, marketing and distribution organization may increase our expenses, divert our management's attention from the acquisition or development of drug candidates or cause us to forgo profitable licensing opportunities in these geographies;
- the occurrence of economic weakness, including inflation or political instability;

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- inadequate intellectual property protection in certain jurisdictions;
- difficulty of ensuring that third-party partners do not infringe, misappropriate, or otherwise violate the patent, trade secret, or other intellectual property rights of others;
- enforcement of anti-corruption and anti-bribery laws;
- trade protection measures, import or export licensing requirements and fines, penalties or suspension or revocation of export privileges;
- delays resulting from difficulty in obtaining export licenses, tariffs and other barriers and restrictions, potentially longer payment cycles, and greater difficulty in accounts receivable collection;
- compliance with tax, employment, immigration and labor;
- the effects of applicable local tax regimes and potentially adverse tax consequences;
- significant adverse changes in local currency exchange rates; and
- business interruptions resulting from geo-political actions and cultural climate or economic condition, including war and acts of terrorism, natural disasters, including earthquakes, volcanoes, typhoons, floods, hurricanes and fires, or the impact of public health pandemics or epidemics.

The occurrence of any one or more of these risks of doing business internationally, alone or in aggregate, could materially adversely affect our business and results of operations.

**If our products are removed or excluded from national, provincial or other government sponsored medical insurance programs or the National Essential Drug List, our operation, revenue and business prospects in relation to the affected products could be materially and adversely affected.**

Under the PRC national medical insurance program, patients can obtain reimbursement of all or a portion of the cost of certain pharmaceutical products listed in the NRDL, the provincial medical insurance drugs catalogues or the National Essential Drug List. Consequently, whether a pharmaceutical product is included or excluded in the NRDL, the provincial medical insurance drugs catalogues or the National Essential Drug List will materially affect the demand for such a pharmaceutical product in the PRC.

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The PRC government considers a range of factors when deciding whether a pharmaceutical product would be listed in the NRDL, the provincial medical insurance drugs catalogues or the National Essential Drug List, including, among other things, the results of clinical trials, frequency of use, effectiveness of the product and the prevalence of the disease or symptom that such a product is designed to treat or prevent. The pharmaceutical products listed in the NRDL, the provincial medical insurance drugs catalogues and the National Essential Drug List are also reviewed and updated from time to time. There is no assurance that the catalogued products will continue to be, or any of our products in the future will be, listed in the NRDL, the provincial medical insurance drugs catalogues or the National Essential Drug List. The entry into, and the removal from, the NRDL, the provincial medical insurance drugs catalogues or the National Essential Drug List are beyond our control. The removal of any of our products from the NRDL, the provincial medical insurance drugs catalogues or the National Essential Drug List, may have a material adverse impact on the demand of our products and in turn a material adverse effect on our sales volume, revenue and profitability.

**If we engage in acquisitions or strategic partnerships, this may increase our capital requirements, dilute our shareholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks.**

From time to time, we may evaluate various acquisitions and strategic partnerships, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses. Any completed, in-process or potential acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent or unforeseen liabilities;
- the issuance of our equity securities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing drugs or drug candidates and regulatory approvals; and



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- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

In addition, if we undertake acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in a significant future amortization expense.

**We had substantial indebtedness and net current liabilities and net liabilities during the Track Record Period, and may continue to incur significant debt going forward.**

As of December 31, 2022, 2023 and 2024, we had net current liabilities of RMB4,807.7 million, net current assets of RMB234.0 million and net current assets of RMB164.5 million, respectively. As of December 31, 2022, 2023 and 2024, we had net liabilities of RMB873.9 million, net assets of RMB4,175.3 million and net assets of RMB4,467.5 million.

A large balance of indebtedness, whether from banks or related parties, may require that we devote our financial resources to servicing such debt rather than funding our operating activities and investments in research and development, which constrains our capital flexibility and may in turn adversely affect our drug development timetable. It may also be a challenge for us to service our interest and principal repayments in a timely manner or at all, which could trigger cross-defaults with other debt, as applicable, as well as limit our ability to obtain further debt financing. Given our historical reliance on external financing, such developments could have a material adverse effect on our business, financial condition and results of operations.

Furthermore, the terms of our indebtedness may contain affirmative and negative covenants, such as restriction on use of loans, restriction on external guarantee, requirement on certain financial ratios and continuing reporting obligations. A breach of any of these covenants could result in a default that would permit our lenders to declare all amounts outstanding thereunder to be due and payable, together with accrued and unpaid interest, trigger cross-default provisions under other debt agreements and, as applicable, cause the termination of commitments of relevant lenders to make further extensions of credit under our financing agreements or credit facilities. If we were unable to repay our indebtedness to our lenders in such an event, the lenders could, among other things, dispose of collateral, which could include substantially all of our assets. Our future ability to comply with financial covenants and other conditions, make scheduled payments of principal and interest or refinance existing borrowings depends on our business performance, which is subject to economic, financial, competitive and other factors, including the other risks described in this Listing Document. Any failure to comply with the covenants of our financing agreements or to obtain financing for our business could have a material adverse effect on our business, financial condition, results of operations and prospects.



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**Failure to manage our inventory effectively would materially and adversely affect our results of operations, financial condition and cash flows.**

Our inventory primarily consists of finished products and certain production materials such as raw materials, excipients, packaging materials, consumables for reagents and consumables for workshops. To operate our business successfully and meet our customers' demands and expectations, we need manage our inventory effectively to ensure immediate delivery when required. We have personnel responsible for reviewing and managing our inventory of finished products and inventory of production materials. In general, we formulate purchase plans for production materials on an order-by-order basis or based on our monthly plans of production, purchase non-production supplies based on the needs of various departments on a monthly basis and perform strict inventory control from the time we have them in stock. We are exposed to inventory risk as a result of changing clinical demands which is difficult to predict. There can be no assurance that we can accurately predict these clinical demands and avoid over-stocking or under-stocking our products. Our average inventory turnover days decreased from 142.6 days in 2022 to 124.9 days in 2023 in line with a continued improvement of our overall business performance. Our average inventory turnover days further increased to 240.8 days in 2024 primarily due to an increase in our inventory as a result of a lower incidence of seasonal flu outbreaks. Please see "Financial Information — Certain Current Balance Sheet Items — Inventories" for more detail.

We may be exposed to increased inventory risks due to accumulated excess inventory of our products. Excess inventory levels may increase our inventory holding costs, obsolescence risks or write-down of inventories. For the year ended December 31, 2022, 2023 and 2024, we recorded write-down of inventories of RMB59.7 million, RMB24.4 million and RMB44.7 million, respectively. The write-down in 2022 was primarily due to our lower than usual sales of Kewei (oseltamivir phosphate) due to travel restrictions, social-distancing measures and business closures which significantly reduced the movement of people, resulting in a decline in the incidence of influenza. The write-downs in 2023 and 2024 were primarily due to low utilization rates of our insulin production lines, which led to increased unit costs; as a result, the net realizable value of our insulin products fell below their book value. If our inventory level increases substantially in the future, our financial condition and cash flows could be materially and adversely affected.

**We may experience impairment losses related to intangible assets, which could materially impact our financial position.**

We may face impairment losses on intangible assets and goodwill, which could significantly affect our financial standing. During the Track Record Period, our intangible assets mainly comprised our (i) hepatitis C drugs patent, (ii) hepatitis C drugs capitalized development costs, (iii) insulin intellectual property rights, (iv) insulin capitalized development costs, (v) other drugs (generic drug) intellectual property rights, and (vi) other drugs capitalized development costs. We had intangible assets of RMB1,914.9 million, RMB1,605.0 million, RMB1,573.4 million as of December 31, 2022, 2023 and 2024, respectively. See "Financial Information — Certain Non-Current Balance Sheet Items —

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Intangible Assets” for further information. We evaluate indicators of impairment for intangible assets at the end of each reporting period. Impairment occurs when the carrying amount of an asset or cash-generating unit surpasses its recoverable amount, defined as the higher of fair value less disposal costs or value in use. Fair value calculations rely on comparable sales data for similar assets, while value in use requires management to estimate future cash flows and select an appropriate discount rate. Adjustments to these assumptions regarding future cash flows or discount rates could diminish the recoverable value of an asset relative to its carrying amount. See Note 2(j)(ii) to the Accountants’ Report set out in the Appendix I to this Listing Document. We may incur impairment losses on intangible assets in the future, which could adversely affect our assets and profitability, ultimately negatively impacting our financial position.

**We are subject to credit risk related to delay in payment and defaults of customers, and we have recorded loss allowance in respect of our trade and bills receivables in the past. Any significant delay in payment or defaults on our trade and bills receivables could materially and adversely affect our liquidity, financial conditions and results of operations.**

We are exposed to credit risk related to delay in payment and defaults of our various customers. As of December 31, 2022, 2023 and 2024, our trade and bills receivables net of loss allowance amounted to RMB808.7 million, RMB1,906.4 million and RMB1,722.6 million, respectively, and our loss allowance in respect of trade and bills receivables amounted to RMB11.6 million, RMB16.6 million and RMB144.6 million, respectively. Our impairment loss in respect of trade and bills receivables increased significantly to RMB127.8 million in 2024. In addition, our average trade and bills receivables turnover days in 2024 increased to 164.8 days from 77.6 days in 2023. The increases in our loss allowance in respect of trade and bills receivables and our average trade and bills receivables turnover days in 2024 were both primarily due to a reduction in seasonal flu outbreaks in 2024, which led to a decline in sales of our major distributors and consequently slowed our payment collection from these distributors. In 2024, our major distributors increased the purchases of Kewei (oseltamivir phosphate) based on metrics such as regional population data and projected pandemic scale to ensure sufficient drug supply amid uncertainties around the timing and severity of potential outbreaks. Such increased purchases were prompted by such distributors’ estimates on how much Kewei (oseltamivir phosphate) they need in order to meet their customers’ demand. However, the actual severity and duration of the flu season were lower than anticipated, resulting in inventory levels exceeding actual market demand. This led to slower inventory turnover for our distributors, which in turn extended our receivables collection period. Please see “Business — Sales, Marketing and Distribution — Measures to Manage Cannibalization and Channel Stuffing” for detail. We may not be able to collect all trade and bills receivables, or any at all, due to a variety of factors that are outside of our control, including adverse market conditions, long payment cycle of certain customers, adverse operating conditions or financial situation of customers, and customers’ inability to pay caused by their end customers’ delay in payment. If any of our customers experience financial difficulties in settling the trade and bills receivables, or if the relationship between us and any of our customers, is terminated or deteriorates, our corresponding trade and bills receivables might be adversely affected in terms of recoverability.

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As the increase of the amount of loss allowance made on our trade and bills receivables is recorded as expenses on our results of operations, if we are not able to manage the credit risk associated with our trade and bills receivables effectively, our results of operations and financial conditions may be materially and adversely affected. Furthermore, substantial defaults or delays by our customers could materially and adversely affect our cash flow, profits and financial positions and we may have to terminate our relationships with such customers.

**Share-based payments may impact our financial performance.**

We adopted a restricted share scheme in 2023 and granted restricted shares to certain employees and directors to incentivize and reward eligible persons who had contributed and would continue to contribute to the success of our Company. For the year ended December 31, 2023 and 2024, we recorded equity-settled share-based payment expenses of RMB130.3 million and RMB266.5 million, respectively. To further incentivize our employees and directors and align their interests with ours, we may grant them additional share-based compensation in the future. Expenses incurred with respect to such share-based payment may increase our operating expenses and therefore have an adverse effect on our financial performance.

**Our Controlling Shareholders, Directors, employees, principal investigators, consultants and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements, and insider trading, which could harm our reputation and subject us to penalties and significant expenses that have a material and adverse effect on our business, financial condition and results of operations.**

We are exposed to risks of fraud, bribery, misconduct or other illegal activity by our Controlling Shareholders, Directors, employees, principal investigators, consultants and commercial partners that could subject us to financial losses and sanctions imposed by government authorities, which may adversely affect our reputation. Misconduct by these parties could include, but not limited to, intentional, reckless and negligent conduct that fails to:

- comply with applicable laws and regulations relating to insider dealing;
- comply with the laws of the NMPA, the FDA and other comparable regulatory authorities;
- provide true, complete and accurate information to the NMPA, the FDA and other comparable regulatory authorities;
- comply with manufacturing standards we have established;
- comply with healthcare fraud and abuse laws in China, the U.S. and similar fraudulent misconduct laws applicable to us; or
- report financial information or data accurately or disclose unauthorized activities to us.

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If we obtain approval for any of our drug candidates and begin commercializing those drugs in China, the U.S., or other applicable jurisdictions, our potential exposure under relevant laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. These laws may impact, among other things, our current activities with principal investigators of our clinical trials, and our use of information obtained in the course of patient recruitment for clinical trials, as well as proposed and future sales and marketing programs. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally.

Additionally, we could be liable for actions taken by them that violate anti-bribery, anti-corruption and other related laws and regulations in China, the U.S. or other jurisdictions. The government authorities may seize the products involved in any illegal or improper conduct engaged in by our employees or commercial partners. We may be subject to claims, fines or suspension of our operations. Our reputation, our sales activities or the price of our H Shares could be adversely affected if we are associated with any negative publicity as a result of illegal or improper actions, or allegations of illegal or improper actions, taken by our Directors, employees or commercial partners.

Furthermore, as we do not and cannot fully control the conduct of our Controlling Shareholders, Directors, employees, principal investigators, consultants and commercial partners, they may, in the course of performing their tasks, attempt to elicit illegal gains, including, among other things, trading on or passing on to third parties material non-public information, altering sales volume, or colluding with distributors or sub-distributors for kickbacks. There can be no assurance that we were, are or will be able to entirely prevent our Controlling Shareholders, Directors, employees, principal investigators, consultants or commercial partners from engaging in such activities. We may also be held liable for actions taken by our Controlling Shareholders, Directors, employees, principal investigators, consultants and commercial partners, which could expose us to regulatory investigations and penalties.

In addition, even if we are not held liable to any of the conducts discussed above, any negative news or publicity concerning us, our Controlling Shareholders, our Directors, management, affiliates or any entity that shares the Sunshine Lake brand name, even if proven untrue, could adversely affect our reputation and business prospects. We cannot guarantee that negative publicity about us or any of our affiliates or any entity that shares such name would not damage our brand image. Given our specialized industry and market, negative publicity and word of mouth could travel quickly and negatively impact our relationships with third parties, which could have a material adverse effect on our business, financial condition and results of operations.

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During the Track Record Period, we were not aware of any instances of fraud, bribery, or other misconduct involving our Directors, employees and other third parties that had any material and adverse impact on our business and results of operations. However, we cannot guarantee that there will not be any such instances in the future. Although we consider our internal control policies and procedures to be adequate, we may be unable to prevent, detect or deter all such instances of misconduct. Any such misconduct committed against our interests, which may include past acts that have gone undetected or future acts, may have a material adverse effect on our business and results of operations.

**We have limited insurance coverage, and any claims beyond our insurance coverage may result in us incurring substantial costs and a diversion of resources.**

We maintain insurance coverage which we believe to be in line with the industry norm in the jurisdictions where we operate. In line with what we consider to be customary for PRC pharmaceutical manufacturing companies, we maintain clinical trial insurance relating to adverse events in clinical trials, property insurance covering our production facilities and equipment, insurance relating to public liability, insurance relating to transport of goods and insurance covering our construction projects (including accidents). We also maintain social security insurance in accordance with the relevant laws and regulations in the PRC. We do not carry any product liability insurance or business interruption insurance, which are not mandatory under PRC law as confirmed by our PRC Legal Advisor. Our insurance coverage may be insufficient to cover any such claims relating to the above or such claims may be excluded from insurance coverage, which in turn may result in us incurring substantial costs and a diversion of resources, and the occurrence of such incidents may lead to an increase in our insurance premiums.

**Product liability claims or lawsuits could cause us to incur substantial liabilities.**

We face an inherent risk of product liability and/or product recalls as a result of the commercialization of our drugs in North America, Europe, Asia and Africa and clinical testing and any future commercialization of our drug candidates globally. For example, we may be sued if our drugs or drug candidates cause or are perceived to cause injury, material adverse event or are found to be otherwise unsuitable during the stages of clinical testing, manufacturing, marketing or sales. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the drug, negligence, strict liability or a breach of warranties. Claims could also be asserted under applicable consumer protection legislation. If we cannot successfully defend ourselves against or obtain indemnification from our collaborators for product liability claims, we may incur substantial liabilities or be required to limit commercialization of our drugs and drug candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in, among others: reduced demand for our drugs; damage to our reputation; withdrawal of clinical trial participants and inability to continue clinical trials; initiation of investigations by regulators; costs to defend the related litigation; a diversion of management's time and our resources; substantial monetary awards to trial participants or patients; product recalls, withdrawals or

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labeling, marketing or promotional restrictions; loss of revenue; exhaustion of any available insurance and our capital resources; the inability to commercialize any drug candidate; and a decline in the ordinary share price.

**We are subject to potential adverse consequences in respect of certain of our existing properties owned and leased and our land use rights in mainland China.**

As at the Latest Practicable Date, we had not obtained building ownership certificates for some of our owned and leased buildings, which are mainly used for production facilities, warehousing facilities, dormitories, office premises and other purposes which are not revenue-generating in nature. For details, please see “Business — Land and Properties”. As advised by our PRC Legal Advisor, relevant PRC government authorities may impose administrative penalties and different levels of fines for violations of applicable regulations. As at the Latest Practicable Date, we had not yet received any administrative penalty from the relevant authorities for the title defects. However, there is no assurance that we will not be subject to any administrative action for these non-compliances in the future, and if this were to happen, our business, results of operation and financial position may be adversely affected.

For some of our leased properties in mainland China, the lessors may not be able to provide property title certificates or other documents evidencing the authorization or consent from the property owners for subleasing. In such case, our rights in relation to such properties might not be entirely protected. Any claim or disputes related to the title of the properties leased by us may affect our ability to continue to lease such properties and may result in relocation. We cannot guarantee that the legality of our use and occupation of the relevant buildings will not be challenged. If we have to find alternative properties, additional relocation costs will be incurred, and our business operations may be disrupted, any of which may have a material and adverse effect on our business, financial condition and results of operations. Furthermore, under PRC law certain leases are required to be registered with the PRC government. We have several leases that have not been registered with the relevant PRC governmental authorities. We may thus be subject to penalties and may result in adverse effects on our results of operations, financial position or prospects. For details, please see “Business — Land and Properties”.

Under PRC laws, if we fail to develop a property development project according to the terms of the land grant contract, including those relating to the designated use of the land and the time for commencement and completion of the property development, government authorities may issue a warning, impose a penalty and/or order us to forfeit the land. If we fail to commence development within one year of the commencement date stipulated in the land grant contract, the relevant PRC land bureau may issue a warning to us and impose an idle land penalty of up to 20% of the land grant premium. If we fail to commence development within two years from the commencement date stipulated in the land grant contract, the relevant PRC land bureau may confiscate our land use rights without compensation, unless the delay in the development is caused by government action or is due to a force majeure. Moreover, if a property developer commences development of the property in accordance with the timeframe stipulated in the then land grant contract but, suspended for more than one year without



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government approval and falls under either of the following two situations: (i) the developed land area is less than one-third of the total land area, or (ii) the total invested capital is less than one-fourth of the total planned investment in the project, then the land may be treated as idle land and will be subject to the risk of forfeiture under the Measures on the Disposal of Idle Land (《閒置土地處置辦法》).

During the Track Record Period, we failed to commence and/or complete construction within the prescribed period as stipulated in certain land grant contracts mainly because of objective constraints such as the government's policy to protect the Yangtze River. We cannot assure you that circumstances leading to delays in the commencement or completion of a property development project will not arise in the future. If our land is repossessed, we will not be able to continue our property development on the forfeited land, recover the costs incurred for the initial acquisition of the repossessed land or recover development costs and other costs incurred. In addition, we cannot assure you that regulations relating to idle land or other aspects of land use rights grant contracts will not become more restrictive or punitive in the future. If we fail to comply with the terms of any land use rights grant contract as a result of delays in project development, or as a result of other factor, we may lose the opportunity to develop the project as well as our past investments in the land, which could materially and adversely affect our business, financial condition and results of operations.

**We may be subject to additional payments or penalties relating to contributions to social security insurance and housing provident funds.**

During the Track Record Period, we had not made full contributions to the social insurance premium and housing provident fund based on the actual salary level of some of our employees as prescribed by relevant laws and regulations. As advised by our PRC Legal Advisor, pursuant to relevant PRC laws and regulations, if we fail to pay the full amount of social insurance contributions as required, we may be ordered to pay the outstanding social insurance contributions within a prescribed period and may be subject to an overdue fine of 0.05% of the delayed payment per day from the date on which the payment is payable. If such payment is not made within the prescribed period, the competent authorities may further impose a fine from one to three times the amount of any overdue payment. In respect of the housing provident fund contributions, if any competent authority is of the view that the housing provident fund contributions we made do not satisfy the requirements under the relevant PRC laws and regulations, it can order us to make the outstanding balance to the relevant local authorities within a given period.

As at the Latest Practicable Date, we had not been subject to any penalty from the relevant labor authorities in relation to social security insurance and housing provident funds. As advised by our PRC Legal Advisor, if the relevant employees bring a complaint before the relevant labor authorities, we may be required to pay the arrears amount in full and pay delay penalties. If we are required to make additional payments in relation to such social security insurance and housing provident funds contributions, our operating expenses will increase and consequently could adversely affect our financial condition and results of operations.

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**Our business benefits from certain financial incentives and discretionary policies granted by local governments. Expiration of, or changes to, these incentives or policies would have an adverse effect on our results of operations.**

In the past, local governments in China granted certain financial incentives from time to time to our PRC subsidiaries as part of their efforts to encourage the development of local businesses. The timing, amount and criteria of government financial incentives are determined within the sole discretion of the local government authorities and cannot be predicted with certainty before we actually receive any financial incentive. We generally do not have the ability to influence local governments in making these decisions. Local governments may decide to reduce or eliminate incentives at any time. In addition, some of the government financial incentives are granted on a project basis and subject to the satisfaction of certain conditions, including compliance with the applicable financial incentive agreements and completion of the specific projects therein. We cannot guarantee that we will satisfy all relevant conditions, and if we fail to satisfy any such conditions, we may be deprived of the relevant incentives. We cannot guarantee the continued availability of the government incentives currently enjoyed by us. Any reduction or elimination of incentives would have an adverse effect on our results of operations.

**We are and may be involved in litigation, legal disputes, claims or administrative proceedings which could be costly and time-consuming to resolve.**

We may become subject, from time to time, to legal proceedings and claims that arise in the ordinary course of business or pursuant to governmental or regulatory enforcement activity. Any litigation or proceeding to which we become a party might result in substantial costs and divert management's attention and resources. Furthermore, any litigation, legal disputes, claims or administrative proceedings which are initially not of material importance may escalate and become important to us due to a variety of factors, such as changes in the facts and circumstances of the cases, the likelihood of loss, the monetary amount at stake and the parties involved. Our insurance might not cover claims brought against us, provide sufficient payments to financially cover all of the costs to resolve such claims or continue to be available on terms acceptable to us.

**Uncertainties embedded in the legal systems of certain geographic markets where we operate could affect our business, financial condition and results of operations.**

Legal systems of the geographic markets where we operate vary significantly from jurisdiction to jurisdiction. Some jurisdictions have a civil law system based on written statutes and others are based on common law. Unlike the common law system, prior court decisions under the civil law system may be cited for reference but have limited precedential value.

The legal systems of some geographic markets where we operate are consistently evolving. Laws and regulations that are recently enacted may not sufficiently cover all aspects of economic activities in such markets. In particular, the interpretation and enforcement of these laws and regulations are subject to future implementations, and the application of some



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of these laws and regulations to our businesses is not settled. Since local administrative and court authorities are authorized to interpret and implement statutory provisions and contractual terms, it may be difficult to evaluate the outcome of administrative and court proceedings and the level of legal protection we have in many of the geographic markets where we operate. Local courts may have discretion to reject enforcement of foreign awards or arbitration awards. These uncertainties may affect our judgment on the relevance of legal requirements and our ability to enforce our contractual rights or claims. In addition, the regulatory uncertainties may be exploited through unmerited or frivolous legal actions, claims concerning the conduct of third parties, or threats in attempt to extract payments or benefits from us.

Furthermore, many of the legal systems in the geographic markets where we operate are based in part on their respective government policies and internal interpretations, some of which are not published on a timely basis or at all and may have retroactive effects. There are other circumstances where key regulatory definitions are unclear, imprecise or missing, or where interpretations that are adopted by regulators are inconsistent with interpretations adopted by a court in analogous cases. As a result, we may not be aware of our violation of certain policies or rules until sometime after the violation. In addition, administrative and court proceedings in certain of our geographic markets may be protracted, resulting in substantial costs and diversion of resources and management attention.

It is possible that a number of laws and regulations may be adopted or construed to be applicable to us in our geographic markets and elsewhere that could affect our businesses and operations. Scrutiny and regulations of the industries in which we operate may further increase, and we may be required to devote additional legal and other resources to addressing these regulations. Changes in current laws or regulations or the imposition of new laws and regulations in our geographic markets may slow the growth of our industries and affect our business, financial condition and results of operations.

**It may be complex to effect service of process upon us or our management or to enforce against them or us any judgments obtained from foreign courts.**

We are a company incorporated under the PRC laws and a majority of our assets are located in mainland China. In addition, most of our Directors, Supervisors and senior management reside in mainland China. As a result, it may be complex for investors to effect service of process outside of mainland China upon us, our Directors, Supervisors or senior management or to enforce judgments obtained against us in courts outside mainland China. A judgment of a court of another jurisdiction may be reciprocally recognized or enforced in mainland China only if the jurisdiction has a treaty with mainland China or if the jurisdiction has been otherwise deemed by the courts of mainland China to satisfy the requirements for reciprocal recognition, subject to the satisfaction of other requirements. However, mainland China is not a party to treaties providing for the reciprocal enforcement of judgments of courts with certain foreign countries such as the United States, and enforcement in mainland China of judgments of a court in these jurisdictions may consequently be difficult. On July 3, 2008, the Supreme People's Court of the People's Republic of China and the Government of the Hong Kong Special Administrative Region signed the Arrangement between the Mainland and the

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HKSAR on Reciprocal Recognition and Enforcement of the Decisions of Civil and Commercial Cases under Consensual Jurisdiction (關於內地與香港特別行政區法院相互認可和執行當事人協議管轄的民商事案件判決的安排) (the “**2008 Arrangement**”). Under the 2008 Arrangement, where any designated court of mainland China or Hong Kong court has made an enforceable final judgment requiring payment of money in a civil and commercial case pursuant to a choice of court agreement, the party concerned may apply to the relevant court of mainland China or Hong Kong court for recognition and enforcement of the judgment. The 2008 Arrangement took effect on August 1, 2008. On January 18, 2019, the Supreme People’s Court and the Department of Justice under the Government of the Hong Kong Special Administrative Region signed the Arrangement on Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Matters by the Courts of the Mainland and of the Hong Kong Special Administrative Region (關於內地與香港特別行政區法院相互認可和執行民商事案件判決的安排) (the “**2019 Arrangement**”). The 2019 Arrangement regulates, among others, the scope and particulars of judgments, the procedures and methods of the application for recognition or enforcement, the review of the jurisdiction of the court that issued the original judgment, the circumstances where the recognition and enforcement of a judgment shall be refused, and the approaches towards remedies for the reciprocal recognition and enforcement of judgments in civil and commercial matters between the courts in mainland China and those in Hong Kong. The 2019 Arrangement came into effect on January 29, 2024 which superseded the 2008 Arrangement.

**Regulations on currency conversion and changes in the exchange rate between RMB and other currencies could negatively affect our financial condition, operations and our ability to pay dividends.**

The conversion and remittance of foreign currencies are subject to certain foreign exchange regulations. As we may convert our cash balance in RMB into other currencies to meet our foreign currency obligations, such as payments of dividends on our H Shares, there is no assurance that we will have sufficient foreign exchange to meet these requirements. For example, under the PRC current foreign exchange regulation system, foreign exchange transactions under the current account conducted by us, including the payment of dividends, do not require advance approval from the SAFE; however, we are required to present relevant documentary evidence of such transactions and conduct such transactions at designated foreign exchange banks within the PRC that have the licenses to carry out foreign exchange business. Foreign exchange transactions under the capital account, however, normally need to be approved by or registered with the SAFE or their local branch unless otherwise permitted by law. Any insufficiency of foreign exchange may restrict our ability to obtain sufficient foreign exchange for dividend payments to holders of H Shares or satisfy any other foreign exchange obligation. Moreover, non-compliance with any applicable foreign exchange regulations could subject us to administrative penalties and fines, and could affect our business and reputation.

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**Fluctuation in the value of the Renminbi may have a material adverse effect on our business.**

We conduct most of all our business in Renminbi, which is our reporting currency. The value of the Renminbi against the US dollar, Hong Kong dollar and other currencies may be affected by changes in the PRC's policies and international economic and political developments. As a result of these and any future changes in currency policy, the exchange rate may become volatile, the Renminbi may be revalued further against the US dollar or other currencies or the Renminbi may be permitted to enter into a full or limited free float, which may result in an appreciation or depreciation in the value of the Renminbi against the US dollar or other currencies. In the three years ended December 31, 2022, 2023 and 2024, respectively, we had net foreign exchange loss of RMB280.7 million, net foreign exchange loss of RMB35.3 million and net foreign exchange loss of RMB4.4 million, respectively. Fluctuations in exchange rates may adversely affect the value, translated or converted into US dollars or Hong Kong dollars (which are pegged to the US dollar), of our cash flows, revenues, earnings and financial position. For example, an appreciation of the Renminbi against the US dollar or the Hong Kong dollar would make any new Renminbi-denominated investments or expenditures more costly to us, to the extent that we need to convert US dollars or Hong Kong dollars into Renminbi for such purposes.

**Our favorable tax treatment in the PRC may change or discontinue.**

Our Company is qualified as a “High and New Technology Enterprise (高新技術企業)” under the relevant PRC tax rules and is entitled to a preferential enterprise income tax rate of 15%. Our Company's enterprise income tax rate during the Track Record Period was 15%. Our current status as a “High and New Technology Enterprise” will expire on December 18, 2026. If we are not able to renew our status as a “High and New Technology Enterprise” after our current status expires, our preferential enterprise income tax rate of 15% will also expire. Under the relevant PRC tax rules, the “High and New Technology Enterprise” qualification is subject to review and approval by the relevant approval authorities every three years.

There can be no assurance that the current favorable tax policies available to our Company and its subsidiary will not be withdrawn or revoked by the PRC government or become less favorable. If the current favorable tax treatments are reduced or are no longer available in the future, our Group's business, financial condition and results of operations in the future may be materially and adversely affected.

**We are a mainland China enterprise and we are subject to mainland China tax on our global income and any gains on the sales of H Shares and dividends on the H Shares may be subject to mainland China income taxes.**

Under the EIT Law and its implementation rules, subject to any applicable tax treaty or similar arrangement between the mainland China and a non-mainland China investor's jurisdiction of residence that provides for a different income tax arrangement, mainland China withholding tax at the rate of 10% is normally applicable to dividends from mainland China

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sources payable to investors that are non-mainland China resident enterprises, which do not have an establishment or place of business in mainland China, or which have an establishment or place of business in mainland China if the relevant income is not effectively connected with such establishment or place of business. Any gains realized on the transfer of shares by such investors are subject to a 10% mainland China income tax rate if such gains are regarded as income from sources within mainland China unless a treaty or similar arrangement provides otherwise.

Under the PRC Individual Income Tax Law (《中華人民共和國個人所得稅法》) and its implementation rules, dividends from sources within mainland China paid to foreign individual investors who are not mainland China residents are generally subject to a mainland China withholding tax at a rate of 20% and gains from mainland China sources realized by such investors on the transfer of shares are generally subject to a 20% mainland China income tax rate, in each case, subject to any reduction or exemption set forth in applicable tax treaties and laws in mainland China. Pursuant to the Circular on Questions Concerning the Collection of Individual Income Tax Following the Repeal of Guo Shui Fa [1993] No. 045 (《關於國稅發[1993]045號文件廢止後有關個人所得稅徵管問題的通知》) (Guo Shui Han [2011] No. 348) (國稅函[2011]348號) dated June 28, 2011, issued by the SAT, dividends paid to non-mainland China resident individual holders of H Shares are generally subject to individual income tax of mainland China at the withholding tax rate of 10%, in which the non-mainland China resident individual holder of H Shares resides as well as the tax arrangement between mainland China and Hong Kong. Non-mainland China resident individual holders who reside in jurisdictions that have not entered into tax treaties with mainland China are subject to a 20% withholding tax on dividends received from us. However, pursuant to the Circular Declaring that Individual Income Tax Continues to be Exempted over Income of Individuals from Transfer of Shares (《關於個人轉讓股票所得繼續暫免徵收個人所得稅的通知》) issued by the MOF of mainland China and the SAT on March 30, 1998, gains of individuals derived from the transfer of listed shares of enterprises may be exempt from individual income tax. In addition, on December 31, 2009, the MOF, the SAT and the CSRC jointly issued the Circular on Relevant Issues Concerning the Collection of Individual Income Tax over the Income Received by Individuals from Transfer of Listed Shares Subject to Sales Limitation (《關於個人轉讓上市公司限售股所得徵收個人所得稅有關問題的通知》) (Cai Shui [2009] No. 167) which states that individuals' income from the transfer of listed shares on certain domestic exchanges shall continue to be exempted from individual income tax, except for the relevant shares which are subject to sales restrictions as defined in the Supplementary Circular on Relevant Issues Concerning the Collection of Individual Income Tax over the Income Received by Individuals from Transfer of the Listed Shares Subject to Sales Limitations (《關於個人轉讓上市公司限售股所得徵收個人所得稅有關問題的補充通知》) (Cai Shui [2010] No. 70). As of the Latest Practicable Date, the aforesaid provision has not expressly provided that individual income tax shall be collected from non-mainland China resident individuals on the sale of shares of mainland China resident enterprises listed on overseas stock exchanges.

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**If we are sued for infringing, misappropriating, or otherwise violating intellectual property rights of third parties or engaging in unfair competition, such litigation could be costly and time-consuming and could prevent or delay us from developing or commercializing our drug candidates.**

Our commercial success depends in part on us and our partners avoiding infringement, misappropriation, and other violations of the patents and other intellectual property rights of third parties. We are aware of numerous issued patents and pending patent applications belonging to third parties that exist in fields in which we are developing our drug candidates. There may also be third-party patents or patent applications of which we are currently unaware, and given the dynamic area in which we operate, additional patents are likely to issue that relate to aspects of our business. There is a substantial amount of litigation and other claims and proceedings involving patent and other intellectual property rights in the pharmaceutical and biopharmaceutical industries generally. As the pharmaceutical and biopharmaceutical industries expand and more patents are issued, the risk increases that our drug candidates may give rise to claims of infringement of the patent rights of others.

Third parties may assert that we are using technology in violation of their patent or other proprietary rights. We may also be subject to allegations by third parties of unfair competition, defamation or violation of their other rights. Defense of these claims, regardless of their merit, could involve substantial litigation expense and divert our technical personnel, management personnel, or both from their normal responsibilities. Even in the absence of litigation, we may seek to obtain licenses from third parties to avoid the risks of litigation, and if a license is available, it could impose costly royalty and other fees and expenses on us.

We are involved in an ongoing patent infringement litigation in connection with the Company's generic drug Linagliptin in which we are the defendant and the amount in dispute is approximately RMB100 million. For details, please see "Business — Legal and Compliance — Recent Intellectual Property Infringement Claim". We cannot assure you that a court would find in our favor on questions of infringement, validity, enforceability, or priority and it could materially and adversely affect our ability to develop and commercialize any of our drug candidates and any other drug candidates covered by the asserted third party patents.

If third parties bring successful claims against us for infringement, misappropriation, or other violations of their intellectual property rights, we may be subject to injunctive or other equitable relief, which could prevent us from developing and commercializing one or more of our drug candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim against us of infringement, misappropriation, or other violation of intellectual property, or a settlement by us of any such claims, we may have to pay substantial damages, which we may not be able to be indemnified by our licensing partners. In the event of an adverse result in any such litigation, or even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our drug candidates. Any such license might not be available on reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive,

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thereby giving our competitors and other third parties access to the same technologies license to us, and it could require us to make substantial licensing and royalty payments. In the event that we are unable to obtain such a license, we would be unable to further develop and commercialize one or more of our drug candidates, which could harm our business significantly. We may also elect to enter into license agreements in order to settle patent and other intellectual property infringement claims or to resolve disputes prior to litigation, and any such license agreements may require us to pay royalties and other fees that could significantly harm our business.

Even if litigation or other proceedings are resolved in our favor, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the market price of our shares. Such litigations or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities.

**If we are unable to obtain and maintain patent protection for our drug candidates through intellectual property rights, or if the scope of such intellectual property rights obtained is not sufficiently broad, third parties could develop and commercialize products and technologies similar or identical to ours and compete directly against us, and our ability to successfully commercialize any product or technology may be adversely affected.**

Our success depends in large part on our ability to protect our proprietary technology and drug candidates from competition by obtaining, maintaining, defending and enforcing our intellectual property rights, including patent rights. As of December 31, 2024, we had filed a total of 2,446 invention patent applications, including 382 PCT applications, 1,131 PRC domestic invention applications and 933 overseas applications, among which, a total of 1,401 invention patents have been granted by the relevant patent authorities, including 746 in the PRC and 655 overseas. For further information on our patent portfolio, please see “Business — Intellectual Property ” in this Listing Document. If we or our licensors are unable to obtain or maintain patent protection with respect to our drug candidates and technologies, our business, financial condition, results of operations and prospects could be materially harmed.

The scope of patent protection in various jurisdictions is also uncertain. Changes in either the patent laws or their interpretation in the relevant markets may diminish our ability to protect our inventions, obtain, maintain, defend, and enforce our intellectual property and, more generally, could affect the value of our intellectual property or narrow the scope of our patent rights. We cannot predict whether the patent applications we are currently pursuing and may pursue in the future will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors.



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The patent prosecution process is expensive, time-consuming and complex, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications at a reasonable cost or in a timely manner in all desirable territories. As a result, we may not be able to prevent competitors from developing and commercializing competitive drugs in all such fields and territories.

Patents may be invalidated and patent applications may not be granted for a number of reasons, including deficiencies in the patent application, a lack of novelty of the underlying invention or technology, or where the subject of the patent application already exists. It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisers and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to obtain patent protection. In addition, publications of discoveries in the scientific literature often lag behind actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases, not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications or that we were the first to file for patent protection of such inventions. Furthermore, China and the United States have adopted the “first-to-file” system under which whoever first files a patent application will be awarded the patent if all other patentability requirements are met. Under the first-to-file system, third parties may be granted a patent relating to a technology which we invented.

In addition, under the PRC patent law, any organization or individual that applies for a patent in a foreign country for an invention or utility model accomplished in China is required to file to the China National Intellectual Property Administration, or CNIPA, for confidentiality examination. Otherwise, if an application is later filed in China, the patent right will not be granted.

The coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we license or own currently or in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents that we hold or in-license may be challenged, narrowed, circumvented, or invalidated by third parties. In addition, the patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain.

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The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patent rights may be challenged in the courts or patent offices in the relevant markets. We may be subject to a third-party pre-issuance submission of prior art to the IP offices in relevant markets, or become involved in opposition, derivation, revocation, re-examination, post-grant review, inter-parties review, or interference proceedings or similar proceedings in foreign jurisdictions challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or drug candidates and compete directly with us without payment to us, or result in our inability to manufacture or commercialize drug candidates without infringing, misappropriating or otherwise violating third-party patent rights. Moreover, we may have to participate in interference proceedings declared by the IP offices in relevant markets to determine priority of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge the priority of our invention or other features of patentability of our patents and patent applications. Such challenges may result in loss of patent rights, loss of exclusivity, or in patent claims being narrowed, invalidated, or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and drug candidates. Such proceedings also may result in substantial costs and require significant time from our scientists and management, even if the eventual outcome is favorable to us. Consequently, we do not know whether any of our technology or drug candidates will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner.

Furthermore, although extensions may be available, the life of a patent and the protection it affords, is limited. Even if we successfully obtain patent protection for an approved drug candidate, it may face competition from generic or biosimilar medications once the patent has expired. Manufacturers of generic or biosimilar drugs may challenge the scope, validity or enforceability of our patents in court or before a patent office, and we may not be successful in enforcing or defending those intellectual property rights and, as a result, may not be able to develop or market the relevant product exclusively, which would have a material adverse effect on any potential sales of that product. The issued patents and pending patent applications, if issued, for our drug candidates are expected to expire on various dates as described in “Appendix VI — Statutory and General Information — B. Further Information about Our Business — 2. Our Intellectual Property Rights” in this Listing Document. Upon the expiration of our issued patents or patents that may issue from our pending patent applications, we will not be able to assert such patent rights against potential competitors and our business and results of operations may be adversely affected.

Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such drug candidates might expire before or shortly after such drug candidates are commercialized. As a result, our patents and patent applications may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Moreover, some of our patents and patent applications are, and may



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in the future be, co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

In addition, periodic maintenance fees on any issued patent are due to be paid to the CNIPA and other patent agencies in several stages over the lifetime of the patent. The CNIPA and various other governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. Although an inadvertent lapse can in many cases be rectified by paying a late fee or by other means in accordance with the applicable rules, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees, and failure to properly legalize and submit formal documents. In any such event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

**We may become involved in lawsuits to protect or enforce our intellectual property, which could be time consuming and unsuccessful. Our patent rights relating to our drug candidates could be found invalid or unenforceable if challenged in court or before the patent authority.**

Competitors may infringe our patent rights or misappropriate or otherwise violate our intellectual property rights. To counter infringement or unauthorized use, litigation may be necessary in the future to enforce or defend our intellectual property rights, to protect our trade secrets or to determine the validity and scope of our own intellectual property rights or the proprietary rights of others. This can be expensive and time consuming. Any claims that we assert against perceived infringers could also provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property rights. Many of our current and potential competitors have the ability to dedicate substantially greater resources to enforce and/or defend their intellectual property rights than we can. Accordingly, we may not be able to prevent third parties from infringing upon or misappropriating our intellectual property. An adverse result in any litigation proceeding could put our patent, as well as any patents that may issue in the future from our pending patent applications, at risk of being invalidated, held unenforceable or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

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**We may not be able to protect our intellectual property rights throughout the world or prevent unfair competition by third parties.**

Filing, prosecuting, maintaining and defending patents on drug candidates in all countries throughout the world could be prohibitively expensive for us, and our intellectual property rights in some countries can have a different scope and strength than do those in some other countries. In addition, the laws of certain countries do not protect intellectual property rights to the same extent as the laws of certain other countries. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries, or from selling or importing drugs made using our inventions in and into certain jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own drugs and further, may export otherwise infringing drugs to certain jurisdictions where we have patent protection, but where enforcement rights are not as strong as those in certain other countries. These drugs may compete with our drug candidates and our patent rights or other intellectual property rights may not be effective or adequate to prevent them from competing.

We currently hold issued trademark registrations and have trademark applications pending, any of which may be the subject of a governmental or third-party objection, which could prevent the registration or maintenance of the same. If we are unsuccessful in obtaining trademark protection for our primary brands, we may be required to change our brand names, which could materially adversely affect our business. Moreover, as our products mature, our reliance on our trademarks to differentiate us from our competitors will increase, and as a result, if we are unable to prevent third parties from adopting, registering or using trademarks and trade dress that infringe, dilute or otherwise violate our trademark rights, or engaging in conduct that constitutes unfair competition, defamation or other violation of our rights, our business could be materially adversely affected.

Many companies have encountered significant problems in protecting and defending intellectual property rights in certain jurisdictions. The legal systems of some countries do not favor the enforcement of patents, trade secrets and other intellectual property, particularly those relating to biopharmaceutical products, which could make it difficult in those jurisdictions for us to stop the infringement, misappropriation or other violation of our patents or other intellectual property rights, or the marketing of competing drugs in violation of our proprietary rights. Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims against us.

We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

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Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations, and prospects may be adversely affected.

**Intellectual property rights do not necessarily address all potential threats.**

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make products that are similar to any drug candidates we may develop or utilize similar technology that are not covered by the claims of the patents that we own or license now or in the future;
- we, or our license partners or current or future collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent application that we license or may own in the future;
- we, or our license partners or current or future collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing, misappropriating or otherwise violating our owned or licensed intellectual property rights;
- it is possible that our pending licensed patent applications or those that we may own in the future will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business; and
- we may choose not to file a patent for certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

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Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations and prospects.

**If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed. We may be subject to claims that our employees, consultants, or advisers have wrongfully used or disclosed alleged trade secrets of their former employers or claims asserting ownership of what we regard as our own intellectual property.**

In addition to our issued patent and pending patent applications, we rely on trade secrets and confidential information, including unpatented know-how, technology and other proprietary information, to maintain our competitive position and to protect our drug candidates. We seek to protect these trade secrets and confidential information, in part, by entering into non-disclosure and confidentiality agreements with parties that have access to them, such as our employees, corporate collaborators, outside scientific collaborators, sponsored researchers, contract manufacturers, consultants, advisers and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. However, any of these parties may breach such agreements and disclose our proprietary information, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome is unpredictable. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us and our competitive position would be harmed.

Furthermore, many of our employees, consultants, and advisers, including our senior management, were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these employees, consultants, and advisers, including each member of our senior management, executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. We may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's former employer. We are not aware of any threatened or pending claims related to these matters or concerning the agreements with our senior management, but in the future litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, while we typically require our employees, consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own, and furthermore, the assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, each of which may result in claims by or against us

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related to the ownership of such intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our management and scientific personnel and could have a material adverse effect on our business, financial condition, results of operations, and prospects.

### **Our business model exposes us to risks of cannibalization and stock obsolescence.**

We sell our products primarily through our third-party distributors covering 32 provinces, cities and autonomous regions and nearly 300 prefecture-level cities in the PRC as of December 31, 2024, and the third-party distributors are required by us to sell our products only in the designated market regions. We may be subject to risks of cannibalization if any distributors selling products outside their designated regions, leading to diminished overall revenue and market share. We may also be subject to the risks of stock obsolescence where products lose their value or become unsellable due to factors such as expiration or the emergence of more advanced alternatives.

We have implemented a series of measures to avoid the occurrence of cannibalization. For further details of our measures, please refer to the paragraph headed “Business — Sales, Marketing and Distribution — Measures to Manage Cannibalization and Channel Stuffing” in this Listing Document. However, we cannot guarantee that our distributors would continue to follow our measures, and that our measures can completely avoid the occurrence of cannibalization among different distributors. Any failure by us to effectively prevent cannibalization could materially and adversely affect our sales and the reach of our products to end-consumers, which would in turn result in a material adverse effect on our financial condition and results of operations.

### **Changes in U.S. and international trade policies, and geopolitical relationships, may cause disruptions to our clinical development, drug manufacturing processes and other aspects of our business and operations.**

The recent U.S.-China trade tensions have led to the introduction of high tariffs on a host of goods trading between the two countries. The trade tensions between the two countries have been rising and there is a possibility that the extent and scale of trade restrictions between the two countries be escalated if the U.S. and China fail to reach any agreement to settle the issues. There is no assurance as to how the U.S.-China trade tensions might develop or whether there will be any changes to the scope and extent of goods that are or will be being subject to such export controls, sanctions, tariffs, or new trade policies introduced by the two countries. We cannot predict the implications of the ongoing U.S.-China trade tensions and the resulting impact on our industry and the global economy. Any unfavorable government policies on international trade, such as capital controls or tariffs, may affect the import or export of raw materials and disrupt our drug development and the manufacturing of our drug candidates. Such unfavorable policies may also negatively impact the hiring of scientists and other research and development personnel, the demand for and competitiveness of our drugs, or

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prevent us from selling our drugs in certain countries. If any new tariffs, policies, legislation and/or regulations are announced or implemented, or if existing trade agreements are renegotiated, such changes could have an adverse effect on our business, financial condition, results of operations and prospects.

Our business could be negatively affected by changes in geopolitical relationships. Fluctuations in diplomatic relations and changes in governments could present challenges in recruiting qualified personnel, obtaining necessary supplies and raw materials, and the ability to ensure a stable supply chain. The implementation of trade sanctions or export controls could lead to compliance requirements and potential delays in product development. The introduction of new tariffs, modifications to legislation and regulations, or the renegotiation of current trade agreements may have a significant negative impact on our business, future prospects, operational results, financial condition, and cash flows. These factors require ongoing attention and could entail costs and require managerial attention in order to adapt to changing market conditions.

### **B. RISKS RELATING TO THE LISTING**

#### **There are uncertainties relating to the Privatization.**

As stated in the 3.5 Announcement and the Composite Document, our Listing is in connection with the Privatization. The Listing and the issuance of the new H Shares to the Share Exchange Shareholders will only take place if all of the Pre-Conditions and the Conditions (being the Conditions to effectiveness and the Conditions to implementation) have been fulfilled or waived (as applicable). Accordingly, the success of the Listing is conditional upon the Privatization becoming successful and it is a condition to the Merger Agreement becoming effective that the approval of Listing Committee of the Stock Exchange for the listing of, and permission to deal in, our H Shares on the Stock Exchange not having been withdrawn and remain valid.

The Merger is subject to various conditions as set forth in detail in the 3.5 Announcement and the Composite Document. As at the date of this Listing Document, the following conditions, amongst others, remain unfulfilled:

- (a) the passing of special resolution(s) by majority of not less than two-thirds of the votes cast by way of poll by the HEC CJ Pharm Shareholders present and voting in person or by proxy at the HEC CJ Pharm EGM to approve the Merger under the Merger Agreement in accordance with the articles of association of HEC CJ Pharm and applicable PRC Laws;
- (b) the passing of special resolution(s) by way of poll approving the Merger under the Merger Agreement at the HEC CJ Pharm H Shareholders' class meeting to be convened for this purpose, provided that: (i) approval is given by at least 75% of the votes attaching to the HEC CJ Pharm H Shares held by the Independent HEC CJ

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## RISK FACTORS

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Pharm Shareholders that are cast either in person or by proxy; and (ii) the number of votes cast against the resolution is not more than 10% of the votes attaching to all HEC CJ Pharm H Shares held by the Independent HEC CJ Pharm Shareholders;

- (c) there being no material breach of the representations, warranties or undertakings given by our Company in the Merger Agreement on the Delisting Date which has a material adverse impact on the Merger;
- (d) there being no material breach of the representations, warranties or undertakings given by HEC CJ Pharm in the Merger Agreement on the Delisting Date which has a material adverse impact on the Merger;
- (e) there being no law, restriction or prohibition of any governmental authority or any judgment, decision or adjudication of any court on the Delisting Date which restricts, prohibits or terminates the Merger; and
- (f) the necessary approval or filing for the Introduction, and permission to deal in the H Shares on the Stock Exchange pursuant to the Introduction not having been withdrawn and remain valid.

The above conditions cannot be waived. Accordingly, if any of the conditions are not satisfied on or before the Long Stop Date, the Privatization will lapse and the Listing will be aborted.

**Future sales or perceived sales or conversion of substantial amounts of our Shares in the public market, including any future offering of H Shares or conversion of our unlisted Shares into H Shares, could have a material adverse effect on the prevailing market price of our H Shares and our ability to raise additional capital in the future, or may result in dilution of your shareholding.**

The market price of our H Shares could decline as a result of future sales or issuances of a substantial number of our H Shares or other securities relating to our H Shares in the public market, or the perception that such sales or issuances may occur. Moreover, such future sales or perceived sales may also adversely affect the prevailing market price of our H Shares and our ability to raise capital in the future at a favorable time and price. The H Shares held by the Controlling Shareholder are subject to certain lock-up undertakings for a period of up to twelve months after the Listing Date. We cannot assure you that they will not dispose of their Shares they may own now or in the future.

According to the stipulations by the State Council's securities regulatory authority and the Articles of Association, our unlisted Shares may be converted into H Shares, and such converted H Shares may be listed or traded on an overseas stock exchange provided that prior to the conversion and trading of such converted H Shares, the requisite internal approval processes (but without the necessity of Shareholders' approval by class) have been duly completed and the approval from the relevant PRC regulatory authorities, including the CSRC,



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## RISK FACTORS

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have been obtained. In addition, such conversion, trading and listing shall in all respects comply with the regulations prescribed by the State Council's securities regulatory authorities and the regulations, requirements and procedures prescribed by the relevant overseas stock exchange. The conversion of a substantial amount of unlisted Shares into H Shares could further increase the supply of H Shares in the market and could negatively impact the market price of H Shares.

Furthermore, if additional funds are raised through our issuance of new equity or equity-linked securities other than on a pro-rata basis to existing Shareholders, the percentage ownership for such Shareholders may be reduced. Such new securities may also confer rights and privileges that take priority over those conferred by the H Shares.

**We may not be able to declare and pay any dividend.**

The amount of dividends that the Company may declare and pay in the future will be proposed by our Board of Directors and subject to the approval of our Shareholders at a shareholders' meeting. In considering the amount of dividends to declare and pay, we will consider a number of factors, including our distributable profits, financial condition, cash flow, expected future capital expenditure, return to our Shareholders, capital requirements, finance costs, the external financing environment and any other factors that the Directors may deem relevant. The payment of dividends may also be limited by legal restrictions and by financing agreements that we may enter into from time to time. No dividends have been declared by the Company during the years ended December 31, 2022, 2023 and 2024. There is no assurance that we will be able to declare and pay any dividend in the future.

**We cannot assure you that the H Shares will remain listed on the Stock Exchange.**

Although it is currently intended that the H Shares will remain listed on the Stock Exchange, there is no guarantee of the continued listing of the H Shares. Among other factors, the Company may not continue to satisfy the listing requirements of the Stock Exchange. Holders of H Shares would not be able to sell their H Shares through trading on the Stock Exchange if the H Shares are no longer listed on the Stock Exchange.

**The market price and trading volume of the Company's H Shares may fluctuate significantly and could decline upon completion of the Listing, and investors could lose some or all of their investment.**

The trading volume and price of our H Shares may fluctuate significantly. The trading price of our H Shares may fluctuate after the Listing as the public offer price is not available for our H Shares in the Introduction. Prior to the Listing, there is no public offer price for our H Shares. The intrinsic value of our H Shares may differ significantly from the market price for the H Shares following the Listing.



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## RISK FACTORS

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The share price is determined by the supply of and demand for the H Shares and may not necessarily reflect the fair value of our Company. Some of the factors that could negatively affect the share price or result in fluctuations in the price or trading volume of the H Shares include, for example, *ad hoc* developments, fluctuations in our actual or projected operating results, changes in projected or expected financial performance, variations in quarterly results, failure to meet securities analysts' expectations, the contents of published research reports about us or our industry segments or securities analysts failing or ceasing to cover us following the Listing, actions by institutional shareholders and general market conditions or special factors influencing companies in the industry in general. Furthermore, the share price could also decline due to future sales or market expectations of sales of a substantial number of shares in us by significant shareholders. Fluctuations in the equity markets could also cause the share price to decline, though such general fluctuations may not necessarily have any particular basis in our business or prospects. If the share price decreases, investors may be unable to resell their shares at or above their purchase price and may lose some or all of their investment in our H Shares.

**Future sales or perceived sales of our Shares in the public market by major Shareholders following the Listing could materially and adversely affect the price of our Shares.**

The market price of our H Shares could decrease as a result of future sales of a substantial number of our H shares or other securities relating to our H shares in the public market, or the perception that such sales may occur. Future sales, or anticipated sales, of substantial amounts of our securities could also materially and adversely affect our ability to raise capital at a specific time and on terms favorable to us. In addition, any of our future offerings of securities may dilute the shareholdings of our H Share shareholders.

**The industry facts, statistics and forecasts in the Listing Document obtained from various government publications and the industry report have not been independently verified.**

Facts, forecasts and statistics in this Listing Document relating to the pharmaceutical industry are obtained from various sources that we believe are reliable, including official government publications as well as a report prepared by Frost & Sullivan that we commissioned. We believe that the sources of such information are appropriate sources for such information and have taken reasonable care in extracting and producing such information. We have no reason to believe that such information is false or misleading or that any fact has been omitted that would render such information false or misleading. However, we cannot guarantee the quality or reliability of information from official government sources. The information from official government sources has not been independently verified by us, the Sole Sponsor, any of our or their respective directors, officers or representatives or any other person involved in the Listing and no representation is given as to its accuracy. You should therefore not place undue reliance on such information. In addition, we cannot assure you that such information is stated or compiled on the same basis or with the same degree of accuracy as or consistent with similar statistics presented elsewhere, and such information may not be complete or up-to-date. In any event, you should consider carefully the importance placed on such information or statistics.

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## RISK FACTORS

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**You should read the entire Listing Document carefully, and we strongly caution you not to place any reliance on any information contained in press articles or other media regarding us or the Listing.**

Prior to the publication of this Listing Document, there had been press and media coverage regarding us and the Listing, which contained, among other things, certain financial information, projections, valuations and other forward-looking information. We have not authorized the disclosure of any such information in the press or media and do not accept responsibility for the accuracy or completeness of such press articles or other media coverage. We make no representation as to the appropriateness, accuracy, completeness or reliability of any of the projections, valuations or other forward-looking information about us. To the extent that such statements are inconsistent with, or conflict with, the information contained in this Listing Document, we disclaim responsibility for them. Accordingly, prospective investors are cautioned to make their investment decisions only on the basis of the information contained in this Listing Document and should not rely on any other information.

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## WAIVERS FROM STRICT COMPLIANCE WITH THE LISTING RULES

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In preparation of the Listing, we have sought the following waivers from strict compliance with the relevant provisions of the Listing Rules.

### MANAGEMENT PRESENCE IN HONG KONG

Pursuant to Rule 8.12 of the Listing Rules, a new applicant applying for a primary listing on the Stock Exchange must have sufficient management presence in Hong Kong. This normally means that at least two of the executive directors must be ordinarily resident in Hong Kong. Rule 19A.15 of the Listing Rules further provides that the requirement in Rule 8.12 of the Listing Rules may be waived by the Stock Exchange in its discretion.

Given that we are headquartered in the PRC with our principal business operation principally located, managed and conducted in the PRC and all of our executive Directors are not ordinarily resident in Hong Kong, our Company considers that it would be practically difficult and commercially unfeasible for us to either relocate two of our executive Directors to Hong Kong or to appoint two additional executive Directors who are ordinarily resident in Hong Kong solely for the purpose of satisfying the requirements under Rule 8.12 and Rule 19A.15 of the Listing Rules.

Accordingly, pursuant to Rule 19A.15 of the Listing Rules, our Company has applied to the Stock Exchange for, and the Stock Exchange has granted, a waiver from strict compliance with the requirements under Rule 8.12 and Rule 19A.15 of the Listing Rules, provided that our Company implements the following arrangements:

- our Company has appointed two authorized representatives (the “**Authorized Representatives**”) pursuant to Rule 3.05 of the Listing Rules, namely, Dr. Zhang Yingjun and Dr. Li Wenjia, both of whom are executive Directors, who will act as our Company’s principal channel of communication with the Stock Exchange. Each of the Authorized Representatives will be available to meet with the Stock Exchange in Hong Kong within a reasonable time frame upon the request of the Stock Exchange and will be readily contactable by telephone and email to deal promptly with enquiries from the Stock Exchange. Each of the Authorized Representatives is authorized by our Board to communicate on behalf of our Company with the Stock Exchange. Our Company is registered as a non-Hong Kong company under Part 16 of the Companies Ordinance, and Mr. Cheng Ching Kit, the company secretary of our Company, has been authorized to accept service of legal process and notice in Hong Kong on behalf of our Company;
- each of the Authorized Representatives has means to contact all members of our Board (including the independent non-executive Directors) and the senior management team promptly at all times as and when the Stock Exchange wishes to contact them or any of them for any matters. To enhance the communication between the Stock Exchange, the Authorized Representatives and our Directors, our Company will implement a number of policies whereby (i) each Director shall provide his/her mobile phone numbers, office phone numbers and email addresses

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## WAIVERS FROM STRICT COMPLIANCE WITH THE LISTING RULES

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to the Authorized Representatives; (ii) in the event that such Director expects to travel and be out of office, he/she shall provide the phone number of the place of his/her accommodation or other contact method to the Authorized Representatives; and (iii) all our Directors and authorized representatives will provide their respective mobile phone numbers, office phone numbers and email addresses to the Stock Exchange. We shall promptly inform the Stock Exchange of any changes to the contact details of the Authorized Representatives and our Directors;

- China Sunrise Capital Limited has been appointed as our Company's compliance advisor, pursuant to Rule 3A.19 of the Listing Rules, to provide our Company with professional advice on continuing obligations under the Listing Rules, and to act at all times, in addition to the two Authorized Representatives, as our Company's additional channel of communication with the Stock Exchange for the period commencing on the Listing Date and ending on the date on which our Company complies with Rule 13.46 of the Listing Rules and publishes its financial results in respect of its first full financial year commencing after the Listing Date. The contact person of the compliance advisor will be fully available to answer enquiries from the Stock Exchange;
- each of our Directors (including independent non-executive Directors) who is not ordinarily resident in Hong Kong has confirmed that he/she possesses or can apply for valid travel documents to visit Hong Kong and would be able to meet with the Stock Exchange in Hong Kong upon reasonable notice; and
- our Company will also appoint other professional advisors (including its legal advisors in Hong Kong) after the Listing to assist our Company in addressing any enquiries which may be raised by the Stock Exchange and to ensure that there will be prompt and effective communication with the Stock Exchange.

### DEALINGS IN THE SHARES PRIOR TO LISTING

According to Rule 9.09(b) of the Listing Rules, there must be no dealing in the securities for which listing is sought by any core connected person of the new listing applicant from four clear business days before the expected hearing date until listing is granted (the “**Restricted Period**”).

Our Company has made the Privatization Proposal to privatize HEC CJ Pharm by way of merger by absorption in accordance with the PRC Company Law, other applicable PRC laws, Hong Kong laws, the Takeovers Code and the Listing Rules and pursuant to which, subject to the fulfilment (or waiver, as applicable) of the Pre-Conditions and all the Conditions (being the Conditions to effectiveness and the Conditions to implementation), our Company will issue H Shares to all Share Exchange Shareholders according to the Share Exchange Ratio as the consideration for the Share Exchange. Accordingly, our Company has made an application to

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## WAIVERS FROM STRICT COMPLIANCE WITH THE LISTING RULES

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the Stock Exchange for our listing of the H Shares by way of introduction. According to the Share Exchange Ratio, for every Share Exchange HEC CJ Pharm H Share canceled under the Privatization Proposal, 0.263614 H Shares will be issued.

As at the Latest Practicable Date, to the best knowledge of the Company after due inquiry, (1) Guangdong HEC Technology, (2) Mr. Tang Xinfu, (3) Mr. Li Shuang, Mr. Wang Danjin, Mr. Jiang Juncai and Mr. Li Xuechen, each of whom being a director of HEC CJ Pharm (collectively, the “**Relevant HEC CJ Pharm Directors**”) and (4) Mr. Wang Shengchao and Mr. Luo Zhonghua, each of whom being a supervisor of HEC CJ Pharm (collectively, the “**Relevant HEC CJ Pharm Supervisors**”) held 21,815,200, 130,400, 204,800 and 98,800 HEC CJ Pharm H Shares, respectively. In anticipation of the Share Exchange and for the purpose of the Introduction, 5,750,792, 34,375, 53,988 and 26,045 H Shares will be issued to Guangdong HEC Technology, Mr. Tang Xinfu, the Relevant HEC CJ Pharm Directors and the Relevant HEC CJ Pharm Supervisors, respectively, in the Restricted Period, as consideration for the cancellation of the HEC CJ Pharm H Shares held by each of them.

In this regard, the Share Exchange to be participated by Guangdong HEC Technology, Mr. Tang Xinfu, the Relevant HEC CJ Pharm Directors and the Relevant HEC CJ Pharm Supervisors, and in particular the issuance of H Shares to them in the Restricted Period, may result in a technical deviation from Rule 9.09(b) which prohibits dealing in securities for which listing is sought by any core connected person of our Company during the Restricted Period.

We have therefore applied for, and the Stock Exchange has granted our Company, a waiver from strict compliance with Rule 9.09(b) of the Listing Rules for the issuance of H Shares to Guangdong HEC Technology and Mr. Tang Xinfu under the Share Exchange, subject to the following conditions:

- (1) that the waiver is only applicable to Guangdong HEC Technology, Mr. Tang Xinfu and each of the Relevant HEC CJ Pharm Directors and Relevant HEC CJ Pharm Supervisors with respect to their participation in the Share Exchange;
- (2) save for the participation of Guangdong HEC Technology, Mr. Tang Xinfu and each of the Relevant HEC CJ Pharm Directors and Relevant HEC CJ Pharm Supervisors in the Share Exchange, that no other core connected persons of our Company will deal in the H Shares seeking for the Listing during the Restricted Period;
- (3) our Company undertakes that it shall notify the Stock Exchange of any dealings or suspected dealings in the H Shares seeking for Listing by any core connected persons of the Company during the Restricted Period; and
- (4) our Company undertakes to release price sensitive information to the public as required by the relevant laws and regulations applicable to our Company so that Guangdong HEC Technology, Mr. Tang Xinfu and each of the Relevant HEC CJ Pharm Directors and Relevant HEC CJ Pharm Supervisors will not be in possession of non-public price sensitive information.

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## WAIVERS FROM STRICT COMPLIANCE WITH THE LISTING RULES

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### SHARE ISSUE RESTRICTION

Rule 10.08 of the Listing Rules provides that no further shares or securities convertible into equity securities of a listed issuer may be issued or form the subject of any agreement to such an issue within six months from the date on which securities of the listed issuer first commence dealings on the Stock Exchange (whether or not such issue of shares or securities will be completed within six months from the commencement of dealing) except for the circumstances more particularly stated in the Listing Rules.

Our Company has applied to the Stock Exchange for a waiver from strict compliance with the restrictions on further issue of Shares (or convertible securities) within the first six months from the Listing Date under Rule 10.08 of the Listing Rules, and the Stock Exchange has granted such a waiver subject to the following conditions:

- (a) any issue of Shares (or convertible securities) by our Company during the first six months from the Listing Date must be for cash to fund a specific acquisition, as part of or full consideration for the acquisitions, or to be used for our R&D expenditures, sales network construction or construction of our production facilities;
- (b) the matter mentioned in (a) above must contribute to the growth of our Group's operation;
- (c) any further issue of new Shares will be made under a general mandate or subject to the Shareholders' approval as required under Rule 13.36 of the Listing Rules with the total number of Shares that are issued or to be issued not exceeding 20% of the total number of Shares in issue as at the Listing Date. Upon completion of any issuance(s) within six months after Listing, our Controlling Shareholders would hold no less than 42.48% of the total issued share capital of our Company; and
- (d) our Controlling Shareholders will not cease to be Controlling Shareholders upon the issue of any Shares within the first 12 months from the Listing Date in compliance with Rule 10.07(1) of the Listing Rules.

The reasons for the application for a waiver from strict compliance with Rule 10.08 of the Listing Rules by our Company are, *inter alia*, as follows:

- (a) our Company is seeking a listing of its H Shares on the Stock Exchange by way of introduction. The relevant H Shares subject to the listing application are H Shares to be issued as consideration for the cancelation of the Share Exchange HEC CJ Pharm H Shares pursuant to the Merger and the Privatization. Our Company is not issuing any other new H Shares or raising new funds pursuant to the Introduction. Accordingly, our Company's listing by way of introduction itself will not result in any dilution of the Shareholders' interests in our Company;

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## **WAIVERS FROM STRICT COMPLIANCE WITH THE LISTING RULES**

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- (b) as our Company continues to expand its business and enrich its product pipeline, it is essential for our Company to have flexibility in raising funds by way of further issue of new H Shares to support our business development or entering into further acquisitions with issuance of H Shares as consideration should an appropriate opportunity arise. In addition, our Company considers that any issue of new H Shares by our Company will enhance our Shareholders' base and increase the trading liquidity of the H Shares. The interests of our Shareholders and prospective investors would be prejudiced if our Company could not raise funds for our business development or expansion due to the restrictions under Rule 10.08 of the Listing Rules;
- (c) the interests of our Shareholders will be protected since any further issue of Shares by our Company will have to be subject to the Shareholders' approval as required under Rule 13.36 of the Listing Rules; and
- (d) since the commencement of the Track Record Period, our Controlling Shareholders have at all times maintained more than 30% interest in our Company. They remained strongly committed to our Company and save for the deemed disposal by our Controlling Shareholders resulting from any issue of securities by our Company within six months from the Listing Date, they intend not to dispose of any Shares owned by them within six months from the Listing Date and have undertaken to remain as Controlling Shareholders for the first 12 months from the Listing Date.

### **CONTINUING CONNECTED TRANSACTIONS**

Our Group entered into and is expected to continue with certain transactions which would constitute partially exempted continuing connected transactions under Chapter 14A of the Listing Rules, following completion of the Listing. We have applied for, and the Stock Exchange has granted, a waiver from strict compliance with the relevant requirements under Chapter 14A of the Listing Rules in respect of such partially exempted continuing connected transactions. For details, please refer to the section headed "Connected Transactions" in this Listing Document.

### **PUBLIC FLOAT**

Rule 8.08(1)(a) of the Listing Rules provides that there must be an open market in the securities for which listing is sought which normally means that at least 25% of the issuer's total issued share capital must at all times be held by the public.

We have applied to the Stock Exchange for, and the Stock Exchange has granted, a waiver from strict compliance with the minimum public float requirement under Rule 8.08(1)(a) of the Listing Rules so that the minimum percentage of our H Shares from time to time held by the public shall be the higher of (1) 18.53% and (2) such percentage of H Shares to be held by the public immediately upon completion of the Introduction and the Privatization.



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## **WAIVERS FROM STRICT COMPLIANCE WITH THE LISTING RULES**

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Assuming that the Merger is approved and all the Dissenting Shareholders request that their HEC CJ Pharm H Shares to be acquired at a “fair price”, the Company is expected to have more than 300 Shareholders upon Listing, which satisfies the requirement under Rule 8.08(2) of the Listing Rules.

Assuming that the Merger is approved and all the Dissenting Shareholders request that their HEC CJ Pharm H Shares to be acquired at a “fair price”, it is expected that the three largest public Shareholders will hold in aggregate not more than 50% of H Shares in public hands, which satisfies the requirement under Rule 8.08(3) of the Listing Rules.

Assuming that the Merger is approved and all the Dissenting Shareholders request that their HEC CJ Pharm H Shares to be acquired at a “fair price”, the expected market capitalisation of the H Shares held by the public upon the Listing is approximately HK\$7,822.3 million (based on the value of each H Share of approximately HK\$73.21 indicated in valuation report appended to the 3.5 Announcement), which satisfies the requirement under Rule 8.09(1) of the Listing Rules.

This waiver has been granted on the basis that (a) the Company will have a market capitalization at the time of Listing of over HK\$10 billion, (b) the Company will have an open market in the H Shares to be held by the public upon the Listing, where the quantity and scale of the H Shares would enable the market to operate properly with a lower percentage of public float, (c) the Company will make appropriate disclosure of the lower prescribed percentage of public float in the Listing Document, (d) the Company will announce the percentage of H Shares held by the public immediately after the completion of the Introduction and the Privatization such that the public will be informed of the minimum public float requirement applicable to the Company, (e) the Company will confirm the sufficiency of the public float prescribed by the Stock Exchange in its successive annual reports after the Listing, and (f) the Company will implement appropriate measures and mechanisms to ensure continual maintenance of the minimum percentage of public float.



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## **INFORMATION ABOUT THIS LISTING DOCUMENT AND THE INTRODUCTION**

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### **DIRECTORS' RESPONSIBILITY FOR THE CONTENTS OF THIS LISTING DOCUMENT**

This Listing Document, for which the Directors (including any proposed Director who is named as such in this Listing Document) collectively and individually accept full responsibility, includes particulars given in compliance with the Securities and Futures (Stock Market Listing) Rules (Chapter 571V of the Laws of Hong Kong) and the Listing Rules for the purpose of giving information with regard to our Group. Our Directors, having made all reasonable enquiries, confirm that to the best of their knowledge and belief the information contained in this Listing Document is accurate and complete in all material respects and not misleading or deceptive, and there are no other matters the omission of which would make any statement herein or this Listing Document misleading.

### **CSRC FILING**

We have filed the required documents with the CSRC, and the CSRC has issued the filing notice dated June 16, 2025, confirming our completion of the filing regarding the application for listing of the H Shares on the Stock Exchange pursuant to the new filing regime introduced by the Overseas Listing Trial Measures for the Listing.

### **INFORMATION AND REPRESENTATIONS**

Our Company has not authorised anyone to provide any information or to make any representation not contained in this Listing Document. You should not rely on any information or representation not contained in this Listing Document as having been authorised by our Group, the Sole Sponsor, or any of our or its respective directors, officers or representatives or any other person involved in the Listing. The delivery of this Listing Document should not, under any circumstances, constitute a representation that there has been no change or development reasonably likely to involve a change in our affairs since the date of this Listing Document or imply that the information contained in this Listing Document is correct as at any date subsequent to the date of this Listing Document.

### **RESTRICTIONS ON THE USE OF THIS LISTING DOCUMENT**

This Listing Document is published solely in connection with providing information on the Introduction. Unless expressly authorized, it may not be used for any other purpose and, in particular, no person is authorised to use or reproduce this Listing Document or any part thereof in connection with any offering of H Shares or other securities of our Company. Accordingly, there is no, and will not be any, offer of or solicitation, or an invitation by or on behalf of our Company and/or the Sole Sponsor to subscribe for or purchase, any of the H Shares or other securities of our Company. Neither this Listing Document nor any other document or information (or any part thereof) delivered or supplied under or in relation to the Introduction may be used for the purpose of, and the delivery, distribution and availability of

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## **INFORMATION ABOUT THIS LISTING DOCUMENT AND THE INTRODUCTION**

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this Listing Document or such other document or information (or any part thereof) does not constitute, any offer of or solicitation or an invitation by or on behalf of our Company and/or the Sole Sponsor, to subscribe for or purchase any of the H Shares or other securities of our Company.

### **NO CHANGE IN THE NATURE OF OUR BUSINESS**

No change in the nature of our business is contemplated immediately following the Introduction.

### **APPLICATION FOR LISTING ON THE STOCK EXCHANGE**

We have applied to the Stock Exchange for the listing of, and permission to deal in, our H Shares to be issued as mentioned in this Listing Document. Please see the section headed “Share Capital” in this Listing Document for more details. Save as disclosed in this Listing Document, no part of our Shares is listed on or dealt in on any other stock exchange and no such listing or permission to list is being or proposed to be sought in the near future.

The Introduction does not involve a public offering of H Shares or any other securities of our Company for purchase or subscription and no money will be raised in conjunction with the Introduction.

### **CONDITIONS OF THE INTRODUCTION**

The Introduction is conditional on the Merger Agreement becoming effective, and the Stock Exchange granting the listing of, and permission to deal in, the H Shares on the Main Board of the Stock Exchange and such approval not having been revoked prior to the Introduction. If such conditions are not satisfied, the Introduction will not take place, in which case an announcement to that effect will be made.

### **H SHARE REGISTRAR AND STAMP DUTY**

All of the H Shares to be issued will be registered on our H Share register of members to be maintained in Hong Kong by our H Share Registrar, Computershare Hong Kong Investor Services Limited. Our principal register of members will be maintained by us at our head office in the PRC. Dealings in our H Shares registered on our H Share Registrar will be subject to Hong Kong stamp duty. Please see the section headed “Appendix III – Taxation and Foreign Exchange” in this Listing Document for more details.

Unless determined otherwise by the Company, dividends payable in respect of our H Shares will be paid to the Shareholders as recorded on the H Share register of our Company in Hong Kong and sent by ordinary post, at the Shareholders’ risk, to the registered address of each Shareholder.

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## INFORMATION ABOUT THIS LISTING DOCUMENT AND THE INTRODUCTION

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### **H SHARES WILL BE ELIGIBLE FOR ADMISSION INTO CCASS**

Subject to the granting of listing of, and permission to deal in, our H Shares on the Stock Exchange and our Company's compliance with the stock admission requirements of HKSCC, our H Shares will be accepted as eligible securities by HKSCC for deposit, clearance and settlement in CCASS with effect from the date of commencement of dealings in the H Shares on the Stock Exchange or any other date HKSCC chooses. Settlement of transactions between Exchange Participants (as defined in the Listing Rules) is required to take place in CCASS on the second settlement day after any trading day. All activities under CCASS are subject to the General Rules of HKSCC and HKSCC Operational Procedures in effect from time to time.

All necessary arrangements have been made for the H Shares to be admitted into CCASS. If you are unsure about the details of CCASS settlement arrangements and how such arrangements will affect your rights and interests, you should seek the advice of your stockbrokers or other professional advisors.

### **PROFESSIONAL TAX ADVICE RECOMMENDED**

You should consult your professional advisors if you are in any doubt as to the taxation implications of receiving, purchasing, holding, disposing of and dealing in our H Shares. It is emphasised that none of our Company, the Sole Sponsor, any member of our Group or the respective directors, officers or representatives of our Company, the Sole Sponsor and members of our Group or any other person involved in the Listing accepts responsibility for any tax effects or liabilities resulting from the receipt of, purchase, holding or disposing of, or dealing in, our H Shares or your exercise of any rights attaching to our H Shares.

### **COMMENCEMENT OF DEALINGS IN THE H SHARES**

Dealings in our H Shares on the Stock Exchange are expected to commence at 9:00 a.m. on Thursday, August 7, 2025. Our H Shares will be traded in board lots of 100 H Shares each and will be traded on the Main Board of the Stock Exchange in Hong Kong dollars. The stock code of our H Shares is 6887.

### **LANGUAGE**

If there is any inconsistency between this Listing Document and the Chinese translation of this Listing Document, this Listing Document shall prevail unless otherwise stated. However, the translated English names of the Chinese and foreign national, entities, departments, facilities, certificates, titles, laws, regulations (including certain of our subsidiaries) and the like included in this Listing Document and for which no official English translation exists are unofficial translations for your reference only. If there is any inconsistency, the names in their original languages shall prevail.

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## INFORMATION ABOUT THIS LISTING DOCUMENT AND THE INTRODUCTION

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### ROUNDING

Certain amounts and percentage figures included in this Listing Document have been subject to rounding adjustments. Any discrepancies in any table, chart or elsewhere between the total shown and the sum of the amounts listed are due to rounding.

### CURRENCY TRANSLATION

Solely for your convenience, this Listing Document contains translations among certain amounts denominated in Renminbi, Hong Kong dollars and US dollars at specified rates.

Unless otherwise specified, the translation of Renminbi into Hong Kong dollars, of Renminbi into US dollars and of Hong Kong dollars into US dollars, and vice versa, in this Listing Document was made at the following rates:

RMB0.92526 to HK\$1.00

RMB7.1996 to US\$1.00

HK\$7.7812 to US\$1.00

No representation is made that any amounts in Renminbi, Hong Kong dollars or US dollars can be or could have been at the relevant dates converted at the above rates or any other rates or at all.

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**DIRECTORS, SUPERVISORS AND PARTIES INVOLVED IN THE INTRODUCTION**

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**DIRECTORS**

<b>Name</b>	<b>Address</b>	<b>Nationality</b>
<i><b>Executive Directors</b></i>		
Dr. Zhang Yingjun (張英俊博士)	Villa 6-1 HEC Scientific Park No. 368 Zhen'an Middle Road Chang'an County Dongguan City Guangdong Province, PRC	Chinese
Dr. Li Wenjia (李文佳博士)	24G, Unit B, Block 6, Yongjing Bay Garden 48 Airon Road Nanshan District Shenzhen City Guangdong Province, PRC	Chinese
<i><b>Non-executive Directors</b></i>		
Mr. Zhang Yushuai (張寓帥先生)	House 8 Living Community 1 HEC Industrial Development Co., Ltd Rucheng Industrial Road Ruyuan Yao Autonomous County Guangdong Province, PRC	Chinese
Mr. Tang Xinfu (唐新發先生)	West Fourth Floor, Building 106 Huafa North Road Futian District Shenzhen City Guangdong Province, PRC	Chinese
Mr. Zhu Yingwei (朱英偉先生)	25, Zone E, Dongfang Garden 9017 Shennan Avenue Nanshan District Shenzhen City Guangdong Province, PRC	Chinese
Mr. Zeng Xuebo (曾學波先生)	2402 34 Shanhu Road Luopu Street Panyu District Guangzhou City Guangdong Province, PRC	Chinese

## DIRECTORS, SUPERVISORS AND PARTIES INVOLVED IN THE INTRODUCTION

Name	Address	Nationality
Ms. Dong Xiaowei (東曉維女士)	Room 401, Haide Pavilion, Building 8 Gelan Mingzhu Dongguan City, Guangdong Province, PRC	Chinese
Ms. Wang Lei (王蕾女士)	11A, Block B, Changyi Garden 59 Baihua Fourth Road Futian District Shenzhen City Guangdong Province, PRC	Chinese
<i>Independent Non-executive Directors</i>		
Dr. Li Xintian (李新天博士)	1-14C, Yin Hai Shangzhuang, No. 52, Hongshan Side Road, Wuchang District, Wuhan City, Hubei Province, PRC	Chinese
Dr. Ma Dawei (馬大為博士)	1301, Building 2 Lane 2455, Xietu Road Xuhui District Shanghai PRC	Chinese
Dr. Yin Hang Hubert (尹航博士)	2601, Unit 1, Building 4 Shuangqingyuan Haidian District Beijing PRC	American
Dr. Lin Aimei (林愛梅博士)	Room 1102, Unit 3, G7 Building, Wenchang Campus China University of Mining and Technology	Chinese
Dr. Ye Tao (葉濤博士)	Flat B, 21/F, Tower 1A Oceanaire 18 Po Tat Street Ma On Shan New Territories, Hong Kong	Chinese

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**DIRECTORS, SUPERVISORS AND PARTIES INVOLVED IN THE INTRODUCTION**

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**SUPERVISORS**

<b>Name</b>	<b>Address</b>	<b>Nationality</b>
Dr. Li Jing (李靜博士)	Room 02, Building 13 HEC Scientific Park No. 368 Zhen'an Middle Road Chang'an County Dongguan City Guangdong Province, PRC	Chinese
Mr. Chen Gang (陳罡先生)	Room 05, Building 08 HEC Scientific Park No. 368 Zhen'an Middle Road Chang'an County Dongguan City Guangdong Province, PRC	Chinese
Mr. Qing Shiwei (青仕偉先生)	Room 931, Building 33 HEC Scientific Park No. 368 Zhen'an Middle Road Chang'an County Dongguan City Guangdong Province, PRC	Chinese

For further details of the biographies and other relevant information of our Directors and Supervisors, see “Directors, Supervisors and Senior Management” in this Listing Document.



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## DIRECTORS, SUPERVISORS AND PARTIES INVOLVED IN THE INTRODUCTION

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### PARTIES INVOLVED IN THE INTRODUCTION

**Sole Sponsor**

**China International Capital Corporation  
Hong Kong Securities Limited**  
29/F, One International Finance Centre  
1 Harbour View Street, Central  
Hong Kong

**Financial Advisors to our Company  
in respect of the Privatization**

**China International Capital Corporation  
Hong Kong Securities Limited**  
29/F, One International Finance Centre  
1 Harbour View Street, Central  
Hong Kong

**Legal Advisors to our Company**

*As to Hong Kong law and U.S. law:*  
**Slaughter and May**  
47/F, Jardine House  
One Connaught Place  
Central  
Hong Kong

*As to Hong Kong law:*  
**Jia Yuan Law Office**  
Suites 3502-3503, 35/F  
Tower 1, Exchange Square  
8 Connaught Place, Central  
Hong Kong

*As to PRC law:*  
**Jia Yuan Law Offices**  
45/F, Media Finance Center  
Pengcheng 1st Road  
Futian District  
Shenzhen  
PRC

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## DIRECTORS, SUPERVISORS AND PARTIES INVOLVED IN THE INTRODUCTION

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### **Legal Advisors to the Sole Sponsor**

*As to Hong Kong law and U.S. law:*

**Freshfields**

55/F, One Island East  
Taikoo Place  
Quarry Bay  
Hong Kong

*As to PRC law:*

**Tian Yuan Law Firm**

509, Tower A  
International Enterprise Building  
35 Financial Street  
Xicheng District  
Beijing  
PRC

### **Auditors and Reporting Accountants**

**KPMG**

*Certified Public Accountants  
Public Interest Entity Auditor  
registered in accordance with the  
Accounting and Financial Reporting  
Council Ordinance  
8th Floor, Prince's Building  
10 Chater Road  
Central  
Hong Kong*

### **Industry Consultant**

**Frost & Sullivan (Beijing) Inc.,  
Shanghai Branch Co.**

Room 2504  
Wheelock Square  
1717 Nanjing West Road  
Shanghai  
PRC

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## CORPORATE INFORMATION

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<b>Registered Office</b>	1 Industrial North Road Songsan Lake Park Dongguan City Guangdong Province, the PRC
<b>Headquarters and Principal Place of Business in the PRC</b>	HEC Scientific Park No. 368 Zhen An Zhong Road Chang'an County Dongguan Guangdong Province, the PRC
<b>Principal Place of Business in Hong Kong</b>	40th Floor, Dah Sing Financial Centre No. 248 Queen's Road East Wanchai, Hong Kong
<b>Company's Website</b>	<u><a href="http://www.hecpharm.com">www.hecpharm.com</a></u> <i>(the information contained on the website does not form part of this Listing Document)</i>
<b>Company Secretary</b>	Mr. Cheng Ching Kit (鄭程傑) (ACG, HKACG) 40th Floor, Dah Sing Financial Centre No. 248 Queen's Road East Wanchai, Hong Kong
<b>Authorized Representatives</b>	Dr. Zhang Yingjun (張英俊) Villa 6-1 HEC Scientific Park No. 368 Zhen'an Middle Road Chang'an County Dongguan City Guangdong Province, PRC  Dr. Li Wenjia (李文佳) 24G, Unit B, Block 6 Yongjing Bay Garden 48 Airong Road Nanshan District Shenzhen City Guangdong Province, PRC
<b>Audit Committee</b>	Dr. Lin Aimei (林愛梅) (Chairman) Mr. Tang Xinfu (唐新發) Dr. Li Xintian (李新天)

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## CORPORATE INFORMATION

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<b>Remuneration and Appraisal Committee</b>	Dr. Lin Aimei (林愛梅) ( <i>Chairman</i> ) Dr. Zhang Yingjun (張英俊) Dr. Li Xintian (李新天)
<b>Nomination Committee</b>	Dr. Yin Hang Hubert (尹航) ( <i>Chairman</i> ) Dr. Zhang Yingjun (張英俊) Dr. Li Xintian (李新天)
<b>Strategic Committee</b>	Dr. Zhang Yingjun (張英俊) ( <i>Chairman</i> ) Mr. Zeng Xuebo (曾學波) Dr. Yin Hang Hubert (尹航)
<b>Compliance Advisor</b>	China Sunrise Capital Limited Units 4513 45th Floor, The Center 99 Queen's Road Central Hong Kong
<b>H Share Registrar</b>	Computershare Hong Kong Investor Services Limited Shops 1712-1716, 17th Floor Hopewell Centre 183 Queen's Road East Wan Chai Hong Kong
<b>Principal Bank</b>	China Merchants Bank Dongguan Chang'an branch First floor Changsheng Xi'an Road Sports Park Activity Center Chang'an County Dongguan Guangdong Province, the PRC

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## INDUSTRY OVERVIEW

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The information and statistics set out in this section and other sections of this Listing Document were extracted from various official government publications, available sources from public market research, other sources from independent suppliers, and the independent industry report prepared by Frost & Sullivan. We engaged Frost & Sullivan to prepare the Frost & Sullivan Report, an independent industry report, in connection with the Listing. The information extracted from official government sources has not been independently verified by us, the Sole Sponsor, any of their respective directors and advisers, or any other persons or parties involved in the Listing, and no representation is given as to its accuracy.

### THE PHARMACEUTICAL MARKET

#### Overview of the Global Pharmaceutical Market

The size of the global pharmaceutical market was USD1,472.3 billion in 2023 and is expected to reach USD1,766.7 billion in 2026 and USD2,069.4 billion in 2030, representing a CAGR of 6.3% from 2023 to 2026 and 4.0% from 2026 to 2030, respectively.

#### Overview of the Pharmaceutical Market in China

Accompanying the growth in demands of the economy and healthcare industry, the size of China's pharmaceutical market increased from RMB1,533.4 billion in 2018 to RMB1,618.3 billion in 2023, representing a CAGR of 1.1%. The PRC pharmaceutical market will further

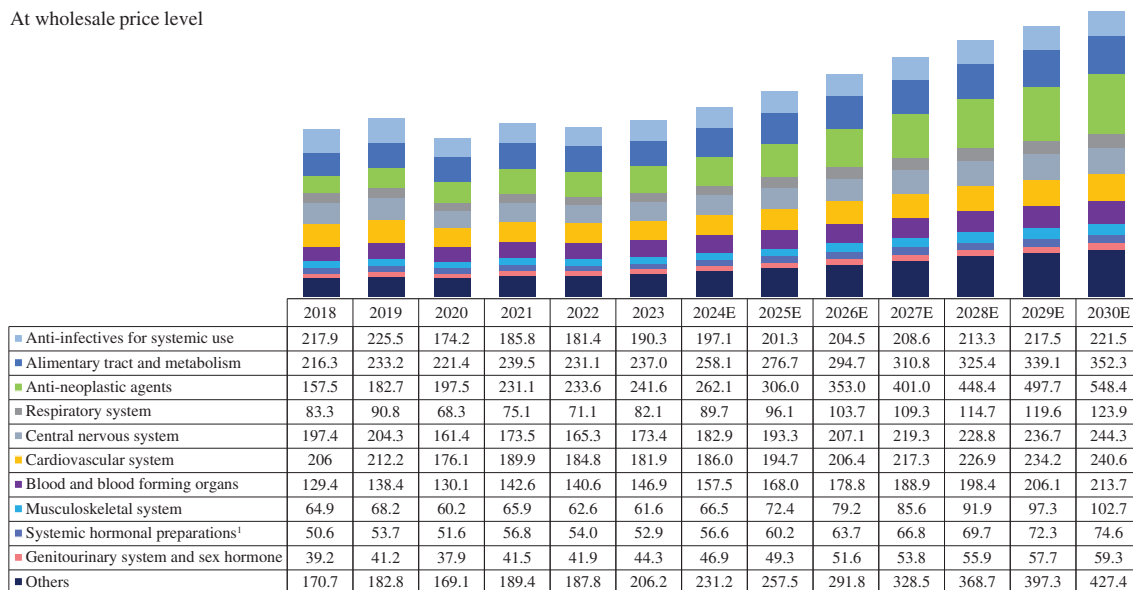
## INDUSTRY OVERVIEW

increase to RMB2,034.5 billion in 2026 and RMB2,608.8 billion in 2030, representing a CAGR of 7.9% from 2023 to 2026 and 6.4% from 2026 to 2030, respectively. The chart below sets forth the size of the pharmaceutical market in China by therapeutic areas from 2018 to 2030.

### Pharmaceutical Market in China, 2018-2030E

Billion RMB

At wholesale price level



Note:

1. Excludes sex hormones and insulins

Source: Annual reports of listed companies, NMPA, CDE, NRDL, Expert interviews, Frost & Sullivan analysis

### Threats and Challenges of the Pharmaceutical Market in China

**Pressure from VBP.** China's VBP policy imposes significant price pressures on pharmaceutical companies. Through large-scale procurement initiatives, the government reduces drug prices, compelling many pharmaceutical companies to lower their prices to remain competitive. This dynamic particularly affects manufacturers of innovative drugs, as the financial strain may hinder their ability to recover R&D costs, thereby impacting the development and market availability of new drugs.

**Challenges in Innovative Drug R&D.** Chinese pharmaceutical companies encounter significant challenges in the research and development of innovative drugs. Despite advancements in biopharmaceuticals and vaccine development, the overall innovation landscape in China remains relatively underdeveloped. The lengthy drug development cycles and substantial financial investments required, coupled with the complex clinical trial and approval processes, elevate risks for companies, particularly those with limited capital and technological capabilities. Furthermore, inadequate intellectual property protection for domestic innovative drugs may discourage investments in R&D.

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## INDUSTRY OVERVIEW

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***Challenges in Drug Internationalization.*** The internationalization of China's pharmaceutical industry presents various challenges. While the domestic market is expanding rapidly, companies aiming to penetrate international markets often face cultural, legal and regulatory hurdles. Variations in drug approval standards across different countries can extend the timelines for market entry. Additionally, the increasing intensity of international competition, combined with relatively weaker brand recognition and influence among domestic companies, necessitates greater effort to meet the demands of the global market.

***Intense Market Competition.*** The Chinese pharmaceutical market is highly competitive, with intense rivalry among domestic companies and multinational pharmaceutical firms. The prevalence of generic drugs and price-driven competition have further compressed profit margins of drugs. Many companies resort to price wars and aggressive promotional tactics to capture market share, which may disrupt market stability and adversely affect drug quality and the pursuit of innovative R&D.

### ***Entry Barriers of the Pharmaceutical Market in China***

***Regulatory hurdles.*** New entrants in the Chinese pharmaceutical market face significant regulatory challenges, with stringent oversight by the NMPA to ensure drug safety, efficacy, and quality. Compliance with regulations, including clinical trials, product testing, manufacturing standards, and marketing approvals, requires substantial investments in regulatory expertise and resources, creating barriers to market entry and product commercialization.

***Established competition.*** The market is highly competitive with numerous domestic and global players. Established companies benefit from strong brand recognition, extensive distribution networks, and established relationships with healthcare providers and regulators. New entrants must contend with these entrenched competitors, who possess considerable resources and experience in navigating the local market.

***Quality and compliance requirements.*** Smaller pharmaceutical companies often struggle to meet stringent quality standards and regulatory requirements, including GMP standards. Compliance demands significant investment in infrastructure, technology, and expertise. Companies that fail to meet these standards may struggle to gain market acceptance and secure necessary product approvals.

### ***Growth Drivers of the Pharmaceutical Market in China***

***Expansion of the Patient Population.*** China's aging population is growing, leading to an enlarged pool of patients with various age-related health issues, such as chronic diseases and cancer. For example, the number of diabetic patients in China reached 143.4 million in 2023 and is expected to increase to 157.6 million in 2030. In China, incidence of cancer was 4.9 million in 2023 and is expected to reach 5.6 million in 2030. The increasing number of patients is expected to spur the demands for medications and treatments, driving the growth of the pharmaceutical market in China.

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## INDUSTRY OVERVIEW

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***Favorable Government Policies.*** The Chinese government promulgated a series of policies to shorten the review and approval process for innovative drugs. In addition, the Chinese government has implemented a priority review system for certain drugs, which aims to accelerate the process of getting to the market the drugs that have the potential to address urgent clinical needs. These include the “Opinions of Encouraging Drug Innovation to Implement Priority Review and Approval” (《總局關於鼓勵藥品創新實行優先審評審批的意見》) issued by the General Office of the State Council in 2017 and the “Notice on Soliciting Opinions on the Working Procedures of Breakthrough Therapeutics and the Priority Review and Approval Process” (《關於突破性治療藥物工作程序和優先審評審批工作程序徵求意見的通知》) issued by the NMPA in 2019. Patent protection in China has been greatly enhanced as well. All these reforms will encourage domestic players to invest more in the research and development of innovative drugs. This increase in range of diverse, innovative drugs available in China will, in turn, boost consumption in the future.

***Increased Medical Insurance Expenditure.*** In recent years, the Chinese government has continuously increased its investment in medical security. This kind of investment not only improves the people’s medical security level but also provides a broad market space for pharmaceutical enterprises. For instance, expenditure of the basic medical insurance fund increased from RMB1,782.2 billion in 2018 to RMB2,814.0 billion in 2023, with a CAGR of 9.6%. New drugs are quickly covered by medical insurance after listing, which provides opportunities for pharmaceutical companies to quickly recover their research and development investment, thus further stimulating the innovation vitality of enterprises. Currently, the national population participation rate in medical insurance schemes remains stable at approximately 95%, and the reimbursement rate of hospitalization expenses under employee medical insurance and urban and rural residents’ medical insurance is also very high. As more people are able to enjoy the benefits brought about by medical insurance, this would further enhance the demands for the growth and expansion of the pharmaceutical market.

***Improvement of China’s Economy and Increase in Per Capita Income.*** With the rapid development of China’s economy, income levels are constantly improving, and the demand for medical care is gradually increasing. This growth trend provides a broad market space and potential for the pharmaceutical market. Economic growth means an increase in the country’s overall wealth, which usually provides the government with greater financial resources to invest in medical security. As a result, the coverage and quality of medical insurance will be improved. China’s disposable income per capita increased from RMB28,228 in 2018 to RMB39,218 in 2023, with a CAGR of 6.8%. The increase in residents’ income means that individuals have more disposable income for medical care consumption. As such, they would be more willing to invest in their own health and that of their families, and the demand for high-quality and efficient medical services and medicines would increase accordingly. In addition, people’s health awareness is gradually improving. More and more people are beginning to pay attention to their health status, actively participate in health management, and are willing to pay more for prevention and healthcare. This increase in health awareness will further promote the development of the pharmaceutical market, especially in the fields of preventive healthcare and chronic disease management.



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## INDUSTRY OVERVIEW

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***Increased Investment in Research and Development.*** The pharmaceutical industry is capital-intensive by nature and requires huge investment in both research and development as well as the manufacturing process. Investment in research and development in China has grown substantially. For example, USD30.1 billion was spent on drug research and development in China in 2023, representing a CAGR of 11.5% from 2018 to 2023. This is expected to rise to USD42.8 billion by 2026 and USD76.0 billion by 2030, representing a CAGR of 12.5% from 2023 to 2026 and 15.5% from 2026 to 2030, respectively. This increase in investment provides abundant capital for research and development of innovative drugs, investigations of emerging categories and the establishment of manufacturing facilities.

***Advancement of Technology.*** The development of technology promotes the development of the pharmaceutical industry in China. In particular, biotechnology can create substances that cannot be found in nature, as well as synthesize different substances to take advantage of synthetic substances, and even exploit the unique characteristics of viruses. Additionally, the increasing prevalence of multidisciplinary fields, such as genome technology and information technology, has promoted the development of precision medicine. Accordingly, it is necessary to develop innovative drugs with more precise targeting.

### ***Market Trends of the Pharmaceutical Market in China***

***Increased Permeability of Drugs for Infectious Diseases.*** Infectious diseases, especially respiratory infections, have always been a major global health problem. The penetration rate of drugs for infectious diseases is expected to increase as people deepen their understanding of these diseases and medical technology continues to advance. With the popularization of medical knowledge and the improvement of public health awareness, people's perception of infectious diseases has changed significantly. People have started to pay more attention to prevention and treatment and are willing to invest more resources and time into managing these diseases. This change in perception will help to promote the development of the drug market for infectious diseases. With the progress of medical science and technology, new drugs for infectious diseases are constantly emerging, which provides more choice for the treatment of these diseases. These drugs have greater curative effect and fewer side effects and are diverse enough to meet the needs of different patients. At the same time, as drug research and development progresses, precise therapeutic drugs targeting specific pathogens may emerge in the future to further improve treatment efficacy. Many national governments and people from all walks of life are also actively promoting the research and development and application of drugs for infectious diseases. For example, some countries have set up special funds to support the research and development of anti-infective drugs and are encouraging pharmaceutical companies to invest more. At the same time, by implementing relevant policies, medical institutions and patients will be encouraged to use these drugs more. In short, with the deepening of people's understanding of infectious diseases, the progress of medical technology and the support of different national governments and people from all walks of life, the penetration rate of infectious diseases drugs is expected to be further improved in the future. This will help to better meet the needs of patients, improve the treatment effect and promote the sustainable development of the pharmaceutical market.

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## INDUSTRY OVERVIEW

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***Increase in Chronic Diseases.*** According to China's Mid- and Long-term Plan for Chronic Diseases (2017-2025) 《中國防治慢性病中長期規劃(2017-2025)》 issued by the State Council, chronic diseases account for 86.6% of total deaths and the disease burden accounted for over 70% of the total disease burden. Therefore, from a clinical demand perspective, China's innovative drug research and development in the coming future will mainly target cardiovascular diseases, diabetes and other chronic diseases.

***Multidisciplinary Integration.*** After the two revolutions in life science led by the development of molecular biology and genomics, the third revolution is characterized by the integration of multiple disciplines, such as life science, physics, engineering and information technology. The cross-fusion of gene editing technology, tumor immunotherapy, big data, artificial intelligence, 3D printing technology and other fields will promote the research and development of new drugs.

***Cooperative Innovation.*** Pharmaceutical enterprises can leverage the resources from other market participants to expedite the time required for research and development, reduce the research and production costs, and accelerate the entry of innovative drugs into the market. Pharmaceutical enterprises can entrust manufacturing enterprises with the production of innovative drugs, thus saving the time and resources of having to build factories and production lines, as well as cooperate with universities and research institutions for innovative drug research, which can help to reduce costs and share the risk of research.

***Improving Affordability.*** The average disposable income in China is expected to continue growing rapidly. This will, in turn, increase the willingness and ability of patients to pay for medication. As more Chinese households increase their spending power, they will be able to afford more expensive medical treatments, particularly those for life-threatening diseases.

## INDUSTRY OVERVIEW

### *Competitive Landscape of the Pharmaceutical Market in the China*

Our key competitors are large national and regional manufacturers of pharmaceutical products, including large state-owned pharmaceutical companies. We also compete with multinational pharmaceutical companies. The table below sets forth a comparison of the top five pharmaceutical companies in China by revenue and their major drug assets:

Rank	Market Player	Headquarters	Year of Establishment	Listing Status	Major Therapeutic Areas	Major Drug Assets	Total Revenue in 2023 (RMB billion)
1	Sinopharm Group	Beijing	1987	Listed	Oncology, antibiotics, blood products, influenza vaccines, cardiovascular diseases	Amoxicillin Nifedipine controlled-release tablets Azithromycin Ceftriaxone sodium Betahistine hydrochloride COVID-19 inactivated vaccine	596.6
2	Shanghai Pharmaceutical Group	Shanghai	1994	Listed	Cardiovascular diseases, digestive system, antibiotics, central nervous system, immunosuppressants and anti-allergy drugs, respiratory system	Thalidomide Duloxetine Ceftioflavone Hydroxychloroquine sulfate tablets Ginkgo biloba ester tablets	260.3
3	China Resources Pharmaceutical Group	Beijing	2007	Listed	Oncology, respiratory system, digestive system	999 Cold Remedy Granular Atorvastatin Calcium Tablets Omeprazole Sodium Pacitaxel Sanju Weitai	244.7
4	Huadong Medicine	Hangzhou, Zhejiang Province	1993	Listed	Oncology, antibiotics, cardiovascular diseases, digestive system, endocrine system	Decitabine Sirolimus Tacrolimus Pioglitazone Metformin Tablets Indobufen Tablets	40.6
5	Neptunus Bioengineering	Shenzhen, Guangdong Province	1992	Listed	Oncology, antibiotics, digestive system, respiratory infectious diseases	S-1 tablets Pediatric Paracetamol, Artificial Cow-bezear and Chlorphenamine Maleate Granules Rehmannia Six Formula	36.4

#### *Note:*

1. This ranking excludes pharmaceutical companies that do not have self-manufactured/in-house R&D products.

*Source: Ministry of commerce PRC, Annual reports of listed companies, Frost & Sullivan Analysis*

### *Competitive Strengths of the Group*

The Group has a robust presence and significant competitive advantages in therapeutic areas of infectious diseases, chronic diseases and oncology. The Group's innovative drug pipeline is extensive and poised to deliver significant advancements in healthcare.

In the anti-infective drug market, the Group's antiviral flu drug Kewei (oseltamivir phosphate) ranked number one in the Chinese oseltamivir phosphate market, and our oseltamivir phosphate products had a market share of 54.8% in 2024 in terms of revenue. The Group has also been advancing its Class I innovative anti-influenza drug candidate, HEC116094, which has successfully completed Phase I clinical trials. Its hepatitis C treatment drug, Emitasvir Phosphate, has achieved an outstanding SVR12 rate of 99.5%, while its Morphothiadine Mesylate Capsule, a promising hepatitis B treatment drug, has entered Phase III clinical trials, demonstrating significant HBsAg suppression.

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## INDUSTRY OVERVIEW

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In the chronic disease drug market, the Group has developed a comprehensive diabetes drug portfolio that includes insulin, SGLT-2 inhibitors, and GLP-1/FGF21 dual-target agonists. The Group's pulmonary fibrosis drug candidate, Yinfenidone Hydrochloride Tablet, has shown superior efficacy compared to Pirfenidone in Phase II clinical trials. Additionally, its NASH treatment drug candidate, HEC96719, has demonstrated a significant reduction in liver fat content.

In the oncology drug market, the Group's targeted drug Clifutinib Besylate for the treatment of AML is currently in Phase III clinical trials, having exhibited a CR/CRh rate of 23.1% in earlier trials. Furthermore, its Larotinib Mesylate is the first small molecule targeted therapy for the treatment of esophageal cancer in China to enter Phase III clinical trial, and it has made significant progress in this regard.

Looking ahead, with the anticipated approval and commercialization of multiple innovative drugs, the Group is well-positioned to further strengthen its leadership position in the Chinese pharmaceutical market.

### THE ANTI-INFECTIVE DRUG MARKET IN CHINA

#### Overview of the Anti-infective Drug Market in China

Anti-infectives are a group of drugs which kill or inhibit different kinds of pathogenic microbes through oral, intramuscular injection, intravenous injection or topical use. Anti-infectives are widely used for all kinds of infectious diseases and complications triggered by other diseases.

In 2023, the size of the anti-infective drug market in China reached RMB190.3 billion. It is predicted that the market size of anti-infective drugs in China will continue to grow in the future, reaching RMB204.5 billion in 2026 and further rising to RMB221.5 billion in 2030.

#### Overview of the Anti-influenza Drug Market in China

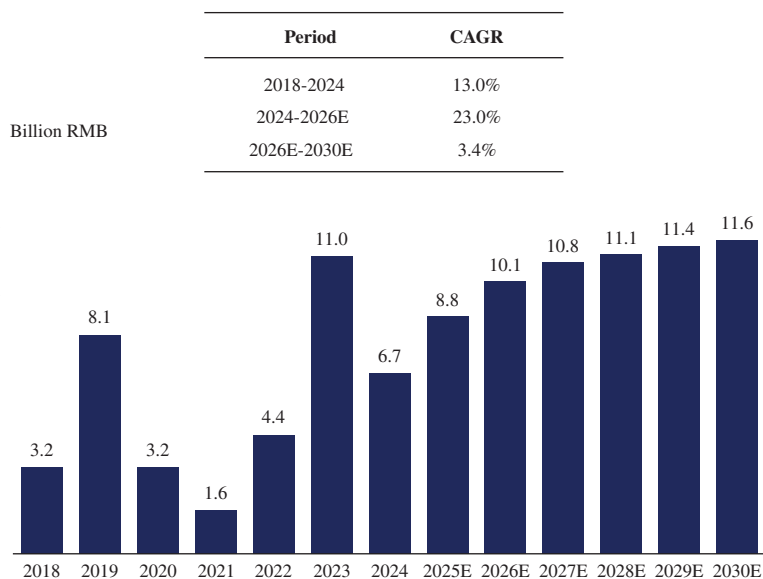
Influenza, commonly known as “the flu”, is an infectious disease with high incidence in children aged below 5 and the elderly. There are four types of influenza viruses, of which human influenza A and B viruses can cause seasonal epidemics of disease (known as the flu season) almost every winter.

The size of the anti-influenza drug market in China increased from RMB3.2 billion in 2018 to RMB4.4 billion in 2022, representing a CAGR of 8.4%. Despite the overall upward trend, due to the impact of COVID-19 in 2020, the number of influenza cases decreased, and the market size declined in 2020 and 2021. However, with the end of the COVID-19 pandemic, there has been a significant increase in other respiratory infectious diseases. The impact of the influenza epidemic in China in 2023 was greater in both scope and duration as compared with the pre-pandemic period, and the size of the market drastically increased to RMB11.0 billion in 2023. Unlike in 2023, there were no significant influenza outbreaks in 2024, which led to

## INDUSTRY OVERVIEW

a decrease in demand for anti-influenza medications. Consequently, the anti-influenza drug market in China decreased to RMB6.7 billion in 2024. The size of the market is expected to rebound and reach RMB10.1 billion in 2026 and further increase to RMB11.6 billion in 2030. The chart below sets forth the size of the anti-influenza drug market in China from 2018 to 2030.

**Anti-influenza Drug Market in China, 2018-2030E**



Source: Annual reports of listed companies, NMPA, CDE, NRDL, Expert interviews, Frost & Sullivan analysis

Note:

1. Excluding traditional Chinese medicines.

### ***Threats and Challenges of the Anti-Influenza Drug Market in China***

**Emerging and Mutating Influenza Strains.** The continuous mutation of influenza viruses poses a significant challenge to the efficacy of existing antiviral drugs. While oseltamivir phosphate remains a widely used treatment, resistance to neuraminidase inhibitors has been reported in certain influenza strains, potentially diminishing patient outcomes and demand for existing drugs. This necessitates ongoing R&D investments for next-generation antiviral therapies, which can be costly and time-consuming.

**Policy Changes and Market Uncertainty.** Government policies on drug procurement and pricing, such as VBP policy, may lead to further price reductions, impacting manufacturers' profit margins. Additionally, changes to the reimbursement drug list and insurance policies may affect market performance. While these policies aim to improve drug accessibility, they may also increase market uncertainty and operational risks for companies.

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## INDUSTRY OVERVIEW

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***Intensifying Competition from Domestic Players.*** The anti-influenza drug market in China is highly competitive, dominated by companies such as the Group, Company A and Company B, which together hold 56.9% of the market share of the anti-influenza drug market in China and 80.9% of the market share of the oseltamivir phosphate market in China, in terms of revenue in 2024. The entry of generic drug manufacturers, particularly following the expiration of key patents for oseltamivir phosphate, has intensified price competition and increased pressure on established brands.

***Rising Vaccination Rates.*** Increasing influenza vaccination rates may impact future demand for antiviral drugs. According to data from the Chinese Center for Disease Control and Prevention, the vaccination rate increased from 2.5% in the 2021-2022 flu season to 3.9% in the 2022-2023 flu season. Although the influenza vaccination rates in China are still significantly lower than those of developed countries, a significant increase in vaccination rates could reduce influenza infections and, consequently, reliance on antiviral treatments.

### ***Entry Barriers of the Anti-influenza Drug Market in China***

***Research and Development Capability.*** Influenza viruses mutate and camouflage to evade recognition and elimination by the immune system. Resistance to existing drugs has become a serious problem, requiring companies to have strong research and development capability, time and sufficient funding.

***Competitive Market.*** At present, the anti-influenza market is dominated by a few companies. For example, sales of oseltamivir phosphate still account for the majority of the anti-influenza drug market, with the revenue of the product, Kewei, together with other oseltamivir phosphate products accounting for 54.8% of the oseltamivir phosphate market in China in 2024. A small number of enterprises participate in VBP schemes, which allows such enterprises to supply their pharmaceutical products to non-profit making hospitals and other non-profit making medical institutions established by the PRC government at the county level or higher. Furthermore, the companies increase the barriers to competition through continuous expansion of product lines in order to achieve long-term success.

***Sales Channels Capabilities.*** At present, hospital and retail channels are the main sales channels for anti-influenza drugs. Doctors diagnose and prescribe drugs based on symptoms, and so new market entrants need to compete with drugs that not only have already been included in the VBP schemes but which are also preferred by physicians. In addition, building and maintaining strong relationships with retail channel partners is key to increasing a drug's market penetration.

***Branding Capabilities.*** When people choose which flu medication to take, their choice is often influenced by the medication's brand name. Due to limited knowledge of medication, consumers often choose to purchase drugs based on brand awareness or by following their doctor's advice and recommendations. In order to appeal more to consumers, companies need a certain amount of funding for marketing purposes.

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## INDUSTRY OVERVIEW

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***Scalable Production Capabilities.*** In order to meet market demands, companies need to have the capability for scaled production. Every time there is an outbreak of the flu, anti-influenza drugs will experience stockouts. New entrants may face challenges in establishing a reliable supply chain if they are unable to quickly expand their production scale to address the spike in demands during flu seasons.

### ***Growth Drivers of the Anti-Influenza Drug Market in China***

***Increasing Cases and Growing Demand.*** The reported 12.5 million new influenza cases in 2023 according to the Statistical Report on China's Health Care Development have driven demand for antiviral medications, particularly oseltamivir phosphate, the most widely prescribed treatment. Growing awareness of timely treatment is expected to further expand the market for antiviral drugs.

***Favorable Policies and Government Support.*** The PRC government has implemented various policies to encourage the development, production, and stockpiling of drugs that target pandemic diseases. For instance, the National Essential Drug List and the National Reimbursement Drug List have included oseltamivir phosphate, significantly improving patient accessibility and driving sales growth. Additionally, the NHC's Guidelines for Influenza Diagnosis and Treatment 《流行性感冒診療方案(2025年版)》 emphasize the importance of early detection and treatment of flu, particularly during seasonal outbreaks. These measures, coupled with government-led procurement initiatives, have ensured a stable supply of influenza drugs and supported market expansion. In addition, the National Medical Reserve Management Measures as amended in 2021 (國家醫藥儲備管理辦法(2021年修訂)) requires the establishment of two levels of medical reserves, namely the central and local (provinces, autonomous regions, and municipalities directly under the central government medical reserves). The central medical reserve mainly reserves medical products for significant and major public emergencies such as pandemic diseases, and those with a high risk of supply shortages. The local medical reserve mainly reserves medical products for responding to relatively major and general public emergencies, ensure regional safety during major events, and address supply shortages within the local jurisdiction. The Ministry of Industry and Information Technology is the main government authority in charge of the medical reserves. Such government policies in general are beneficial for the sales of antiviral drugs, including oseltamivir phosphate.

***Expansion of Distribution Channels.*** The distribution network for influenza antiviral drugs has significantly improved, with a rise in online sales facilitated by e-commerce and digital healthcare platforms. Government initiatives, such as the Internet + Healthcare policy, also support online prescription and drug delivery, increasing accessibility in rural areas and contributing to higher sales volume.

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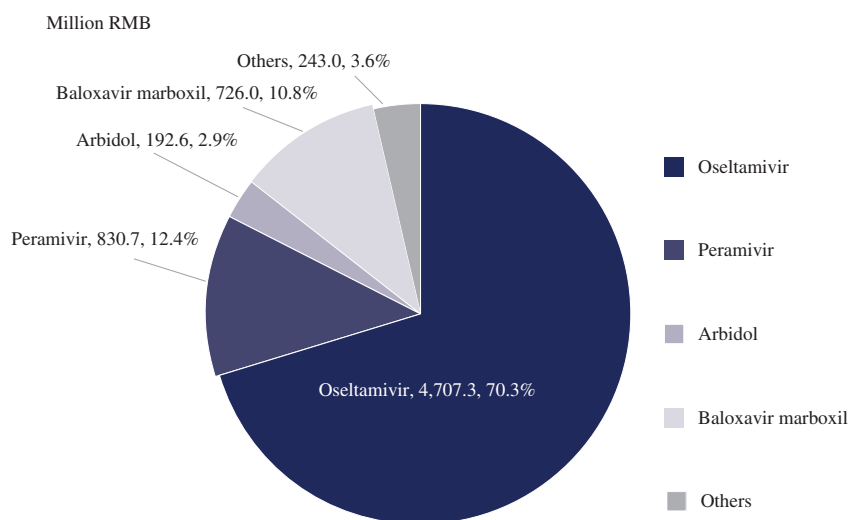
## INDUSTRY OVERVIEW

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### *Competitive Landscape of the Anti-influenza Drug Market in China*

The size of the anti-influenza drug market in China was RMB6.7 billion in 2024, of which the sales value of oseltamivir phosphate in 2024 was RMB4.7 billion, accounting for 70.3% of the total market share for that year. In the same year, the sales value of peramivir was RMB830.7 million, accounting for 12.4% of the total market share. The anti-influenza drug market in China is highly competitive, with over 120 pharmaceutical companies producing influenza medications. In particular, the three companies, including the Group, collectively hold 56.9% of the market share of the anti-influenza drug market in China in terms of revenue in 2024. In 2024, sales of the Group's product, Kewei (oseltamivir phosphate), together with oseltamivir phosphate products reached RMB2.6 billion and accounted for 38.5% of the anti-influenza drug market in China. The chart below sets forth the sales value and market share of various anti-influenza drugs in China in 2024.

**Anti-influenza Drug Market in China, 2024**



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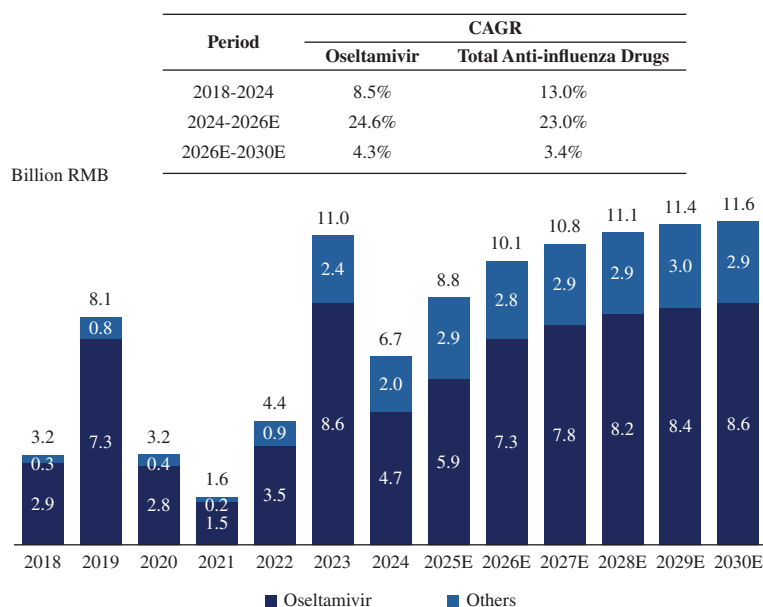
Source: Annual reports of listed companies, NMPA, Expert interviews, Frost & Sullivan analysis



## INDUSTRY OVERVIEW

The size of the oseltamivir phosphate drug market in China increased from RMB2.9 billion in 2018 to RMB4.7 billion. The size of the market is expected to reach to RMB7.3 billion by 2026 and RMB8.6 billion by 2030. The chart below sets forth the size of the anti-influenza drug market and the oseltamivir phosphate drug market in China from 2018 to 2030.

### Anti-influenza Drug and Oseltamivir Phosphate Drug Markets in China, 2018-2030E



*Note:* Excluding traditional Chinese medicines.

*Source:* Annual reports of listed companies, NMPA, CDE, NRDL, Expert interviews, Frost & Sullivan analysis

Currently, there are more than 70 participants in China's oseltamivir phosphate market. The main manufacturer is the Group, which has well-established production and commercialization scale. The other key players in China's oseltamivir phosphate drug market include F. Hoffmann-La Roche AG, ApicHope Pharmaceutical Group Co., Ltd., Sinocep Allsino Bio Pharmaceutical Co., Ltd. and Zhongshan Wanhan Pharmaceutical Co., Ltd. In 2024, sales of the Group's product, Kewei, together with other oseltamivir phosphate products accounted for 54.8% of the entire oseltamivir phosphate market in China. The Group is also a market leader in the oseltamivir phosphate granules market in China in terms of sales volume of and revenue derived from oseltamivir phosphate granules. Sales of the Group's oseltamivir

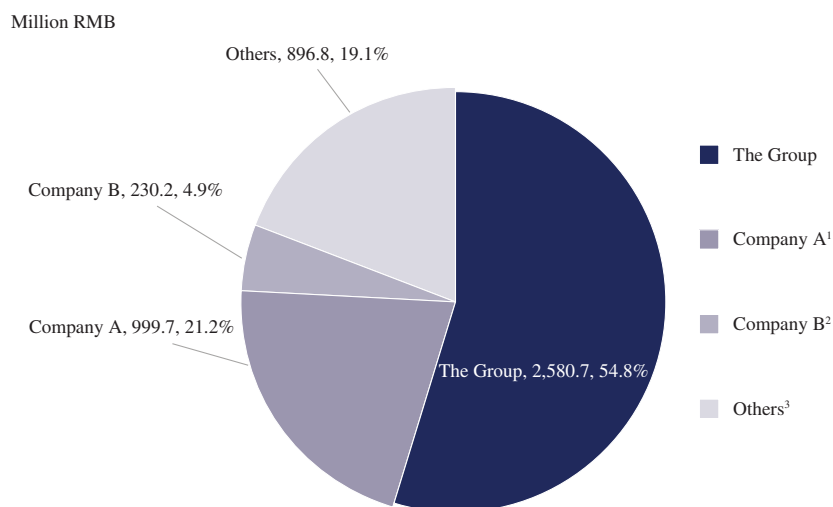
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## INDUSTRY OVERVIEW

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phosphate granules accounted for over 99% of the oseltamivir phosphate granules market in China during the Track Record Period. The chart below sets forth the revenue and market share of the top three players in the oseltamivir phosphate drug market in China in 2024.

### Selected Information of Top Three Players in the Oseltamivir Phosphate Drug Market in China, 2024



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#### Notes:

1. Company A is a listed multinational holding healthcare company headquartered in Switzerland. It mainly focuses on developing drugs and diagnostics. It is a global leader in oncology, immunology, and personalized healthcare, with two core divisions: pharmaceuticals and diagnostics. The company also invests heavily in biotechnology and collaborates with various partners in precision medicine.
2. Company B is an A-share listed company headquartered in Guangzhou. It focuses on research and development, production, and sale of pharmaceutical products. Its product portfolio includes both chemical and traditional Chinese medicines, with key therapeutic areas including pediatrics, cardiovascular diseases, and anti-infectives.
3. This segment is relatively fragmented.

Source: Annual reports of listed companies, NMPA, Expert interviews, Frost & Sullivan analysis

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The table below sets out the prices displayed on the government's platform with respect to oseltamivir phosphate capsules (75mg per capsule, 10 capsules per box) of the Group, Company A and Company B during the Track Record Period.

	For the year ended December 31,		
	2022	2023	2024
	RMB/capsule	RMB/capsule	RMB/capsule
The Group (Kewei (oseltamivir phosphate)) <sup>(1)</sup> . . . . .	13.01	13.01	9.86
Company A . . . . .	20.49	17.16	17.16
Company B . . . . .	7.98	1.99	1.99

*Note:*

- (1) The Group sold drugs to its distributors at a price which is lower than the price the distributors subsequently sold to hospital, medical institution or pharmacies. The discrepancy in the average selling price of Kewei capsules and the price of Kewei capsules displayed on the government's platform is mainly because the average selling price of Kewei is calculated by dividing the revenue the Group received from distributors by the sales volume while the price of Kewei displayed on the government's platform is the price that public hospital paid to the distributors. The price difference mainly represented the fees the distributors received for their distribution and delivery services and/or their marketing the promotion services.

*Source: Chinese Government Procurement Center, Public Resource Trading Center*

The table below sets forth the sales volume of oseltamivir phosphate drugs of the Group, Company A and Company B for each of the years during the Track Record Period. During the Track Record Period, the Group's revenue generated from the sales of oseltamivir phosphate products fluctuated with flu incidence in China and the Group's revenue fluctuation was generally in line with the Group's competitors during the Track Record Period.

		Year ended December 31,					
		2022		2023		2024	
		Sales Volume	Revenue	Sales Volume	Revenue	Sales Volume	Revenue
Dosage Form		('000 units)	(RMB'000)	('000 units)	(RMB'000)	('000 units)	(RMB'000)
The Group . . . Capsule <sup>(1)</sup>		71,835	512,252	111,118	714,139	126,630	394,687
Granule		861,788	2,585,151	1,488,517	4,824,593	735,522	2,181,509
Company A . . . Capsule <sup>(2)</sup>		23,500	376,862	86,900	1,391,390	62,500	999,831
Company B . . . Capsule <sup>(2)</sup>		12,000	15,019	262,000	337,359	179,000	230,187

*Notes:*

- (1) Only includes the Group's oseltamivir phosphate capsules in 75mg doses sold under the brands Kewei and Yangjiantai.
- (2) Company A and Company B only manufacture oseltamivir phosphate capsules.

*Source: Annual reports of listed companies, Expert interviews, Frost & Sullivan analysis*

### *Pediatric Influenza Medication*

Among anti-influenza drugs approved in China, oseltamivir phosphate is the preferred choice for influenza in children. Oseltamivir phosphate granules have unique advantages over traditional dosage forms. This formulation allows for more precise dosages, as physicians can adjust the dosage based on a child's weight or specific medical needs. Oseltamivir phosphate granules combine the advantages of both solid and liquid formulae, and are both portable and easy to take, which makes them especially suitable for children and elderly with dysphagia. Oseltamivir phosphate should be taken within 48 hours of the onset of flu symptoms, and the course of medication is usually 5 days.

### **Overview of the Anti-Hepatitis B Drug Market in China**

Hepatitis B is an infectious disease characterized by inflammation of the liver caused by the hepatitis B virus (HBV). Clinical symptoms include loss of appetite, liver pain and physical weakness. HBV infections may be acute or chronic. HBV infections may develop into chronic hepatitis, which can lead to cirrhosis, liver failure and liver cell carcinoma.

With the improvement of health management awareness of patients with hepatitis B, the progress of detection of hepatitis B in primary medical institutions and the introduction of various innovative HBV drugs, the number of patients diagnosed with hepatitis B in China will increase rapidly in the future. The number of patients diagnosed with chronic hepatitis B in China was approximately 15.4 million in 2018 and approximately 19.1 million in 2023, representing a CAGR of 4.4%. It is estimated that the number of diagnosed chronic hepatitis B patients will increase to approximately 23.2 million in 2026 and approximately 31.9 million in 2030, representing a CAGR of 6.7% from 2023 to 2026 and 8.3% from 2026 to 2030, respectively.

In 2023, the market size of anti-HBV drugs in China was RMB9.9 billion. Given the large population of chronic hepatitis B patients, significant investment in drug development and the promising efficacy data of upcoming new therapies, the penetration rate of anti-hepatitis B drugs is expected to gradually increase. Additionally, as treatments become more affordable, market demand is projected to expand rapidly. As such, it is predicted that the market size of anti-HBV drugs in China will continue to grow in the future, reaching RMB16.7 billion in 2026

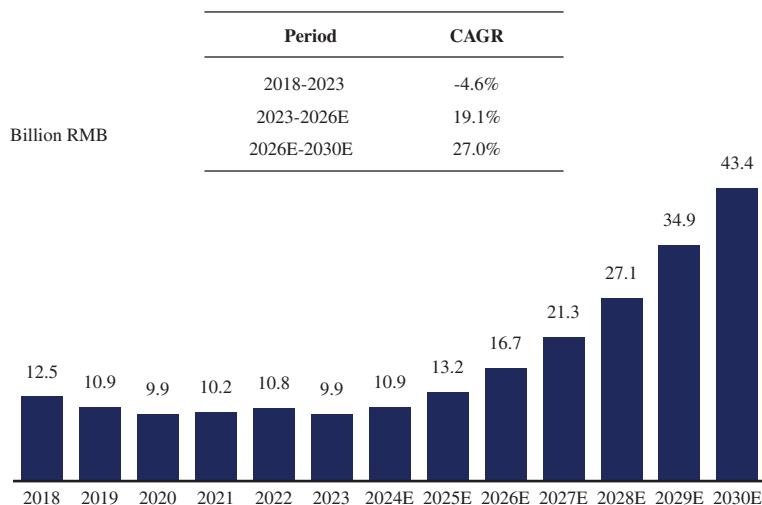
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and a further RMB43.4 billion in 2030, representing a CAGR of 19.1% from 2023 to 2026 and 27.0% from 2026 to 2030, respectively. The chart below sets forth the size of the anti-hepatitis B drug market in China from 2018 to 2030.

**Anti-HBV Drug Market in China, 2018-2030E**



*Source: Annual reports of listed companies, NMPA, CDE, NRDL, Expert interviews, Frost & Sullivan analysis*

### ***Competitive Landscape of Anti-Hepatitis B Drug Market in China***

As of the Latest Practicable Date, there are more than 50 participants in the anti-hepatitis B drug market in China, and a total of 19 drugs for the treatment of hepatitis B have been approved in China, including seven nucleotide analogs, seven interferon-based therapies, and five other immunomodulatory agents. Common nucleotide/nucleoside analogs include Entecavir, Adefovir Dipivoxil, Lamivudine, Tenofovir and Telbivudine. In addition, interferon-based drugs are also widely used, including recombinant human interferon  $\alpha$ -2a, recombinant human interferon  $\alpha$ -2b, recombinant human interferon, pegylated interferon  $\alpha$ -2a and pegylated interferon  $\alpha$ -2b. Current treatments for hepatitis B, such as nucleotide analogs and interferons, have significant limitations. These medications do not achieve complete eradication of HBV and require long-term treatment regimens. Discontinuation of therapy often results in relapse, with notably low rates of HBsAg clearance. Furthermore, interferons are associated with substantial side effects and are suitable only for a limited patient population, leaving some patients at continued risk for liver cancer. Consequently, the prolonged nature of these treatments leads to high long-term healthcare costs, presenting considerable economic burden for patients.

Self-assembly of capsid is a critical step in the life cycle of a virus, and the core protein is extremely conservative and acts as a natural barrier to drug resistance. Therefore, anti-HBV drugs targeting the core protein have emerged as a key focus in current research and development. Unlike existing nucleos(t)ide analogs that only inhibit viral reverse transcription,

## INDUSTRY OVERVIEW

capsid inhibitors interfere with the assembly of the HBV capsid, thereby strongly suppressing HBV replication and the production of mature viral particles. The Group's Morphothiadin Mesylate Capsule is the fastest anti-HBV capsid inhibitor in China, and it is the only capsid inhibitor in China that has entered Phase III clinical trial. In addition, the Group's other capsid inhibitor, Freethiadine Tablet, is currently in Phase I clinical trial.

As of the Latest Practicable Date, there is no approved capsid inhibitor for the treatment of hepatitis B in China, and there are 9 pipelines under clinical research in China as set forth in the table below.

### Capsid Inhibitor Pipelines in China

Drug Name	Company	Indication	Target	Status	First Posted Date
<b>Morphothiadin Mesylate Capsules</b>	<b>The Group</b>	<b>Hepatitis B</b>	<b>Capsid</b>	<b>Phase III</b>	<b>December 10, 2021</b>
GST-HG141 Tablets	Cosunter	Hepatitis B	Capsid	Phase II	November 17, 2022
ZM-H1505R Tablets	Zhimeng Biopharma	Hepatitis B	Capsid	Phase II	August 30, 2022
QL007 Tablets	Qilu Pharma	Hepatitis B	Capsid	Phase II	September 18, 2019
JNJ-56136379 Tablets	Janssen Pharma	Hepatitis B	Capsid	Phase II	August 6, 2018
ALG-000184 Tablets	Aligos	Hepatitis B	Capsid	Phase I	June 9, 2021
<b>Freethiadine Tablets</b>	<b>The Group</b>	<b>Hepatitis B</b>	<b>Capsid</b>	<b>Phase I</b>	<b>September 7, 2021</b>
HRS5091 Tablets	Hengrui Pharma	Hepatitis B	Capsid	Phase I	July 20, 2020
KL060332 Tablets	Kelun-Biotech	Hepatitis B	Capsid	Phase I	May 27, 2020

Source: CDE, Frost & Sullivan analysis

### Overview of the Anti-Hepatitis C Drug Market in China

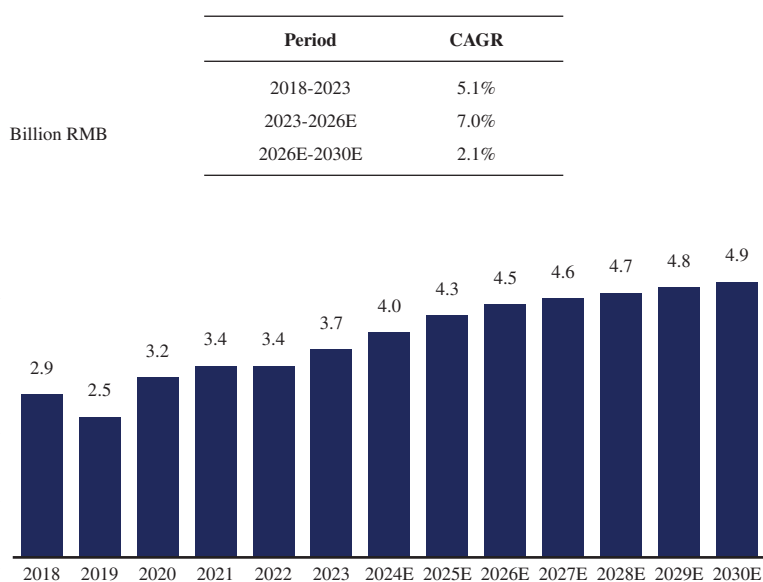
Without treatment, around 55-85% of acute hepatitis C virus (HCV) patients will carry the hepatitis C virus for the rest of their lives and are considered to have chronic HCV infection. Symptoms of chronic hepatitis C may also be difficult to recognize in the early stages. The most common symptom is fatigue, which can last 20-25 years. Jaundice, or yellowing of the skin or eyes, may indicate serious disease progression. Some patients with cirrhosis may also clinically progress to hepatocellular carcinoma.

The current diagnosis rate of chronic hepatitis C in China is extremely low because of various factors, such as the lack of obvious symptoms. Currently, the treatments are already capable of fully curing HCV. With the increasing awareness of health management of HCV, the HCV diagnosis rate is set to increase substantially. The number of patients diagnosed with chronic hepatitis C in China was 2.0 million in 2018 and 2.6 million in 2023, representing a CAGR of 5.2%. It is estimated that the number of diagnosed chronic hepatitis C patients will increase to 2.8 million in 2026 and 3.1 million in 2030, representing a CAGR of 2.5% from 2023 to 2026 and 2.6% from 2026 to 2030, respectively.

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In 2023, the market size of anti-HCV drugs in China reached RMB3.7 billion. As a result of (i) the increasing penetration of DAAs as a result of their inclusion to the NRDL in 2020 and the growing number of approved DAAs in China, (ii) the implementation of the National Action Plan for Eliminating Hepatitis C as a Public Health Threat (2021–2030) by the National Health Commission of China and eight other government departments in 2021, which has an overarching goal and 15 specific targets that cover health education, comprehensive prevention interventions, testing and treatment, and (iii) increasing production capacity, the anti-HCV drug market in China will continue to grow. It is estimated that the market size of anti-HCV drugs in China will reach RMB4.5 billion in 2026 and a further RMB4.9 billion in 2030, representing a CAGR of 7.0% from 2023 to 2026 and 2.1% from 2026 to 2030, respectively.

### Anti-HCV Drug Market in China, 2018-2030E



Source: Annual reports of listed companies, NMPA, CDE, NRDL, Expert interviews, Frost & Sullivan analysis

### Competitive Landscape of Anti-Hepatitis C Drug Market in China

As of the Latest Practicable Date, the NMPA has approved a total of 24 drugs for the treatment of hepatitis C, including seven interferon-based therapies and 17 DAAs. Interferon-based therapies are further divided into recombinant IFN- $\alpha$  and PEG-IFN- $\alpha$ . DAAs target three key viral proteins: (i) NS3/4A, which is involved in the post-translational processing of the HCV polyprotein; (ii) NS5A, which plays a role in the formation of the replication complex, and (iii) NS5B, a key enzyme catalyzing HCV RNA synthesis. Traditional treatment for hepatitis C has primarily been based on interferon and ribavirin therapy. However, in recent years, treatment strategies have gradually shifted towards DAAs, which offer greater safety, shorter treatment durations, and improved tolerability compared to conventional therapies.

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The Group's Emitasvir Phosphate was approved for marketing in 2020, and it was used in combination with Sofosbuvir to treat adult genotype 1 non-cirrhotic chronic hepatitis C, which is the most common chronic hepatitis C genotype in China. Emitasvir Phosphate was included in the NRDL in 2022. In addition, the Group has developed a combination therapy of Netanasvir Phosphate Capsules and Encofosbuvir Tablets for people with pan-genotype chronic hepatitis C. The Group's Netanasvir Phosphate and Encofosbuvir were approved by the NMPA for launching in China in February 2025 and March 2025, respectively. The combination treatment regimen will be a new alternative treatment regimen for pan-genotypic chronic hepatitis C. As of the Latest Practicable Date, 17 DAAs for treating chronic hepatitis



## INDUSTRY OVERVIEW

C have been approved in China, eight of which have been included in the NRDL. The following table sets forth the details of the approved DAAs for chronic hepatitis C in China as of the Latest Practicable Date.

### Approved DAAs in China

Drug Name	Company	Formulation	Target	Indication	Approval Date	Approved Generic Drugs	NRDL
Encofosbuvir	The Group	Tablet	NS5B	Combination with Netanasvir Phosphate for the treatment of primary or interferon-treated genotypes 1, 2, 3, and 6 chronic HCV infection in adults with or without compensated cirrhosis	March 25, 2025	No	Not included
Netanasvir Phosphate	The Group	Capsule	NS5A	Combination with Encofosbuvir for the treatment of primary or interferon-treated genotypes 1, 2, 3, and 6 chronic HCV infection in adults with or without compensated cirrhosis	February 8, 2025	No	Not included
Alfosbuvir	Sanhome	Tablet	NS5B	Combination with Daclatasvir Hydrochloride for the treatment of primary or interferon-treated genotypes 1, 2, 3, and 6 chronic HCV infection in adults with or without compensated cirrhosis	May 12, 2023	No	Category B
Emitasvir Phosphate	The Group	Capsule	NS5A	Combined Sofosbuvir for the treatment of genotype 1 non-cirrhotic chronic hepatitis C in adults	December 21, 2020	No	Category B
Ravidasvir	Ascletis	Tablet	NS5A	Combination of Ritonavir-boosted Danoprevir and Ribavirin for the treatment of primed genotype 1b chronic HCV infection with non-cirrhotic liver disease in adults	July 29, 2020	No	Category B
Coblopassvir	Beijing Kawin	Capsule	NS5A	Combined Sofosbuvir for the Treatment of primary or interferon-treated genotypes 1, 2, 3, and 6 chronic HCV infection in adults with or without compensated cirrhosis	February 11, 2020	No	Category B
Sofosbuvir + Velpatasvir + Voxilaprevir	Gilead	Tablet	NS5B, NS5A, NS3/4A	Chronic HCV infection in adults	December 18, 2019	No	Category B
Glecaprevir + Pibrentasvir	AbbVie	Tablet	NS3/4A, NS5A	Genotype 1, 2, 3, 4, 5, or 6 chronic HCV infection in adults without cirrhosis or with compensated cirrhosis; patients with HCV genotype 1 who have received a prior regimen containing either an NS5A inhibitor or an NS3/4A protease inhibitor (but not a regimen involving both)	May 15, 2019	No	Not included
Ledipasvir + Sofosbuvir	Gilead	Tablet	NS5B, NS5A	Chronic HCV infection in adults and teens aged 12 to 18 years	November 21, 2018	No	Category B
Danoprevir	Ascletis	Tablet	NS3/4A	Combination with ritonavir, PEG-IFNα and ribavirin to treat genotype 1b chronic hepatitis C in adults	June 8, 2018	No	Category B
Sofosbuvir + Velpatasvir	Gilead	Tablet	NS5B, NS5A	Chronic HCV infection in adults	May 23, 2018	No	Category B
Elbasvir + Grazoprevir	MSD	Tablet	NS3/4A, NS5A	Genotype 1 or 4 chronic hepatitis C (CHC) infection in adults	April 28, 2018	No	Not included
Dasabuvir	AbbVie	Tablet	NS5B	Combination with other drugs to treat genotype 1 chronic hepatitis C in adults	September 20, 2017	No	Not included
Ombitasvir + Paritaprevir + Ritonavir	AbbVie	Tablet	NS5A, NS3/4A, CYP3A4	Combination with other drugs to treat genotype 1 or 4 chronic hepatitis C in adults	September 20, 2017	No	Not included
Sofosbuvir	Gilead	Tablet	NS5B	Combination with other drugs to treat chronic HCV infection	September 20, 2017	Yes	Not included
Daclatasvir	BMS	Tablet	NS5A	Combination with other drugs to treat chronic HCV infection	April 24, 2017	Yes	Not included
Asunaprevir	BMS	Capsule/Tablet	NS3/4A	Combination with daclatasvir to treat genotype 1b chronic hepatitis C in adults	April 24, 2017	No	Not included

Source: NMPA, Frost & Sullivan analysis

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### THE METABOLIC DISEASES DRUG MARKET IN CHINA

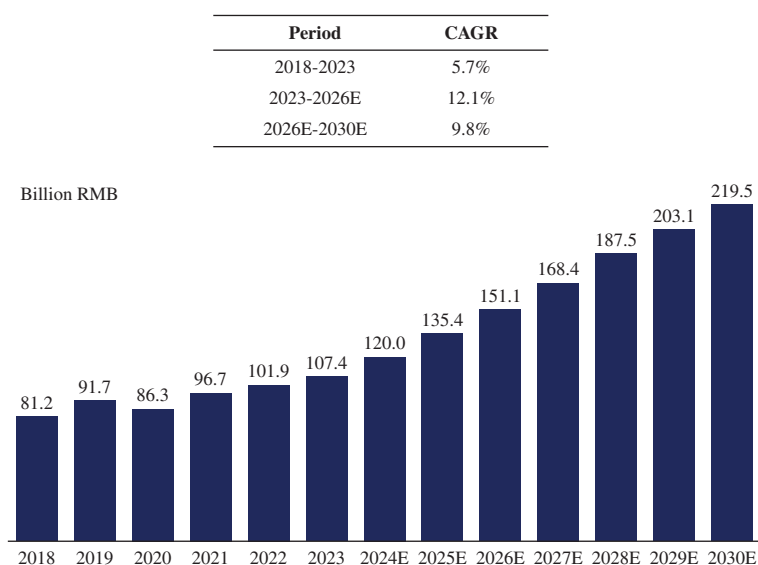
Chronic disease is defined by the World Health Organization as a disease of long duration, generally slow in progression and non-contagious. Chronic disease requires long-term treatment, nursing and special rehabilitation. Chronic disease has the characteristics of a prolonged illness. With the improvement of people's living standards, chronic diseases have become a leading cause of death globally. Chronic diseases generally include metabolic diseases such as diabetes, chronic respiratory diseases such as COPD, and neuropsychiatric diseases.

#### Overview of the Metabolic Diseases Drug Market in China

Problems caused by impaired metabolism may lead to metabolic diseases, affecting the whole body's tissues, organs, cognitive function, growth and development, and mental state. Primary risk factors include unhealthy living habits, aging, obesity, environmental pollutants, abnormal blood sugar, blood pressure, blood lipids, uric acid, etc. Patients may suffer from multiple complications or comorbidities, such as obesity, non-alcoholic steatohepatitis, hypertension and dyslipidemia.

In 2023, the metabolic disease drug market in China reached RMB107.4 billion, with a CAGR of 5.7% from 2018 to 2023. Metabolic diseases are often comorbidities of other conditions. Lifestyle changes, such as poor diets and sedentary behavior, contribute to this growing prevalence, leading to a larger patient population in need of treatment. With advancements in drug development and growing awareness of health management, the metabolic disease drug market is expected to rise steadily. The market size is expected to reach RMB151.1 billion in 2026 and RMB219.5 billion in 2030, with a CAGR of 12.1% from 2023 to 2026 and 9.8% from 2026 to 2030, respectively. The chart below sets forth the size of the metabolic diseases drug market in China from 2018 to 2030.

#### Metabolic Disease Drug Market in China, 2018-2030E



Source: Annual reports of listed companies, NMPA, CDE, NRD, Expert interviews, Frost & Sullivan analysis

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### Overview of the Diabetes Drug Market

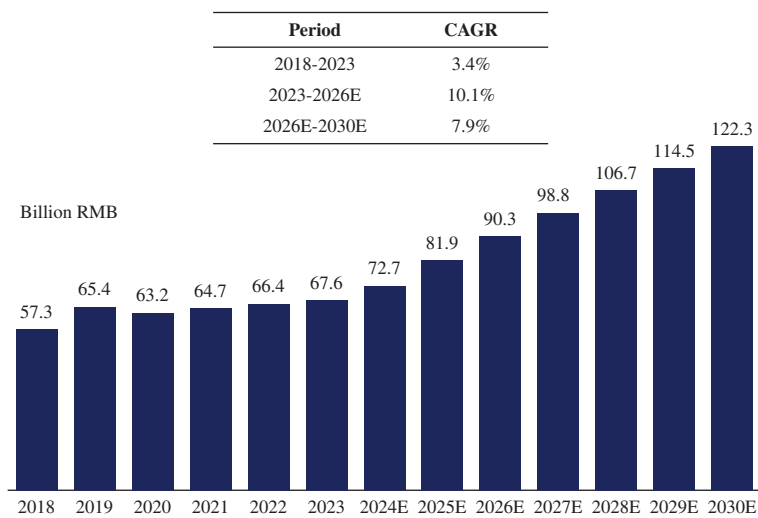
Diabetes mellitus is a group of metabolic diseases characterized by hyperglycemia resulting from defects in insulin secretion, insulin action, or both. Chronic hyperglycemia of diabetes is associated with long-term damage, dysfunction, and failure of various organs, especially the eyes, kidneys, nerves, heart, and blood vessels.

In 2023, the number of diabetic patients in China reached 143.4 million, among which approximately 137.0 million patients had type 2 diabetes. As a result of the aging population, it is estimated that the number of diabetic patients in China will reach 151.1 million in 2026 and 157.6 million in 2030, with a CAGR of 1.8% from 2023 to 2026 and 1.1% from 2026 to 2030, respectively.

### Overview of the Diabetes Drug Market in China

From 2018 to 2023, the market size of diabetes drugs in China increased from RMB57.3 billion to RMB67.6 billion, with a CAGR of 3.4%. As a result of unhealthy lifestyle habits and an aging population, the prevalence of diabetes in China is high and continues to rise. There is also greater awareness of metabolic diseases among healthcare professionals and the public, leading to earlier diagnosis and treatment. Recent introductions of GLP-1 receptor agonists and other innovative therapies have injected new momentum into the diabetes drug market. As public acceptance of these innovative drugs continues to grow, steady market growth is anticipated. In the future, the market size of diabetes drugs in China is expected to reach RMB90.3 billion in 2026 and RMB122.3 billion in 2030, with a CAGR of 10.1% from 2023 to 2026 and 7.9% from 2026 to 2030, respectively. The chart below sets forth the size of the diabetes drug market in China from 2018 to 2030.

**Diabetes Drug Market in China, 2018-2030E**



Source: Annual reports of listed pharmaceutical companies, Frost & Sullivan analysis

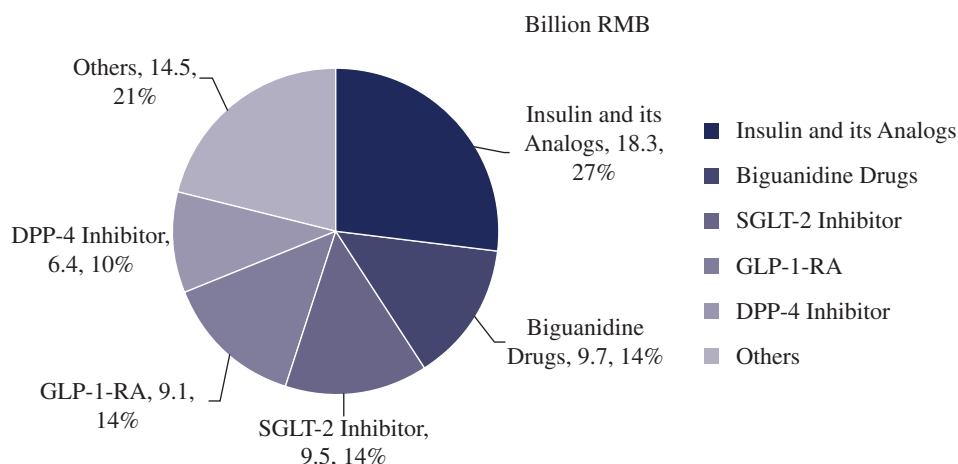
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For the sales of diabetes drugs, there are obvious differences in the sales structure between China's diabetes drug market and that of the global market. Traditional oral drugs such as Biguanides, Sulfonylureas and  $\alpha$ -glucosidase inhibitors, which have been on the market for decades, are currently still the mainstream in China. However, the global market share of these drugs is less than that of the new drugs represented by DPP-4 inhibitors, GLP-1 receptor agonists ("GLP-1RAs") and SGLT-2 inhibitors. Since these new drugs entered the Chinese market late, the proportion of sales revenue generated by them in China is far less than that of other developed countries in the world. With the combined clinical benefits of DPP-4 inhibitors, GLP-1RAs and SGLT-2 inhibitors, such as cardiovascular and renal benefits, there is potential for the market share of these new drugs to increase in China. The chart below sets forth a breakdown of the diabetes drug market in China by drug type.

**Diabetes Drug Market in China, 2023**



*Source: Annual reports of listed pharmaceutical companies, Frost & Sullivan analysis*

### ***Overview of the Diabetes Drug Market in the U.S.***

From 2018 to 2023, the market size of diabetes drugs in the U.S. increased from USD33.2 billion to USD40.4 billion, with a CAGR of 4.0%. The market size of diabetes drugs in the U.S. will continue to grow steadily and is expected to reach USD46.0 billion in 2026 and USD52.0 billion in 2030, representing a CAGR of 4.4% from 2023 to 2026 and 3.1% from 2026 to 2030, respectively. In 2023, sales of insulin and its analogs accounted for approximately 20% of the diabetes drugs market in the U.S.

### *Competitive Landscape of the Diabetes Drug Market in China*

#### *Insulin*

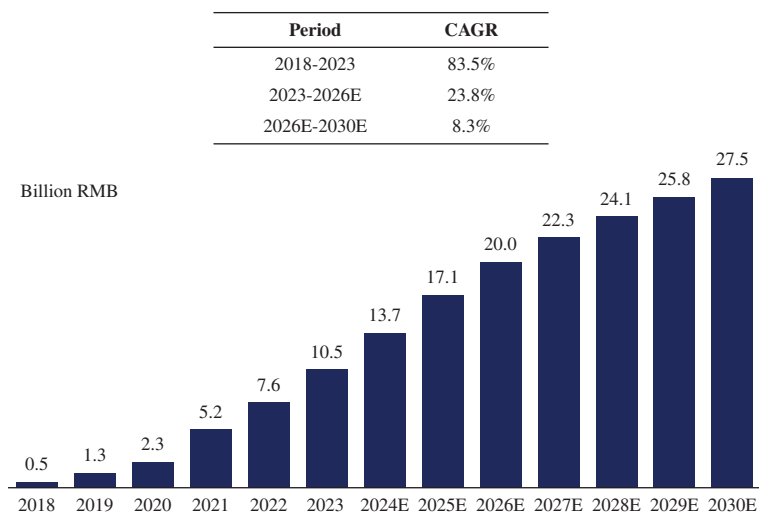
From 2018 to 2023, the market size of insulin and its analogs in China decreased from RMB26.4 billion to RMB18.3 billion due to the declining price of insulin and its analogs as a result of the VBP scheme of insulin products and the increased penetration rate of alternative therapeutics. The insulin analogs that are designed to closely mimic both basal and prandial insulin secretion, such as insulin glargine and insulin degludec, still have room for expansion. At the same time, the domestic substitution trend is becoming increasingly obvious, and the domestic insulin analogs are expected to grow. As of the Latest Practicable Date, there are over 60 companies that have received approval to manufacture insulin products in China, and the top six market players hold an aggregate of over 55.0% of the market share of the insulin market in China in terms of revenue in 2023. The key players of the insulin market in China include Novo Nordisk, Eli Lilly and Company, Sanofi and Gan & Lee Pharmaceuticals Co., Ltd. There are currently 18 approved insulin products categorized by their mechanism of action in China: prandial insulins (rapid-acting/short-acting), basal insulins (intermediate-acting/long-acting), premixed insulins, and other formulations. Regular insulins, which are short-acting, are produced by 39 manufacturers. Rapid-acting insulins, including insulin aspart, insulin lispro and insulin glulisine, are produced by eight, five, and one manufacturers, respectively. Intermediate-acting insulins, such as protamine insulin, are produced by 11 manufacturers. Long-acting insulins, including insulin glargine, insulin detemir, and insulin degludec, are produced by 12, two and three manufacturers, respectively. Common premixed insulins include premixed insulin aspart, recombinant human premixed protamine/regular insulin and premixed insulin lispro, which are manufactured by eight, 13, and four companies, respectively. Additionally, other formulations, including insulin degludec/aspart, insulin degludec/liraglutide and insulin glargine/lixisenatide I/II, are produced by three, one, and one manufacturers, respectively.

#### *SGLT-2 Inhibitor*

SGLT-2 inhibitor is a type of innovative medication for treating diabetes and heart failure that can lower the renal glucose threshold and promote urinary glucose excretion, thus reducing blood glucose levels. From 2018 to 2023, the market size of SGLT-2 inhibitor in China increased from RMB0.5 billion to RMB10.5 billion, with a CAGR of 83.5%. SGLT-2 inhibitors have demonstrated significant efficacy in lowering blood glucose levels while also providing cardiovascular and renal protection. As healthcare providers and patients become more aware of these benefits, the demand for these medications is anticipated to increase. In the future, the market size of SGLT-2 inhibitor in China will continue to grow rapidly in the short term, and it is expected to reach RMB20.0 billion in 2026, with a CAGR of 23.8% from 2023 to 2026. As the diabetes drug market matures and becomes more saturated, the growth rate is anticipated to gradually slow down, particularly as more SGLT-2 inhibitor drugs gain inclusion in medical insurance coverage. As such, the market is expected to reach RMB27.5 billion in 2030, with a CAGR of 8.3% from 2026 to 2030. The chart below sets forth the size of the SGLT-2 inhibitor drug market in China from 2018 to 2030.

## INDUSTRY OVERVIEW

### SGLT-2 Inhibitor Drug Market in China, 2018-2030E



Source: Annual reports of listed pharmaceutical companies, Frost & Sullivan analysis

The following charts set forth the details of the SGLT-2 inhibitors approved in China and the innovative SGLT-2 inhibitors that are at the NDA stage in China as of the Latest Practicable Date.

#### Approved SGLT-2 Inhibitor in China

Drug Name	Company	Indication	Approval Date	Approved Generic Drugs	NRDL
Dapagliflozin	Astrazeneca	Type 2 diabetes; Heart failure; Chronic kidney disease	March 20, 2017	Yes	Category B
Empagliflozin	Boehringer-ingenlheim	Type 2 diabetes; Heart failure; Chronic kidney disease	September 20, 2017	Yes	Category B
Canagliflozin	J&J	Type 2 diabetes	September 29, 2017	Yes	Category B
Ertugliflozin	MSD/Pfizer	Type 2 diabetes	July 29, 2020	No	Category B
Henagliflozin	Hengrui	Type 2 diabetes	December 31, 2021	No	Category B
Janagliflozin	Xuatnzh Bio/Sihuan Pharma	Type 2 diabetes	January 19, 2024	No	Not implemented

#### Innovative SGLT-2 Inhibitor at NDA Stage in China

Drug Name	Company	Indication	Status	First Posted Date
Bexagliflozin	Theracos	Type 2 diabetes	NDA	January 4, 2024
Ologliflozin	The Group	Type 2 diabetes	NDA	January 11, 2024

Source: NMPA, Frost & Sullivan analysis

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## INDUSTRY OVERVIEW

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### Overview of the Non-Alcoholic Steatohepatitis (NASH) Drug Market

Non-alcoholic steatohepatitis (NASH, recently renamed as metabolic dysfunction-associated steatohepatitis or MASH) is the most severe form of non-alcoholic fatty liver disease (NAFLD, recently renamed as metabolic dysfunction-associated steatotic liver disease or MASLD). As NASH evolves, it can result in fibrosis, liver cirrhosis and liver cancer. There are no symptoms in the early stages of NASH. However, as NASH progresses, symptoms of fatigue, unexplained weight loss, general physical weakness and pain in the upper right part of the belly may appear.

In recent years, the number of patients with NASH in China has increased significantly from 36.2 million in 2018 to 42.5 million in 2023, representing a CAGR of 3.3%, due to factors such as changes to dietary and lifestyle habits, and rising obesity rates. It is predicted that the number of patients with NASH in China will continue to increase, reaching 47.2 million in 2026 and 54.9 million in 2030, representing a CAGR of 3.6% from 2023 to 2026 and 3.9% from 2026 to 2030, respectively.

In 2023, there are 386.1 million people suffering from NASH worldwide. It is estimated that by 2026, this number will increase to 425.5 million with a CAGR of 3.3%, and by 2030, this number will reach 486.2 million.

### *Competitive landscape of the NASH/NAFLD Drug Market*

On March 14, 2024, Resmetirom from Madrigal Pharmaceuticals was approved by the FDA, making it the first FDA-approved medication for NASH. Resmetirom is a thyroid hormone receptor-beta agonist indicated in conjunction with diet and exercise for the treatment of adults with NASH with moderate to advanced liver fibrosis. The only other drug listed in the world is Saroglitazar Magnesium, which was developed by the Indian company Zydus Cadila and was approved by the Indian Drug Management Center on March 6, 2020. As of the Latest Practicable Date, no drugs for the treatment of NASH/NAFLD have been approved in China and Europe.

## INDUSTRY OVERVIEW

As of the Latest Practicable Date, there are two approved drugs and 185 active clinical trials globally for treating NASH/NAFLD, among which one is under NDA, 14 are in Phase III clinical trials and the remaining are in Phase II clinical trials and Phase I clinical trials. The chart below sets forth a breakdown of the global NASH/NAFLD drug pipelines by regions.

### Global NASH/NAFLD Drug Pipelines by Regions<sup>1</sup>

	Approved	NDA	Phase III	Phase II/III	Phase II <sup>2</sup>	Phase I/II	Phase I
China	0	0	3	0	18	2	26
USA	1	0	9	2	47	1	30
Others <sup>3</sup>	1	1	12	0	40	4	42
Total	2	1	14	2	70	7	91

#### Notes:

- Only the most advanced clinical stage for each drug candidate for the indication of NASH is included. If a drug candidate is in the same clinical stage across multiple regions, each region is counted separately.
- The Group's HEC88473 and HEC96719 are currently in Phase II clinical trials in China. The Group's HEC96719 has also completed Phase I clinical trials in Australia.
- Others mainly include EU and Japan.

Source: Clinicaltrials.gov, CDE, NMPA, Frost & Sullivan analysis

### Overview of the Obesity/Overweight Drug Market

Overweight and obesity are defined as abnormal or excessive fat accumulation that presents a health risk. At present, the commonly used body mass index (BMI) is an internationally recognized grading method for evaluating the degree of obesity. The specific calculation method is  $BMI = \text{weight}/\text{height}^2$  ( $\text{kg}/\text{m}^2$ ).

According to the classification of World Health Organization (WHO) and National Institutes of Health (NIH),  $BMI \geq 25 \text{kg}/\text{m}^2$  is defined as overweight, and  $BMI \geq 30 \text{kg}/\text{m}^2$  is defined as obese. The Guidelines for Prevention and Control of Overweight and Obesity among Adults in China issued by the Department of Disease Control and Prevention of the Ministry of Health of China have put forward the BMI cut-off value for an obesity diagnosis, in which  $24 \text{kg}/\text{m}^2 \leq BMI < 28 \text{kg}/\text{m}^2$  was categorized as overweight and  $BMI \geq 28 \text{kg}/\text{m}^2$  was categorized as obese.



## INDUSTRY OVERVIEW

In recent years, the number of obese/overweight patients in China has appreciably increased, from 531.8 million in 2018 to 622.4 million in 2023, with a CAGR of 3.2%, due to factors such as changes to dietary and lifestyle habits. It is predicted that the number of obese/overweight patients in China will continue to rise, reaching 674.2 million in 2026 and 740.4 million in 2030, with a CAGR of 2.7% from 2023 to 2026 and 2.4% from 2026 to 2030, respectively.

### GLP-1/FGF21

HEC88473 is the first GLP-1/FGF21 dual agonist product in the world to enter the clinical stage. Phase II clinical trials have started for the indication of type 2 diabetes mellitus. The Group's HEC88473 has the potential to concurrently target three major indications, namely type 2 diabetes, NASH and obesity. The following chart sets forth the details of GLP-1/FGF21 dual-target drug candidates in China as of the Latest Practicable Date.

#### GLP-1/FGF21 Dual-target Drug Pipelines in China

Drug Name	Company	Target	Major Indication	Status	First Posted Date
HEC88473	The Group	GLP-1 FGF21	Type 2 diabetes	Phase II	August 17, 2023
DR10624	Doer Biologics/Huadong Medicine	GLP-1 GCG FGF21	Hypertriglyceridemia	Phase II	July 11, 2024
AP026	Ampsource Biopharma	GLP-1 FGF21	Type 2 diabetes	Phase I	March 13, 2023
MWN105	Minwei Biotechnology	GLP-1 GIP FGF21	Type 2 diabetes, obesity	Phase I	December 13, 2024

#### Notes:

1. The Group has submitted the IND application for NASH to the U.S. FDA and obtained clinical trial approval and submitted the IND application for obesity to the NMPA and obtained clinical trial approval, respectively, for HEC88473.
2. DR10624 is a tri-specific drug that agonizing GLP-1, glucagon receptor GCG, and FGF21.

Source: CDE, Frost & Sullivan analysis

## THE RESPIRATORY SYSTEM DISEASE DRUG MARKET IN CHINA

Respiratory diseases are diseases that affect the lungs and other parts of the respiratory system. Respiratory diseases may be caused by infection, smoking, breathing in secondhand tobacco smoke, radon, asbestos, or other forms of air pollution. Common respiratory diseases include, among others, COPD, asthma, bronchitis, pneumonia, pulmonary fibrosis. The market size of respiratory system disease drugs in China reached approximately RMB82.1 billion in 2023. Driven by a growing aging population, poor lifestyle choices such as smoking, as well as air pollution and other factors, the pool of patients suffering from respiratory system diseases continues to expand. Meanwhile, as more new drugs such as respiratory targeted therapeutic drugs and drugs with more convenient administration routes such as inhalation

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## INDUSTRY OVERVIEW

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preparations are expected to be approved in the future, this will continue to drive the growth of this market. It is estimated that the market size will grow in the future, reaching approximately RMB103.7 billion in 2026 and RMB123.9 billion in 2030.

### Overview of the Pulmonary Fibrosis Drug Market in China

Idiopathic pulmonary fibrosis (IPF), the most common type of pulmonary fibrosis, is a type of lung disease which causes scarring (fibrosis) of the lungs. Scarring causes stiffness in the lungs and makes it difficult to breathe. Lung damage from IPF is irreversible and progressive, meaning it worsens over time. In some cases, this gradual worsening can be slowed down by certain medications. Occasionally, people with IPF will be recommended for lung transplant. Despite conventional treatment, a proportion of interstitial lung disease (ILD) patients develop a progressive phenotype known as fibrosing ILD with a progressive phenotype (PF-ILD), characterized by worsening respiratory symptoms, decline in lung function and early mortality.

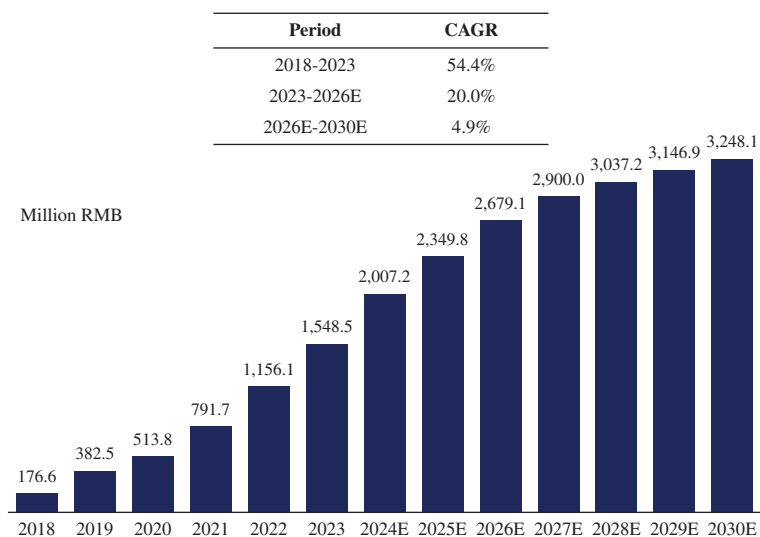
The growth in aging population, tobacco use and environmental air pollution all contribute to the rapid growth of IPF incidence. At the same time, the popularization and promotion of medical intervention measures and the education of patients and doctors will prolong the survival time of patients, reduce the mortality rate and increase the IPF patient base. In 2023, the number of IPF patients reached 164.3 thousand, and the CAGR from 2018 to 2023 was 13.0%. It is estimated that the number of IPF patients will reach 231.1 thousand by 2026 and 339.2 thousand by 2030, with a CAGR of 12.0% from 2023 to 2026 and 10.1% from 2026 to 2030, respectively.

Pirfenidone and Nintedanib (the only two drugs currently available globally for the treatment of IPF) were added to the NRDL since 2017 and 2020, respectively, which drove the rapid growth of the pulmonary fibrosis drug market in China from 2018 to 2023. In 2023, the market size of pulmonary fibrosis drugs in China reached approximately RMB1.5 billion, with a CAGR of 54.4% from 2018 to 2023. Given the complex epidemiology of pulmonary fibrosis, driven by environmental exposures, an aging population and underlying conditions, such as autoimmune diseases, the demand for effective treatments continues to rise. With the growing number of approved drugs in the future and the expansion of indication of such drugs from IPF

## INDUSTRY OVERVIEW

to other types of pulmonary fibrosis, it is estimated that this market size will continue to grow, reaching approximately RMB2.7 billion in 2026 and RMB3.2 billion in 2030. The chart below sets forth the size of the pulmonary fibrosis drug market in China from 2018 to 2030.

### Pulmonary Fibrosis Drug Market in China, 2018-2030E



Source: Annual reports of listed companies, NMPA, CDE, NRDL, Expert interviews, Frost & Sullivan analysis

### Competitive Landscape of the Pulmonary Fibrosis Drug Market in China

The following charts set forth the details of pulmonary fibrosis drugs approved in China and pulmonary fibrosis innovative drug candidates in Phase II clinical trials, Phase III clinical trials and NDA stage in China as of the Latest Practicable Date.

#### Approved Pulmonary Fibrosis Drugs in China

Brand Name	Drug Name	Company	Indication	Approval Date	NRDL
Ofev	Nintedanib	Boehringer Ingelheim	IPF, SSc-ILD, chronic fibrotic interstitial lung disease with a progressive phenotype	September 20, 2017	Category B
Etuary®	Pirfenidone	Continent	Mild and moderate IPF	December 25, 2013	Category B

## INDUSTRY OVERVIEW

### Pulmonary Fibrosis Innovative Drug Pipelines in China

Drug Name	Company	Target	Indication	Status	First Posted Date
Nerandomilast/ BI 1015550 Tablets	Boehringer Ingelheim	PDE4B	IPF	NDA	February 25, 2025
			PF-ILD	NDA	May 15, 2025
BMS-986278 Tablets	BMS	LPAR1	IPF	Phase III	December 28, 2023
			Progressive pulmonary fibrosis	Phase III	December 15, 2023
SC1011 Tablets	Biocity	/	IPF	Phase II/III	February 23, 2023
Bexotegrast	Pliant Therapeutics	Integrin $\alpha\beta1$ Integrin $\alpha\beta6$	IPF	Phase II/III	October 18, 2024
HSK44459	Haisco Pharmaceutical	PDE4B	IPF	Phase II	January 6, 2025
BI 1839100	Boehringer Ingelheim	ion channel	Progressive pulmonary fibrosis IPF	Phase II	October 22, 2024
BI 1819479	Boehringer Ingelheim	/	IPF	Phase II	August 26, 2024
TDI01 Oral Suspension	Tide Pharmaceutical	ROCK2	IPF	Phase II	August 21, 2023
HW021199 Tablets	Wuhan Humanwell Likang Pharmaceutical	/	IPF	Phase II	August 16, 2023
ISM001-055/ INS018_055 Capsules	Shanghai SynTheAll/ Insilico Medicine	TNIK	IPF	Phase II	March 21, 2023
Butaselen Tablets	Yuanxi Medicine	/	PF-ILD	Phase II	November 8, 2022
AK3280 Tablets	Ark Bio	/	IPF	Phase II	May 30, 2022
REGEND001 Cell Autotransfusion Preparation	Regend	/	IPF	Phase II	May 12, 2022
Yinfenidone Hydrochloride Tablets	The Group	/	PF-ILD	Phase II	December 1, 2021
			IPF	Phase II	January 26, 2021
Jaktinib Hydrochloride Tablets	Zelgen	JAK	IPF	Phase II	July 23, 2020

Source: CDE, Frost & Sullivan analysis

## INDUSTRY OVERVIEW

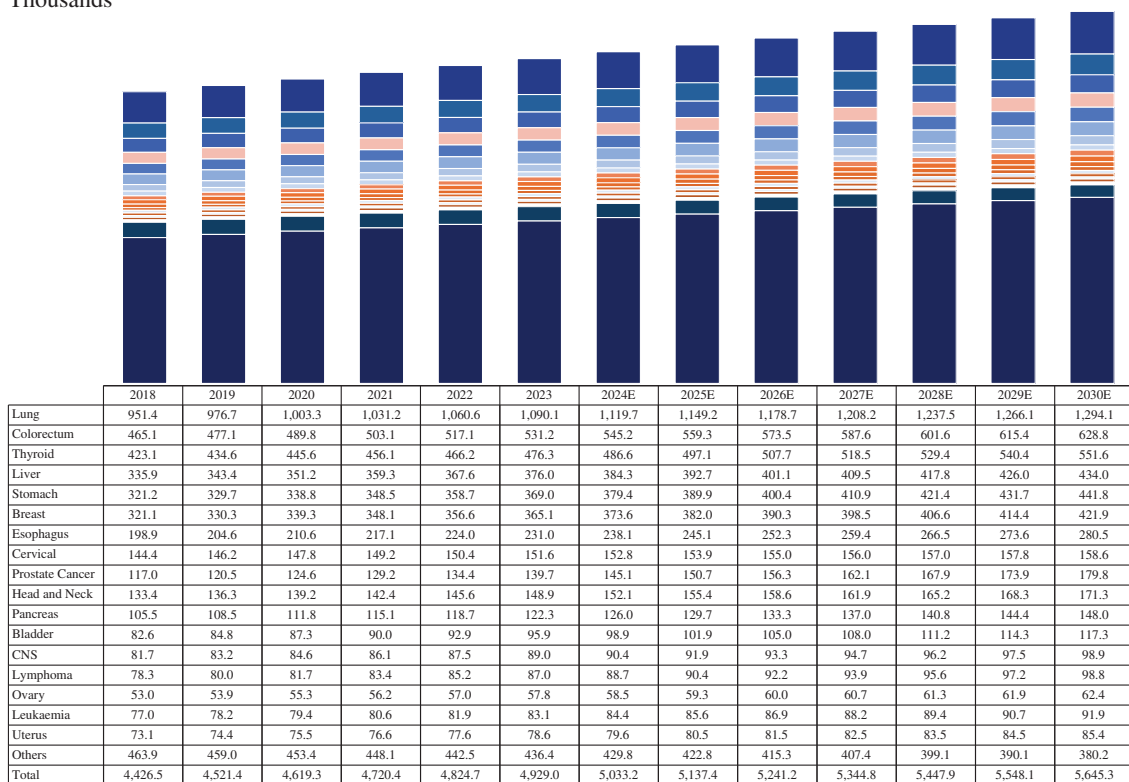
### THE ONCOLOGY DRUG MARKET IN CHINA

#### Overview of the Oncology Drug Market in China

Cancer is the second most common disease in China. The number of new cases grew from 4.4 million in 2018 to 4.9 million in 2023, with a CAGR of 2.2%. Due to the increasing number of cancer diagnoses, the number of new cases in 2026 is predicted to increase to 5.2 million and further to 5.6 million in 2030 with the CAGR of 2.1% from 2023 to 2026 and 1.9% from 2026 to 2030, respectively. The chart below sets forth incidence of major cancer types in China from 2018 to 2030.

#### Incidence of Major Cancer Types in China, 2018-2030E

Thousands



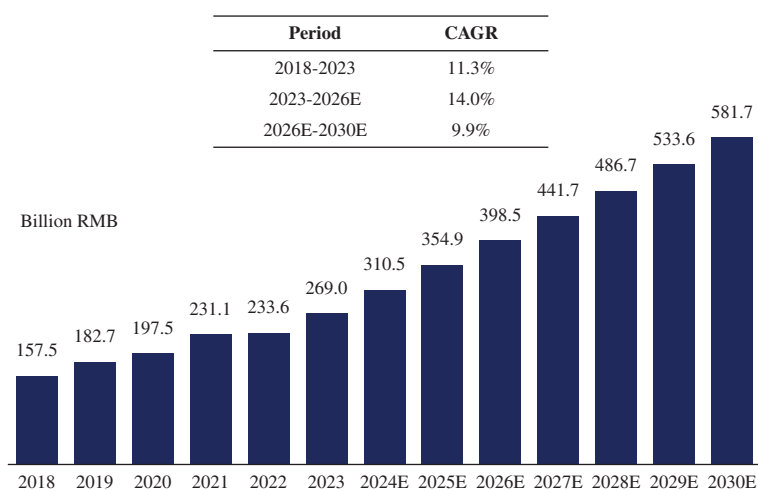
Source: Globocan, NCCR, Frost & Sullivan analysis

In the Chinese drug market, sales of oncology products have risen steadily in recent years. China's oncology drug market, which generated RMB269.0 billion in 2023, experienced a CAGR of 11.3% over the past five years. The increasing prevalence of cancer in China, driven by an aging population, lifestyle changes and environmental influences, has led to higher demand for oncology drugs. As more individuals are diagnosed with various types of cancer, the need for effective treatment options continues to grow. The constantly evolving array of successful innovative oncology treatments is expected to bring in high return for pharmaceutical manufacturers. In the future, stronger and more innovative therapies, such as

## INDUSTRY OVERVIEW

ADCs and bispecific antibodies, are expected to enter the market, significantly driving the overall market expansion. The Chinese oncology drug market is expected to be on an upward trend in the coming years. From 2023 to 2026, China's oncology market is predicted to reach RMB398.5 billion at wholesale price level with CAGR of 14.0%. It is estimated that China's oncology drug market would be valued at RMB581.7 billion in 2030, representing a CAGR of 9.9% from 2026 to 2030. The chart below sets forth the size of the oncology drug market in China from 2018 to 2030.

**Oncology Drug Market in China, 2018-2030E**



*Source: Annual reports of listed pharmaceutical companies, NMPA, CDE, NRD, Ministry of Human Resources and Social Security, National Central Cancer Registry of China, Frost & Sullivan analysis*

While competition in China's oncology drug market is fierce, companies with in-house capabilities throughout the entire value chain of oncology drug development, including drug discovery, process development, clinical development, quality control and assurance and commercialization, are better positioned to capture the growth potential of this market.

Currently, China's oncology drug market is dominated by chemotherapy drugs. In 2023, chemotherapy drugs accounted for 47.5% of the total oncology drug market while targeted drugs, including small molecular targeted drugs and biologics, accounted for 42.4% and immuno-oncology therapy accounted for 10.1%. With medical insurance and reimbursement policies, new drug developments and patients' increasing spending ability, targeted drugs and immuno-oncology therapy would occupy most of the market by 2030. It is expected that the

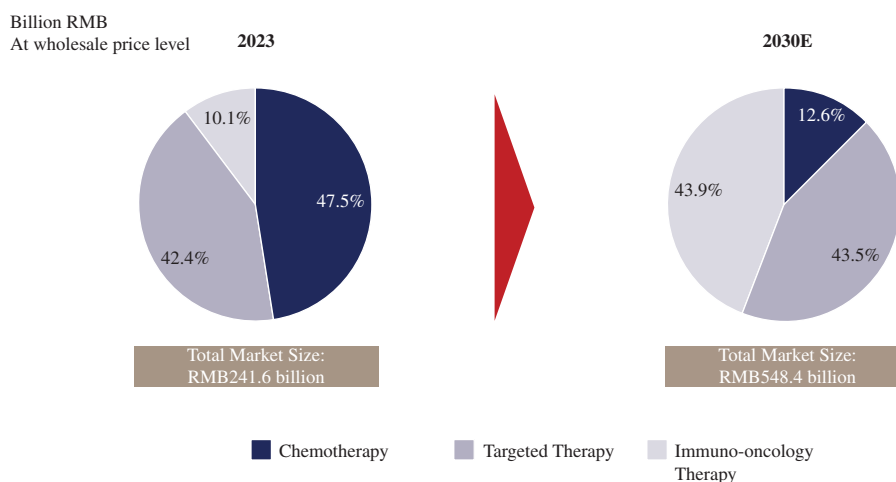
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## INDUSTRY OVERVIEW

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share of immuno-oncology therapy will account for 43.9% while targeted drugs will account for 43.5% in 2030. The chart below sets forth a breakdown of the oncology drug market in China by therapy type in 2023 and 2030.

### Breakdown of the Oncology Drug Market by Therapy in China, 2023 and 2030E



Source: Annual reports of listed pharmaceutical companies, NMPA, CDE, NRDL, Ministry of Human Resources and Social Security, National Central Cancer Registry of China, Frost & Sullivan analysis

### Overview of the Acute Myeloid Leukemia (AML) Drug Market in China

Acute myeloid leukemia (AML) is the most common type of leukemia among the adult population and accounts for approximately 80% of all cases of leukemia. It is characterized by clonal expansion of immature “blast cells” in the peripheral blood and bone marrow, resulting in ineffective erythropoiesis and bone marrow failure. The French-American-British (FAB) classification divides AMLs into subtypes M0 to M7. This was based on the type of cell from which the leukemia developed and the level of maturity of the cells. The FAB classification relies on the appearance of leukemia cells under the microscope after routine staining.

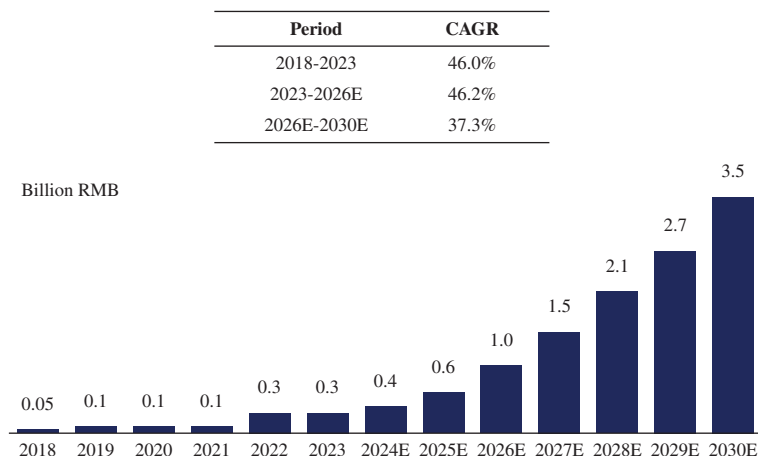
In 2023, there were approximately 29.1 thousand new cases of AML in China, with a CAGR of 1.5% from 2018 to 2023. It is estimated that there will be approximately 30.4 thousand new cases in 2026 and approximately 32.2 thousand new cases in 2030.

In 2023, the market size of AML drugs in China reached RMB0.3 billion, with a CAGR of 46.0% from 2018 to 2023. Epidemiological data indicate a continuous rise in AML incidence, necessitating accelerated clinical trial progress and new drug development. As a result, a greater number of innovative therapies are expected to gain approval and enter the

## INDUSTRY OVERVIEW

market, thereby fostering the growth of the AML drug market. It is predicted that this market size will continue to grow, reaching RMB1.0 billion in 2026 and RMB3.5 billion in 2030. The chart below sets forth the size of the AML drug market in China from 2018 to 2030.

### AML Drug Market in China, 2018-2030E



Source: Annual reports of listed companies, NMPA, CDE, NRDL, Expert interviews, Frost & Sullivan analysis

### Competitive Landscape of the AML Drug Market in China

As of the Latest Practicable Date, a total of 13 drugs have been approved in China for the treatment of AML, including eight chemotherapy drugs and five targeted therapies. Among these targeted therapies, Venetoclax, which targets BCL-2, is most commonly used. Additionally, Gilteritinib, which targets FLT3, and Ivosidenib, which targets IDH1, were recently approved in China. There are more than 20 manufacturers of approved drugs for the treatment of AML in China.

As of the Latest Practicable Date, only one FLT3 inhibitor was approved for the treatment of AML in China. 10 FLT3 inhibitors are at clinical trial stages, among which one is in NDA stage, four are in Phase III clinical trials and five are in Phase I clinical trials and Phase II clinical trials. The Group's Clifutinib Besylate is the first domestically developed highly selective FLT3 inhibitor to enter Phase III clinical trials in China in October 2022. In Phase I clinical trials, it demonstrated a high CR/CRh rate and good tolerability in patients. The following charts set forth the details of the FLT3 inhibitor approved for the treatment of AML in China and the FLT3 inhibitor drug candidates for the treatment of AML in Phase III clinical trials in China as of the Latest Practicable Date.



## INDUSTRY OVERVIEW

### Approved FLT3 Inhibitors for the treatment of AML in China

Brand Name	Drug Name	Company	Indication	Approval Date	NRDL
Xospata	Gilteritinib	Astellas	Recurrent or refractory AML with FLT3 mutation in adults	March 5, 2020	Not included

### FLT3 Inhibitor Pipelines for the treatment of AML in China

Drug Name	Company	Target	Indication	Status	First Posted Date
Quizartinib	Daiichi Sankyo/ Patheon France/Covance	FLT3	Newly diagnosed AML with FLT3-ITD mutation	NDA	January 18, 2025
XY0206	Yiling Pharmaceutical	FLT3, KIT, PDGFRB, RET, VEGFR2	Relapsed/refractory AML with FLT3-ITD mutation	Phase III	April 6, 2023
Clifutinib Besylate	The Group	FLT3	Relapsed/refractory AML with FLT3-ITD mutation	Phase III	October 19, 2022
			AML in newly diagnosed adult	Phase I/II	October 22, 2021
SKLB1028	CSPC	FLT3, EGFR, LYN, ABL	Relapsed/refractory AML with FLT3 mutation	Phase III	December 28, 2020
			Newly diagnosed AML	Phase I/II	June 7, 2021
Crenolanib	Arog Pharmaceuticals/ Patheon	FLT3, KIT, PDGFR	Relapsed/refractory AML with FLT3 mutation	Phase III	April 15, 2020

Source: NMPA CDE, Frost & Sullivan analysis

### REPORT COMMISSIONED BY FROST AND SULLIVAN

In connection with the Listing, we have engaged Frost & Sullivan to conduct a detailed analysis and prepare an industry report on the pharmaceutical market, anti-infective drug market, metabolic disease drug market, oncology drug market, respiratory disease drug market and neuropsychiatric drug market in China, the U.S. and globally (as applicable). Frost & Sullivan is an independent global market research and consulting company, founded in 1961, and is based in the United States. Services provided by Frost & Sullivan include market assessments, competitive benchmarking and strategic and market planning for a variety of industries. The contract sum to Frost & Sullivan is RMB400,000 for the preparation of the Frost & Sullivan Report. The payment of such amount was not contingent upon our successful Listing or on the results of the Frost & Sullivan Report. Except for the Frost & Sullivan Report, we did not commission any other industry report in connection with the Listing. Except as otherwise noted, all of the data and forecasts contained in this section are derived from the Frost & Sullivan Report. Frost & Sullivan prepared its report based on its in-house database, independent third-party reports and publicly available data from reputable industry organizations. Where necessary, Frost & Sullivan contacts companies operating in the industry to gather and synthesize information in relation to the market, prices and other relevant information. Frost & Sullivan believes that the basic assumptions used in preparing the Frost & Sullivan Report, including those used to make future projections, are factual, correct and not misleading. Frost & Sullivan has independently analyzed the information, but the accuracy of the conclusions of its review largely relies on the accuracy of the information collected. Frost & Sullivan research may be affected by the accuracy of these assumptions and the choice of these primary and secondary sources.

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## REGULATORY ENVIRONMENT

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### LAWS AND REGULATIONS OF THE PRC

We are subject to a variety of PRC laws, rules and regulations affecting many aspects of our business. This section summarizes the major PRC regulatory authorities and PRC laws and regulations that we believe are relevant to our business and operations in the PRC.

### PRINCIPAL REGULATORY AUTHORITIES

#### NMPA and Center for Drug Evaluation

National Medical Products Administration (國家藥品監督管理局) (formerly the China Food and Drug Administration (國家食品藥品監督管理總局) (the “CFDA”)) (the “NMPA”) is the department in charge of the pharmaceutical industry of China. It is responsible for drawing up the laws and regulations related to pharmaceuticals and medical devices, making policies and plans, establishing department manuals and procedures, organizing the development and issuance of pharmaceutical and medical device standards, classification and management regulations, such as national formulary, and supervising the implementation. Center for Drug Evaluation (the “CDE”) is the technical evaluation unit for drug registration with NMPA. It is mainly responsible for conducting technical evaluation on the drugs applying for registration and verifying the relevant aspects with drug registrations.

#### NHC

The National Health Commission (國家衛生健康委員會) (formerly known as the National Health and Family Planning Commission (國家衛生和計劃生育委員會)) (the “NHC”), is primary national agency for public health and family planning management. It is primarily responsible for drafting national health policies, supervising and regulating public health, healthcare services, and health emergency systems, coordinating the reform of medical and health system, organizing the establishment of national drug policies and national essential medicine system, performing pharmacovigilance and drug shortage alert, giving suggestions on the pricing policy of national essential medicine, and monitoring the operation of medical institutions and practicing of healthcare practitioners.

#### NHSA

The National Healthcare Security Administration (國家醫療保障局) (the “NHSA”), a new agency established in May 2018, directly under the State Council, is responsible for the management of the healthcare security system. It is primarily responsible for drafting and implementing policies and standards on medical insurance, maternity insurance and medical assistance; supervising and administering the healthcare security funds; formulating a uniform medical insurance catalogue and payment standards on drugs, medical disposables and healthcare services; and formulating and supervising the implementation of the bidding and tendering policies for drugs and medical disposables.

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## REGULATORY ENVIRONMENT

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### Ministry of Commerce

The Ministry of Commerce of the PRC (中華人民共和國商務部) (the “**MOFCOM**”) is responsible for the overall guidance and management of foreign investment. It drafts, revises and implements the laws, regulations, rules and policies of foreign investment. It also participates in the drafting and promulgation of the Special Management Measures for the Market Entry of Foreign Investment (Negative List) (《外商投資准入特別管理措施(負面清單)》 the “**Negative List**”) and Catalog of Industries for Encouraging Foreign Investment (《鼓勵外商投資產業目錄》). The MOFCOM is also responsible for the administration and supervision of the approval and registration of foreign investment in China.

### General Administration of Customs of the People’s Republic of China

The General Administration of Customs of the People’s Republic of China (the “**GACC**”) is a directly affiliated institution of the State Council. The GACC is the state’s customs supervision and administration authority and is responsible for collection and management of import/export duties and other taxes and fees, outbound and inbound health quarantine and entry-exit inspection and quarantine of animals and plants and the related products, inspection of import and export commodities under the laws, compilation of customs statistics for national trading of items including import/export goods, formulating and implementing planning to develop customs technologies and the planning to support the development of laboratories and technologies. According to the Decision on the State Council Institutional Reform Proposal issued by the State Council and effective on March 17, 2018, the duty of the entry-exit inspection and quarantine management and relevant staff of the former State Administration for Quality Supervision and Inspection and Quarantine were assigned to the GACC.

## PRINCIPAL REGULATORY PROVISIONS

### Laws and Regulations on Company Establishment and Foreign Investment in the PRC

The establishment, operation and management of corporate entities in China are governed by the Company Law of the PRC (《中華人民共和國公司法》) (the “**PRC Company Law**”), which was promulgated by the Standing Committee of the NPC in December 1993 and further amended in December 1999, August 2004, October 2005, December 2013, October 2018 and December 2023, respectively. According to the PRC Company Law, companies are generally classified into two categories: limited liability companies and companies limited by shares. The PRC Company Law also applies to foreign-invested limited liability companies and foreign-invested companies limited by shares. According to the PRC Company Law, where laws on foreign investment have other stipulations, such stipulations shall prevail.

Currently investment activities in the PRC by foreign investors are primarily governed by the Special Administrative Measures for the Access of Foreign Investment (Negative List) (Edition 2024) (《外商投資准入特別管理措施(負面清單)(2024年版)》) which were promulgated by the MOFCOM in September 2024 and came into effect since November 1, 2024 and Special Administrative Measures for the Access of Foreign Investment in Pilot Free

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Trade Zones (Negative List) (Edition 2021) (《自由貿易試驗區外商投資准入特別管理措施(負面清單)(2021年版)》) (collectively, the “**Negative Lists**”), which were promulgated by the MOFCOM and the NDRC in December 2021 and came into effect since January 1, 2022. The Negative Lists set out the special administrative measures in a unified manner in respect of the access of foreign investments, such as the industries that are prohibited for foreign investment, the limits on shareholding percentages of foreign investors and the requirements on the participation of foreign investors in the operation and management. The Negative Lists cover 11 industries, and any field not falling in the Negative Lists shall be administered under the principle of equal treatment for domestic and foreign investment. Our business, as currently conducted, does not fall within the confines of the Negative Lists and is not subject to foreign investment restrictions.

Foreign Investment Law of the PRC (《中華人民共和國外商投資法》) (the “**Foreign Investment Law**”) was promulgated by the NPC in March 2019 and came into effect in January 2020. After the Foreign Investment Law came into effect, the trio of Law on Wholly Foreign-owned Enterprises of the PRC (《中華人民共和國外資企業法》), the Law on Sino-foreign Equity Joint Ventures of the PRC (《中華人民共和國中外合資經營企業法》) and the Law on Sino-foreign Cooperative Joint Ventures of the PRC (《中華人民共和國中外合作經營企業法》) have been repealed simultaneously. The investment activities of foreign natural persons, enterprises or other organizations (hereinafter referred to as “**foreign investors**”) directly or indirectly within the territory of China shall comply with and be governed by the Foreign Investment Law, including: 1) foreign investors establishing foreign-invested enterprises in China alone or jointly with other investors; 2) foreign investors acquiring shares, equity, property shares, or other similar interests of Chinese domestic enterprises; 3) foreign investors investing in new projects in China alone or jointly with other investors; and 4) other forms of investment prescribed by laws, administrative regulations or the State Council.

In December 2019, the State Council promulgated the Regulations on Implementing the Foreign Investment Law of the PRC (《中華人民共和國外商投資法實施條例》) (the “**Implementation Rules**”), which came into effect in January 2020. The Implementation Rules further clarified that the state shall encourage and promote foreign investment, protect the lawful rights and interests in foreign investments, regulate foreign investment administration, continue to optimize foreign investment environment, and advance a higher-level opening.

In December 2019, the MOFCOM and the SAMR promulgated the Measures on Reporting of Foreign Investment Information (《外商投資信息報告辦法》) (the “**Reporting Measures**”), which came into effect in January 2020. After the Reporting Measures came into effect, the Interim Measures for the Administration of Filing for Establishment and Changes in Foreign Investment Enterprises (《外商投資企業設立及變更備案管理暫行辦法》) has been repealed simultaneously. Since January 1, 2020, foreign investors or foreign-invested enterprises carrying out investment activities directly or indirectly in China shall submit investment information to the relevant commerce administrative authorities according to the Reporting Measures.

### Laws and Regulations on Drugs

#### *Research and development of new drugs*

The Drug Administration Law of the PRC (《中華人民共和國藥品管理法》) (the “**Drug Administration Law**”) promulgated by the Standing Committee of the National People’s Congress (the “**SCNPC**”) in September 1984, last amended on August 26, 2019 and became effective on December 1, 2019, and the Implementation Regulations of the Drug Administration Law of the PRC (《中華人民共和國藥品管理法實施條例》) (the “**Implementation Regulations**”) promulgated by the State Council in August 2002 and last amended on March 2, 2019, have laid down the legal framework for the establishment and maintenance of pharmaceutical manufacturing and trading enterprises, as well as for the administration of pharmaceutical products including the development and manufacturing of new drugs. According to the Drug Administration Law and the Implementation Regulations, the PRC encourages the research and development of new drugs and protects the legal rights and interests in the research and development of new drugs. The developer and clinical trial sponsor of any new drug shall truthfully submit the new drug’s manufacturing method, quality specifications, results of pharmacological and toxicological tests and the related data, documents and samples to the NMPA for approval before any clinical trial is conducted.

#### *Non-clinical research and Animal Testing*

The non-clinical safety evaluation study for drugs for the purpose of applying for marketing authorization shall be conducted in accordance with the Administrative Measures for Good Laboratories Practice (《藥物非臨床研究質量管理規範》), which was promulgated in August 2003 and amended in July 2017 by the CFDA. In April 2007, the CFDA issued the Circular on Measures for Certification of Good Laboratory Practice (《藥物非臨床研究質量管理規範認證管理辦法》), last amended on January 19, 2023 and taking effect on July 1, 2023, which set forth the requirements for an institution to apply for a Certification of Good Laboratory Practice to undertake non-clinical research on drugs.

According to the Regulations for the Administration of Affairs Concerning Experimental Animals (《實驗動物管理條例》) issued by the State Scientific and Technological Commission on November 14, 1988 and last amended by the State Council on March 1, 2017, the Administrative Measures on Good Practice of Experimental Animals (《實驗動物質量管理辦法》) jointly issued by the State Scientific and Technological Commission and the State Bureau of Quality and Technical Supervision on December 11, 1997 and the Administrative Measures on the Certificate for Experimental Animals (Trial) (《實驗動物許可證管理辦法(試行)》) issued by the Ministry of Science and Technology and other regulatory authorities on December 5, 2001 and effective from January 1, 2002, using and breeding experimental animals shall be subject to some rules and performing experimentation on animals requires a Certificate for Use of Experimental Animals. Any entity without such certification must engage a qualified third party to conduct such non-clinical studies regulated under relevant laws and regulations.

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### *Application for clinical trial*

According to the Decision on Adjusting the Approval Procedures of Certain Administrative Approval Items for Drugs (《關於調整部分藥品行政審批事項審批程序的決定》) promulgated by the CFDA on March 17, 2017, the decision on the approval of clinical trials of drugs shall be made by the CDE from May 1, 2017. According to the Administrative Measures for Drug Registration (《藥品註冊管理辦法》) (the “**Circular 27**”), which was promulgated on January 22, 2020 and took effect on July 1, 2020, drug clinical trials shall be divided into Phase I clinical trial, Phase II clinical trial, Phase III clinical trial, Phase IV clinical trial, and bioequivalence trial. In accordance with Circular 27 and the Announcement on Adjusting Evaluation and Approval Procedures for Clinical Trials for Drugs (《關於調整藥物臨床試驗審評審批程序的公告》) issued in July 2018, if a clinical trial applicant does not receive any negative or questioned opinions from the CDE within 60 days after the date when the trial application is accepted and the fees are paid, the applicant can proceed with the clinical trial in accordance with the trial protocol submitted to the CDE.

After obtaining the approval of clinical trial from the NMPA, the applicant must complete the clinical trial registration at the Drug Clinical Trial Information Platform for public disclosure in accordance with the Circular on Drug Clinical Trial Information Platform (《關於藥物臨床試驗信息平台的公告》), which came into effect in September 2013. The applicant shall complete the initial registration of the trial within one month after obtaining the approval of clinical trial to obtain an exclusive trial registration number, and then complete the subsequent information registration before the first patient is enrolled in the trial and submit the registration for public disclosure for the first time.

### *Conduct of clinical trial*

After obtaining clinical trial approval, the applicant shall conduct clinical trials at qualified clinical trial institutions. The qualified clinical trial institution refers to institutions that have the conditions to conduct clinical trials in accordance with the requirements and technical guidelines set forth in the Regulations for the Administration of Drug Clinical Trial Institutions (《藥物臨床試驗機構管理規定》), which came into effect on December 1, 2019. Such clinical trial institutions shall be subject to registration requirements, with the exception of institutions that only engage in analysis of biological samples which shall not be subject to such registration requirements. The NMPA is responsible for setting up a registration management information platform for the registration and operation management of drug clinical trial institutions, as well as the entry, sharing and disclosure of information from the supervision and inspection activities conducted by the drug regulatory authorities and competent healthcare authorities.

Clinical trials must be conducted in accordance with the Good Clinical Practice for Drug Trials (《藥物臨床試驗質量管理規範》) promulgated by NMPA and NHC on April 23, 2020 and effective on July 1, 2020, which stipulates the requirements for the procedures of



conducting clinical trials, including clinical trial preparation, trial protocols, protection of subject's rights and interests, duties of investigators, sponsors and monitors, as well as data management and statistical analysis.

According to the Announcement on Adjusting Evaluation and Approval Procedures for Clinical Trials for Drugs (《關於調整藥物臨床試驗審評審批程序的公告》), where the application for clinical trial of investigational new drug has been approved, upon the completion of Phases I and II clinical trials and prior to Phase III clinical trial, the sponsor shall submit the application for communication meetings to CDE to discuss with CDE the key technical issues including the design of Phase III clinical trial protocol. According to the Administrative Measures for Communication on the Research, Development and Technical Evaluation of Drugs (《藥物研發與技術審評溝通交流管理辦法》), revised by the NMPA on December 10, 2020, during the research and development stage including the review stage of the investigational new drug application, the applicants may propose to have communication meetings with the CDE. The communication meetings can be classified into three types. Type I meetings are intended to address key safety issues in clinical trials of drugs and key technical issues in the research and development of breakthrough therapeutic drugs. Type II meetings are held during the key research and development stages of drugs, mainly including meetings before submitting the clinical trial application, meetings upon the completion of Phase II trials or prior to Phase III trials, meetings before submitting the marketing application for a new drug, and meetings for risk evaluation and mitigation strategies (REMS). Type III meetings refer to other meetings not classified as Type I or Type II.

### *Classification of Chemical Drugs*

According to the Administrative Measures for Drug Registration, the drug registration administration shall be classified into traditional Chinese drugs, chemical drugs and biological products; among them, the registration of chemical drugs shall be classified into innovative chemical drugs, improved new chemical drugs, generic chemical drugs, etc.

Pursuant to the Reform Plan for Registration Classification of Chemical Drugs (《化學藥品註冊分類改革工作方案》) issued by the CFDA on March 4, 2016, new registration of chemical drugs are divided into 5 categories: (i) Class 1: innovative drugs that have not been marketed in the PRC or abroad which shall contain new compounds with clear structure and pharmacological effects and clinical value; (ii) Class 2: improved new drugs that have not been marketed in the PRC or abroad with optimization in structure, dosage form, prescription technology, route of drug administration and indications on the basis of known active ingredients as well as obvious clinical advantages; (iii) Class 3: drugs imitated by domestic applicants which are marketed overseas while originator's drugs are not marketed in the PRC. Such drugs should possess quality and efficacy in line with that of the originator's drugs (i.e. the first drugs approved to be marketed in the PRC or overseas with complete and sufficient safety and efficacy data to serve as the basis for its launch); (iv) Class 4: drugs imitated by domestic applicants while originator's drugs have been marketed in the PRC. The quality and efficacy of such drugs should be consistent with that of the originator's drugs; and (v) Class 5: drugs which have been marketed abroad with the applications to be marketed in the PRC.

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Among them, the reporting procedure for Class 1 and 2 shall comply with those for new drugs and for Class 3 and 4 it shall be in accordance with those for generic drugs, while Class 5 shall be reported pursuant to the procedures for imported drugs.

According to the Registration Classification of Chemical Drugs and the Reporting Information Requirements (《化學藥品註冊分類及申報資料要求》) issued by the NMPA on June 29, 2020 with implementation of the Registration Classification of Chemical Drugs from July 1, 2020, the registration of chemical drugs is classified into innovative drugs, improved new drugs, generic drugs, and chemical drugs marketed abroad only. The Registration Classification of Chemical Drugs and the Reporting Information Requirements reaffirmed the classification principles for chemical drugs set forth by the Reform Plan for Registration Classification of Chemical Drugs (《化學藥品註冊分類改革工作方案》) and made further adjustments to the chemical drugs subclassifications of Class 2 and 5 among which as well as elaboration regarding the quality and efficacy requirements for generic drugs in Class 3 and 4; in addition, it also proposed the registration requirements and reporting information requirements for various types of chemical drugs.

According to the Announcement on Registration Classification of Biological Products and the Requirements for Application Materials (《關於發佈生物製品註冊分類及申報資料要求的通告》) issued by the NMPA on June 29, 2020, which divided biological products into 3 classes, Class I therapeutic biological products or vaccines refer to those have not been marketed in the PRC or abroad. Class II therapeutic biological products or vaccines refer to improved ones which, compared with the existing products marked in the PRC or abroad, could improve the safety, effectiveness and quality controllability, and have obvious advantages. Class III therapeutic biological products or vaccines refer to those have been marketed in the PRC or abroad.

### *New drug application*

Pursuant to Circular 27, upon completion of clinical trials, determination of quality standards, completion of validation of commercial-scale production processes and completion of other related preparation works, the applicant may apply with the NMPA for the marketing authorization. The NMPA then determines whether to approve the application according to applicable laws and regulations. The applicant must obtain the marketing authorization before the drug can be manufactured and sold in the China market. According to Circular 27, the applicants of any of the following drugs can apply for conditional approval of such drugs: (1) drugs which are used for the treatment of severe life-threatening diseases currently lacking effective treatment and the data of clinical trials can confirm their efficacy and forecast their clinical value; (2) drugs which are urgently needed for public health and data of clinical trials can demonstrate their efficacy and forecast their clinical value; and (3) vaccines which are urgently needed to deal with major public health emergencies or other vaccines which the NHC deems to be urgently needed, which benefits are assessed to outweigh the risks.



### ***Marketing Authorization Holder Mechanism***

Pursuant to the Drug Administration Law, China implements the marketing authorization holder mechanism for management of the drug industry. The drug marketing authorization holder refers to an enterprise or a drug research and development institution that has obtained the drug registration certificate. The drug marketing authorization holder shall be responsible for non-clinical research, clinical trials, production and operation, post-marketing research, adverse reaction monitoring, reporting and processing of drugs in accordance with the provisions of the law.

The marketing authorization holders may manufacture drugs by themselves or entrust a pharmaceutical manufacturing enterprise to manufacture drugs. Likewise, they may sell drugs by themselves or entrust a pharmaceutical distribution enterprise to sell drugs. However, marketing authorization holders may not entrust a pharmaceutical manufacturing enterprise to produce blood products, narcotic drugs, psychotropic drugs, medical-use toxic drugs or pharmaceutical precursor chemicals, except as otherwise stipulated by the drug regulatory department under the State Council.

The drug marketing authorization holder shall establish a drug quality assurance system and be equipped with special personnel to take charge of quality management on drugs independently. The drug marketing authorization holder shall regularly review the quality management system of the drug manufacturer and the drug distributor and supervise its continuous quality assurance and control capabilities.

Where the marketing authorization holder is an overseas enterprise, its designated domestic enterprise shall perform the obligations of the marketing authorization holder and jointly assume responsibilities of the marketing authorization holder with the overseas enterprise.

### ***Gathering, Collection and Filing of Human Genetic Resources***

Pursuant to the Service Guide for Administrative Licensing of Gathering, Collection, Deal, Export and Exit Approval of Human Genetic Resources (《人類遺傳資源採集、收集、買賣、出口、出境審批行政許可事項服務指南》) promulgated by the Ministry of Science and Technology in July 2015 and the Notice on the Implementation of the Administrative License for the Gathering, Collection, Deal, Export and Exit of Human Genetic Resources (《關於實施人類遺傳資源採集、收集、買賣、出口、出境行政許可的通知》) promulgated by the Ministry of Science and Technology in August 2015, the gathering and collection of human genetic resources through clinical trials by a foreign-invested sponsor shall be filed for record with the China Human Genetic Resources Management Office through an online system.

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Pursuant to the Regulations on the Management of Human Genetic Resources of the PRC (《中華人民共和國人類遺傳資源管理條例》) promulgated by the State Council in May 2019 and came into effect on July 1, 2019, and amended on March 10, 2024, foreign organizations, individuals and the institutions established or actually controlled thereby shall not collect, preserve China's human genetic resources within the territory of China, nor shall they provide China's human genetic resources out of the country.

On May 26, 2023, the Ministry of Science and Technology promulgated the Implementation Rules for the Administrative Regulation on Human Genetic Resources (《人類遺傳資源管理條例實施細則》), or the Implementation Rules for HGR, which has come into effect on July 1, 2023. The Implementation Rules for HGR further clarify the criteria to constitute a Foreign Entity, which shall include (i) any foreign organization or individual that holds directly or indirectly more than 50% of the shares, equity interests, voting rights, property shares or other interests in the institution, (ii) any foreign organization or individual that is able to dominate or have material effect on the decision-making or management of the institution through its voting right or other interests, although the shares, equity interests, voting rights, property share or other interests it directly or indirectly holds in the institution is less than 50%, (iii) any foreign organization or individual that is able to dominate or have material effect on the decision-making or management of the institution through investment relationship, contract or other arrangement; and (iv) other situations stipulated by laws, regulations and rules.

The Standing Committee of the NPC adopted the Biosecurity Law of the PRC (《中華人民共和國生物安全法》) (the “**Biosecurity Law**”), which issued on October 17, 2020 and last amended on April 26, 2024. The Biosecurity Law establishes an integrated system to regulate biosecurity related activities in China, including the security regulation of human genetic resources and biological resources. The Biosecurity Law for the first time expressly declares that China has sovereignty over its human genetic resources, and further endorses the Regulation on the Management of Human Genetic Resources by recognizing the fundamental regulatory principles and systems established by it over the utilization of Chinese human genetic resources by foreign entities in China. Although the Biosecurity Law does not provide any specific new regulatory requirements for human genetic resources, because it is a law adopted by China's highest legislative authority, it gives China's major regulatory authority of human genetic resources, the NHC, significantly more power and discretion to regulate human genetic resources, and it is expected that the overall regulatory landscape of Chinese human genetic resources will evolve and become even more rigorous and sophisticated. Failure to comply with the requirement under the Biosecurity Law will result in penalties, including fines, suspension of related activities and confiscation of related human genetic resources and gains generated from conducting these activities.

### *Regulations of Biosimilars*

According to the Technical Guideline for the Research, Development and Evaluation Biosimilars (Trial) (《生物類似藥研發與評價技術指導原則(試行)》) (the “**Biosimilar Guidelines**”), biosimilars refer to therapeutic biological products that are similar to approved reference drugs in terms of quality, safety and efficacy. The R&D and marketing of biosimilars need to comply with the relevant regulations of the Drug Administration Law and Circular 27. After completion of pre-clinical studies, the applicant is required to submit an application for a clinical trial, and after receiving the approval to conduct a clinical trial, the applicant should complete the clinical trial in accordance with the clinical trial protocol. The applicant shall submit an application for marketing authorization after completion of the clinical trials and related preparation works.

According to Circular 27, drug registration shall be subject to registration and administration by categories, namely Chinese medicine, chemical medicine and biological products, etc. Biological product registration shall be categorized in accordance with innovative biological products, modified biological products, marketed biological products (including biosimilars), etc. In order to cooperate with the implementation of the Circular 27, the NMPA established the Registration Classification of Biological Products and Requirements for Application Dossiers (《生物製品註冊分類及申報資料要求》), and the Registration Classification of Biological Products part came into effect on July 1, 2020 while the Requirements for Application Dossiers part came into effect on October 1, 2020. According to the Registration Classification of Biological Products and Requirements for Application Dossiers, biosimilars are classified as category 3.3.

According to the Biosimilar Guidelines, biosimilars shall be filed under the application procedures for new drugs. Application dossiers for therapeutic biological products shall be submitted following specific requirements in the Biosimilar Guidelines.

In February 2015, the CFDA released the Biosimilar Guidelines, which outline the regulatory framework for biosimilars in China and provide the basic principles for the evaluation and management of biosimilars. It sets forth the definition of biosimilars and reference drugs, the requirements in relation to the selection of reference drugs, the basic principles for the technical review, the criteria for comparability, and the conditions under which extrapolations of indications would be permissible. According to the Biosimilar Guidelines, R&D of biosimilar drugs is based on comparability studies to prove their similarities with reference drugs, supporting their safety, efficacy and quality control. A biosimilar drug should in principle have the same amino acid sequence as the reference drug, and the R&D and evaluation of biosimilars should be carried out in accordance with basic principles (i.e. comparison principle, stepwise principle, consistency principle and equivalence principle) and should cover pharmaceutical, non-clinical and clinical research and evaluation. For PK comparability studies, equivalence design is usually used to study similarities of absorption/bioavailability. Equivalence thresholds should be set in advance and justified, and elimination characteristics (e.g., clearance rate, elimination half-lives) should be analyzed.

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The Biosimilar Guidelines set out provisions for the extrapolation of indications of biosimilars. When similarities are proved in comparative trials, the indications of biosimilars may be expanded to include other indications of reference drugs. The extrapolated indications shall be those with same pathological mechanisms and/or receptors and the same action mechanisms and targets. In comparative trials, appropriate indications shall be selected, and subsequent evaluation shall be made on the safety and immunogenicity of the extrapolated indications. The extrapolation of indications shall be considered according to product features on a case-by-case basis. However, caution shall be taken in expanding indications for patients with concomitant medication, with different combined diseases or different recommended dosages.

On February 10, 2021, the NMPA issued the Technical Guidelines for Similarity Evaluation and Indication Extrapolation of Biosimilars (《生物類似藥相似性評價和適應症外推技術指導原則》) to further standardize the development and evaluation of biosimilars, which came into effect on the same day. According to the Technical Guidelines for Similarity Evaluation and Indication Extrapolation of Biosimilars, “similarity” refers to a drug candidate that is overall similar to an approved reference drug and does not present clinically meaningful differences in terms of quality, safety and efficacy, and “Indication Extrapolation” refers to that, in respect to a drug candidate that is overall similar to the reference drug, when clinical trials showing that the candidate is clinically similar to the reference drug in at least one indication, it may be possible to extrapolate the scientific arguments for indication related study data and information in support of its use for other indications not directly studied but approved for the reference drug in China. The similarity evaluation of biosimilars should be carried out comprehensively from the perspective of pharmaceutical, non-clinical and clinical studies to determine the overall similarity and should be carried out at different stages of biopharmaceutical development.

### ***Registration of Generic Drugs***

According to the Registration Measures, the applicants which apply for registration of generic drugs shall be manufacturers of the same drugs. The applicant’s drugs shall also be within the manufacturing scope specified in the Drug Manufacturing Certificate. Furthermore, clinical trials are required to be conducted in accordance with the Registration Measures. According to the Circular on Implementation of Notification Management of Bioequivalence Trials of Chemical Drug (《關於化學藥生物等效性試驗實行備案管理的公告》), the management of bioequivalence trials of chemical drug has been changed from examination and approval to notification. With reference to the technical review opinions, the NMPA will either grant a drug registration number or issue a disapproval notice.

Pursuant to the Opinions on Conducting the Consistency Evaluation for the Quality and Efficacy of Generic Drugs issued by the General Office of the State Council (《國務院辦公廳關於開展仿製藥質量和療效一致性評價的意見》) promulgated on February 6, 2016 and the Opinions of Relevant Matters Concerning Implementing the Opinions on Conducting the Consistency Evaluation for the Quality and Efficacy of Generic Drugs issued by the NMPA (《關於落實〈國務院辦公廳關於開展仿製藥質量和療效一致性評價的意見〉的有關事項的意

見》), promulgated on May 25, 2016, generic drugs approved for marketing before the implementation of the new registration classification of chemical drugs, including domestic generic drugs, imported generic drugs and the indigenous varieties of the innovative drugs, shall carry out consistency evaluation. In principle, the consistency evaluation should be completed before the end of 2018 for the generic oral solid preparations approved for sale before October 1, 2007 and listed in the National Essential Drug List (2012 version) (《國家基本藥物目錄(2012年版)》). For any other generic drugs approved for marketing before the implementation of the new registration classification of chemical drugs, after the first drug produced by a pharmaceutical enterprise passes the consistency evaluation, other pharmaceutical enterprises shall complete the consistency evaluation for their identical drugs within three years in principle; no registration will be granted in case of failure to do so as required within the prescribed time limit.

Pursuant to the Circular on Relevant Matters Concerning Consistency Evaluation for Quality and Curative Effect of Generic Drugs (《關於仿製藥質量和療效一致性評價有關事項的公告》) further promulgated by NMPA on December 28, 2018, the time limit for consistency evaluation of the drugs included in the National Essential Drug List (2018 version) (《國家基本藥物目錄(2018年版)》) will no longer be set uniformly. For generic drugs, including essential drug varieties, approved for marketing before the implementation of new registration classification of chemical drugs, after the first drug has passed the consistency evaluation, other drug manufacturers should complete the consistency evaluation for their identical drugs within three years in principle. If it is not completed within the time limit, the enterprise may apply to the local provincial drug regulatory authority for an extension of the evaluation if the drug is deemed to be clinically necessary and in short supply in the market. If the registration is not completed within the extended time limit, it shall not be re-registered.

### **Laws and Regulations on the Manufacturing of Drugs**

#### ***Drug Manufacturing Certificate***

Pursuant to the Drug Administration Law and the Implementing Regulations, a drug manufacturer must obtain a Drug Manufacturing Certificate (藥品生產許可證) from the drug regulatory authority at provincial, autonomous regional or municipal level before it may start manufacturing drugs in the PRC. The Drug Manufacturing Certificate shall indicate the validity period and the scope of production. Each Drug Manufacturing Certificate is valid for a period of five years and the manufacturer is required to apply for renewal of the permit within six months prior to its expiration date.

#### ***Good Manufacturing Practice***

Prior to December 1, 2019, pursuant to the Certification Measures for Good Manufacturing Practice for Drugs (《藥品生產質量管理規範認證管理辦法》) issued by the CFDA in August 2011, when establishing a pharmaceutical manufacturer or a new factory or expanding the production scope, the drug manufacturer is required to submit an application for a good manufacturing practice certification (the “**GMP certification**”) with the drug regulatory

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authority. If the Good Manufacturing Practices (the “GMP”) are satisfied, a GMP certificate will be issued. Pursuant to the Circular on the Relevant Issues Concerning the Implementation of the Drug Administration Law of the PRC (《關於貫徹實施〈中華人民共和國藥品管理法〉有關事項的公告》), promulgated by the NMPA on November 29, 2019, and the Drug Administration Law, since December 1, 2019, the GMP and Good Supply Practice (the “GSP”) certifications have been canceled, applications for GMP and GSP certifications are no longer accepted, and GMP and GSP certificates are no longer issued. The legal representative of and principal person in charge of a drug manufacturer is fully responsible for the drug manufacturing activities of the enterprise.

The drug manufacturer must conduct the manufacturing process in accordance with the Good Manufacturing Practice for Drugs (《藥品生產質量管理規範》) issued by the Ministry of Health in January 2011, which sets forth a set of detailed standard guidelines governing the manufacture of drugs including organization and staff qualifications, production premises and facilities, equipment, hygiene conditions, production management, quality controls, drug supply, raw material management, maintenance of distribution records and management of customer complaints and adverse event reports.

### **Laws and Regulations on Drug Supply**

According to the Drug Administration Law, the operation of drug business, including drug wholesale and drug retail, is prohibited without a Drug Supply Permit. A Drug Supply Permit shall state the validity period and the scope of business and be subject to review and reissuance upon expiry of the validity period.

According to the Measures for the Supervision and Administration of Drug Supply and Usage (《藥品經營和使用質量監督管理辦法》) took into effect on January 1, 2024, a Drug Supply Permit is valid for five years. Each holder of the Drug Supply Permit must apply for an extension of its permit six months prior to expiration.

The Good Supply Practice for Pharmaceutical Products (《藥品經營質量管理規範》) (the “GSP Rules”) was last amended and came into effect on July 13, 2016. The GSP Rules set forth the basic standards in management of drug supply and apply to enterprises engaged in drug supply in the PRC, which require drug suppliers to implement strict controls on its supply of pharmaceutical products, including standards regarding staff qualifications, premises, warehouses, inspection equipment and facilities, management and quality control. Under the Drug Administration Law of the PRC, the GSP certification is no longer required for drug suppliers, but drug suppliers are still required to comply with the GSP Rules.

### ***National Essential Drugs List***

On August 18, 2009, the Ministry of Health (later restructured as the National Health Commission) and eight other state agencies jointly issued the Implementation Opinions on Establishing the National Essential Drugs System (《關於建立國家基本藥物制度的實施意見》), which aims to facilitate the provision of essential medicines to Chinese consumers at



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reasonable prices and ensure equitable public access to drugs listed in the National Essential Drugs List (《國家基本藥物目錄》). The National Essential Drugs List (2018 Edition) (《國家基本藥物目錄(2018年版)》) (the “National Essential Drugs List”) was promulgated by the NHC on September 30, 2018. Under these regulations, all government-funded primary healthcare institutions (primarily including county-level hospitals, county-level traditional Chinese medicine hospitals, township health centers, and community clinics) are required to fully stock and utilize drugs specified in the National Essential Drugs List. Drugs listed in the National Essential Drugs List used by public hospitals must be procured through centralized public bidding mechanisms and are subject to management by the NDRC, the NHC and other government departments.

### ***NRDL***

Pursuant to the Interim Measures for the Administration of Drugs Covered by Basic Medical Insurance (《基本醫療保險用藥管理暫行辦法》) promulgated by the NHSA on July 30, 2020 and effective as of September 1, 2020, the scope of drugs covered under the basic medical insurance system shall be administered through the NRDL.

The National Drug Catalog for Basic Medical Insurance, Work-Related Injury Insurance, and Maternity Insurance (the “NRDL”), jointly issued by the NHSA and the Ministry of Human Resources and Social Security (MOHRSS) on November 27, 2024 and effective as of January 1, 2025, establishes reimbursement standards for drugs under the basic medical insurance, work-related injury insurance, and maternity insurance funds. Local governments are mandated to implement the NRDL strictly and are prohibited from making any modifications to its contents. The NRDL comprises Part A and Part B. Part A drugs are clinically essential medicines characterized by broad clinical applicability, proven therapeutic efficacy, and comparatively lower pricing than alternative drugs in the same therapeutic class. Part B drugs are clinically essential medicines with proven therapeutic efficacy but relatively higher pricing than Part A drugs.

In accordance with the Interim Measures for the Administration of Drugs Covered by Basic Medical Insurance (《基本醫療保險用藥管理暫行辦法》), provincial medical insurance drug catalogs must be formulated by provincial healthcare security authorities. Provincial healthcare security authorities are authorized to include ethnic medicines and medical institution-prepared formulations in the Part B drug list of provincial medical insurance catalogs under applicable regulations.

Eligible drugs in the National Essential Drugs List may be incorporated into the NRDL according to the Interim Measures for the Administration of Basic Medical Insurance Drugs (《基本醫療保險用藥管理暫行辦法》).

### *Drug Purchases by Hospitals*

According to the Opinion on the Guidance of the Reform of Urban Medical and Health Care System (《關於城鎮醫藥衛生體制改革的指導意見》) promulgated and took into effect on February 16, 2000 and the Opinion on the Implementation of Classification Management of Urban Medical Institutions (《關於城鎮醫療機構分類管理的實施意見》) promulgated on July 18, 2000 and became effective from September 1, 2000, a medical institution must be defined as a profit-making or non-profit-making institution at the time when it is established. A non-profit-making medical institution is established to provide services to the general public, with its revenue used for maintaining and developing such institution, while a profit-making medical institution is established by investors for the purpose of investment return. The PRC government does not establish any profit-making medical institutions, while non-government entities may establish profit-making medical institutions. Any non-profit-making medical institutions must implement a collective tender system in respect of any drug purchases and any profit-making medical institutions need not to implement such a system according to PRC law.

According to the Notice on the Trial Implementation of the Centralized Tender with Respect to Drug Purchases by Medical Institutions (《關於印發醫療機構藥品集中招標採購試點工作若干規定的通知》) promulgated and became effective on July 7, 2000, the Notice on the Further Standardizing of the Centralized Tender with respect to Drug Purchases By Medical Institutions (《關於進一步做好醫療機構藥品集中招標採購工作的通知》) promulgated and became effective on August 8, 2001 and the Opinions concerning Further Regulating Purchase of Medicines by Medical Institutions through Centralized Tendering (《關於進一步規範醫療機構藥品集中採購工作的意見》) promulgated and took into effect on January 17, 2009, any non-profit-making medical institutions established and/or controlled by any government at a county level or above must implement the centralized tender system in respect of purchase of any drugs which are contained in the Medicines List for National Basic Medical Insurance and are generally used for clinical purposes and purchased in relatively large amount.

The Circular on the Good Practice of Medical Institutions with respect to Centralized Procurement of Drugs (《醫療機構藥品集中採購工作規範》) promulgated and was effective on July 7, 2010, provides stipulations in detail in respect of the catalog for centralized procurement and methods, procedures, evaluators, expert database construction and management of drugs, further regulating the centralized drug procurement and clarifying the code of conduct on the part of purchasing parties. According to the Good Practice of Medical Institutions with respect to Centralized Procurement of Drugs, any non-profit-making medical institutions established by the government at the county level or above or state-owned enterprises (including stock-holding enterprises) must participate in the centralized procurement of medical institutions. The centralized procurement management authority at provincial (municipal or district) level is responsible for compiling the catalog of drugs for centralized procurement by medical institutions within its own administrative region, and narcotic drugs and first class psychoactive drugs with respect to which the special administration is carried out by the state are not included in such catalog for centralized



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procurement; second class psychoactive drugs, radioactive pharmaceuticals, toxic drugs for medical use, crude drugs, traditional Chinese medicinal materials and traditional Chinese medicine decoction pieces may be excluded from such catalog for centralized procurement.

According to the Guidance Opinion of the General Office of the State Council on the Improvement of the Drug Centralized Procurement Work of Public Hospitals (《國務院辦公廳關於完善公立醫院藥品集中採購工作的指導意見》) promulgated and came into effect on February 9, 2015, the centralized procurement work of public hospitals will be improved through the classification purchase of drugs. All drugs used by public hospitals (with the exception of traditional Chinese medicine decoction pieces) should be procured through a provincial centralized pharmaceutical procurement platform. The provincial procurement agency should work out a summary of the procurement plans and budget submitted by hospitals and compile reasonably a drug procurement catalog of the hospitals with its own administration region, listing by classification the drugs to be procured through bids, negotiations, direct purchases by hospitals or to be manufactured by appointed manufacturers.

### *VBP of Drugs in “4+7 Cities” and Nationwide*

On November 15, 2018, the Joint Procurement Office, formed by representatives from pilot regions for the national VBP of drugs (comprising Beijing, Tianjin, Shanghai, Chongqing, and 11 other cities including Shenyang, Dalian, Xiamen, Guangzhou, Shenzhen, Chengdu, and Xi'an (“4+7 Cities”)), issued the 4+7 Cities VBP Document (《4+7城市藥品集中採購文件》). This document initiated a pilot program for nationwide volume-based drug procurement with minimum purchase quantities within the 4+7 Cities.

On January 1, 2019, the General Office of the State Council issued the Notice of the General Office of the State Council on Printing and Distributing the National VBP and Use Pilot Program (《國務院辦公廳關於印發國家組織藥品集中採購和使用試點方案的通知》), which set out detailed measures for implementing the nationwide VBP pilot program with minimum purchase quantities in the 4+7 Cities. In principle, the pilot program for VBP and use shall select pilot drugs from generic drugs that have passed consistency evaluation under their respective generic names.

The procurement procedure varies depending on the number of manufacturers meeting the qualification criteria for each drug: for drugs with three or more qualified manufacturers, a bidding process is adopted; for drugs with two qualified manufacturers, a price negotiation process is used; and for drugs with only one qualified manufacturer, a negotiation-based procurement method is applied.

According to the Implementation Opinions on Expanding the Regional Scope of the National VBP and Use Pilot Program (《關於國家組織藥品集中採購和使用試點擴大區域範圍的實施意見》), issued and effective on September 25, 2019, the VBP program was expanded nationwide. The nationwide VBP program allows all pharmaceutical manufacturers, exclusive import agents, and marketing authorization holders with eligible drugs under the procurement program to participate.

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The Notice on Carrying Out the Second Batch of National VBP and Use Work (《關於開展第二批國家組織藥品集中採購和使用工作的通知》), which came into effect on January 13, 2020, established several principles for implementing the national VBP program to deepen reform and build a standardized, routine drug procurement plan nationwide.

On January 22, 2021, the General Office of the State Council issued the Opinions on Promoting the Normalization and Institutionalization of the VBP of Drugs (《關於推動藥品集中帶量採購工作常態化制度化開展的意見》), the “Normalization Opinions”, which stated that various measures would be adopted to promote the normalization and institutionalization of nationwide VBP. All public medical institutions are required to participate in the VBP program. The procurement program will focus on drugs with high demand and high procurement costs in the National Essential Medicines List, gradually covering clinically necessary, reliable-quality drugs available on the domestic market. Future procurement lists are expected to include widely demanded or high-priced drugs in the National Medical Insurance List, aiming to encompass as many clinically necessary, high-quality drugs as possible.

According to the Normalization Opinions, VBP is to be carried out in a tiered manner. The state will organize centralized VBP for certain drugs that have passed consistency evaluation and conduct special procurement based on market conditions while guiding local authorities in their procurement efforts. Provincial-level regions (provinces, autonomous regions, and municipalities) are responsible for independently conducting or forming alliances with other provinces for centralized VBP of drugs not included in the national procurement scope. They are also tasked with guiding eligible prefecture-level regions to conduct procurement. Prefecture-level regions are expected to independently or collaboratively conduct VBP for drugs not covered by upper-level organizations, according to their provincial arrangements. For drugs not yet included in the government-organized VBP scope, medical institutions may independently or delegate procurement via the provincial-level drug procurement platform.

The table below sets forth the key differences between national and provincial VBP schemes:

	National VBP scheme	Provincial VBP scheme
<b>Issuing authority</b> . . . . .	Issued by the National Healthcare Security Administration (國家醫療保障局), with policies and standards set uniformly at the national level.	Issued by individual provincial healthcare security bureaus or regional alliances, with policies tailored to local circumstances.
<b>Geographical coverage</b> . . . . .	Nationwide coverage, integrating procurement resources across the country with uniform standards.	Limited to single provinces or regional alliances, allowing for flexibility to address local needs.

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	National VBP scheme	Provincial VBP scheme
<b>Procuring institution</b> . . . . .	Primarily involves public medical institutions operating through a centralized platform for large-scale negotiations.	Also primarily involves public medical institutions; however, the procurement scale is smaller and more focused on local demand.
<b>Drug category</b> . . . . .	Prioritizes high-demand, high-value medicines included in the NRDL, and is progressively extended to include clinically essential, reliably manufactured medicines available on the domestic market. Preference is given to generic drugs, including both chemically synthesized generics and biosimilars.	Serves as a supplement to the national scheme, covering drugs that have not yet been included in the national VBP scheme or drugs requiring re-procurement after national VBP scheme expire.
<b>Impact on drug price</b> . . . . .	Due to larger purchasing volumes and more competitive negotiations, it generally achieves a more significant price reduction effect.	With relatively limited market scale and negotiating power, the price reduction effect is generally more moderate.
<b>Other characteristics</b> . . . . .	Facilitates nationwide unified pricing, enhances resource integration, and strengthens overall market competitiveness.	Provides flexibility in adjusting procurement strategies and standards according to local conditions and needs.

### *Drug Price*

On May 4, 2015, the NDRC, the National Health and Family Planning Commission, the Ministry of Human Resources and Social Security, the Ministry of Industry and Information Technology of the PRC, the Ministry of Finance, the MOFCOM and the NMPA issued the Opinion on Furthering Pharmaceutical Price Reform (《推進藥品價格改革的意見》) (the “Price Reform Opinion”) and the Notice on Issuing the Opinion on Furthering Pharmaceutical Price Reform (《關於印發推進藥品價格改革意見的通知》) (the “Price Reform Notice”). Pursuant to the Price Reform Notice, government price controls on pharmaceutical products (other than narcotic drugs and psychiatric drugs of category I) has been lifted on June 1, 2015. According to the Price Reform Opinion, after price controls are lifted, prices of pharmaceutical products will be mainly determined by market competition. Instead of direct price controls, the

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government will regulate prices mainly by establishing a consolidated procurement mechanism, revising medical insurance reimbursement standards and strengthening regulation of medical and pricing practices.

On 26 November 2019, the NHSA issued the Opinions on Effectively Managing Current Drug Prices, confirming that, except for narcotic drugs and psychiatric drugs of category I which are subject to government-guided pricing, all other drugs are subject to market-regulated pricing.

In addition, as for the drug prices at which pharmaceutical manufacturers sell to the public hospitals, according to the specific documents formulated by the provincial medical insurance department or health department in accordance with policies and guidelines issued by NHSA, unless otherwise expressly provided by the laws and regulations, all drugs used by public hospitals (with the exception of traditional Chinese medicine decoction pieces) should be procured via the centralized drug procurement platforms/the public procurement platforms established by provincial-level healthcare security administrations (collectively, the “government’s platforms”).

Relevant pharmaceutical manufacturers are required to declare their products on government’s platforms in accordance with relevant laws and regulations before they are allowed to sell their drugs to public medical institutions. For the drugs that are selected in the centralized tender process and VBP schemes, their prices on the government’s platforms are the selected prices displayed on the relevant government’s platform. As for other non-centralized procurement drugs, the drug prices on the government’s platforms are those declared by relevant pharmaceutical manufacturers and officially vetted by the competent authorities, with such prices being subject to routine monitoring by the provincial healthcare security administration. The relevant policies of the above government’s platforms are implemented and refined by the provincial-level healthcare security administrations.

### *Two-invoice System*

In order to further optimize the order of purchasing and selling pharmaceutical products and reduce circulation steps, as required at the executive meeting of the State Council dated April 6, 2016 and under the 2016 List of Major Tasks in Furtherance of the Healthcare and Pharmaceutical Reforms (《深化醫衛生體制改革2016年重點工作任務》) issued by the General Office of the State Council on April 21, 2016, the “two-invoice System” (兩票制) will be fully implemented in the PRC. According to the Circular on Issuing the Implementing Opinions on Carrying out the Two-invoice System for Drug Procurement among Public Medical Institutions (for Trial Implementation) 《印發<關於在公立醫療機構藥品採購中推行“兩票制”的實施意見(試行)>的通知》) (the “**Circular**”), which was effective from December 26, 2016, the two-invoice system means one invoice between the pharmaceutical manufacturer and the pharmaceutical distributor, and one invoice between the pharmaceutical distributor and the hospital, and thereby only allows a single level of distributor for the sale of pharmaceutical products from the pharmaceutical manufacturer to the hospital. According to the Circular, two-invoice system will be promoted in pilot provinces (autonomous regions and

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municipalities directly under the Central Government) involved in the comprehensive medical reform program and pilot cities for public hospital reform on a priority basis, while other regions are encouraged to implement such system, so that such system can be promoted in full swing nationwide in 2018.

### *Import and Export of Goods*

Pursuant to the Provisions of the PRC for the Administration of Filing of Customs Declaration Entities (《中華人民共和國海關報關單位備案管理規定》) promulgated by the General Administration of Customs on November 19, 2021 and became effective on January 1, 2022, customs declaration entities refer to consignees or consignors of imported or exported goods or customs declaration enterprises that have filed for record with Customs in accordance with the Provisions. Consignors or consignees of imported or exported goods or customs declaration enterprises that apply for record-filing shall obtain market entity qualifications.

Pursuant to the Regulation of the People's Republic of China on the Administration of the Import and Export of Goods (《中華人民共和國貨物進出口管理條例》) (hereinafter referred to as the “**Regulation on the Administration of the Import and Export of Goods**”) promulgated by the State Council on December 10, 2001 and last amended on May 1, 2004, enterprises engaged in the import of goods to the customs territory of the People's Republic of China or export of goods from the customs territory of the People's Republic of China, shall comply with the Regulation on the Administration of the Import and Export of Goods. For goods that are prohibited from importation or exportation, they cannot be imported or exported; for goods that are subject to import or export restrictions, a license or quota management system shall be implemented; for goods that are freely imported or exported, there is no restriction. The import and export business operator shall present the automatic import and export licenses, import and export license or the quotas certificate issued by the administrative departments of import quotas to the customs offices for handling the formalities of customs declaration and examination.

### *Import and Export of Special Articles*

Pursuant to the Administrative Provisions on the Sanitation and Quarantine of Entry/Exit Special Articles (《出入境特殊物品衛生檢疫管理規定》) (Order No. 160 of the General Administration of Quality Supervision, Inspection and Quarantine, effective on March 1, 2015 and amended on October 18, 2016, April 28, 2018, May 29, 2018 and November 23, 2018 respectively), the import or export of special articles, including micro-organisms, human tissues, biological products, blood and blood products shall be subject to the supervision and administration over health quarantine. The customs office is responsible for the health quarantine and approval of import and export of special articles in its relevant jurisdictions. The enterprise conducting import or export of special articles shall establish safety management system for special articles, and shall produce, use or sell the special articles in strict accordance with the purposes for the approval of such special articles.

### *Export of Drugs*

Pursuant to the Reply by NMPA on Certain Issues of Pharmaceutical Products Export (《國家藥品監督管理局關於藥品出口有關問題的批覆》), both promulgated on and effective from September 20, 1999, enterprise's right to operate import and export of pharmaceutical products and the qualification shall be decided by the foreign trade authority. Export of pharmaceutical products shall mainly comply with the requirements of the importing country, so long as there is no special requirement by the importation country, the NMPA would support the export in principle based on the national policy of encouraging exports. However, pursuant to the PRC Drug Administration Law, the export license issued by NMPA is required for the export of narcotics and psychotropic drugs prescribed by the PRC.

### *Product Liability*

The Product Quality Law of the PRC (《中華人民共和國產品質量法》) (the “**Product Quality Law**”), promulgated by the Standing Committee of the NPC on February 22, 1993 and latest amended on December 29, 2018, is the principal governing law relating to the supervision and administration of product quality. According to the Product Quality Law, manufacturers shall be liable for the quality of products produced by them, and sellers shall take measures to ensure the quality of the products sold by them. A manufacturer shall be liable for compensating for any bodily injuries or property damages, other than the defective product itself, resulting from the defects in the product, unless the manufacturer is able to prove that (1) the product has never been distributed; (2) the defects causing injuries or damages did not exist at the time when the product was distributed; or (3) the science and technology at the time when the product was distributed was at a level incapable of detecting the defects. A seller shall be liable for compensating for any bodily injuries or property damages of others caused by the defects in the product if such defects are attributable to the seller. A seller shall pay compensation if it fails to indicate either the manufacturer or the supplier of the defective product. A person who is injured or whose property is damaged by the defects in the product may claim for compensation from the manufacturer or the seller.

On May 28, 2020, the Civil Code of the PRC (《中華人民共和國民法典》) was adopted by the third session of the 13th NPC, which came into effect on January 1, 2021. According to the Civil Code of the PRC, a patient may make a claim against the drug marketing authorization holder, a medical institution or producer for any damage arising from defects of drugs.

The Law of the PRC on the Protection of the Rights and Interests of Consumers (《中華人民共和國消費者權益保護法》) was promulgated on October 31, 1993 and was amended on August 27, 2009 and October 25, 2013 to protect consumers' rights when they purchase or use goods and accept services. All business operators must comply with this law when they manufacture or sell goods and/or provide services to customers. Where the goods or services provided by a business operator do not satisfy quality requirements, the consumer may require the business operator to perform replacement or repair obligations.



### *Drug Advertisement*

Pursuant to the Advertisement Law of the PRC (《中華人民共和國廣告法》), which was promulgated by Standing Committee of the NPC on October 27, 1994 and effective from February 1, 1995 and latest amended and effective from April 29, 2021, advertisements shall not contain false statements or be deceitful or misleading to consumers. Advertisements relating to pharmaceuticals and medical devices, shall be reviewed by relevant authorities in accordance with applicable rules before being distributed by broadcasting, movies, television, newspapers, journals or otherwise. The Advertisement further stipulates that advertisements for medical treatment, pharmaceutical products or medical devices shall not contain: (i) any assertion or guarantee for efficacy and safety; (ii) any statement on cure rate or effectiveness rate; (iii) any comparison with the efficacy and safety of other pharmaceutical products or medical devices or with other healthcare institutions; (iv) recommendation or endorsement of an advertising endorser; or (v) other items as prohibited by laws and regulations.

Pursuant to the Interim Measures for the Administration of Internet Advertisement (《互聯網廣告管理暫行辦法》) which was promulgated by the State Administration of Industry and Commerce on July 4, 2016 and became effective as of September 1, 2016, the Internet advertisement must be visibly marked as “advertisement”. Advertisements for special commodities or services such as medical treatment, pharmaceuticals, foods for special medical purposes, medical instruments, agrochemicals, veterinary medicines and other health foods must be reviewed by competent authorities before online publication. On February 25, 2023, the SAMR promulgated the Measures for Administration of Internet Advertising (《互聯網廣告管理辦法》) (the “**Internet Advertising Measures**”), which replaced the Interim Measures for the Administration of Internet Advertisement, and came into effect as of 1 May 2023. Pursuant to the Internet Advertising Measures, Internet advertisers are prohibited from publishing advertisements of prescription drugs on the Internet. Besides, Internet advertisers are prohibited from publishing advertisements for medical treatment, drugs, medical devices, health food and formula food for special medical purposes in disguised form by way of introducing knowledge on health or health maintenance. When introducing knowledge on health or health maintenance, the address, contact information, shopping links and other contents of sellers or service providers of relevant medical treatment, drugs, medical devices, health food, or formula food for special medical purposes shall not be presented on the same page or together with other contents.

Pursuant to the Measures for Administration of Medical Advertisement (《醫療廣告管理辦法》), which were jointly promulgated by the SAIC and the Ministry of Health on November 10, 2006 and effective on January 1, 2007, medical advertisements shall be reviewed by relevant health authorities and obtain a Medical Advertisement Examination Certificate before being released. Medical Advertisement Examination Certificate is valid for one year and maybe renewed upon application.

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Pursuant to the Interim Measures for the Administration of Censorship of Advertisements on Drugs, Medical Devices, Dietary Supplements and Formula Foods for Special Medical Purposes (《藥品、醫療器械、保健食品、特殊醫學用途配方食品廣告審查管理暫行辦法》) which were promulgated by the SAMR on December 24, 2019 and became effective from March 1, 2020, for medical devices advertisement to be released and published, a manufacturer of medical devices shall obtain an approval from the NMPA at provincial level. In addition, the content of advertisements for medical devices is subject to certain guidelines as approved by the NMPA or its local counterparts at provincial level.

Pursuant to the Measures Regarding the Administration of Drug Information Service through the Internet (《互聯網藥品信息服務管理辦法》), which was promulgated by the CFDA and effective from July 8, 2004, and amended and effective from November 17, 2017, the Internet drug information services, referring to that of providing medical information (including medical devices information) services to Internet users through the Internet, are classified into two categories, namely, profit-making services and non-profit services. Any website intending to provide drug information services through Internet shall be approved by NMPA at provincial level before applying for an operation permit or record-filing from the authority in charge of information industry under the State Council or the administration of telecommunication at the provincial level.

### **Laws and Regulations on Intellectual Properties**

#### ***Patent***

Patents in the PRC are mainly protected by the Patent Law of the PRC (《中華人民共和國專利法》), which was promulgated by the SCNPC on March 12, 1984, last amended on October 17, 2020 and became effective on June 1, 2021, and the Implementation Rules of the Patent Law of the PRC (《中華人民共和國專利法實施細則》), which were promulgated by the State Council on June 15, 2001 and last amended on December 11, 2023. The Patent Law of the PRC and its Implementation Rules provide for three types of patents, “invention”, “utility model” and “design.” “Invention” refers to any new technical solution relating to a product, a process or improvement thereof; “utility model” refers to any new technical solution relating to the shape, structure, or their combination, of a product, which is suitable for practical use; and “design” refers to a new design of the shape, pattern, or a combination thereof, as well as a combination of the color, shape and pattern, of the entirety or a portion of a product, which creates an aesthetic feeling and is fit for industrial application. The duration of a patent right for “invention” is twenty years, the duration of a patent right for “utility model” is ten years, and the duration of a patent right for “design” is fifteen years, from the date of application. For the purpose of making up the time required for the assessment and approval of the marketing of a new drug, the patent administrative department of the State Council may, at the request of the patentee, provide patent term extension for an invention patent relating to the new drug approved for marketing in China. The extension may not exceed five years, and the total effective term of the patent after the new drug is approved for marketing shall not exceed 14 years. According to the Patent Law of the PRC, for the purpose of public health, the patent



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administrative department of the State Council may grant mandatory licensing to manufacture and export patented drugs to countries or regions in comply with provisions of the relevant international treaty participated by the PRC.

### *Trade Secret*

According to the Anti-Unfair Competition Law of the PRC (《中華人民共和國反不正當競爭法》), promulgated by the SCNPC in September 1993 and last amended on April 23, 2019, the term “trade secrets” refers to technical and business information that is unknown to the public, has utility, may create business interests or profits for its legal owners or holders, and is maintained as a secret by its legal owners or holders. Under the Anti-Unfair Competition Law of the PRC, business persons are prohibited from infringing others’ trade secrets by: (1) acquiring a trade secret from the right holder by theft, bribery, fraud, coercion, electronic intrusion, or any other means; (2) disclosing, using, or allowing another person to use a trade secret acquired from the right holder by any means as specified in the item (1) above; (3) disclosing, using, or allowing another person use a trade secret in its possession, in violation of its confidentiality obligation or the requirements of the right holder for keeping the trade secret confidential; (4) abetting a person, or tempting another person into or in acquiring, disclosing, using, or allowing another person to use the trade secret of the right holder in violation of his or her non-disclosure obligation or the requirements of the right holder for keeping the trade secret confidential. If a third party knows or should have known of the above-mentioned illegal conduct but nevertheless obtains, uses or discloses trade secrets of others, the third party may be deemed to have committed a misappropriation of the others’ trade secrets. The parties whose trade secrets are being misappropriated may petition for administrative corrections, and regulatory authorities may stop any illegal activities and impose fines on the infringing parties.

### *Trademark*

Pursuant to the Trademark Law of the PRC (《中華人民共和國商標法》) promulgated by the SCNPC on August 23, 1982, last amended on April 23, 2019 and became effective on November 1, 2019, the period of validity for a registered trademark is ten years, commencing from the date of registration. Upon expiry of the period of validity, the registrant shall go through the formalities for renewal within twelve months prior to the date of expiry as required if the registrant needs to continue to use the trademark. Where the registrant fails to do so, a grace period of six months may be granted. The period of validity for each renewal of registration is ten years, commencing from the day immediately after the expiry of the preceding period of validity for the trademark. In the absence of a renewal upon expiry, the registered trademark shall be canceled. Industrial and commercial administrative authorities have the authority to investigate any behavior in infringement of the exclusive right under a registered trademark in accordance with the law. In case of a suspected criminal offense, the case shall be timely referred to a judicial authority and decided in accordance with applicable laws.

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### ***Copyright***

Copyright in the PRC is primarily protected by the Copyright Law of the PRC (《中華人民共和國著作權法》), which was promulgated by the SCNPC on September 7, 1990, last amended on November 11, 2020 and became effective on June 1, 2021, and Implementation Regulations of the Copyright Law of PRC (《中華人民共和國著作權法實施條例》), which was promulgated by the State Council on August 2, 2002 and last amended on January 30, 2013. These laws and regulations provide provisions on the classification of works and the obtaining and protection of copyright.

### ***Domain Names***

In accordance with the Measures for the Administration of Internet Domain Names (《互聯網域名管理辦法》) which was issued by the Ministry of Information Industry on August 24, 2017 and came into effect on November 1, 2017, the MIIT is responsible for supervision and administration of domain name services in the PRC. Communications administrative bureaus at provincial levels shall conduct supervision and administration of the domain name services within their respective administrative jurisdictions. Domain name registration services shall, in principle, be subject to the principle of “first apply, first register.” A domain name registrar shall, in the process of providing domain name registration services, ask the applicant for which the registration is made to provide authentic, accurate and complete identity information on the holder of the domain name and other domain name registration related information.

### **Laws and Regulations on Labor and Employee Incentives**

#### ***Labor, Social Insurance and Housing Provident Funds***

According to the Labor Law of the PRC (《中華人民共和國勞動法》), which was promulgated by the SCNPC in July 1994 and last amended and came into effect in December 2018, the Labor Contract Law of the PRC (《中華人民共和國勞動合同法》), which was promulgated by the SCNPC in June 2007 and amended in December 2012 and came into effect in July 2013, and the Implementing Regulations of the Labor Contracts Law of the PRC (《中華人民共和國勞動合同法實施條例》), which was promulgated by the State Council and came into effect in September 2008, labor contracts in written form shall be executed to establish labor relationships between employers and employees. In addition, wages shall not be lower than local minimum wages. The employers must establish a system for labor safety and sanitation, strictly comply with national rules and standards, provide education regarding labor safety and sanitation to its employees, provide employees with labor safety and sanitation conditions and necessary protection materials in compliance with national rules, and carry out regular health examinations for employees engaged at work involving occupational hazards.

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According to the Social Insurance Law of PRC (《中華人民共和國社會保險法》), which was promulgated by the SCNPC in October 2010 and last amended and came into effect in December 2018, and the Interim Regulations on the Collection and Payment of Social Security Funds (《社會保險費徵繳暫行條例》), which was promulgated by the State Council in January 1999 and last amended in March 2019, and the Regulations on the Administration of Housing Provident Funds (《住房公積金管理條例》), which was promulgated by the State Council in April 1999 and last amended in March 2019, employers are required to contribute, on behalf of their employees, to a number of social security funds, including funds for basic pension insurance, unemployment insurance, basic medical insurance, occupational injury insurance and maternity insurance and to housing provident funds. Any employer who fails to make the required contributions may be fined and ordered to compensate the deficit within a stipulated time limit.

The Prevention and Control of Occupational Diseases Law of the PRC (《中華人民共和國職業病防治法》), which was promulgated by the SCNPC on October 27, 2001 and latest amended on December 29, 2018 (the “**Prevention and Control of Occupational Diseases Law**”), is the basic law for the prevention and control of occupational diseases. According to the Prevention and Control of Occupational Diseases Law, budget for facilities for the prevention and control of occupational diseases of a construction project shall be included in the budget of the project and those facilities shall be designed, constructed and put into operation simultaneously with the main body of the project. The entity that takes charge of the project should carry out the assessment of the effectiveness of measures for the prevention and control of occupational diseases before the final acceptance of the construction project. In addition, employers shall take required administrative measures to prevent and control occupational diseases in work.

### **Laws and Regulations on Environmental Protection**

#### ***Environment Protection***

The Environmental Protection Law of the PRC (《中華人民共和國環境保護法》) (“**the Environmental Protection Law**”), which was promulgated by the SCNPC on December 26, 1989, came into effect on the same day and last amended on April 24, 2014, outlines the authorities and duties of various environmental protection regulatory agencies. The Ministry of Ecology and Environment is authorized to issue national standards for environmental quality and emissions, and to monitor the environmental protection scheme of the PRC. Meanwhile, local environment protection authorities may formulate local standards which are more rigorous than the national standards, in which case, the concerned enterprises must comply with both the national standards and the local standards.

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### *Environmental Impact Appraisal*

According to the Administration Rules on Environmental Protection of Construction Projects (《建設項目環境保護管理條例》), which was promulgated by the State Council on November 29, 1998, amended on July 16, 2017 and became effective on October 1, 2017, depending on the impact of the construction project on the environment, a construction employer shall submit an environmental impact report or an environmental impact statement, or file a registration form. As to a construction project, for which an environmental impact report or the environmental impact statement is required, the construction employer shall, before the commencement of construction, submit the environmental impact report or the environmental impact statement to the relevant authority at the environmental protection administrative department for approval. If the environmental impact assessment documents of the construction project have not been examined or approved upon examination by the approval authority in accordance with the law, the construction employer shall not commence the construction. According to the Environmental Impact Appraisal Law of PRC (《中華人民共和國環境影響評價法》) (the “**Environmental Impact Appraisal Law**”), which was promulgated by the SCNPC on October 28, 2002, amended on July 2, 2016 and December 29, 2018, for any construction projects that have an impact on the environment, an entity is required to produce either a report, or a statement, or a registration form of such environmental impacts depending on the seriousness of effect that may be exerted on the environment.

### *Management of Waste Discharge*

Pursuant to the Catalog of Classified Management of Pollutant Discharge Permits for Stationary Pollution Sources (2019 Version) (《固定污染源排污許可分類管理名錄(2019年版)》) issued by the Ministry of Ecology and Environment of the PRC and became effective on December 20, 2019, the State implements the primary management, simplified management and registration management of pollutant discharge permits based on the pollutant production, emission amount and the extent of environmental impact of the pollutant discharge entities. A pollutant discharge unit under registration management does not need to apply for a pollutant discharge license.

Pursuant to the Regulations on the Administration of Pollutant Discharge Permits (《排污許可管理條例》) promulgated by the State Council on January 24, 2021 and became effective on March 1, 2021, based on the quantity of pollutants generated and discharged, their impacts on the environment and other factors, categorical administration of pollutant discharge permit system is implemented to regulate pollutant-discharging entities: (1) key administration of pollutant discharge permits shall be implemented for pollutant discharging entities which generate and discharge relatively large quantities of pollutants or have a relatively serious impact on the environment; and (2) administration of pollutant discharge permits shall be simplified for pollutant-discharging entities which generate and discharge relatively small quantities of pollutants and have a relatively small impact on the environment. The entities that generate and discharge relatively small quantities of pollutants and have a relatively small impact on the environment shall fill in the waste discharge registration form (排污登記表) and are no longer required to obtain a waste discharge license (排污許可證). Entity that is required

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to fill in the waste discharge registration form shall report the basic information, waste discharge destination, waste discharge standards implemented, waste prevention and control measures adopted and other information to the national waste discharge license information platform. If the information reported is changed, it shall be changed in the platform within 20 days as of the date when such change occurs.

### **Regulations on Information Security and Data Privacy**

#### ***Data security and data export***

The NPCSC promulgated the Data Security Law of the People's Republic of China (《中華人民共和國數據安全法》), on June 10, 2021 (effective from September 1, 2021), for the establishment of a data classification and grading protection system to conduct classified and hierarchical protection of data. Entities engaged in data processing activities shall, in accordance with laws and regulations, establish a sound full-process data security management system, organize data security education and training, and take corresponding technical measures and other necessary measures to ensure data security. According to the Measures on Security Assessment of Cross-border Data Transfer (《數據出境安全評估辦法》) issued by the Cyberspace Administration of China on July 7, 2022 and effective on September 1, 2022, a data processor that provides data overseas under any of the following circumstances shall apply to the national cyberspace administration for the security assessment of the outbound data transfer through local provincial cyberspace administration: (I) a data processor provides important data abroad; (II) the critical information infrastructure operator or the data processor that has processed the personal information of more than 1 million people provides personal information abroad; (III) the data processor that has provided the personal information of over 100,000 people or the sensitive personal information of over 10,000 people cumulatively since January 1 of the previous year provides personal information abroad.; and (IV) any other circumstance where an application for the security assessment of outbound data transfer is required by the national cyberspace administration.

According to the Measures for Standard Contract for Outbound Transfer of Personal Information (《個人信息出境標準合同辦法》) issued by the Cyberspace Administration of China on February 22, 2023 and effective from June 1, 2023, to provide personal information to an overseas recipient through the conclusion of the standard contract, a personal information processor shall meet all of the following circumstances: (I) it is not a critical information infrastructure operator; (II) it has processed the personal information of less than one million individuals; (III) it has cumulatively provided the personal information of less than 100,000 individuals to overseas recipients since January 1 of the previous year; and (IV) it has cumulatively provided the sensitive personal information of less than 10,000 individuals since January 1 of the previous year. In addition, the Measures for Standard Contract for Outbound Transfer of Personal Information require that all Outbound Transfers of personal information that have been carried out before June 1, 2023 and do not comply with the provisions of the Measures for Standard Contract for Outbound Transfer of Personal Information be rectified within 6 months.

### *Personal information protection*

According to the Civil Code of the PRC, personal information of natural persons is protected by law. If any organization or individual needs to obtain other people's personal information, they should obtain it in accordance with the law and ensure the security of the information. They must not illegally collect, use, process, or transmit other people's personal information, and must not illegally buy, sell, provide, or disclose the information. The Personal Information Protection Law of the People's Republic of China (《中華人民共和國個人信息保護法》) promulgated by the NPCSC on August 20, 2021 and implemented on November 1, 2021, further emphasizes the obligations and responsibilities of processors for the protection of personal information, and requests higher level of protective measures on the processing of sensitive personal information. According to the Cybersecurity Law of the People's Republic of China (《中華人民共和國網絡安全法》) promulgated by the NPCSC on November 7, 2016 and effective on June 1, 2017, network operators must follow the principles of legality, legitimacy and necessity when collecting and using personal information, and publicly disclose the rules for collection and use, clearly state the purpose, method and scope of collecting and using information, and obtain the consent of the person whose data is being collected. Network operators shall not collect personal information unrelated to the services they provide. Network operators are not allowed to leak, tamper with, or damage the personal information they collect; they are not allowed to provide personal information to others without the consent of the person whose data is being collected. However, this does not apply to cases where a specific individual cannot be identified and the identity cannot be recovered after processing. Network operators should take technical measures and other necessary measures to ensure the security of the personal information they collect and prevent leakage, damage and loss of information.

NHC released the Administrative Measures on the Standards, Security and Service of National Health and Medical Big Data (Trial) (《國家健康醫療大數據標準、安全和服務管理辦法(試行)》) on July 12, 2018 (hereinafter referred to as the “**Health and Medical Big Data Measures**”). The Health and Medical Big Data Measures stipulate the guidelines and principles for standard management, security management and service management of health and medical big data. According to the Health and Medical Big Data Measures, medical and health institutions at all levels and related enterprises and institutions should adopt data classification, important data backup, encryption authentication and other measures to ensure the security of health and medical big data. Health and medical big data should be used in accordance with laws and regulations. Data-related information should provide secure information query and copy channels to ensure privacy protection and data security; data access and use permissions of users at different levels should be strictly regulated to ensure that data is used within the scope of authorization. No unit or individual may use or publish health and medical big data without authorization or beyond the scope of authorization, and it is prohibited to obtain data through illegal means. When various types of medical and health institutions at all levels and related service institutions disclose health and medical big data to the public, they must abide by relevant national regulations and must not disclose state secrets, business secrets and personal data, and must not infringe on national interests, public interests and legitimate rights and interests of citizens, legal persons and other organizations.



### Laws and Regulations on Foreign Exchange and Taxation

#### *Foreign Exchange*

On January 29, 1996, the State Council promulgated the Administrative Regulations on Foreign Exchange of the PRC (《中華人民共和國外匯管理條例》) which became effective on April 1, 1996 and was amended on January 14, 1997 and August 5, 2008. Foreign exchange payments under current account items shall, pursuant to the administrative provisions of the foreign exchange control department of the State Council on payments of foreign currencies and purchase of foreign currencies, be made using self-owned foreign currency or foreign currency purchased from financial institutions engaging in conversion and sale of foreign currencies by presenting the valid document. Domestic entities and domestic individuals making overseas direct investments or engaging in issuance and trading of overseas securities and derivatives shall process registration formalities pursuant to the provisions of the foreign exchange control department of the State Council.

On November 19, 2012, the SAFE issued the Circular of Further Improving and Adjusting Foreign Exchange Administration Policies on Foreign Direct Investment (《國家外匯管理局關於進一步改進和調整直接投資外匯管理政策的通知》) (the “**SAFE Circular 59**”), which came into effect on December 17, 2012 and was revised on May 4, 2015, October 10, 2018 and partially abolished on December 30, 2019. The SAFE Circular 59 aims to simplify the foreign exchange procedure and promote the facilitation of investment and trade. According to the SAFE Circular 59, the opening of various special purpose foreign exchange accounts, such as pre-establishment expenses accounts, foreign exchange capital accounts and guarantee accounts, the reinvestment of RMB proceeds derived by foreign investors in the PRC, and remittance of foreign exchange profits and dividends by a foreign-invested enterprise to its foreign shareholders no longer require the approval or verification of SAFE, as well multiple capital accounts for the same entity may be opened in different provinces. Later, the SAFE promulgated the Circular on Further Simplifying and Improving Foreign Exchange Administration Policies in Respect of Direct Investment (《關於進一步簡化和改進直接投資外匯管理政策的通知》) on February 13, 2015, which was partially abolished on December 30, 2019 and prescribed that the bank instead of SAFE can directly handle the foreign exchange registration and approval under foreign direct investment while SAFE and its branches indirectly supervise the foreign exchange registration and approval under foreign direct investment through the bank.

On May 11, 2013, the SAFE issued the Administrative Provisions on Foreign Exchange in Domestic Direct Investment by Foreign Investors (《外國投資者境內直接投資外匯管理規定》) (the “**SAFE Circular 21**”), which became effective on May 13, 2013, amended on October 10, 2018 and partially abolished on December 30, 2019. The SAFE Circular 21 specifies that the administration by SAFE or its local branches over direct investment by foreign investors in the PRC must be conducted by way of registration and banks must process foreign exchange business relating to the direct investment in the PRC based on the registration information provided by SAFE and its branches.

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According to the Notice of the State Administration of Foreign Exchange on Issues Concerning the Foreign Exchange Administration of Overseas Listing (《國家外匯管理局關於境外上市外匯管理有關問題的通知》) issued by the SAFE on December 26, 2014, a domestic company shall, within 15 business days from the date of the end of its overseas listing issuance, register the overseas listing with the local branch office of state administration of foreign exchange at the place of its establishment; the proceeds from an overseas listing of a domestic company may be remitted to the domestic account or deposited in an overseas account, but the use of the proceeds shall be consistent with the content of the document and other disclosure documents.

According to the Notice of the State Administration of Foreign Exchange on Reforming the Management Mode of Foreign Exchange Capital Settlement of Foreign Investment Enterprises (《國家外匯管理局關於改革外商投資企業外匯資本金結匯管理方式的通知》) (the “**SAFE Circular 19**”) promulgated on March 30, 2015, coming effective on June 1, 2015 and partially abolished on December 30, 2019, foreign-invested enterprises could settle their foreign exchange capital on a discretionary basis according to the actual needs of their business operations. Whilst, foreign-invested enterprises are prohibited to use the foreign exchange capital settled in RMB (a) for any expenditures beyond the business scope of the foreign invested enterprises or forbidden by laws and regulations; (b) for direct or indirect securities investment; (c) to provide entrusted loans (unless permitted in the business scope), repay loans between enterprises (including advances by third parties) or repay RMB bank loans that have been on lent to a third party; and (d) to purchase real estate not for self-use purposes (save for real estate enterprises).

On June 9, 2016, SAFE issued the Notice of the State Administration of Foreign Exchange on Reforming and Standardizing the Foreign Exchange Settlement Management Policy of Capital Account (《國家外匯管理局關於改革和規範資本項目結匯管理政策的通知》) (the “**SAFE Circular 16**”), which came into effect on the same day. The SAFE Circular 16 provides that discretionary foreign exchange settlement applies to foreign exchange capital, foreign debt offering proceeds and remitted foreign listing proceeds, and the corresponding RMB capital converted from foreign exchange may be used to extend loans to related parties or repay inter-company loans (including advances by third parties).

On October 23, 2019, SAFE promulgated the Notice on Further Facilitating Cross-Board Trade and Investment (《國家外匯管理局關於進一步促進跨境貿易投資便利化的通知》), which became effective on the same date (except for Article 8.2, which became effective on January 1, 2020). This notice canceled restrictions on domestic equity investments made with capital funds by non-investing foreign-funded enterprises. In addition, restrictions on the use of funds for foreign exchange settlement of domestic accounts for the realization of assets have been removed and restrictions on the use and foreign exchange settlement of foreign investors’ security deposits have been relaxed. Eligible enterprises in the pilot area are also allowed to use revenues under capital accounts, such as capital funds, foreign debts and overseas listing revenues for domestic payments without providing materials to the bank in advance for authenticity verification on an item by item basis, while the use of funds should be true, in compliance with applicable rules and conforming to the current capital revenue management regulations.



### *Taxation*

#### *Enterprise Income Tax*

The Enterprise Income Tax Law of the PRC (《中華人民共和國企業所得稅法》) (the “**EIT Law**”), promulgated by the NPC on March 16, 2007, came into effect on January 1, 2008 and amended on February 24, 2017 and December 29, 2018, as well as the Implementation Rules of the EIT Law (《中華人民共和國企業所得稅法實施條例》) (the “**Implementation Rules**”), promulgated by the State Council on December 6, 2007, came into force on January 1, 2008 and amended on April 23, 2019, are the principal law and regulation governing enterprise income tax in the PRC. According to the EIT Law and its Implementation Rules, enterprises are classified into resident enterprises and non-resident enterprises. Resident enterprises refer to enterprises that are legally established in the PRC, or are established under foreign laws but whose actual management bodies are located in the PRC. And non-resident enterprises refer to enterprises that are legally established under foreign laws and have set up institutions or sites in the PRC but with no actual management body in the PRC, or enterprises that have not set up institutions or sites in the PRC but have derived incomes from the PRC. A uniform income tax rate of 25% applies to all resident enterprises and non-resident enterprises that have set up institutions or sites in the PRC to the extent that such incomes are derived from their set-up institutions or sites in the PRC, or such income are obtained outside the PRC but have an actual connection with the set-up institutions or sites. And non-resident enterprises that have not set up institutions or sites in the PRC or have set up institutions or sites, but the incomes obtained by the said enterprises have no actual connection with the set-up institutions or sites, shall pay enterprise income tax at the rate of 10% in relation to their income sources from the PRC.

#### *Value-Added Tax (the “VAT”)*

The major PRC law and regulation governing value-added tax are the Interim Regulations on Value-added Tax of the PRC (《中華人民共和國增值稅暫行條例》) issued on December 13, 1993 by the State Council, came into effect on January 1, 1994, and revised on November 10, 2008, February 6, 2016 and November 19, 2017, as well as the Implementation Rules for the Interim Regulations on Value-Added Tax of the PRC (《中華人民共和國增值稅暫行條例實施細則》) issued on December 25, 1993 by the Ministry of Finance (中華人民共和國財政部) (the “**MOF**”), came into effect on the same day and revised on December 15, 2008 and October 28, 2011, any entities and individuals engaged in the sale of goods, supply of processing, repair and replacement services, and import of goods within the territory of the PRC are taxpayers of VAT and shall pay the VAT in accordance with the law and regulation. The rate of VAT for sale of goods is 17% unless otherwise specified, such as the rate of VAT for sale of transportation is 11%. With the VAT reforms in the PRC, the rate of VAT has been changed several times. The MOF and the STA issued the Notice of on Adjusting VAT Rates (《財政部、國家稅務總局關於調整增值稅稅率的通知》) on April 4, 2018 to adjust the tax rates of 17% and 11% applicable to any taxpayer’s VAT taxable sale or import of goods to 16% and 10%, respectively, this adjustment became effect on May 1, 2018. Subsequently, the MOF, the STA and the General Administration of Customs jointly issued the Announcement on

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Relevant Policies for Deepening the VAT Reform (《財政部、國家稅務總局關於深化增值稅改革有關政策的公告》) on March 20, 2019 to make a further adjustment, which came into effect on April 1, 2019. The tax rate of 16% applicable to the VAT taxable sale or import of goods shall be adjusted to 13%, and the tax rate of 10% applicable thereto shall be adjusted to 9%.

### **Laws and Regulations on Overseas Securities Offering and Listing by Domestic Companies**

On February 17, 2023, the CSRC promulgated the Overseas Listing Trial Measures and relevant supporting guidelines, which came into effect on March 31, 2023. The Overseas Listing Trial Measures comprehensively improve and reform the existing regulatory regime for overseas offering and listing of PRC domestic companies' securities and regulate both direct and indirect overseas offering and listing of PRC domestic companies' securities. Any domestic company that is deemed to conduct overseas offering and listing activities shall file with the CSRC in accordance with the Overseas Listing Trial Measures.

The Overseas Listing Trial Measures provide that the overseas securities offering and listing will be considered a direct overseas offering by a PRC domestic company if the issuer is a company limited by shares registered and established in mainland China. In addition, the overseas securities offering and listing will be considered an indirect overseas offering by a PRC domestic company if the issuer meets both of the following criteria: (i) 50% or more of any of the issuer's operating revenue, total profit, total assets or net assets as documented in its audited consolidated financial statements for the most recent fiscal year is accounted for by a domestic company; and (ii) the main parts of the issuer's business activities are conducted in mainland China, or its main place(s) of business are located in mainland China, or the majority of senior management staff in charge of its business operations and management are PRC citizens or have their usual place(s) of residence located in mainland China.

Pursuant to the Overseas Listing Trial Measures, an issuer shall file with the CSRC within three business days after its application for initial public offering is submitted to competent overseas securities regulators.

### ***H-share Full Circulation***

"Full circulation" means listing and circulating on the stock exchange of the domestic unlisted shares of an H-share listed company, including unlisted domestic shares held by domestic shareholders prior to overseas listing, unlisted domestic shares additionally issued after overseas listing, and unlisted shares held by foreign shareholders. On November 14, 2019, the CSRC issued the Guidelines for the "Full Circulation" Program for Domestic Unlisted Shares of H-share Listed Companies (《H股公司境內未上市股份申請“全流通”業務指引》) (the "**Guidelines for the Full Circulation**"), which was partly revised on August 10, 2023 according to the Decision on Revising and Abolishing Part of Securities and Futures Policy Documents by CSRC (《中國證券監督管理委員會關於修改、廢止部分證券期貨制度文件的決定》).

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According to the Guidelines for the Full Circulation, shareholders of domestic unlisted shares may determine by themselves through consultation the amount and proportion of shares, for which an application will be filed for circulation, provided that the requirements laid down in the relevant laws and regulations and set out in the policies for state-owned asset administration, foreign investment and industry regulation are met, and the corresponding H-share listed company may be entrusted to file the said application for full circulation. To apply for full circulation, an H-share listed company shall file the application with the CSRC according to the administrative filing procedures necessary for the Overseas Listing Trial Measures. After the application for full circulation has been approved by the CSRC, the H-share listed company shall submit a report on the relevant situation to the CSRC within 15 days after the registration with CSDCC of the shares related to the application has been completed.

On December 31, 2019, CSDCC and the Shenzhen Stock Exchange (“SZSE”) jointly announced the Measures for Implementation of H-share Full Circulation Business (《H股“全流通”業務實施細則》) (the “Measures for Implementation”). The businesses in relation to the H-share full circulation business, such as cross-border transfer registration, maintenance of deposit and holding details, transaction entrustment and instruction transmission, settlement, management of settlement participants, services of nominal holders, etc. are subject to the Measures for Implementation.

In order to fully promote the reform of H-share full circulation and clarify the business arrangement and procedures for the relevant shares’ registration, custody, settlement and delivery, CSDCC promulgated the Guide to the Program for Full Circulation of H-shares (《H股“全流通”業務指南》) on February 7, 2020, which specifies the business preparation, account arrangement, cross-border share transfer registration and overseas centralized custody, and other relevant matters. In February 2020, China Securities Depository and Clearing (Hong Kong) Limited (“CSDC (Hong Kong)”) also promulgated the Guide of China Securities Depository and Clearing (Hong Kong) Limited to the Program for Full Circulation of H-shares to specify the relevant escrow, custody, agent service, arrangement for settlement and delivery, risk management measures and other relevant matters.

According to the Measures for Implementation and the Guide to the Program for Full Circulation of H-shares, shareholders who apply for H Share Full Circulation (“**Participating Shareholders**”) shall complete the cross-border transfer registration for conversion of relevant domestic unlisted shares into H Shares before dealing in the shares, i.e., CSDCC as the nominal shareholder, deposits the relevant securities held by Participating Shareholders at CSDC (Hong Kong), and CSDC (Hong Kong) will then deposit the securities at HKSCC in its own name, and exercise the rights to the securities issuer through HKSCC, while HKSCC Nominees as the ultimate nominal shareholder is listed on the register of shareholders of H-share listed companies.

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According to the Guide to the Program for Full Circulation of H-shares, H-share listed companies shall be authorized by Participating Shareholders to designate the only domestic securities company (“**Domestic Securities Company**”) to participate in the transaction of converted H shares. The specific procedure is as follows:

Participating Shareholders submit trading orders of the converted H Shares through the Domestic Securities Company, which transmits the orders to the Hong Kong Securities Company designated by the Domestic Securities Company through Shenzhen Securities Communications Co., Ltd.; and Hong Kong Securities Company conducts corresponding securities transactions in the Hong Kong market in accordance with the aforementioned trading orders and the rules of the Stock Exchange.

According to the Guide to the Program for Full Circulation of H-shares, upon the completion of the transaction, settlements between each of the Hong Kong Securities Company and CSDC (Hong Kong), CSDC (Hong Kong) and CSDCC, CSDCC and the Domestic Securities Company, and the Domestic Securities Company and the Participating Shareholders, will all be conducted separately.

### **LAWS AND REGULATIONS OF GERMANY**

#### **Laws and Regulations Relating to the Marketing Authorization for Medicinal Products**

The authorization of medicinal products in Germany is governed by European Union (“**EU**”) legislation and additional national legislation.

The main legislation that governs the authorization of medicinal products include Regulation (EC) No. 726/2004 as well as Directive (EC) No. 2001/83 and its implementing provisions under national laws of the EU member states.

Medicinal products must undergo an official marketing authorization procedure before they can be placed on the market in the EU or Germany. In the case of novel medicinal products, such authorization procedure requires that evidence of comprehensive and often cost-intensive clinical trials are submitted as proof of clinical efficacy and safety. For medicinal products with active ingredients that are not novel (generics), a simplified referential drug approval is available.

For particularly innovative medicinal products, the European Medicines Agency (“**EMA**”) is the competent approval authority. An authorization granted by EMA applies directly to all EU member states. For other medicinal products, the national authorities are responsible for the marketing authorization application. In Germany, this is generally the Federal Institute for Drugs and Medical Devices (*Bundesinstitut für Arzneimittel und Medizinprodukte* – “**BfArM**”).

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The authorizations granted by the national authorities are only valid in the respective EU member state. However, there are simplified mutual recognition procedures in place so that manufacturers can obtain further marketing authorizations in other member states in a simplified way by making reference to the marketing authorization already obtained in a member state.

### Laws and Regulations Relating to Manufacturing of Medicinal Products

The manufacturing of medicinal products is mainly governed by the German Medicinal Products Act (*Gesetz über den Verkehr mit Arzneimitteln* – “**AMG**”), the German Ordinance on the Manufacture of Medicinal Products and Active Pharmaceutical Ingredients (*Arzneimittel- und Wirkstoffherstellungsverordnung*) and the principles and guidelines of Good Manufacturing Practice (“**GMP**”) for medicinal products for human use of the European Commission.

The manufacturing of medicinal products, which includes all stages of the production and processing right up to the packaged medicinal product ready for sale, is subject to an authorization. The authorization is granted to the business owner of a specific manufacturing facility and is limited to the manufacturing activities specified therein. The manufacturing authorization is also linked to the applicant and therefore cannot be transferred to another person.

A wholesaler, whose activities are limited to the decanting, packaging or labeling of medicinal products, does not require a manufacturing authorization for such activities.

### Laws and Regulations Relating to the Wholesale of Medicinal products

The wholesale of medicinal products is mainly governed by the AMG, the German Medicinal Products Trade Ordinance (*Verordnung über den Großhandel und die Arzneimittelvermittlung* – “**AM-HandelsV**”) and Directive 2001/83/EC of the European Parliament (“**Directive 2001/83/EC**”).

The wholesale of medicinal products requires an official authorization and Good Distribution Practice (“**GDP**”) certification. In order to obtain such wholesale authorization, the wholesaler must have a qualified person in charge who has the necessary reliability to carry out the required activities, and is able to ensure compliance with the applicable regulations (namely the AM-HandelsV and the GDP guidelines). The license is granted for a specific wholesale storage site.

Wholesalers are obliged to notify any change to the mandatory information contained in the application for the wholesale license (such as the qualified person or the operating site for which the license is to be granted) and any significant change to the wholesale activity (such as significant changes to the product range and in the supplier or customer structure) to the competent authorities in advance.

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The wholesale authorization is not limited in time. However, if it subsequently becomes known that the requirements for granting the authorization were not fulfilled when the authorization was granted or if the requirements for granting the authorization are no longer met, the authorization can be withdrawn (*zurücknehmen*), revoked (*widerrufen*) or suspended.

A GDP certificate is issued to the holder of a wholesale authorization by the competent authority for a maximum period of five years, provided that the findings obtained during the inspection have led to compliance with the requirements of the GDP regulations. If the wholesaler's GDP compliance cannot be confirmed as a result of the inspection, a non-compliance report should be published in the EudraGMDP database (<https://eudragmdp.ema.europa.eu/inspections/logonGeneralPublic.do>). In case of negative inspection results after the certificate has been issued, the certificate has to be revoked. A revocation of the GDP certificate implies the existence of a reason for refusal to grant the wholesale authorization, which can then lead to a revocation of the wholesale authorization.

During the COVID-19 pandemic, GMP and GDP inspections were postponed or only carried out online. On-site inspections have resumed in mid-May 2023. The validity period of existing certificates was extended until the end of 2023. It has now been decided by EMA, the European Commission and the Heads of Medicines Agencies that the existing certificates will be extended until 2024 or until the next inspection can be carried out. The inspections will be prioritized according to the risk of operation and the duration of the previous certificates.

### **Laws and Regulations Relating to Import of Medicinal Products and Active Pharmaceutical Ingredients**

The import of medicinal products from a third country (non-EU country) requires an import permit and, in principle, an official certification in accordance with the AMG.

Both the import permit and the manufacturing authorization include the authorization to wholesale the corresponding medicinal products. However the wholesale authorization does not include any import or manufacturing license.

In a scenario, in which a wholesaler in the EU agrees on the purchase of medicinal products with a company based in a non-EU country, but the medicinal products to be delivered to the purchaser were either manufactured in the EU or have already been imported into the EU internal market (e.g. by a subsidiary of the selling company), the acquisition process is not considered an import as there is no physical crossing of the EU external border. The acquisition process is rather categorized as a wholesale trade with the consequence that the third-country seller needs a wholesale authorization.



### **Laws and Regulations Relating to Research and Development of Medicinal Products**

The research and development of medicinal products is mainly governed by Regulation (EU) No. 536/2014 and the AMG. The clinical trial of a medicinal product in humans requires approval by the responsible independent ethics committee and from BfArM. The clinical trial further requires insurance coverage; the minimum coverage per insured event must be EUR 500,000 in the event of the death or permanent disability of a person affected by the clinical trial.

### **Legal Consequences of non-compliance with the AMG and AM-HandelsV**

Breaches of the AMG and AM-HandelsV can constitute crimes and administrative offences. Breaches that constitute crimes are punishable by up to one year in prison or a fine (*Geldstrafe*). Administrative offences are subject to administrative fines (*Bußgeld*) of up to EUR 25,000 per case. Fines may exceed this amount if the economic benefit resulting from the offense is higher.

In case of any breach, the competent authorities are entitled and obliged to take appropriate measures to eliminate or prevent future violations, e.g. by banning the placement, or by issuing recalls and public warnings, etc.

### **Outlook of Future Changes to the Legal Framework of Medicinal Products**

The European Union is currently discussing comprehensive changes to pharmaceutical legislation, probably the biggest pharmaceutical reform in over 20 years. The so-called EU pharmaceutical package was presented by the EU Commission on April 26, 2023. With a new Directive 2023/0132 (COD) and a new Regulation 2023/0131 (COD), this package consists of two legislative proposals that would replace Directives 2001/83/EC and 2009/35/EC. The aim is to replace and simplify previous pharmaceutical regulations and to improve the supply of medicinal products throughout Europe and effectively combat the shortage of medicinal products. There is also an additional focus on environmental protection and reducing bureaucracy. The proposals must now go through the ordinary legislative procedure. It is currently not expected that the new rules will be effective before 2026/2027.

From the information available so far, the obligation to obtain marketing authorization for medicinal products and the basic obligation to obtain authorizations for the manufacture, wholesale and import of medicinal products will remain basically unchanged.

Noteworthy regulatory proposals include incentives for the development of priority antimicrobials, the acceleration of the authorization procedure, the simplification of procedures for the authorization of generics and biosimilars, the reduction of the environmental impact of medical products as well as the reduction of the regulatory burden and a flexible regulatory framework to support innovation and competitiveness.

### Laws and Regulations Relating to Export Controls

Exports from Germany are governed by EU regulations (directly applicable to all exports from the EU customs territory) and additional national legislation.

The main legislation that governs German export controls include, on EU level, the Union Customs Code Regulation (EU) No. 952/2013. Various regulations on EU level govern exports of specific goods, in particular the Dual-Use Regulation (EU) No. 2021/821 relating to goods that can be used for both civilian and military applications, the Anti-Torture Regulation (EU) No. 2019/125 relating to goods that could be used for capital punishment, torture or other cruel, inhuman or degrading treatment or punishment, the Firearms Regulation (EU) No. 258/2012 relating to certain fire arms, the Hazardous Chemical Regulation (EU) No. 649/2012 relating to export and import of hazardous chemicals and the Waste Shipments Regulation (EU) No. 1013/2006 relating to exports and imports of waste.

The national export control regime is set out in the German Foreign Trade Act (*Außenwirtschaftsgesetz* – “AWG”), the German Foreign Trade and Payment Ordinance (*Außenwirtschaftsverordnung* – “AWV”), the War Weapons Control Act (*Kriegswaffenkontrollgesetz*) and the Firearms Ordinance (*Feuerwaffenverordnung*).

In addition, important guidance on export control regulations is provided for in Political Principles adopted by the German federal government and official guidelines of the competent authorities, such as the Federal Office for Economic Affairs and Export Control (*Bundesamt für Wirtschaft und Ausfuhrkontrolle*).

EU and German regulations contain specific export prohibitions and authorization requirements relating to specific goods.

Non-compliance with export prohibitions and authorization requirements can constitute criminal offenses with the risk of imprisonment of up to three to 15 years, depending on the type of offense and whether or not a violation was intentional (*vorsätzlich*) or negligent (*fahrlässig*). Administrative offenses are subject to fines of, depending on the type of offense, up to EUR 500,000 or EUR 30,000 per case against individuals. Violations of export controls may also fall within the scope of the administrative offense of violation of supervisory obligations under the Act on Regulatory Offenses (*Ordnungswidrigkeitengesetz*). The owner of a company or business and authorized persons (such as managers, directors, and authorized proxies) may be liable to a fine if they acted with negligence or intent when failing to take measures to prevent operational violations. The maximum amount of the fine depends on whether the operational violation is a criminal offense or an administrative offense (up to EUR 10,000,000 or EUR 5,000,000).



### Laws and Regulations Relating to Sanctions and Embargoes

Sanctions law in Germany is primarily governed by EU regulations and additional national legislation.

According to the Treaty on the Functioning of the European Union, the EU has exclusive competence to impose economic and financial embargo measures. These measures must be based on a decision defining a common position of the EU member states, in accordance with the Treaty on the European Union. EU sanctions bind Germany. They are generally implemented through EU regulations, which are directly applicable in all EU member states.

EU sanctions usually implement decisions of the United Nations Security Council (UNSC) or the Organization for Security and Co-operation in Europe (OSCE). The EU can also impose sanctions on its own initiative.

EU sanctions can target specific individuals and organisations or include embargoes on trade with specific jurisdictions. Typically, restrictive measures include prohibitions on the export or import of certain goods, technology, and software (including sale and transfer of these goods), prohibitions on technical assistance and financial aid relating to listed goods, export licensing requirements, financial sanctions and restrictions on financial transfers.

Financial sanctions targeting specific organisations, entities, or individuals typically include a freeze of assets and economic resources of the listed persons (or non-listed persons/entities owned or controlled by listed persons) as well as a prohibition to make (new) funds or economic resources directly or indirectly available to them.

EU sanctions and embargoes are currently in force against 30 countries. There are also sanctions against terrorist groups such as Al-Qaeda and the so-called Islamic State. Country-independent embargo measures have also been issued to prevent cyberattacks and serious human rights violations or the harboring and proliferation of chemical weapons. Furthermore, arms embargoes based on OSCE decisions have an indirect effect on EU law, as the countries concerned are considered embargoed countries within the meaning of the Dual-Use Regulation (EU) No. 2021/821.

Non-compliance with EU sanctions and embargoes can, under the AWG and AWV, constitute criminal offenses with the risk of imprisonment of up to three to 15 years, depending on the type of offense and whether or not a violation was intentional (*vorsätzlich*) or negligent (*fahrlässig*). Administrative offenses are subject to fines of, depending on the type of offense, up to EUR 500,000 or EUR 30,000 per case against individuals. Violations of EU sanctions and embargoes may also fall within the scope of the administrative offense of violation of supervisory obligations under the Act on Regulatory Offenses (*Ordnungswidrigkeitengesetz*). The owner of a company or business and authorized persons (such as managers, directors, and authorized proxies) may be liable to a fine if they acted with negligence or intent when failing to take measures to prevent operational violations. The maximum amount of the fine depends on whether the operational violation is a criminal offense or an administrative offense (up to EUR 10,000,000 or EUR 5,000,000).

### Laws and Regulations Relating to Data Privacy

Data privacy in the EU, including Germany, is mainly governed by Regulation (EU) No. 2016/679 (General Data Protection Regulation — “**GDPR**”). The GDPR allows EU member states to adopt national rules on certain matters, and in Germany, such national legislation is in particular the Federal Data Protection Act (*Bundesdatenschutzgesetz* — “**BDSG**”) and the Act on Data Protection and the Protection of Privacy in Telecommunications and Digital Services (*Gesetz über den Datenschutz und den Schutz der Privatsphäre in der Telekommunikation und bei digitalen Diensten*). Moreover, certain sector-specific laws include provisions on data privacy, including, for example, the AMG on the processing of personal data in the context of clinical trials.

The GDPR applies to the processing of personal data carried out wholly or partly by automated means, or of data that forms part or is intended to form part of a filing system. This covers most personal data-related activities. Personal data under the GDPR means any information relating to an identified or identifiable natural person, covering a broad range of information such as names, physical and digital addresses, photos, medical information, or IP addresses, and all data connected to identifiers (e.g., a document that is related to its author via the author’s name).

The GDPR requires that personal data be processed according to six principles, namely, (i) lawfulness, fairness and transparency; (ii) purpose limitation; (iii) data minimization; (iv) accuracy; (v) storage limitation; and (vi) integrity and confidentiality. The company that determines the purposes and means of the processing (the so-called controller of personal data) is required to be able to demonstrate compliance with these principles, in particular that the processing is covered by a legal basis, either a certain provision under statutory law or consent.

The GDPR further imposes notification obligations in case of a data breach. If a data breach occurs, the controller may be required to notify the supervisory authority or even the data subjects (i.e., the persons to whom the data relates), depending on the risk prognosis. The GDPR also restricts data transfers outside the EU/EEA, including within a company group, requiring that appropriate safeguards be put in place prior to such transfer. Moreover, the GDPR gives the data subjects certain rights, in particular the right to access to their personal data. Finally, it imposes on companies a number of other transparency and documentation requirements.

Non-compliance with the GDPR can result in administrative measures, including fines of up to EUR 20,000,000 or up to 4% of the annual worldwide turnover of the company group in the financial year preceding the supervisory authority’s decision, whichever is higher. In addition, the GDPR entitles data subjects to claim material or non-material damages. Under the BDSG, the intentional (*vorsätzlich*) and unlawful processing, transfer and/or collection of certain personal data qualify as criminal offenses subject to imprisonment of up to two to three years or a criminal fine, depending on the type of offense.

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Lastly, Germany is looking to implement the upcoming cybersecurity Directive (EU) 2022/2555 (“**NIS2 Directive**”), likely in the first half of 2025. The NIS2 Directive and its German implementing legislation (*Entwurf eines Gesetzes zur Umsetzung der NIS-2-Richtlinie und zur Regelung wesentlicher Grundzüge des Informationssicherheitsmanagements in der Bundesverwaltung (NIS-2-Umsetzungs- und Cybersicherheitsstärkungsgesetz)*) require companies in certain sectors (including the health sector) and of a certain size to take appropriate and proportionate technical, operational and organisational measures to manage the risks posed to the security of network and information systems. Companies will also be obliged to notify the authority in case of a significant incident and train their management and staff in cybersecurity practices. Violations of these requirements will be subject to administrative measures, including fines of up to EUR 10,000,000 or 2% of annual worldwide turnover of the group in the year preceding the violation.

### **Laws and Regulations Relating to Income Taxation**

Under the German Corporate Income Tax Act (*Körperschaftsteuergesetz*), corporations tax resident in Germany are subject to corporate income tax (*Körperschaftsteuer*) on their taxable income, which is determined mainly based on the provisions of the German Income Tax Act (*Einkommensteuergesetz*) and German Generally Accepted Accounting Principles (*Grundsätze ordnungsmäßiger Buchführung und Bilanzierung*). The corporate income tax rate is currently 15% plus 5.5% solidarity surcharge (*Solidaritätszuschlag*) thereon, i.e. 15.825% in total.

Additionally, business income (including all income of a German limited liabilities company (*Gesellschaft mit beschränkter Haftung, GmbH*)) is subject to trade tax (*Gewerbesteuer*), the rate of which is determined by the municipality the business is conducted from. Since 2021, the trade tax rate for the municipality of Berlin has been 14.35%. The total income tax rate of a corporation based in Berlin is therefore 30.175% (corporate income tax, including solidarity surcharge, plus trade tax).

From a compliance perspective, corporations have to file yearly corporate income and trade tax returns. Filing such tax returns late, incorrectly or not at all may be punishable by late filing and administrative fees (up to EUR 25,000 or EUR 50,000 respectively) or, if intentionally (*vorsätzlich*), as criminal tax evasion (sentence determined by a criminal court on a case-by-case basis).

### **Laws and Regulations Relating to Value-Added Taxation**

Under the German VAT Act (*Umsatzsteuergesetz*), supplies and services rendered in Germany are generally subject to value-added tax (*Umsatzsteuer* — “**VAT**”) at 19% (or 7% for specific supplies and services) of the remuneration for such supplies and services. VAT is invoiced to the customer and typically owed to the tax authorities by the supplier. Any such supplier is generally entitled to a refund of any VAT it pays for supplies and services as input VAT (*Vorsteuerabzug*).

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The taxpayers have to file monthly VAT returns (*Umsatzsteuervoranmeldung*), showing the balance of owed VAT and input VAT, which is paid to or refunded by the tax authorities, as applicable, as well as yearly VAT returns. Filing such tax returns late, incorrectly or not at all may be punishable by late filing and administrative fees (up to EUR 25,000 or EUR 50,000 respectively) or, if intentionally (*vorsätzlich*), as criminal tax evasion (sentence determined by a criminal court on a case-by-case basis).

### **Laws and Regulations regarding the Taxation of Dividends**

Dividends distributed by German corporations are generally subject to capital gains tax (*Kapitalertragsteuer*), which has to be withheld by the corporation distributing the dividends for the account of the recipient. Currently, the capital gains tax rate is at 25% plus solidarity surcharge of 5.5% thereon, i.e. 26.375% in total. The capital gains tax may be reduced or refunded if the shareholder of the relevant German corporation is entitled to a reduction, e.g. under an applicable double taxation treaty or other tax reliefs. The reduction requires an exemption certificate to be applied for with the Federal Central Office of Taxation.

### **Laws and Regulations regarding Payroll Obligations**

Under the German Income Tax Act (*Einkommensteuergesetz*) and the German Social Code IV (*Sozialgesetzbuch IV*), Germany-based employers are required to withhold wage tax (*Lohnsteuer*) and social security contributions (*Sozialversicherungsbeiträge*) for its employees from their wage payments and remit these amounts to the respective authorities (including employer social security contributions) on a monthly basis. Failing to do so may be punishable by late filing and administrative fees (up to EUR 25,000 or EUR 50,000 respectively) or, if intentionally (*vorsätzlich*), as criminal tax evasion (sentence determined by a criminal court on a case-by-case basis).

## **LAWS AND REGULATIONS OF THE U.S.**

We are subject to a variety of U.S. laws, rules and regulations affecting many aspects of our business in the U.S. This section summarizes the major U.S. regulatory authorities and U.S. laws and regulations that we believe are relevant to our business and operations in the U.S.

### **PRINCIPAL REGULATORY AUTHORITIES**

#### **U.S. Food and Drug Administration**

The United States Food and Drug Administration (the “**FDA**”) regulates drugs in the U.S. under the Federal Food, Drug, and Cosmetic Act (the “**FDCA**”) and its implementing regulations, and biologics under the FDCA and the Public Health Service Act (the “**PHSA**”) and its implementing regulations. The FDA is the regulatory, scientific, public health and consumer protection agency responsible for ensuring all human drugs, medical devices, and other pharmaceutical products marketed in the U.S. are safe and properly labeled, stored, transported, manufactured, packaged, and regulated. As part of its responsibility, the FDA also

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oversees and monitors the developmental process, approval process, and post-approval compliance with the relevant laws, rules and regulations of the U.S., in relation to any pharmaceutical products. If there were failure to comply with the applicable U.S. laws, rules or regulations at any stage, the FDA could take administrative actions or subject the violator to judicial sanctions, which could include, among other actions and sanctions, the FDA's refusal to approve pending applications, withdrawal of an approval, license revocation, a clinical hold, untitled letters or warning letters, voluntary or mandatory product recalls or market withdrawals, product seizures, total or partial suspension of production or distribution, injunctions, fines, restitution, disgorgement, or civil or criminal fines or penalties.

### **U.S. Patent and Trademark Office**

The U.S. Patent and Trademark Office (the “**USPTO**”) is the federal agency for granting U.S. patents and registering trademarks.

### **U.S. Customs and Border Protection**

The U.S. Customs and Border Protection (the “**CBP**”), under the Tariff Act of 1930, as amended, the Customs Modernization Act of 1983, and the regulations of the CBP, is the federal agency that regulates the importation of products and materials into the U.S. and that enforces the import and export-related laws, rules and regulations of the U.S. The CBP is charged with ensuring that imports or exports comply with the relevant laws, rules and regulations, and it has the authority to effect seizures, forfeitures, and rejection of entry of non-conforming goods.

### **U.S. International Trade Commission**

The United States International Trade Commission (the “**ITC**”) is a federal agency that advises the legislative and executive branches of the federal government on matters of trade. It analyzes trade issues and data, both domestic and international, and provides guidance on matters such as tariffs, trade, and competition. It also investigates and makes determinations in proceedings involving imports claimed to injure a domestic industry or violate U.S. intellectual property rights. The ITC maintains the Harmonized Tariff Schedule, which identifies applicable import duties for products and materials imported into the U.S., organized by class and specific article.

## **PRINCIPAL REGULATORY PROVISIONS**

### **Laws and Regulations on Company Establishment and Foreign Investment in the U.S.**

The establishment, operation and management of corporate entities in the U.S. are governed by the corporate and business laws of the individual states in which an entity is established or does business. Such corporate and business laws are promulgated by the legislative branches of the individual states of the U.S. Under such corporate and business

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laws, companies can operate under a myriad of forms, including as a corporation, limited liability company, partnership, etc. These corporate and business laws also apply to foreign-invested companies created and registered in the U.S.

### Laws and Regulations on Drug

In the United States, the FDA regulates drugs under the FDCA and its implementing regulations, and biologics under the FDCA and the PHSA and their implementing regulations. Both drugs and biologics also are subject to other federal, state, and local statutes and regulations, such as those related to competition. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, and local statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or following approval may subject an applicant to administrative actions or judicial sanctions. These actions and sanctions could include, among other actions, the FDA's refusal to approve pending applications, withdrawal of an approval, license revocation, a clinical hold, untitled or warning letters, voluntary or mandatory product recalls or market withdrawals, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement and civil or criminal fines or penalties. Any administrative proceeding, action, or judicial enforcement action could have a material adverse effect on our business, financial condition, and results of operations as well as the market's acceptance of our products and reputation.

Once a product candidate is identified for development, it enters preclinical testing, which includes laboratory evaluations of product chemistry, toxicity, formulation, and stability, as well as animal studies. Preclinical testing is conducted in accordance with the FDA's Good Laboratory Practice regulations. A sponsor of an Investigational New Drug application ("IND") must submit the results of the preclinical tests (such as animal tests), manufacturing information, analytical data, the clinical trial protocol, and any available clinical data or literature to the FDA. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions and places the trial on a clinical hold within that 30-day period. The FDA may also impose clinical holds or partial clinical holds at any time during clinical trials due to safety concerns or non-compliance. Although information a sponsor submits in an IND is confidential, general clinical trial information such as the number of patients involved and the type of adverse events studied can be made public information and can be available for public review through publication on government websites such as [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

All clinical trials which involve the administration of the investigational product to humans must be conducted under the supervision of one or more qualified investigators in accordance with Good Clinical Practice ("GCPs") and human subjects protection regulations, including the requirement that all research subjects provide informed consent in writing before their participation in any clinical trial. Further, an Institutional Review Board ("IRB"), often under the auspices of a university and sometimes a private, independent organization, must review and approve the plan for any clinical trial before it commences at any institution, and

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the IRB must conduct continuing review and reapprove the study at least annually. Each new clinical protocol and any amendments to the protocol must be submitted for FDA review, and to the IRBs for approval. An IRB can suspend or terminate approval of a clinical trial at its institution if the trial is not being conducted in accordance with the IRB's requirements or human subject research regulations or if the product has been associated with unexpected serious harm to subjects and the IRB believes patients are at risk.

Clinical trials generally are conducted in three sequential phases, known as Phase I, Phase II and Phase III, and may overlap:

- Phase I clinical trials generally involve a small number of healthy volunteers or disease-affected patients who are initially exposed to a single dose and then multiple doses of the product candidate. The primary purpose of these clinical trials is to assess the metabolism, pharmacologic action, side effect tolerability and safety of the product candidate.
- Phase II clinical trials involve studies in disease-affected patients to evaluate proof of concept and/or determine the dose required to produce the desired benefits. At the same time, safety and further pharmacokinetics and pharmacodynamics information is collected, possible adverse effects and safety risks are identified and a preliminary evaluation of efficacy is conducted.
- Phase III clinical trials generally involve a large number of patients at multiple sites and are designed to provide the data necessary to demonstrate the effectiveness of the product for its intended use, its safety in use and to establish the overall benefit/risk relationship of the product and provide an adequate basis for product labeling.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA before marketing approval is received. Safety reports must be submitted to the FDA and the investigators 15 calendar days after the trial sponsor determines that the information qualifies for reporting. The sponsor also must notify FDA of any unexpected fatal or life-threatening suspected adverse reaction as soon as possible but in no case later than 7 calendar days after the sponsor's initial receipt of the information. Sponsors of clinical trials of FDA-regulated products, including drugs, are required to register and disclose certain clinical trial information, which is publicly available at [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

Concurrent with clinical trials, companies usually complete additional animal studies and must also finalize a process for manufacturing the product in commercial quantities in accordance with FDA's current Good Manufacturing Practices ("cGMP").



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### *U.S. Review and Approval Processes*

Before the marketing or sale of drugs and pharmaceutical products in the U.S., such drugs or pharmaceutical products must be registered with the FDA by the submission to it of a New Drug Application (“NDA”), which will contain, among other information, the results of product development, pre-clinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the product and proposed labeling of the product. Unless deferred or waived, NDAs must contain data adequate to assess the safety and effectiveness of the product for the claimed indications in all relevant populations and to support dosing and administration for each population for which the product is safe and effective. The submission of an NDA is subject to the payment of a substantial user fee and an annual prescription drug product program fee.

Within 60 days of its receipt, the FDA reviews the NDA to ensure that it is sufficiently complete for substantive review before it accepts the NDA for filing. After accepting the NDA filing, the FDA begins an in-depth substantive review to determine, among other things, whether a product is safe and effective for its intended use. The FDA also evaluates whether the product’s manufacturing is cGMP-compliant to assure the product’s identity, strength, quality, and purity. Before approving the NDA, the FDA typically will inspect whether the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. The FDA may refer the NDA to an advisory committee, a panel of experts, for review whether the application should be approved and under what conditions and may consider such recommendations when making decisions.

The FDA may refuse to approve the NDA if the applicable regulatory criteria are not satisfied or may require additional clinical data or other data and information. The FDA will issue a complete response letter describing all of the specific deficiencies that the FDA identified in the NDA that must be satisfactorily addressed before it can be approved. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. The applicant may either resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application or request an opportunity for a hearing.

The regulatory approval may be limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. In addition, the FDA may require post-approval studies, including phase IV clinical trials, to further assess a product’s safety and effectiveness after NDA approval and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized.

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In the United States, products composed of components that would normally be regulated by different centers at the FDA are known as combination products. Typically, the FDA's Office of Combination Products assigns a combination product to a specific Agency Center as the lead reviewer. The FDA determines which Center will lead a product's review based upon the product's primary mode of action. Depending on the type of combination product, its approval, clearance or licensure may usually be obtained through the submission of a single marketing application. However, the FDA sometimes will require separate marketing applications for individual constituent parts of the combination product which may require additional time, effort, and information. Even when a single marketing application is required for a combination product, the relevant Centers may participate in the review. An applicant will also need to discuss with the Agency how to apply certain premarket requirements and post-marketing regulatory requirements, including conduct of clinical trials, adverse event reporting and good manufacturing practices, to their combination product.

A drug that is the subject of a NDA, where the drug's exclusivity period is expired, is eligible for approval as a generic drug. A generic drug product is one that is comparable to an innovator drug product in dosage form, strength, route of administration, quality, performance characteristics, and intended use. All approved products, both innovator and generic, are listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (Orange Book).

Generic drug applications are termed "abbreviated" because they are generally not required to include preclinical (animal) and clinical (human) data to establish safety and effectiveness. Instead, generic applicants must scientifically demonstrate that their product performs in the same manner as the innovator drug. One way applicants demonstrate that a generic product performs in the same way as the innovator drug is to measure the time it takes the generic drug to reach the bloodstream in healthy volunteers. This demonstration of "bioequivalence" gives the rate of absorption, or bioavailability, of the generic drug, which can then be compared to that of the innovator drug. To be approved by the FDA, the generic version must deliver the same amount of active ingredients into a patient's bloodstream in the same amount of time as the innovator drug.

The "Drug Price Competition and Patent Term Restoration Act of 1984," also known as the Hatch-Waxman Amendments, established bioequivalence as the basis for approving generic copies of drug products. These Amendments permit the FDA to approve applications to market generic versions of brand-name drugs without repeating costly and duplicative clinical trials to establish safety and efficacy. Under the Hatch-Waxman Amendments, brand-name companies gained patent term extensions to compensate for the time the patented product was under review by the FDA and also gained certain periods of marketing exclusivity. In addition to the Abbreviated New Drug Application ("ANDA") approval pathway, generic drug companies gained the ability to challenge patents in court prior to marketing as well as 180-day generic drug exclusivity.

### *Expedited Development and Review Programs*

Under FDA's accelerated approval regulations, the FDA may approve a drug or biologic candidate for a serious or life-threatening illness that provides meaningful therapeutic benefit to patients over existing treatments and demonstrates an effect on either a surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality ("**IMM**"), that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity, or prevalence of the disease or condition and the availability or lack of alternative treatments. A product candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of post-approval clinical trial to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or to confirm a clinical benefit during post-marketing studies, may allow the FDA to consider withdrawal of the product from the market on an expedited basis. All promotional materials for product candidates approved under accelerated regulations are subject to prior review by the FDA.

Another program available for sponsors is the breakthrough therapy designation. A drug or biologic may be eligible for designation as a breakthrough therapy if the product is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening condition, and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. A sponsor may request that a product be designated as a breakthrough therapy concurrently with, or at any time after, the submission of an Investigational New Drug Application ("**IND**"), and the FDA must determine if the candidate qualifies for such designation within 60 days of receipt of the request. If so designated, the FDA shall act to expedite the development and review of the product's marketing application, including by meeting with the sponsor throughout the product's development, providing timely advice to the sponsor to ensure that the development program to gather preclinical and clinical data is as efficient as practicable.

### *Designating Orphan Drug and Biological Products*

Public Law 97-414 established the Orphan Drug Act which amended the FDCA to allow sponsors of a drug for a rare disease or condition ("**orphan drug**") to request the Secretary of Health and Human Services to provide written recommendations for the non-clinical and clinical investigations which must be conducted with the drug before it may be approved as a new drug under such Act, or it may be licensed as a biological product under the PHSA. Orphan drug designation qualifies sponsors for incentives including:

- Tax credits for qualified clinical trials
- Exemption from user fees
- Potential seven years of market exclusivity after approval

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Sponsors seeking orphan drug designation for a drug must submit a request for designation to the FDA. Sponsors requesting designation of the same drug for the same rare disease or condition as a previously designated product must submit their own data and information to support their designation request. Orphan drug designation is a separate process from seeking approval or licensing. Drugs for rare diseases go through the same rigorous scientific review process as any other drug for approval or licensing.

### ***Content of Labeling***

FDA has issued regulations (the electronic labeling rule) requiring the submission of the content of labeling in electronic format for marketing applications. The requirements of the electronic labeling rule are established by regulation for annual reports to marketing applications.

### ***Promotional Materials***

Applicants must submit specimens of mailing pieces and any other labeling or advertising devised for promotion of the drug product at the time of initial dissemination of the labeling and at the time of initial publication of the advertisement for a prescription drug product. Each submission (also referred to as a 2253 submission) is required to be accompanied by a completed fillable Form FDA 2253 (Transmittal of Advertisements and Promotional Labeling for Drugs and Biologics for Human Use) and is required to include a copy of the product's current professional labeling.

### ***Changes to An Approved ANDA***

Under section 506A of the Federal Food, Drug, and Cosmetic Act (FD&C Act), certain changes in the conditions described in approved ANDAs require an approved supplemental application before the change may be made.

### ***Combination Product Safety Reporting***

ANDA products that are combination products as defined by 21 CFR 3.2(e) are subject to post-marketing safety reporting (PMSR) requirements for combination products.

### ***Annual Facility Fees***

The Generic Drug User Fee Amendments (GDUFA) requires owners of facilities producing generic drug products or active pharmaceutical ingredients (API), and certain other sites and organizations that support the manufacture or approval of these products to electronically self-identify with the FDA and update that information annually. Most facilities that self-identify are required to pay an annual facility user fee.

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### *Post-Marketing Requirements*

Following approval of a new product, the manufacturer and the approved product are subject to continuing regulation by the FDA, including, among other things, monitoring and record-keeping activities, reporting of adverse experiences, complying with promotion and advertising requirements, which include restrictions on promoting products for unapproved uses or patient populations (known as “off-label use”) and limitations on industry-sponsored scientific and educational activities. Although physicians may prescribe legally available products for off-label uses, manufacturers may not market or promote such uses. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including investigation by federal and state authorities. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use or first publication. Post-marketing reporting requirements applicable to ANDAs require ANDA holders to notify the FDA of the marketing status of drug products approved under ANDAs, and section 506I of the FDCA imposes additional marketing status reporting requirements in certain circumstances. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing.

FDA regulations require that products be manufactured in specific approved facilities according to approved manufacturing processes and in accordance with cGMP regulations. These manufacturers must comply with cGMP regulations that require, among other things, quality control and quality assurance, the maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. The manufacturer is ultimately responsible for its products and the manufacturing practices of its contract manufacturers; therefore, the manufacturer must take responsibility for the failure for the contract manufacturers to manufacture according to cGMPs.

Manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP requirements and other laws. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance. The discovery of violative conditions, including failure to conform to cGMP regulations, could result in enforcement actions, and the discovery of problems with a product after approval may result in restrictions on a product, manufacturer or holder of an approved NDA, including recall, any of which could have a material adverse effect on our business, financial condition and results of operations.

Once an approval is granted, the FDA may issue enforcement letters or withdraw the approval of the product if compliance with regulatory requirements and standards is not maintained or if problems occur after the drug or biologic reaches the market. Corrective action could delay drug distribution and require significant time and financial expenditures. Later

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discovery of previously unknown problems with a drug, including adverse events (“AEs”) of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the drug, suspension of the approval, complete withdrawal of the drug from the market or product recalls;
- fines, warning letters or holds on post-approval market studies;
- refusal of the FDA to approve applications or supplements to approved applications, or suspension or revocation of drug approvals; drug or biologic seizure or detention, or refusal to permit the import or export of drugs; or
- injunctions or the imposition of civil or criminal penalties.

### *Patent Term Extension and Marketing Exclusivity*

If approval of the application is for the first permitted commercial marketing or use of a medical drug containing an active ingredient or of a biologic under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Act, then upon approval, the patent owner of the relevant drug or biologic may apply for a patent term extension of up to five years to compensate for the portion of the patent term lost during product development and FDA review of the NDA/BLA. The patent term extension that may be granted is half of the post-patent grant product testing phase (i.e., the time between the submission of the IND and the NDA/BLA, not including the period prior to the grant of the patent) and the post-patent grant review phase (i.e., the time between the submission of the NDA/BLA and approval, not including the period prior to the grant of the patent), up to a maximum of five years. This time can be shortened if the FDA believes that the applicant did not pursue approval with due diligence. The total patent term after the extension may not exceed more than 14 years from the date of FDA approval of the product. Only one patent claiming each approved product is eligible for patent term extension; only those claims covering the approved product, a method for using it, or a method for manufacturing it may be extended, and the patent holder must apply for patent term extension within 60 days of approval. The USPTO, in consultation with the FDA, reviews and approves the application for patent term extension. For patents that might expire during the application phase, the patent owner may request an interim patent extension. An interim patent extension increases the patent term by one year and may be renewed up to four times. For each interim patent extension granted, the post-approval patent extension is reduced by one year. The director of the USPTO must determine that approval of the drug candidate covered by the patent for which a patent extension is being sought is likely. Interim patent extensions are not available for a drug candidate for which a NDA/BLA has not been submitted.



### **Laws and Regulations on Product Liability**

The United States' state laws generally impose liability on all manufacturers and retailers (and parties in the supply chain) for injuries that result from unsafe, defective and dangerous products sold to consumers. Foreign manufacturers outside of the United States can be sued and held liable for product liabilities for their products sold in the United States. The term "product liability" refers to the legal liability of manufacturers and sellers to compensate buyers, users, and even bystanders for damages or injuries suffered because of defects in goods purchased. In addition, the United States laws and regulations (for example, the Consumer Product Safety Improvement Act of 2008) can impose obligations on manufacturers and retailers to remedy product defects, which can include safety recall campaigns. In the United States, there are two separate and distinct aspects that govern product liability: (i) product liability law, and (ii) product safety law.

#### ***Product Liability Law***

The first body of law that governs the manufacture, distribution and sale of products is known as product liability law. There is no federal product liability law in the United States. Instead, the law of each state determines the liability of product manufacturers. While several states have passed comprehensive statutes, most state product liability law is based on common law. Although state law varies, there are many similarities among the states. Manufacturers, however, should be aware of the intricacies of the product liability law in the states in which they do business. In application, product liability law governs private litigation of product accidents. It operates *ex post*, meaning it is a body of law that governs after a product accident has already occurred.

Product liability law sets out the full range of legal responsibilities of manufacturers, distributors and sellers of products. Parties involved in selling or distributing a product are subject to liability for harm caused by a defect in that product. Generally speaking, any entities in the supply chain of a product can potentially be held liable. This includes manufacturers of component parts (at the top of the chain), assembling manufacturers, the wholesalers, and the retail store owners (at the bottom of the chain). There are three types of product defects, namely, design defects, manufacturing defects and warning defects. Product liability claims may be based on negligence, strict liability or breach of warranty. In a negligence claim, the defendant could be held liable for a personal injury or property damage caused by a failure to use due care. Strict liability claims, however, do not depend on the degree of carefulness by the defendant. A defendant is liable when it is shown that an injury (personal or to property) occurred as the result of a product's defect. Breach of warranty is also a form of strict liability in the sense that a showing of fault is not required. The plaintiff need only establish the warranty was breached, regardless of how that came about.

Defenses to the product liability claims are a matter of state law as well. Defenses can vary from state to state, and generally may include: (i) contributory negligence/comparative fault, (ii) assumption of risk, and (iii) intervening/superseding cause. Under contributory negligence, a claimant is barred from recovery if his own negligence caused or contributed to



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his injury. However, most states have abandoned contributory negligence in favor of comparative fault. Under comparative fault, a claimant's recovery is reduced if his own negligence (or fault) contributed to his injury. In some states, a claimant may also be barred from recovery if he is aware of a product defect and the accompanying dangers, but uses the product anyway (i.e. assumption of risk). The assumption of risk defense is based on what the claimant actually knew, not what a reasonable person would have known. In most states, if a claimant's injury was caused by the intervening conduct of another and that conduct is also a superseding cause, a defendant may avoid liability (an intervening act is a superseding cause when a manufacturer could not reasonably be expected to protect against things such as: (i) criminal acts; (ii) use of a product in an unforeseeable manner; (iii) alteration of the product; (iv) negligent use; and/or (v) failure to properly maintain a product.)

### ***Product Safety Law***

The second body of law is commonly referred to as product safety law. Product safety law operates *ex ante*, meaning that it seeks to prevent product-caused accidents and diseases before they occur. Enacted in 1972 by the United States Congress, the Consumer Product Safety Act ("CPSA") is federal law with respect to product safety of consumer products sold in the United States. CPSC established the United States Consumer Product Safety Commission ("CPSC"), which is a permanent independent agency of the United States federal government, and defines CPSC's basic authority and authorizes CPSC to develop standards and bans pertaining to consumer products. CPSC had promulgated a series of regulations under the CPSA. A major amendment to the CPSA is the Consumer Product Safety Improvement Act ("CPSIA"), effective in 2008 and provides the CPSC with significant new regulatory and enforcement tools. Products manufactured in the United States that fail to comply with CPSIA's requirements are subject to confiscation, and manufactures and/or distributors in the United States are subject to civil penalties and fines, as well as possible criminal prosecution. CPSC jurisdiction does not extend beyond the territorial limits of the United States.

CPSA contains several reporting requirements for manufacturers and sellers of consumer products sold in the U.S. Section 15 of the CPSA requires a manufacturer or a seller to inform the CPSC immediately in the event it obtains information that any of its products (i) fails to comply with certain consumer product safety rules, (ii) contains certain defect or (iii) creates an unreasonable risk of serious injury or death. The CPSC may require the manufacturer or the seller to cease distribution of the product, and notify each person to whom the manufacturer or the seller knows such product was sold of such non-compliance, defects or risk. In certain circumstances, the CPSC may require the manufacturer or the seller to bring the product into conformity with the applicable product safety rules, repair the defect in the product, replace the product with an equivalent product that complies with the applicable product safety rules, effect a product recall and/or refund the purchase price of the product.

Under the CPSIA, a general conformity certification is required for any consumer product imported into the United States that is subject to a consumer product safety rule issued under CPSA, or a similar rule, standard, regulation, or ban issued by the CPSA or under any statute issued by the CPSC. The requirement applies to all manufacturers of goods. Those parties must

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test certain products and certify that their products comply with all applicable consumer product safety rules and similar rules, bans, standards, and regulations under any law administered by the CPSC. The CPSIA specifies that certification must be based on a *test of each product or a reasonable testing program*. The certificate must accompany the product or shipment of products, and a copy must be furnished to each distributor or retailer. If requested by the commission, a copy must be furnished to the CPSC.

### **Laws and Regulations on Trade**

#### ***Importation***

Importation of goods into the customs territory of the United States is governed principally by the Tariff Act of 1930, as amended, the Customs Modernization Act of 1983, and the regulations of U.S. Customs and Border Protection (“**CBP**”).

Under these laws and regulations, U.S. importers have primary legal responsibility for initially valuing, classifying, and determining the rate of duty applicable to imported merchandise. The importer is required to exercise *reasonable care* in entering merchandise into the United States. This includes when providing to CBP information and documentation necessary for it to assess duties on imported merchandise, collect accurate import statistics, and determine whether an import complies with applicable laws. Civil penalties may be assessed against any person who uses false or misleading statements to enter goods into the United States. In determining the applicable penalty for such a wrongdoing, CBP first determines the applicable degree of culpability of the offending party.

In addition to regulating the process of importation into the United States, CBP is charged with enforcing the import and export-related regulations of approximately 40 other U.S. federal agencies. Each such agency promulgates regulations governing importation of the products under their jurisdiction. CBP is charged with ensuring that imports (and exports) comply with those regulations and is authorized, in many cases, to effect seizures, forfeitures, and rejection of entry of non-conforming goods.

#### ***Import Tariffs***

Raw materials and work-in-progress imported from us in China are generally subject to the United States import duties. China is subject to the general rates applicable to most countries with which the United States does not have a free-trade agreement in place. The rates of duty are set forth in the Harmonized Tariff Schedule of the United States (“**HTS**”) which identifies applicable duties for the universe of imported goods and materials, organized by class and specific article.

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Sections 201 through 204 of the Trade Act of 1974 provide the authority and procedures for the United States to take various actions to facilitate a domestic industry's adjustment to import competition. Under such Sections, if the International Trade Commission determines that an article is being imported in such increased quantities as to threaten domestic producers of similar products, the United States may, among other things, increase or impose a duty, or a tariff-rate quota.

### **Laws and Regulations on Export Control**

Federal laws and regulations control, regulate, and restrict the exporting of critical materials, items, and services to foreign nationals and foreign countries for purposes of national security, foreign policy, anti-terrorism, or non-proliferation. The Export Administration Regulations (the “**EAR**”) and the International Traffic in Arms Regulations (the “**ITAR**”) constitute the major constituents of U.S. export control. The primary federal entities involved in the implementation and enforcement of U.S. export control are the Treasury Department's Office of Foreign Assets Control (the “**OFAC**”), the Department of Commerce (Bureau of Industry and Security), and the State Department. Export-related laws and regulations may encompass the exporting of patient or medical data and information to foreign nations or foreign individuals, whether overseas or in the U.S. In deciding the extent to which an export is controlled, the federal government and the aforementioned federal entities under the executive branch primarily examine the destination to which an export is made, the specific material, item, or service being exported, the end user of the export, and the end use of the export. Depending on the material, item, or service being exported and the applicability of OFAC, EAR, and ITAR, an export may be unlawful, or a license may be required for export. Penalties for the violations of the export control laws and regulations of the U.S. include significant fines, imprisonment, or both.

On February 28, 2024, President Biden issued an executive order (the “**EO**”) establishing the framework for upcoming regulations that will introduce new restrictions on transactions involving U.S. persons' sensitive personal data and countries of concern, including China, or related parties, for purposes of national security and protecting U.S. persons' sensitive data and privacy. The EO and the upcoming regulations will impact the use and export of genomic data, biometric data, personal health care data, geolocation data, personal financial data, and other personally identifiable information. Given enforcement authority under the EO, the Department of Justice expects companies to develop and put in place compliance procedures to ensure compliance with the EO and the relevant upcoming regulations. The inadequacy of compliance procedures or violations of the EO or the upcoming regulations could lead to enforcement actions resulting in civil or criminal penalties. Companies wishing to export data encompassed under the EO and the relevant upcoming regulations may need to apply for a license with the Department of Justice, which will have considerable discretion in making such determinations. Companies will also be able to request advisory opinions from the Department of Justice as to whether encompassed data can be exported or will require a license.

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### **Laws and Regulations on Intellectual Property**

The U.S. provides trademark protection at both federal and state levels. Federal law is the principal source of trademark protection in the U.S., although state laws also provide common law protection. The Trademark Act of 1946, which is commonly known as the Lanham Act, is the main federal trademark statute. There are two ways to acquire ownership of a trademark: (i) being the first to actually use the mark in commerce, and (ii) being the first to register the mark with the U.S. Patent and Trademark Office (“USPTO”). The USPTO is the federal agency for granting U.S. patents and registering trademarks. It examines trademark applications and grants registrations when applicants are entitled to them. Most applications are based on the current use of the mark in commerce or the intent to use the mark in commerce in the future. For an application filed under the use-in-commerce basis, the applicant must be using the mark in the sale or transport of goods or the rendering of services in interstate commerce. If an applicant has not used the mark yet but plans to do so in the future, it may file the application based on a bona fide intent to use the mark in commerce.

Federal law has exclusive domain over patents and patent disputes. A patent is a government grant providing the patent owner with the right to exclude others from using a claimed invention or practicing a claimed method. A patent is obtained by filing an application with the USPTO claiming a useful, novel invention. The application must comply with various requirements set forth in the Patent Act (codified at 35 U.S.C. § 1 et seq) and regulations established by the USPTO.

### **Laws and Regulations on Labor and Employment**

The employment of individuals in the United States is governed by federal laws, state laws and local laws. The following highlights important areas of regulatory activity to illustrate the legal issues involved but does not explain every single law, interpretation or application because in many cases, the issues will be highly fact-specific. Labor and employment laws can generally be categorized as (i) equal employment opportunity, (ii) wage and hour obligations, and (iii) workplace safety. Typically, national laws set the minimum legal standard for employee rights, and state and local laws enhance those rights. Most employees in the United States are hired “at-will,” meaning that their employment can be terminated at any time, with or without notice or cause. However, individual employment agreements between an employee and employer may vary this status, and even an at-will employee may not be terminated for an illegal reason (such as discrimination or harassment, as described below), nor may an employee be terminated or otherwise retaliated against for engaging in protected activity under the law. All employees must provide verification of their eligibility to work in the United States.

Regarding equal employment opportunity, employers in the United States are prohibited from discriminating against individuals based on age, physical or mental disability, race, color, national origin, religion, sex or gender, sexual orientation, veteran status, marital status, citizenship, political activity or affiliation, ancestry, medical condition, taking or requesting statutorily protected leave, or any other basis protected by law. These protections apply to individuals who are applying for jobs as well as to actual employees. In addition, employees

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are required to maintain workplaces that are free of any of the forgoing harassment or discrimination by taking reasonable steps of prevention. Individuals who have suffered discrimination or harassment may be awarded compensatory damages consisting of back pay (money the individual would have earned but for the discriminatory conduct), front pay (additional money the individual is paid to reflect diminished future earnings), pain and suffering, emotional distress and their attorneys' fees and costs. In addition, courts may award punitive damages when the illegal conduct is deemed to have been willful.

For wage and hour obligations, all employers are required to pay employees a minimum wage for hours worked and to pay employees premium pay for overtime hours unless the employee fits within an exemption. The exemptions are narrowly construed and generally apply to executives, managers and professionals, as well as certain computer and sales personnel. The failure to comply with these laws or technical requirements can result in awards of damages and penalties to be paid to employees and to the state, if applicable. Prevailing employees are eligible to recover their attorneys' fees and costs, as well as the actual underpaid wages and penalties.

In respect of workplace safety, the Federal Occupational Safety and Health Act ("OSHA") sets minimum standards for workplace safety in the United States. As a general proposition, both the U.S. federal and state OSHA laws require employers to furnish employees with a place of employment that is safe and healthful. Factors employees should take into consideration when evaluating the worksite include, but are not limited to, (i) environmental hazards such as chemicals or exposure to other toxic substances; (ii) the safe use of machinery; (iii) risk of repetitive stress injuries; (iv) outside risks such as the risk of crime activity; and (v) access to first responders such as ambulance, fire, and police. An employer's failure to comply with OSHA laws can result in awards of fines and damages.

### **Laws and Regulations on Taxation**

The U.S. federal government levies a variety of taxes on U.S. businesses, non-U.S. businesses trading in the United States, and business owners and their employees. Depending on the business structure, such taxes include corporate franchise tax, income tax, capital gains tax on long-term sales, income tax on dividends and interest, income tax on partnership profits and employee payroll taxes.

In addition to the federal government, the 50 states, local counties and city governments tax and regulate business activities within their respective jurisdictions. For example, business activities within a state may be subject to the state's business and personal income tax, payroll tax, sales tax, franchise and other taxes. In addition, some local governments, such as counties and cities, may impose their own similar taxes. If a business has sales or employees in more than one location, state and local taxes generally will be pro-rated depending on the percentage of income, number of employees and other factors associated with each location.

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### **Laws and Regulations on Competition and Antitrust**

The U.S. antitrust laws are developed in response to unfair business practices and anti-competitive conduct by companies, corporate monopolies, and trusts. At the heart of U.S. antitrust laws is the Sherman Antitrust Act (“**Sherman Act**”), which prohibits agreements that unreasonably restrain trade and the unilateral abuse of monopoly power. Conducts such as price-fixing, bid-rigging, limitation of output, allocation of territories or customers, and exclusionary conduct to achieve monopoly, are prohibited under the Sherman Act. Violation of the Sherman Act and other anti-trust laws and regulations would lead to criminal and/or civil sanctions.

The U.S. antitrust laws apply to businesses and individuals alike. Certain laws and regulations also have an extraterritorial reach. Pursuant to the Foreign Trade Antitrust Improvement Act of 1982, the Sherman Act would apply to conduct that occurs outside of the U.S. if such conduct (i) has a direct, substantial and reasonably foreseeable effect on U.S. commerce, including U.S. import or export commerce; and (ii) gives rise to a claim under the Sherman Act.

### **U.S.-Based Data Privacy Regulations**

U.S. law provides a patchwork of data privacy protections. These laws generally regulate the collection, use, disclosure, and storage of data subjects’ personal information, obligate regulated entities to implement safeguards and adhere to compliance requirements, and grant data subjects certain rights with respect to their data. There is no comprehensive federal privacy law in the U.S., as such, federal data privacy requirements are pursuant to sectoral privacy laws. States have different laws providing privacy protections including consumer privacy laws, which apply to personal information, and consumer health data laws. Pharmaceutical companies are also subject to federal and state laws pertaining to marketing communications and laws prohibiting unfair or deceptive business acts or practices. This fragmented legal landscape necessitates a case-by-case, jurisdiction-specific analysis, creating multiple layers of legal and regulatory risk, complicating compliance efforts for organizations.

### ***Marketing Communications***

Marketing communications by pharmaceutical companies must comply with the Telephone Consumer Protection Act (“TCPA”) and the Controlling the Assault of Non-Solicited Pornography and Marketing Act of 2003 (“CAN-SPAM”), including by: obtaining consumer consent prior to initiating communications, providing clear opt-out mechanisms for future communications, identifying the communication as an advertisement, and implementing measures to protect sensitive consumer information.

The TCPA generally prohibits calls, faxes, and texts to residential and wireless lines using an automatic telephone dialing systems or artificial or prerecorded voice recordings without the recipient’s prior express consent and allows consumers to opt-out of receiving such communications, subject to exceptions (e.g., calls or texts for emergency purposes, such as to



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issue natural disaster or public safety warnings). The Federal Communications Commission (“FCC”) is the primary enforcement authority of the TCPA. The FCC may impose civil forfeiture penalties and criminal fines via administrative action against parties that violate the TCPA. TCPA enforcement may also be initiated by state attorneys general or other state officials or agencies, who may seek injunctive relief and actual monetary loss or damages of \$500 per violation. Courts may award treble damages if it finds willful or knowing violations. The TCPA also provides a private right of action, permitting private litigants to seek injunctive relief, monetary damages (including treble damages), or both. Most states have their own telemarketing laws, which the TCPA does not preempt if the state law has more restrictive requirements. Therefore, Pharmaceutical companies that conduct marketing communications via telephone, fax, or text communications must factor the requirements of the TCPA and state laws into their marketing communications compliance strategy.

CAN-SPAM prohibits the transmission of unsolicited commercial emails, such as email messages that advertise or promote a commercial product or service, including website content, to individual consumers and business email accounts. CAN-SPAM does not apply to transactional email messages, such as emails to complete or confirm a previously agreed upon commercial transaction or emails providing product safety information for a product purchased by the email recipient. At a high level, CAN-SPAM prohibits the transmission of email messages containing false or misleading information or deceptive subject headings, and requires senders of commercial emails to, among other things, provide clear notice of the recipient’s right to opt-out of future messages and a functional opt-out mechanism. The Federal Trade Commission (“FTC”) is the primary enforcement authority for CAN-SPAM, and the FTC may seek civil money penalties and injunctive relief pursuant to its Section 5 of the FTC Act authority (discussed more in the next section) to enforce against CAN-SPAM violations. CAN-SPAM enforcement may also be initiated by state attorneys general or other state officials or agencies, who may seek injunctive relief, the greater of damages for actual loss or statutory damages (up to \$250 per violation, maximum of \$2 million statutory damages award), and reasonable attorney’s fees and costs. Courts may award treble damages if it finds willful or knowing violations. Unlike TCPA, CAN-SPAM does not grant a private right of action and preempts all state and local laws that directly regulate commercial email, except that it expressly does not preempt state laws to the extent they deal with fraud or deception or computer crime.

### ***Unfair or Deceptive Business Acts or Practices***

Section 5 of the FTC Act prohibits companies from engaging in unfair or deceptive acts or practices (“UDAP”) in or affecting commerce, including invading consumers’ privacy, misrepresenting data practices (e.g., health data practices), or failing to safeguard personal information. The FTC enforces the FTC Act, and may seek injunctive relief and civil penalties. The FTC may also seek equitable remedies like restitution and disgorgement (i.e., the deletion of data and other outcomes, like AI models, derived from unfair or deceptive conduct) through administrative proceedings. The FTC Act does not grant a private right of action, meaning that private individuals or entities may not file a lawsuit against a party that engaged in UDAP pursuant to the Section 5.



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Most states, including New Jersey, also have UDAP laws, and state enforcement authorities have carried out privacy enforcement activities under these laws, even in the absence of a state consumer privacy law. Remedies available under state UDAP laws vary, but generally include restitution, attorneys' fees, and civil penalties. State courts have broad discretion to interpret their state's UDAP law, which could impact the calculation of the civil penalty amount. Unlike the FTC Act, many state UDAP laws grant a private right of action (e.g., New Jersey), giving consumers and others impacted by violations constituting UDAP an avenue for directly seeking redress.

### *Federal Data Privacy Protections*

The Health Insurance Portability and Accountability Act of 1996 ("HIPAA") is a federal law that establishes privacy and security protections for individuals' protected health information ("PHI") maintained in electronic health records and other formats. HIPAA applies to covered entities (e.g., health care providers, health plans) and business associates (e.g., collection agencies, billing or coding companies, IT consultants and other vendors creating or maintaining PHI on behalf of covered entities) (together, "HIPAA-regulated entities"). Non-compliance with HIPAA requirements may result in civil and criminal penalties. The primary HIPAA enforcement authority is the U.S. Department of Health and Human Services, Office for Civil Rights ("OCR"), however, if a non-compliance report implicates a potential (or actual) criminal violation of HIPAA, OCR may refer the matter to the U.S. Department of Justice for investigation. State attorneys general also have authority to bring civil actions against HIPAA-regulated entities for non-compliance with HIPAA requirements and obtain damages and injunctions on behalf of state residents. HIPAA does not preempt stricter state laws protecting the privacy of individuals' health data if such laws are not inconsistent with federal mandates.

In general, pharmaceutical companies are only indirectly impacted by HIPAA, such as in their interactions with HIPAA-regulated entities (e.g., providers, pharmacies, and payors) and individuals who have rights under HIPAA (e.g., patients). Some opt to benchmark their data privacy compliance programs against HIPAA to align with data practices with which their stakeholders have grown accustomed. However, pharmaceutical companies conducting clinical trials and undertaking research and development activities requiring the use of PHI may be required to comply with certain HIPAA requirements, including executing a valid written HIPAA authorization for a provider's disclosure of PHI to the company. Whenever possible, it is recommended for pharmaceutical companies to conduct clinical trials and research and development activities using data that has been de-identified according to the HIPAA de-identification standards set forth at 45 C.F.R. § 164.514(b) because such data is no longer considered to be PHI, and is therefore no longer subject to HIPAA. Doing so will mitigate the company's compliance risks. Pharmaceutical companies engaged only in pharmaceutical importing, marketing, and distribution activities do not generally deal with data that is PHI because their activities primarily implicate only business-to-business data from direct interactions with their healthcare provider customers.

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### *State Data Privacy Protections*

State data privacy protections form a patchwork of laws, including state-specific corollaries to HIPAA, consumer privacy laws, and consumer health data (CHD) laws, necessitating a state-by-state analysis. The relatively recent enactment of many of these laws — particularly state consumer privacy and CHD regulations — adds to the complexity, as their interpretation and application are still evolving. This ongoing uncertainty further complicates compliance efforts for organizations.

As noted, HIPAA does not preempt stricter state laws protecting the privacy of individually identifiable health information. For example, California’s Confidentiality of Medical Information Act (“CMIA”) governs the privacy and security of medical information and applies to, among others, pharmaceutical companies. Under CMIA, a pharmaceutical company is defined as “a company or business, or an agent or representative thereof, that manufactures, sells, or distributes pharmaceuticals, medications, or prescription drugs,” excluding pharmacy benefits managers. The CMIA requires regulated entities to implement procedures safeguard the confidentiality of medical information, including security systems, and protocols for employees handling medical information and other measures to protect medical information from unauthorized use and disclosures. It prohibits the use or disclosure of medical information for any purpose not necessary to provide health care services to a patient — such as marketing — unless expressly authorized by the patient or permitted or required by law. The California Attorney General, district attorney, county counsel, or city attorney may bring civil enforcement actions for violations of CMIA. The State Public Health Officer may recommend cases for civil action to state enforcement authorities. Unlike HIPAA, CMIA grants a private right of action, enabling individuals whose medical information has been used or disclosed in a manner that violates CMIA and that sustained economic loss or personal injury to recover compensatory damages, punitive damages (not exceeding \$3,000), attorney’s fees (not exceeding \$1,000), and the costs of litigation. Individuals may also bring civil suits for negligent disclosure of their medical information. Penalties for negligent disclosure include actual damages or nominal damages of up to \$1,000, with no requirement to prove actual damages. Administrative penalties of up to \$2,500 per violation may also apply to negligent disclosures. Violations of the CMIA that result in an economic loss or personal injury are criminally punishable as misdemeanors.

As of January 2025, twenty (20) states have passed consumer privacy laws: California, Colorado, Connecticut, Delaware, Florida, Indiana, Iowa, Kentucky, Maryland, Minnesota, Montana, Nebraska, New Hampshire, New Jersey, Oregon, Rhode Island, Tennessee, Texas, Utah, and Virginia. This number is expected to grow as several more states consider enacting consumer privacy bills. The scope, applicability, requirements, and risks under each of the state consumer privacy laws vary per jurisdiction, and the interpretation of these laws is still evolving. These laws apply to the personal information of consumers, but the definitions of personal information and consumer, or similar terms, varies per state. For example, under the California Consumer Privacy Act, as amended by the California Privacy Rights Act, (“CCPA”), the term “consumer” includes California residents acting in the individual or household context; who are employees, job applicants or independent contractors; or acting in the

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business-to-business (“B-to-B”) context. In contrast, under the New Jersey Data Privacy Act (“NJDPa”), a consumer is a New Jersey resident acting only in an individual or household context and does not include an individual acting in a commercial or employment context. As such, unlike the CCPA, NJDPa does not apply to human resources or B-to-B data. Key categories for data and organizations may be excluded or exempted from the requirements of state consumer privacy laws, but the level and scope of exclusion or exemption varies per jurisdiction. For example, the CCPA offers data-level exemptions and exclusions for PHI collected by HIPAA regulated entities, medical information governed by the CMIA, and information that is collected, used, or disclosed in research, including clinical trials, conducted in accordance with the HIPAA Privacy Rule, the Federal Policy for the Protection of Human Subjects (the “Common Rule”), good clinical practice guidelines issued by the International Council for Harmonisation, or human subject protection requirements of the FDA. Similarly, the NJDPa offers data-level exemptions and exclusions for PHI collected by HIPAA regulated entities, and personal information collected, processed, or disclosed as part of research conducted in accordance with the Common Rule and the FDA Policy for the Protection of Human Subjects. The CCPA also offers organization-level exemptions and exclusions, such that the CCPA does not apply to HIPAA covered entities and providers of health care under CMIA, but only to the extent such organizations are maintaining PHI according to HIPAA or medical information according to CMIA. In contrast, NJDPa does not offer organization-level exemptions or exclusions for organizations subject to HIPAA or HIPAA state law corollaries. The state consumer privacy laws do not offer consumers a private right of action, except that the CCPA offers a private right of action for certain data breaches. Taking the above together, whether a state consumer privacy law applies to the data processed and maintained by pharmaceutical companies requires a state-by-state analysis. We likely will need to comply with CCPA requirements as to B-to-B data from California customers, which is not PHI or derived from clinical trials. However, compliance with the NJDPa or other state consumer privacy laws is not likely required at this time because, unlike the CCPA, these laws generally apply only to the personal information of individual consumers and not to B-to-B or human resources data.

A smaller contingent of states adopted CHD laws, which are laws that generally apply to personal information that is linked or reasonably linkable to an individual and that identifies the individual’s past, present, or future physical or mental health status. These laws are drafted broadly to reach data and businesses outside the scope of HIPAA. As with state consumer privacy laws, the interpretation of CHD laws is still evolving. The current landscape of CHD laws is a patchwork of CHD-specific state laws (i.e., Washington and Nevada), state consumer privacy laws that designate CHD and other health data as a subset of sensitive personal data (e.g., Connecticut), and laws not specifically drafted to address privacy but amended to include CHD-related restrictions (i.e., New York). In general, these laws require additional disclosures and consumer consent and authorization for data collection, sharing, and sales; grant consumers rights to CHD similar to consumer rights available under state consumer privacy laws; impose security and processor obligations; prohibit geofencing around health care service facilities; and more. Like state consumer privacy laws, CHD laws are enforceable by the state’s attorney general, and some (i.e., Washington) grant a private right of action. Analysis of the applicability of and risks under CHD laws also require a case-by-case and state-specific analysis.

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## HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

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### OVERVIEW

We are a comprehensive pharmaceutical company driven by independent R&D, rooted in China and facing the world, having full capabilities integrating R&D, production and sales, and focusing on the three key areas of infection, chronic diseases and oncology.

Our company was founded on December 29, 2003, as a sino-foreign joint venture in Dongguan, Guangdong, the PRC, marking our entry into the pharmaceutical industry. In 2005, we established a research institute and focused on developing our own R&D platform. From 2006 to 2010, we initiated our independent work on small molecule new drug development. Progressing into 2011 to 2015, we achieved significant milestones in globalization by securing approval for our Azithromycin tablets in Europe. Advancing to 2016 to 2020, our Class I innovative drug, Dongweien (emitasvir phosphate), received marketing approval from the NMPA. On an international scale, we launched overseas clinical trials for insulin glargine and obtained clinical trial approval from the U.S. FDA for our innovative drug, Yinfenidone.

In November 2021, we acquired 51.41% of the total share capital of HEC CJ Pharm from Guangdong HEC Technology (the “**Acquisition**”). Guangdong HEC Technology is a joint stock company established in the PRC whose shares are listed on Shanghai Stock Exchange (stock code: 600673) and is a subsidiary of Shenzhen HEC Industrial, which is in turn ultimately owned by Mr. Zhang and Ms. Guo. Guangdong HEC Technology’s main business focuses on electronic components, high-end aluminum foil, new chemical materials and energy materials. For Guangdong HEC Technology, divesting HEC CJ Pharm allowed it to concentrate its efforts and resources on its core industries. Before the Acquisition, our Company had long been empowering HEC CJ Pharm, enriching its product range. However, the non-competition commitments made by Shenzhen HEC Industrial, Mr. Zhang and Ms. Guo to HEC CJ Pharm affected our Company’s business stability and asset independence. This, in turn, impacted our Company’s subsequent R&D investments and progress, which also hindered HEC CJ Pharm’s ability to secure further commercialization rights for domestic pharmaceutical products. Therefore, the Acquisition is beneficial for both our Company and HEC CJ Pharm as it facilitated the expansion of business cooperation and allowed for a more focused approach towards our respective strategic goals.

The Acquisition marked a significant milestone in the business expansion of our Company, enabling us to strengthen our market presence, enhance product offerings, and optimize our financial structure. In particular, HEC CJ Pharm owned a robust domestic sales network, while our Company had already established a foothold in international markets at the time of the Acquisition. By acquiring the majority shares in the HEC CJ Pharm, we were able to integrate domestic and international sales channels, leveraging HEC CJ Pharm’s extensive domestic network to accelerate the promotion of our innovative drug pipeline. Before the Acquisition, HEC CJ Pharm had well-established commercialization capabilities in anti-infective drugs and chronic disease treatments, while our Company specialized in the R&D of innovative drugs and biosimilars. The Acquisition allowed us to integrate these complementary strengths, enriching our product pipeline and creating a more comprehensive portfolio. The

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Acquisition also introduced new profit growth drivers and provided a more stable cash flow to support our operations and future investments by optimizing our asset-liability structure, further improving our profitability and financial resilience.

At the time of our establishment, our equity interest was held as to 41% by Shenzhen HEC Industrial and 10% by HEC CJ Pharm, and the remaining aggregate 49% equity interest was held by three Independent Third Parties. Each of Shenzhen HEC Industrial and HEC CJ Pharm was jointly controlled by the founders of our Company, namely Ms. Guo and Mr. Zhang Zhongneng (張中能), the father of Mr. Zhang, through a number of shareholding platforms. Accordingly, Ms. Guo and Mr. Zhang Zhongneng were the ultimate controllers of our Company when we were established.

Since establishment, our Company had undergone several rounds of capital increases and equity transfers for expansion of our business and adjustments of our shareholding structure. On May 29, 2020, Yichang HEC Research was the largest direct shareholder of our Company, which held 65% of our equity interest. Yichang HEC Research was wholly-owned by Dongguan HEC Research, which was in turn controlled by Mr. Zhang Zhongneng and Ms. Guo through Shenzhen HEC Industrial and other shareholding platforms. In November 2020, Mr. Zhang (by way of inheritance) and Ms. Guo became the ultimate controllers of our Company.

From July 2020 to March 2023, our Company has undergone a series of capital increases and equity transfers for further adjustments of our shareholding structure and introduction of external investments. See “Development of Our Company” in this section for further details. On June 19, 2023, in preparation for the Listing, all of our then Shareholders entered into a promoters’ agreement, pursuant to which our Company was converted into a joint stock limited company on June 21, 2023.

### OUR BUSINESS DEVELOPMENT MILESTONES

The following is a summary of our key business development milestones:

Time	Milestones
2003 . . . . .	Our Company was established in Dongguan, Guangdong Province and started to engage in pharmaceutical business.
2005 . . . . .	Our Company established a research institute and began to build an R&D team as well as an independent R&D platform.
2006 . . . . .	Our Group’s main product, oseltamivir phosphate, received patent authorization from Roche.

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Time	Milestones
2012 . . . . .	Our Company's first product in Europe, Azithromycin tablets, was approved, which was listed in Germany under our own brand in the same year.
2015 . . . . .	Our Company was approved by the Ministry of Science and Technology of the PRC to establish a state key laboratory for the R&D of new anti-infective drugs.
2017 . . . . .	Our Company's first innovative drug, Yinfenidone, received clinical trial approval from the U.S. FDA and received FDA's orphan drug designation in the same year.
2020 . . . . .	<p>We started to introduce Pre-Listing Investors.</p> <p>Our first Class I innovative drug developed in-house, Dongweien (emitasvir phosphate), was approved for listing by the NMPA through the priority review and approval process.</p>
2021 . . . . .	Our Company's insulin analog insulin glargine injection was approved for marketing by the NMPA.
2022 . . . . .	According to Frost & Sullivan, our Company's Fingolimod capsules became the first generic drug in China to successfully challenge the patent of a U.S. overseas drug.
2023 . . . . .	<p>We submitted a listing application to the NMPA in respect of our major products, Netanasvir Phosphate Capsules and Encofosbuvir Tablets, which are Category 1 new drugs, and the application was accepted.</p> <p>Our Company was converted into a joint stock limited company.</p>
2024 . . . . .	<p>We submitted a listing application to the NMPA in respect of our major product, Olorigliflozin Capsules, a Category 1 new drug, and the application was accepted.</p> <p>We obtained clinical trial approval for HEC169584, which is our first new small molecule drug candidate discovered through AIDD.</p>

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Time	Milestones
	We entered into an exclusive license and commercialization agreement with Apollo Therapeutics Group Limited in respect of our product candidate HEC88473.
	Through a licensing agreement, we have granted Shenyang Sunshine Pharmaceutical Co., Ltd.* (瀋陽三生製藥有限責任公司) exclusive commercialization rights of Clifutinib Besylate in respect of specific indications in China.

### DEVELOPMENT OF OUR COMPANY

#### Establishment of our Company

Our Company was established as a sino-foreign joint venture in Dongguan, Guangdong Province on December 29, 2003 with an initial registered capital of US\$20,000,000. At the time of establishment, our equity interest was held as to 41% by Shenzhen HEC Industrial, as to 38% by North & South Brother (HK), as to 10% by Guenther Kinast (“**Guenther**”), as to 10% by HEC CJ Pharm, and as to 1% by Ni Chi Sung (倪齊嵩). Of which, Shenzhen HEC Industrial and HEC CJ Pharm were then ultimately and jointly controlled by Mr. Zhang Zhongneng and Ms. Guo, and North & South Brother (HK) was ultimately wholly owned by Mo Kit (毛傑). Each of North & South Brother (HK), Mo Kit, Guenther and Ni Chi Sung is an Independent Third Party.

#### Major changes in shareholding and corporate form of our Company

Since our establishment until May 2020, our Company had undergone a capital increase and a series of equity transfers, among which certain major transfers are set out below:

- On December 1, 2009, for internal restructuring purpose, Shenzhen HEC Industrial and HEC CJ Pharm entered into an equity transfer agreement, pursuant to which Shenzhen HEC Industrial agreed to transfer 41% equity interest in our Company held by it to HEC CJ Pharm at a consideration of US\$13.12 million. The consideration was determined after arm’s length negotiations between the parties with reference to the registered capital of our Company subscribed by Shenzhen HEC Industrial. Registration with the local commerce department was completed on December 29, 2009, and HEC CJ Pharm held 51% equity interest in our Company upon completion of the aforesaid transfer;



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- On February 28, 2010, HEC CJ Pharm entered into equity transfer agreements with Ni Chi Sung, Guenther and North & South Brother (HK), pursuant to which Ni Chi Sung, Guenther and North & South Brother (HK) agreed to transfer 1%, 10% and 13% equity interest in our Company held by them to HEC CJ Pharm at a consideration of US\$29,900, US\$299,900 and US\$1, respectively. The above considerations were determined after arm's length negotiations between the parties with reference to the paid-up capital of their respective equity interests in our Company. Registration with the local commerce department was completed on December 28, 2010. Upon the completion of the equity transfers in December 2010, Ni Chi Sung and Guenther ceased to be shareholders of our Company, and HEC CJ Pharm held 75% equity interest in our Company;
- On June 28, 2011, for internal restructuring purpose, HEC CJ Pharm entered into an equity transfer agreement with Yichang HEC Medicine, a non-wholly owned subsidiary of Shenzhen HEC Industrial, in relation to transfer of 75% equity interest in our Company from HEC CJ Pharm to Yichang HEC Medicine at a consideration of US\$24 million. The relevant 75% equity interest in our Company was later transferred from Yichang HEC Medicine to Yichang HEC Research at a consideration of RMB168,461,310.01 on December 18, 2014. The above considerations were determined after arm's length negotiations between the parties with reference to the paid-up capital of the transferred equity interest in our Company at the respective time of transfers. Registrations with the local commerce department were completed on August 30, 2011 and December 30, 2014, respectively; and
- On May 20, 2020, for internal restructuring purpose, Yichang HEC Research entered into an equity transfer agreement with Shenzhen HEC Industrial in relation to transfer of 10% equity interest in our Company from Yichang HEC Research to Shenzhen HEC Industrial at a consideration of RMB23,897,479. The consideration was determined after arm's length negotiations between the parties with reference to the paid-up capital of the transferred equity interest in our Company. Registration with the local commerce department was completed on May 29, 2020.

Upon the completion of the equity transfer in May 2020, our Company had a registered capital of US\$32,000,000, with its equity interest held as to 65%, 25% and 10% by Yichang HEC Research, North & South Brother Pharma and Shenzhen HEC Industrial, respectively. North & South Brother Pharma was ultimately wholly owned by Mo Kit and was an Independent Third Party.

Since July 2020, our Company has undergone a series of equity financing for introduction of new shareholders and Pre-Listing Investors to our Group, so as to obtain funds for the development of our Company and continuous optimization of our governance structure.

## HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

### *Capital increases between July to September 2020 (introduction of Shenzhen Dicheng, Xingsheng Dongyan and Xingsheng Guangchuang as our Pre-Listing Investors)*

On June 23, 2020, CIIT Asset Management Co., Ltd.\* (興業國信資產管理有限公司) (“**CIIT**”) and Shenzhen Dicheng Investment Center (L.P.)\* (深圳市帝成投資中心(有限合夥)) (“**Shenzhen Dicheng**”) entered into a capital increase agreement (the “**2020 Capital Increase Agreement**”) with, among others, our Company and Shenzhen HEC Industrial, pursuant to which the parties agreed that CIIT would subscribe for the increased registered capital of US\$688,400 of our Company at a consideration of RMB500.00 million, Shenzhen Dicheng would subscribe for the increased registered capital of US\$132,400 of our Company at a consideration of RMB96.00 million, and Shenzhen HEC Industrial would subscribe for the increased registered capital of US\$274,700 of our Company at a consideration of RMB200.00 million. The considerations for these capital increases were determined after arm’s length negotiation between the parties with reference to the pre-investment valuation of our Company. As of June 24, 2020, our Company had received the total amount for these capital increases. For further details on the investment made by Shenzhen Dicheng as our Pre-Listing Investor, please see “Pre-Listing Investment” in this section. Our Company completed the registration with the local commerce department for the aforementioned capital increase on July 17, 2020.

On September 6, 2020, as agreed under the 2020 Capital Increase Agreement, CIIT designated Jiaying Xingsheng Dongyan Investment Partnership (L.P.)\* (嘉興興晟東研投資合夥企業(有限合夥)) (“**Xingsheng Dongyan**”) and Jiaying Xingsheng Guangchuang Investment Partnership (L.P.)\* (嘉興興晟廣創投資合夥企業(有限合夥)) (“**Xingsheng Guangchuang**”), the entities affiliated with CIIT, as the transferees for the transfer of 1.83% and 0.25% equity interest in our Company at a consideration of RMB440 million and RMB60 million, respectively, and they shall assume rights and obligations of CIIT under the 2020 Capital Increase Agreement. For further details of the investments made by Xingsheng Dongyan and Xingsheng Guangchuang as our Pre-Listing Investors, please see “Pre-Listing Investment” in this section. Registration with the local commerce department was completed on September 22, 2020. The table below sets out the shareholding structure of our Company immediately following the completion of the abovementioned equity transfers:

Name of Shareholders	Registered capital held in our company	Approximate percentage of shareholding in our Company
	(USD'000)	(%)
Yichang HEC Research . . . . .	20,800.00	62.85
North & South Brother Pharma . . . . .	8,000.00	24.17
Shenzhen HEC Industrial . . . . .	3,474.70	10.50
Xingsheng Dongyan . . . . .	605.80	1.83
Shenzhen Dicheng . . . . .	132.40	0.40
Xingsheng Guangchuang . . . . .	82.60	0.25
<b>Total . . . . .</b>	<b>33,095.50</b>	<b>100</b>

## HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

### *Equity transfers between November to December 2020*

In October 2020, Yidu Junjiafang and Yidu Shuaixinwei were established respectively as platforms of the share incentive scheme at the shareholder level of our Company, with Mr. Zhang as their general partner. On November 5, 2020, Yichang HEC Research transferred its 2% equity interest in our Company to Yidu Junjiafang at a consideration of RMB4.4243 million, and transferred its 8% equity interest in our Company to Yidu Shuaixinwei at a consideration of RMB17.6974 million, for the implementation of the employee incentive scheme at the shareholder level of our Company. Each of these equity transfers was transaction between shareholding platforms controlled by the beneficial controllers at a consideration that was determined after arm's length negotiation between the parties. Our Company has completed the registration with the local commerce department for such equity transfers on November 11, 2020.

On December 22, 2020, North & South Brother Pharma transferred its 10% equity interests in our Company to its wholly-owned subsidiary, Yidu Anjierui Pharmaceutical Technology Co., Ltd.\* (宜都安捷瑞醫藥科技有限公司) (“**Yidu Anjierui**”), for a consideration of RMB1,600 million. Yidu Anjierui was ultimately beneficially owned by Mo Kit and was an Independent Third Party. The consideration for this equity transfer was determined after arm's length negotiations between the parties with reference to the valuation of total shareholders' equity of our Company as of June 30, 2020 conducted by the independent valuer. Our Company has completed the registration with the local commerce department for such equity transfer on December 25, 2020.

The table below sets out the shareholding structure of our Company following the abovementioned equity transfers:

Name of Shareholders	Registered capital held in our Company	Approximate percentage of shareholding in our Company
	(RMB'000) <sup>(note)</sup>	(%)
Yichang HEC Research . . . . .	130,383.972	52.85
North & South Brother Pharma . . . . .	34,965.239	14.17
Shenzhen HEC Industrial. . . . .	25,902.358	10.50
Yidu Anjierui. . . . .	24,671.237	10.00
Yidu Shuaixinwei . . . . .	19,736.692	8.00
Yidu Junjiafang . . . . .	4,934.173	2.00
Xingsheng Dongyan . . . . .	4,515.972	1.83
Shenzhen Dicheng . . . . .	986.984	0.40
Xingsheng Guangchuang . . . . .	615.747	0.25
<b>Total . . . . .</b>	<b>246,712.374</b>	<b>100</b>

*Note:*

On December 22, 2020, our Company convened a general meeting and approved a resolution to change the registered capital currency of our Company from US dollars to RMB, based on the foreign exchange rate of the actual paid-up capital at each period.

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## HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

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*Equity transfers and capital increases between January to March 2021 (introduction of Dongyang Guangsheng, Advanced Manufacturing, Xinquanxin, Qinzhi Kanghong, Gongqingcheng Jianyi, Mige Investment, Jiaxing Ximian and Cuiheng New Era as our Pre-Listing Investors)*

*Introduction of Dongyang Guangsheng and Advanced Manufacturing as our Pre-Listing Investors*

On December 25, 2020, Yidu Anjierui entered into an equity transfer agreement with Dongyang Guangsheng Enterprise Management Partnership (L.P.)\* (東陽光盛企業管理合夥企業(有限合夥)) (“**Dongyang Guangsheng**”), pursuant to which the parties agreed that Yidu Anjierui shall transfer 2.32% equity interests in our Company held by it to Dongyang Guangsheng at a consideration of RMB370.80 million. On the same day, Shenzhen HEC Industrial entered into an equity transfer agreement with Guangdong Advanced Manufacturing Industry Investment Fund Partnership (L.P.)\* (廣東先進製造產業投資基金合夥企業(有限合夥)) (“**Advanced Manufacturing**”), Xingsheng Dongyan, Xingsheng Guangchuang and Shenzhen Dicheng, pursuant to which the parties agreed that Shenzhen HEC Industrial shall transfer 2.25% equity interests in our Company held by it to Dongyang Guangsheng at a consideration of RMB360.00 million, and transfer 0.70%, 0.10% and 0.15% equity interest in our Company held by it to Xingsheng Dongyan, Xingsheng Guangchuang and Shenzhen Dicheng<sup>1</sup>, respectively, at a consideration of RMB1. For further details on the investment made by Dongyang Guangsheng and Advanced Manufacturing as our Pre-Listing Investors, please see “Pre-Listing Investment” in this section.

On the same day, at the general meeting of our Company, a resolution was passed to increase the registered capital of our Company to RMB252,722,287, where Dongyang Guangsheng subscribed for increased registered capital of RMB3,049,365 at a consideration of RMB247.2 million and Advanced Manufacturing subscribed for increased registered capital of RMB2,960,548 at a consideration of RMB240.0 million. As of February 2, 2021, our Company has fully received the payment of aforesaid capital increases. The considerations for the transfers of equity interest in our Company to Dongyang Guangsheng and Advanced Manufacturing and the capital increases to our Company made by them were determined among the parties after arm’s length negotiation with reference to the valuation of the entire shareholders’ interest of our Company as of June 30, 2020 made by the independent valuer. Our Company completed the registration with the local commerce department for such equity transfers and capital increases on January 12, 2021.

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1. According to the 2020 Capital Increase Agreement, the investors had anti-dilution right before our Company conducted a qualified listing or was acquired by a listed company. Xingsheng Dongyan and Xingsheng Guangchuang assumed such rights under the equity interest transfer agreement they entered into with CIIT on September 6, 2020. Based on the aforementioned agreements and as a result of the increased capital subscribed by Dongyang Guangsheng and Advanced Manufacturing in December 2020, Shenzhen HEC Industrial transferred its 0.70%, 0.10% and 0.15% equity interests in our Company to Xingsheng Dongyan, Xingsheng Guangchuang and Shenzhen Dicheng, respectively, at a nominal price.

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## HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

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*Introduction of Xinquanxin, Qinzhi Kanghong, Gongqingcheng Jianyi, Mige Investment, Jiaxing Ximian and Cuiheng New Era as our Pre-Listing Investors*

On January 27, 2021, Yidu Anjierui entered into an equity transfer agreement with Guangzhou Xinquanxin Investment Partnership (L.P.)\* (廣州新泉信投資合夥企業(有限合夥)) (“**Xinquanxin**”), Shenzhen Qinzhi Kanghong Venture Capital Partnership (L.P.)\* (深圳勤智康宏創業投資合夥企業(有限合夥)) (“**Qinzhi Kanghong**”), Gongqingcheng Jianyi Investment Partnership (L.P.)\* (共青城漸益投資合夥企業(有限合夥)) (“**Gongqingcheng Jianyi**”), Wuhan Mige Investment Management Partnership (L.P.)\* (武漢米格投資管理合夥企業(有限合夥)) (“**Mige Investment**”), Jiaxing Ximian Equity Investment Partnership (L.P.)\* (嘉興西緬股權投資合夥企業(有限合夥)) (“**Jiaxing Ximian**”) and Zhuhai Hengqin Cuiheng New Era Industrial Investment Fund (L.P.)\* (珠海橫琴翠亨新時代產業投資基金(有限合夥)) (“**Cuiheng New Era**”), pursuant to which Yidu Anjierui shall transfer 0.01%, 0.35%, 0.95%, 0.33%, 0.11% and 0.20% equity interests in our Company held by it to Xinquanxin, Qinzhi Kanghong, Gongqingcheng Jianyi, Mige Investment, Jiaxing Ximian and Cuiheng New Era, at a consideration of RMB1.62 million, RMB57.00 million, RMB156.00 million, RMB53.40 million, RMB18.00 million and RMB33.00 million, respectively. For further details on the investments made by Xinquanxin, Qinzhi Kanghong, Gongqingcheng Jianyi, Mige Investment, Jiaxing Ximian and Cuiheng New Era as our Pre-Listing Investors, please see “Pre-Listing Investment” in this section.

On January 27, 2021, at the general meeting of our Company, a resolution was passed to increase the registered capital of our Company to RMB255,345,826, where Xinquanxin subscribed for increased registered capital of RMB13,322 at a consideration of RMB1.08 million; Qinzhi Kanghong subscribed for increased registered capital of RMB468,754 at a consideration of RMB38.00 million; Gongqingcheng Jianyi subscribed for increased registered capital of RMB1,282,904 at a consideration of RMB104.00 million; Mige Investment subscribed for increased registered capital of RMB439,148 at a consideration of RMB35.60 million; Jiaxing Ximian subscribed for increased registered capital of RMB148,027 at a consideration of RMB12.00 million; and Cuiheng New Era subscribed for increased registered capital of RMB271,384 at a consideration of RMB22.0 million. As of February 14, 2022, our Company has fully received the payment of aforesaid capital increases. The considerations for the transfers of equity interest in our Company to Xinquanxin, Qinzhi Kanghong, Gongqingcheng Jianyi, Mige Investment, Jiaxing Ximian and Cuiheng New Era and the capital increases to our Company made by them were determined among the parties after arm’s length negotiation with reference to the valuation of the entire shareholders’ interest of our Company as of June 30, 2020 made by the independent valuer. Our Company has completed the registration with the local commerce department for such equity transfers and capital increases on January 29, 2021.

*Transfers of equity interests in our Company to Yidu Yingwenfang and Yidu Fangwenwen*

On March 15, 2021, Yichang HEC Research entered into an equity transfer agreement with Yidu Yingwenfang, an employee incentive platform of our Group, pursuant to which Yichang HEC Research shall transfer 2.90% equity interests in our Company held by it to Yidu

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Yingwenfang at a consideration of RMB7,401,371. On the same day, North & South Brother Pharma entered into equity transfer agreements with Yidu Fangwenwen, Yidu Anjierui and Dongyang Anjierui Pharmaceutical Technology Co., Ltd.\* (東陽市安捷瑞醫藥科技有限公司) (“**Dongyang Anjierui**”), pursuant to which North & South Brother Pharma shall transfer 2.90%, 0.94% and 9.85% equity interests in our Company held by it to Yidu Fangwenwen, Yidu Anjierui and Dongyang Anjierui, at a consideration of RMB7,401,371, RMB156,019,988 and RMB1,631,575,334, respectively. Yidu Fangwenwen is an employee incentive platform of our Group, and Dongyang Anjierui is a wholly-owned subsidiary of Yidu Anjierui. Our Company completed the registration with the local commerce department for such equity transfers on March 22, 2021.

The equity transfers between Yichang HEC Research and Yidu Yingwenfang, and between North & South Brother Pharma and Yidu Fangwenwen, were made at considerations based on the registered capital of our Company after the arm’s length negotiations among the parties. The considerations of equity transfers made by North & South Brother Pharma with Yidu Anjierui and Dongyang Anjierui were determined after arm’s length negotiations among the parties with reference to the valuation of total shareholders’ equity of our Company as of June 30, 2020 made by the independent valuer.

After the completion of the aforementioned share transfers and capital increases, the shareholding structure of our Company is as shown in the following table:

Name of Shareholders	Registered capital held in our Company	Approximate percentage of shareholding in our Company
	(RMB'000)	(%)
Yichang HEC Research . . . . .	122,982.601	48.17
Dongyang Anjierui . . . . .	25,158.114	9.85
Yidu Shuaixinwei . . . . .	19,736.692	7.73
Shenzhen HEC Industrial. . . . .	18,015.199	7.06
Yidu Anjierui. . . . .	16,440.295	6.44
Yidu Yingwenfang. . . . .	7,401.371	2.90
Yidu Fangwenwen . . . . .	7,401.371	2.90
Yidu Junjiafang . . . . .	4,934.173	1.93
Pre-Listing Investors <sup>(Note)</sup> . . . . .	33,276.010	13.02
<b>Total</b> . . . . .	<b>255,345.826</b>	<b>100</b>

*Note:*

Following the completion of share transfers and capital increases in March 2021, there were 11 Pre-Listing Investors in aggregate, their names and the approximately percentage of shareholding in our Company were: Dongyang Guangsheng (3.43%), Advanced Manufacturing (3.33%), Xingsheng Dongyan (2.44%), Gongqingcheng Jianyi (1.44%), Shenzhen Dicheng (0.53%), Qinzhi Kanghong (0.53%), Mige Investment (0.49%), Xingsheng Guangchuang (0.33%), Cuiheng New Era (0.31%), Jiaying Ximian (0.17%) and Xinquanxin (0.02%).



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### *Equity transfers and capital increases between May to December 2021 (introduction of Cinda Asset, Orient Asset and 27 other investors as our Pre-Listing Investors)*

#### *Introduction of Cinda Asset and Orient Asset as our Pre-Listing Investors*

On May 14, 2021, Shenzhen HEC Industrial entered into an equity transfer agreement with China Cinda Asset Management Co., Ltd.\* (中國信達資產管理股份有限公司) (“**Cinda Asset**”), pursuant to which Shenzhen HEC Industrial shall transfer 2.59% equity interests in our Company held by it to Cinda Asset at a consideration of RMB428.2 million.

On the same day, at the general meeting of our Company, a resolution was passed to increase the registered capital of our Company to RMB261,498,833, where China Orient Asset Management Co., Ltd.\* (中國東方資產管理股份有限公司) (“**Orient Asset**”) subscribed for increased registered capital of RMB6,153,007 at a consideration of RMB498.8 million. For further details on the investments made by Cinda Asset and Orient Asset, please see “Pre-Listing Investment” in this section. As of April 16, 2021, our Company has fully received the payment of aforesaid capital increases. The considerations for the transfer of equity interest in our Company to Cinda Asset and the capital increase to our Company made by Orient Asset were determined among the parties following arm’s length negotiations with reference to the valuation of the entire shareholders’ interest of our Company as of June 30, 2020 made by the independent valuer. Our Company completed the registration with the local commerce department for such equity transfer and capital increase on May 18, 2021.

Unlike the other Pre-Listing Investors in the same year which participated in both equity transfer and capital increase, Cinda Asset invested in our Company solely through equity transfer, and Orient Asset invested in our Company solely through subscription for our increased registered capital. In the case of equity transfer, it typically involves more intricate negotiations between the parties involved in the transfer, potentially leading to a discounted valuation; while when it came to capital increase, our Company had more discretion in determining the consideration, and Orient Asset exhibited greater confidence in our Company’s future prospect, influencing the cost per Share.

#### *Introduction of 22 Pre-Listing Investors*

On July 15, 2021, Shenzhen HEC Industrial, Yidu Anjierui and Dongyang Anjierui entered into equity transfer agreements with each of the other 22 Pre-Listing Investors. Pursuant to such agreements, these 22 Pre-Listing Investors agreed to subscribe for 1.93%, 3.95% and 4.13% equity interests in our Company held by Shenzhen HEC Industrial, Yidu Anjierui and Dongyang Anjierui, at a total consideration of approximately RMB328.80 million, RMB670.32 million and RMB700.62 million, respectively. On the same day, the general meeting of our Company resolved to approve the increase in the registered capital of our Company to RMB275,477,062 and the subscription of increased registered capital of RMB13,978,229 by these 22 Pre-Listing Investors at a total consideration of approximately RMB1,133,160,000. For details of the background of these 22 Pre-Listing Investors and the related Pre-Listing Investments, please see “Pre-Listing Investment” in this section. As of June



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2, 2021, our Company has received the total amount of such capital increases. The considerations for the transfers of equity interests in our Company to these 22 Pre-Listing Investors and the capital increases to our Company made by them were determined among the parties following arm's length negotiations with reference to the valuation of the entire shareholders' interest of our Company as of June 30, 2020 made by the independent valuer. Our Company completed the registration with the local commerce department for such equity transfers and capital increases on July 20, 2021.

### *Introduction of Yidu Guotong, Qianhai Xizheng and CICC SAIC as our Pre-Listing Investors*

On July 26, 2021, Yidu Anjierui entered into an equity transfer agreement with Yidu Guotong Investment Development Co., Ltd.\* (宜都市國通投資開發有限責任公司) (“**Yidu Guotong**”), pursuant to which Yidu Anjierui shall transfer 0.33% equity interests in our Company held by it to Yidu Guotong at a consideration of RMB60.00 million; Dongyang Anjierui entered into equity transfer agreements with each of Shaoguan Qianhai Xizheng Industry Development Fund Enterprise (L.P.)\* (韶關前海熙正產業發展基金企業(有限合夥)) (“**Qianhai Xizheng**”) and Suzhou CICC SAIC Emerging Industry Equity Investment Fund Partnership (L.P.)\* (蘇州中金上汽新興產業股權投資基金合夥企業(有限合夥)) (“**CICC SAIC**”), pursuant to which Dongyang Anjierui shall transfer 0.33% and 0.50% equity interests in our Company held by it to Qianhai Xizheng and CICC SAIC at a consideration of RMB60.00 million and RMB90.00 million, respectively; Yichang HEC Research entered into an equity transfer agreement with HEC CJ Pharm, pursuant to which Yichang HEC Research shall transfer 10% equity interests in our Company held by it to HEC CJ Pharm at a consideration of RMB1<sup>2</sup>. For further details of investments made by Yidu Guotong, Qianhai Xizheng and CICC SAIC as our Pre-Listing Investors, please see “Pre-Listing Investment” in this section.

On the same day, the general meeting of our Company resolved to approve the increase in the registered capital of our Company to RMB277,204,049 and the subscription of increased registered capital of RMB493,425 by Yidu Guotong at a consideration of RMB40.00 million, the subscription of increased registered capital of RMB493,425 by Qianhai Xizheng at a consideration of RMB40.00 million and the subscription of increased registered capital of RMB740,137 by CICC SAIC at a consideration of RMB60.00 million. As of July 5, 2021, our Company has received the total amount of such capital increases. The considerations for the transfers of equity interests in our Company to Yidu Guotong, Qianhai Xizheng and CICC SAIC and the capital increases to our Company made by them were determined among the parties following arm's length negotiations with reference to the valuation of the entire shareholders' interest of our Company as of June 30, 2020 made by the independent valuer. Our Company completed the registration with the local commerce department for such equity transfers and capital increases on August 9, 2021.

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2. In 2021, Shenzhen HEC Industrial entered into an equity grant agreement with HEC CJ Pharm, under which the parties agreed that, to further protect the interests of HEC CJ Pharm, Guangdong HEC Technology and their minority shareholders, Shenzhen HEC Industrial shall transfer 10% equity interest in our Company to HEC CJ Pharm on its own or through a third party designated by it. Pursuant to such agreement, Shenzhen HEC Industrial had designated Yichang HEC Research to transfer the relevant equity interest to HEC CJ Pharm at a nominal price.

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### *Introduction of Zhuhai Kangpu and CCB Investment as our Pre-Listing Investors*

On December 10, 2021, Dongyang Anjierui entered into equity transfer agreements with each of Zhuhai Kangpu Equity Investment Partnership (L.P.)\* (珠海康普股權投資合夥企業(有限合伙)) (“**Zhuhai Kangpu**”) and Shenzhen HEC Industrial, pursuant to which Dongyang Anjierui shall transfer 0.64% and 3.70% equity interests in our Company held by it to Zhuhai Kangpu and Shenzhen HEC Industrial at a consideration of RMB114.60 million and RMB666,355,486, respectively; Shenzhen HEC Industrial entered into an equity transfer agreement with CCB Financial Asset Investment Co., Ltd.\* (建信金融資產投資有限公司) (“**CCB Investment**”), pursuant to which Shenzhen HEC Industrial shall transfer 1.00% equity interest in our Company held by it to CCB Investment at a consideration of RMB180 million; Yidu Anjierui entered into an equity transfer agreement with Shenzhen HEC Industrial, pursuant to which Yidu Anjierui shall transfer 1.87% equity interests in our Company held by it to Shenzhen HEC Industrial at a consideration of RMB335.88 million. For details of investments made by Zhuhai Kangpu and CCB Investment as our Pre-Listing Investors, please see “Pre-Listing Investment” in this section. On the same day, the general meeting of our Company resolved to approve the increase in the registered capital of our Company to RMB279,626,765 and the subscription of increased registered capital of RMB942,441 by Zhuhai Kangpu at a consideration of RMB76.40 million and increased registered capital of RMB1,480,275 by CCB Investment at a consideration of RMB120.00 million, respectively. As of February 15, 2022, our Company has received the total amount of such capital increases. The aforementioned considerations for the transfers of equity interest and the capital increases were determined among the parties following arm’s length negotiations with reference to the valuation of the entire shareholders’ interest of our Company as of June 30, 2020 made by the independent valuer. Our Company completed the registration with the local commerce department for such equity transfers and capital increases on December 13, 2021.

The following table sets forth the shareholding structure of our Company upon the completion of these equity transfers and capital increases:

Name of Shareholders	Registered capital held in our Company	Approximate percentage of shareholding in our Company
	(RMB’000)	(%)
Yichang HEC Research . . . . .	95,262.196	34.09
HEC CJ Pharm . . . . .	27,720.405	9.91
Yidu Shuaixinwei . . . . .	19,736.692	7.06
Shenzhen HEC Industrial . . . . .	19,021.098	6.80
Yidu Yingwenfang . . . . .	7,401.371	2.65
Yidu Fangwenwen . . . . .	7,401.371	2.65
Yidu Junjiafang . . . . .	4,934.173	1.76
Pre-Listing Investors <sup>(Note)</sup> . . . . .	98,149.500	35.08
<b>Total . . . . .</b>	<b>279,626.765</b>	<b>100</b>

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*Note:*

There were 40 Pre-Listing Investors in total upon the completion of the equity transfers and capital increases in December 2021, with their names and approximate percentages of shareholding in our Company listed as follows: Dongyang Guangsheng (3.14%), Advanced Manufacturing (3.04%), Cinda Asset (2.36%), Xingsheng Dongyan (2.23%), Orient Asset (2.20%), Jiaxing Jiayu (2.03%), CCB Investment (1.52%), Yuan Zhimin (1.52%), Dongguan Science City (1.52%), Zhuhai Kangyang (1.52%), Gongqingcheng Jianyi (1.32%), Huzhou Rongrui (1.15%), Zhuhai Kangpu (0.97%), Wenzhou Zhenrui (0.85%), CICC SAIC (0.76%), Xinshi Xinxing (0.75%), Yidu Guotong (0.51%), Qianhai Xizheng (0.51%), Guanzhiguang (0.51%), Dongguan Kejin (0.51%), Dongguan Biotechnology (0.51%), Daxie Hansheng (0.51%), Shunyin Industry Financing (0.51%), Shenzhen Dicheng (0.49%), Qinzhi Kanghong (0.48%), Mige Investment (0.45%), Yuanshi No. 1 (0.35%), Xingsheng Guangchuang (0.30%), Wolun Jingfu (0.30%), Cuiheng New Era (0.28%), Wenzheng Changxing (0.27%), Xingxiang Jiecheng (0.25%), Changsheng Yingkang (0.25%), Yinyuan Power (0.25%), Guiyang Development Fund (0.25%), Jiehui Chuanglong (0.23%), Jiaxing Aomin (0.21%), Jiaxing Ximian (0.15%), Junyuan Tongchuang (0.10%) and Xinquanxin (0.01%),

### ***Equity transfer in March 2022***

On March 14, 2022, Yichang HEC Research entered into an equity transfer agreement with Shenzhen HEC Industrial, pursuant to which Yichang HEC Research shall transfer 0.77% equity interest in our Company held by it to Shenzhen HEC Industrial at a consideration of RMB2.160334 million; Shenzhen HEC Industrial entered into an equity transfer agreement with Guangdong HEC Technology, pursuant to which Shenzhen HEC Industrial shall transfer 7.58% equity interest in our Company held by it to Guangdong HEC Technology (2.48% of which shall be transferred at a consideration of RMB1<sup>3</sup>, representing registered capital of RMB6,930,101 and 5.10% of which shall be transferred at a consideration of RMB910,171,779).

For the aforesaid equity transfers, Yichang HEC Research transferred the 0.77% equity interest to Shenzhen HEC Industrial at a consideration equaling to the amount of the registered capital, and each of the parties to the equity transfer was a shareholding platform held by the beneficial controllers, while the consideration for the transfer of additional 5.10% equity interest by Shenzhen HEC Industrial to Guangdong HEC Technology was determined among the parties following arm's length negotiation with reference to the valuation of entire shareholders' interest of our Company as of July 31, 2021 made by the independent valuer. Our Company completed the registration with the local commerce department for such equity transfers on March 30, 2022. The following table sets forth the shareholding structure of our Company upon the completion of these equity transfers:

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3. To protect the interests of Guangdong HEC Technology and its minority shareholders, Shenzhen HEC Industrial as the controlling shareholder of Guangdong HEC Technology undertook in 2021 that upon the completion of the relevant transactions involving the transfer of 51.41% equity interest in HEC CJ Pharm held by Guangdong HEC Technology to our Company, Shenzhen HEC Industrial shall transfer registered capital of RMB6,930,101 in our Company to Guangdong HEC Technology at nil consideration on its own or through a designated third party. Pursuant to the undertaking, Shenzhen HEC Industrial transferred the 2.48% equity interest in our Company held by its to Guangdong HEC Technology at a nominal price. For details of the transaction in relation to the acquisition of 51.41% equity interest in HEC CJ Pharm by our Group, please see "Acquisitions and Disposals during the Track Record Period" in this section.

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Name of Shareholders	Registered capital held in our Company	Approximate percentage of shareholding in our Company
	(RMB'000)	(%)
Yichang HEC Research . . . . .	93,101.862	33.31
HEC CJ Pharm . . . . .	27,720.405	9.91
Guangdong HEC Technology . . . . .	21,181.432	7.58
Yidu Shuaixinwei . . . . .	19,736.692	7.06
Yidu Yingwenfang . . . . .	7,401.371	2.65
Yidu Fangwenwen . . . . .	7,401.371	2.65
Yidu Junjiafang . . . . .	4,934.173	1.76
Pre-Listing Investors <sup>(Note)</sup> . . . . .	98,149.500	35.08
<b>Total . . . . .</b>	<b>279,626.765</b>	<b>100</b>

*Note:*

There were 40 Pre-Listing Investors in total upon the completion of the equity transfers and capital increases in March 2022, with their names and approximate percentages of shareholding in our Company listed as follows: Dongyang Guangsheng (3.14%), Advanced Manufacturing (3.04%), Cinda Asset (2.36%), Xingsheng Dongyan (2.23%), Orient Asset (2.20%), Jiaying Jiayu (2.03%), CCB Investment (1.52%), Yuan Zhimin (1.52%), Dongguan Science City (1.52%), Zhuhai Kangyang (1.52%), Gongqingcheng Jianyi (1.32%), Huzhou Rongrui (1.15%), Zhuhai Kangpu (0.97%), Wenzhou Zhenrui (0.85%), CICC SAIC (0.76%), Xinshi Xinxing (0.75%), Yidu Guotong (0.51%), Qianhai Xizheng (0.51%), Guanzhiguang (0.51%), Dongguan Kejin (0.51%), Dongguan Biotechnology (0.51%), Daxie Hansheng (0.51%), Shunyin Industry Financing (0.51%), Shenzhen Dicheng (0.49%), Qinzhi Kanghong (0.48%), Mige Investment (0.45%), Yuanshi No. 1 (0.35%), Xingsheng Guangchuang (0.30%), Wolun Jingfu (0.30%), Cuiheng New Era (0.28%), Wenzheng Changxing (0.27%), Xingxiang Jiecheng (0.25%), Changsheng Yingkang (0.25%), Yinyuan Power (0.25%), Guiyang Development Fund (0.25%), Jiehui Chuanglong (0.23%), Jiaying Aomin (0.21%), Jiaying Ximian (0.15%), Junyuan Tongchuang (0.10%) and Xinquanxin (0.01%).

### *Equity transfer in June 2022*

On April 13, 2022, Guangdong HEC Technology entered into an equity transfer agreement with Yichang HEC Research, pursuant to which Guangdong HEC Technology shall transfer 6.5505% equity interest in HEC CJ Pharm held by it to Yichang HEC Research at a consideration of RMB776,721,316. The parties agreed that the consideration payable by Yichang HEC Research to Guangdong HEC Technology shall be settled by Yichang HEC Research's transferring registered capital of RMB11,698,588 in our Company held by it at a consideration of RMB776,721,316. Pursuant to such agreement, Yichang HEC Research has transferred 4.18% equity interest in our Company to Guangdong HEC Technology. The consideration for the transfer of equity interest was determined among the parties following arm's length negotiation with reference to the valuation of the entire shareholders' interest of our Company as of October 31, 2021 made by the independent valuer. Our Company completed

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the registration with the local commerce department for such equity transfer on June 16, 2022. The following table sets forth the shareholding structure of our Company upon the completion of the equity transfer:

Name of Shareholders	Registered capital held in our Company	Approximate percentage of shareholding in our Company
	(RMB'000)	(%)
Yichang HEC Research . . . . .	81,403.274	29.13
Guangdong HEC Technology . . . . .	32,880.020	11.76
HEC CJ Pharm . . . . .	27,720.405	9.91
Yidu Shuaixinwei . . . . .	19,736.692	7.06
Yidu Yingwenfang . . . . .	7,401.371	2.65
Yidu Fangwenwen . . . . .	7,401.371	2.65
Yidu Junjiafang . . . . .	4,934.173	1.76
Pre-Listing Investors <sup>(Note)</sup> . . . . .	98,149.500	35.08
<b>Total . . . . .</b>	<b>279,626.765</b>	<b>100</b>

*Note:*

There were 40 Pre-Listing Investors in total upon the completion of the equity transfer in June 2022, with their names and approximate percentages of shareholding in our Company listed as follows: Dongyang Guangsheng (3.14%), Advanced Manufacturing (3.04%), Cinda Asset (2.36%), Xingsheng Dongyan (2.23%), Orient Asset (2.20%), Jiaying Jiayu (2.03%), CCB Investment (1.52%), Yuan Zhimin (1.52%), Dongguan Science City (1.52%), Zhuhai Kangyang (1.52%), Gongqingcheng Jianyi (1.32%), Huzhou Rongrui (1.15%), Zhuhai Kangpu (0.97%), Wenzhou Zhenrui (0.85%), CICC SAIC (0.76%), Xinshi Xinxing (0.75%), Yidu Guotong (0.51%), Qianhai Xizheng (0.51%), Guanzhiguang (0.51%), Dongguan Kejin (0.51%), Dongguan Biotechnology (0.51%), Daxie Hansheng (0.51%), Shunyin Industry Financing (0.51%), Shenzhen Dicheng (0.49%), Qinzhi Kanghong (0.48%), Mige Investment (0.45%), Yuanshi No. 1 (0.35%), Xingsheng Guangchuang (0.30%), Wolun Jingfu (0.30%), Cuiheng New Era (0.28%), Wenzheng Changxing (0.27%), Xingxiang Jiecheng (0.25%), Changsheng Yingkang (0.25%), Yinyuan Power (0.25%), Guiyang Development Fund (0.25%), Jiehui Chuanglong (0.23%), Jiaying Aomin (0.21%), Jiaying Ximian (0.15%), Junyuan Tongchuang (0.10%) and Xinquanxin (0.01%).

### ***Capital increases and equity transfer in March 2023 (introduction of Hangzhou Zhonghe as our Pre-Listing Investor)***

On December 23, 2022, Hangzhou Zhonghe Guoxin No. 1 Equity Investment Fund Partnership (L.P.)\* (杭州中合國信壹號股權投資基金合夥企業(有限合夥)) (“**Hangzhou Zhonghe**”) entered into a capital increase agreement with Yichang HEC Research, Shenzhen HEC Industrial, Ms. Guo, Mr. Zhang and our Company, pursuant to which the registered capital of our Company shall be increased to RMB279,986,799 and the increased registered capital of RMB360,034 shall be subscribed by Hangzhou Zhonghe at a consideration of RMB30.00 million. As of March 28, 2023, our Company has received the total amount of the capital increase. The consideration for such capital increase to the Company made by Hangzhou Zhonghe was determined among the parties following arm’s length negotiation with reference to the valuation of the entire shareholders’ interest of our Company as of October 31, 2022 made by the independent valuer. Our Company completed the registration with the local commerce department for such capital increase on March 22, 2023. For further details of the investment made by Hangzhou Zhonghe as our Pre-Listing Investor, please see “Pre-Listing Investment” in this section.

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### *Capital increase and equity transfer in March 2023*

On March 28, 2023, HEC CJ Pharm, a subsidiary of our Company, entered into an equity transfer agreement with Shenzhen HEC Industrial, pursuant to which HEC CJ Pharm shall transfer 9.90% equity interest in our Company held by it to Shenzhen HEC Industrial at a consideration of RMB2,312,319,650 to resolve the issue of cross-shareholding.

On March 28, 2023, the registered capital of our Company increased to RMB290,176,716 and the increased registered capital was subscribed by Shenzhen HEC Industrial at a consideration of RMB850.00 million. Our Company completed the registration with the local commerce department for the equity transfer and the capital increase on March 28, 2023.

As of June 29, 2023, our Company has received the total amount of such capital increase. The aforementioned consideration for each of the transfer of equity interest and the capital increase was determined among the parties following arm's length negotiation with reference to the valuation of the entire shareholders' interest of our Company as of October 31, 2022 made by the independent valuer. The following table sets forth the shareholding structure of our Company upon the completion of the equity transfer and the capital increase:

Name of Shareholder	Registered capital held in our Company	Approximate percentage of shareholding in our Company
	(RMB'000)	(%)
Yichang HEC Research . . . . .	81,403.274	28.05
Shenzhen HEC Industrial . . . . .	37,910.322	13.06
Guangdong HEC Technology . . . . .	32,880.020	11.33
Yidu Shuaixinwei . . . . .	19,736.692	6.80
Yidu Yingwenfang . . . . .	7,401.371	2.55
Yidu Fangwenwen . . . . .	7,401.371	2.55
Yidu Junjiafang . . . . .	4,934.173	1.70
Pre-Listing Investors <sup>(Note)</sup> . . . . .	98,509.500	33.96
<b>Total</b> . . . . .	<b>290,176.716</b>	<b>100</b>

*Note:*

There were 41 Pre-Listing Investors in total upon the completion of the capital increase in March 2023, with their names and approximate percentages of shareholding in our Company as follows: Dongyang Guangsheng (3.02%), Advanced Manufacturing (2.93%), Cinda Asset (2.28%), Xingsheng Dongyan (2.15%), Orient Asset (2.12%), Jiaying Jiayu (1.96%), CCB Investment (1.47%), Yuan Zhimin (1.47%), Dongguan Science City (1.47%), Zhuhai Kangyang (1.47%), Gongqingcheng Jianyi (1.27%), Huzhou Rongrui (1.11%), Zhuhai Kangpu (0.93%), Wenzhou Zhenrui (0.82%), CICC SAIC (0.73%), Xinshi Xinxing (0.72%), Yidu Guotong (0.49%), Qianhai Xizheng (0.49%), Guanzhiguang (0.49%), Dongguan Kejin (0.49%), Dongguan Biotechnology (0.49%), Daxie Hansheng (0.49%), Shunyin Industry Financing (0.49%), Shenzhen Dicheng (0.47%), Qinzhi Kanghong (0.46%), Mige Investment (0.44%), Yuanshi No. 1 (0.34%), Xingsheng Guangchuang (0.29%), Wolun Jingfu (0.29%), Cuiheng New Era (0.27%), Wenzheng Changxing (0.26%), Xingxiang Jiecheng (0.24%), Changsheng Yingkang (0.24%), Yinyuan Power (0.24%), Guiyang Development Fund (0.24%), Jiehui Chuanglong (0.22%), Jiaying Aomin (0.20%), Jiaying Ximian (0.15%), Hangzhou Zhonghe (0.12%), Junyuan Tongchuang (0.10%) and Xinquanxin (0.01%).



## HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

### *Conversion into joint stock limited company*

On June 19, 2023, all of the then Shareholders entered into a promoter's agreement, pursuant to which it was agreed that our Company shall be converted from a limited liability company to a joint stock limited company. Upon the completion of the conversion, our Company had a registered capital of RMB450 million divided into 450,000,000 Shares with a par value of RMB1.00 each, which shall be subscribed by all Shareholders in proportion to their shareholdings in our Company before the conversion. The conversion was completed on June 21, 2023, with the shareholding structure of our Company immediately upon the completion of the conversion as follows:

Name of Shareholders	Number of Shares	Percentage of shareholding
	('000)	(%)
Yichang HEC Research . . . . .	126,238.500	28.05
Shenzhen HEC Industrial. . . . .	58,790.537	13.06
Guangdong HEC Technology. . . . .	50,989.649	11.33
Yidu Shuaixinwei . . . . .	30,607.250	6.80
Yidu Yingwenfang . . . . .	11,477.892	2.55
Yidu Fangwenwen . . . . .	11,477.892	2.55
Yidu Junjiafang . . . . .	7,651.813	1.70
Pre-Listing Investors <sup>(Note)</sup> . . . . .	152,766.500	33.96
<b>Total . . . . .</b>	<b>450,000.000</b>	<b>100</b>

*Note:*

There were 41 Pre-Listing Investors in total, with their names and approximate percentages of shareholding in our Company listed as follows: Dongyang Guangsheng (3.02%), Advanced Manufacturing (2.93%), Cinda Asset (2.28%), Xingsheng Dongyan (2.15%), Orient Asset (2.12%), Jiaying Jiayu (1.96%), CCB Investment (1.47%), Yuan Zhimin (1.47%), Dongguan Science City (1.47%), Zhuhai Kangyang (1.47%), Gongqingcheng Jianyi (1.27%), Huzhou Rongrui (1.11%), Zhuhai Kangpu (0.93%), Wenzhou Zhenrui (0.82%), CICC SAIC (0.73%), Xinshi Xinxing (0.72%), Yidu Guotong (0.49%), Qianhai Xizheng (0.49%), Guanzhiguang (0.49%), Dongguan Kejin (0.49%), Dongguan Biotechnology (0.49%), Daxie Hansheng (0.49%), Shunyin Industry Financing (0.49%), Shenzhen Dicheng (0.47%), Qinzhi Kanghong (0.46%), Mige Investment (0.44%), Yuanshi No. 1 (0.34%), Xingsheng Guangchuang (0.29%), Wolun Jingfu (0.29%), Cuiheng New Era (0.27%), Wenzheng Changxing (0.26%), Xingxiang Jiecheng (0.24%), Changsheng Yingkang (0.24%), Yinyuan Power (0.24%), Guiyang Development Fund (0.24%), Jiehui Chuanglong (0.22%), Jiaying Aomin (0.20%), Jiaying Ximian (0.15%), Hangzhou Zhonghe (0.12%), Junyuan Tongchuang (0.10%) and Xinquanxin (0.01%).



## HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

### *Capital increase in June 2023*

On June 25, 2023, the general meeting of our Company resolved to approve the increase of registered capital of our Company to RMB463,943,215 and the subscription of increased registered capital of RMB13,943,215 by Shenzhen HEC Industrial at a consideration of RMB750 million. The consideration for such capital increase was determined among the parties following arm's length negotiation with reference to the valuation of the entire shareholders' interest of our Company as of October 31, 2022 made by the independent valuer. As of June 29, 2023, our Company has received the total amount of such capital increase. Our Company has completed the registration with the local commerce department for such capital increase on June 28, 2023. The following table sets forth the shareholding structure of our Company upon the completion of the capital increase:

Name of Shareholders	Number of Shares	Percentage of shareholding
	('000)	(%)
Yichang HEC Research . . . . .	126,238.500	27.21
Shenzhen HEC Industrial . . . . .	72,733.752	15.68
Guangdong HEC Technology . . . . .	50,989.649	10.99
Yidu Shuaixinwei . . . . .	30,607.250	6.60
Yidu Yingwenfang . . . . .	11,477.892	2.47
Yidu Fangwenwen . . . . .	11,477.892	2.47
Yidu Junjiafang . . . . .	7,651.813	1.65
Pre-Listing Investors <sup>(Note)</sup> . . . . .	152,766.500	32.93
<b>Total . . . . .</b>	<b>463,943.215</b>	<b>100</b>

*Note:*

There were 41 Pre-Listing Investors in total, with their names and approximate percentages of shareholding in our Company listed as follows: Dongyang Guangsheng (2.93%), Advanced Manufacturing (2.85%), Cinda Asset (2.21%), Xingsheng Dongyan (2.09%), Orient Asset (2.06%), Jiaying Jiayu (1.90%), CCB Investment (1.42%), Yuan Zhimin (1.42%), Dongguan Science City (1.42%), Zhuhai Kangyang (1.42%), Gongqingcheng Jianyi (1.23%), Huzhou Rongrui (1.08%), Zhuhai Kangpu (0.91%), Wenzhou Zhenrui (0.80%), CICC SAIC (0.71%), Xinshi Xinxing (0.70%), Yidu Guotong (0.47%), Qianhai Xizheng (0.47%), Guanzhiguang (0.47%), Dongguan Kejin (0.47%), Dongguan Biotechnology (0.47%), Daxie Hansheng (0.47%), Shunyin Industry Financing (0.47%), Shenzhen Dicheng (0.46%), Qinzhi Kanghong (0.45%), Mige Investment (0.42%), Yuanshi No. 1 (0.33%), Xingsheng Guangchuang (0.28%), Wolun Jingfu (0.28%), Cuiheng New Era (0.26%), Wenzheng Changxing (0.26%), Xingxiang Jiecheng (0.24%), Changsheng Yingkang (0.24%), Yinyuan Power (0.24%), Guiyang Development Fund (0.24%), Jiehui Chuanglong (0.22%), Jiaying Aomin (0.20%), Jiaying Ximian (0.14%), Hangzhou Zhonghe (0.12%), Junyuan Tongchuang (0.09%) and Xinquanxin (0.01%).

## HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

### PRE-LISTING INVESTMENT

#### 1. Overview

	Pre-Listing Investors	Date of capital increase/equity transfer agreement	Subscription amount of registered capital	Consideration	Date of completion of payment of consideration	Number of Shares as of the Latest Practicable Date	Average cost per Share <sup>(1)</sup>	Interests held in our Company immediately before the completion of the Introduction and the Privatization	Interests held in our Company immediately after the completion of the Introduction and the Privatization <sup>(2)</sup>	Discount to the estimated value of the H Shares <sup>(3)</sup>
(RMB)										
1. . . .	Xingsheng Dongyan	June 23, 2020	RMB6,241,823	RMB440.00 million	June 24, 2020	9,679,689	45.46	2.09%	1.68%	31.59%
2. . . .	Xingsheng Guangchuan	June 23, 2020	RMB851,158	RMB60.00 million	June 24, 2020	1,319,958	45.46	0.28%	0.23%	31.59%
3. . . .	Shenzhen Dicheng	June 23, 2020	RMB1,361,853	RMB96.00 million	June 24, 2020	2,111,933	45.46	0.46%	0.37%	31.59%
4. . . .	Dongyang Guangsheng	December 25, 2020	RMB8,766,924	RMB618.00 million	December 25, 2020	13,595,563	45.46	2.93%	2.36%	31.59%
5. . . .	Advanced Manufacturing	December 25, 2020	RMB8,511,576	RMB600.00 million	February 2, 2021	13,199,575	45.46	2.85%	2.29%	31.59%
6. . . .	Xinquanxin	January 27, 2021	RMB38,302	RMB2.70 million	February 8, 2021	59,398	45.46	0.01%	0.01%	31.59%
7. . . .	Qinzhi Kanghong	January 27, 2021	RMB1,347,667	RMB95.00 million	February 14, 2022	2,089,934	45.46	0.45%	0.36%	31.59%

## HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

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## HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

	Pre-Listing Investors	Date of capital increase/equity transfer agreement	Subscription amount of registered capital	Consideration	Date of completion of payment of consideration	Number of Shares as of the Latest Practicable Date	Average cost per Share <sup>(1)</sup>	Interests held in our Company immediately before the completion of the	Interests held in our Company immediately after the completion of the	Discount to the estimated value of the H Shares <sup>(3)</sup>
								Introduction and the Privatization	Introduction and the Privatization <sup>(2)</sup>	
								(RMB)		
17. . .	Xinshi Xinxing	July 15, 2021	RMB2,099,523	RMB148.00 million	June 2, 2021	3,255,896	45.46	0.70%	0.56%	31.59%
18. . .	Jiaxing Aomin	July 15, 2021	RMB587,299	RMB41.40 million	June 11, 2021	910,771	45.46	0.20%	0.16%	31.59%
19. . .	Junyuan Tongchuang	July 15, 2021	RMB283,719	RMB20.00 million	April 15, 2021	439,986	45.46	0.09%	0.08%	31.59%
20. . .	Huzhou Rongrui	July 15, 2021	RMB3,220,213	RMB227.00 million	April 16, 2021	4,993,839	45.46	1.08%	0.87%	31.59%
21. . .	Yuan Zhimin	July 15, 2021	RMB4,255,788	RMB300.00 million	February 26, 2021	6,599,787	45.46	1.42%	1.14%	31.59%
22. . .	Yuanshi No. 1	July 15, 2021	RMB975,994	RMB68.80 million	April 27, 2021	1,513,551	45.46	0.33%	0.26%	31.59%
23. . .	Wolun Jingfu	July 15, 2021	RMB851,158	RMB60.00 million	January 6, 2021	1,319,958	45.46	0.28%	0.23%	31.59%
24. . .	Xingxiang Jiecheng	July 15, 2021	RMB709,298	RMB50.00 million	March 19, 2021	1,099,965	45.46	0.24%	0.19%	31.59%
25. . .	Jiehui Chuanglong	July 15, 2021	RMB645,461	RMB45.50 million	March 16, 2021	1,000,967	45.46	0.22%	0.17%	31.59%

## HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

	Pre-Listing Investors	Date of capital increase/equity transfer agreement	Subscription amount of registered capital	Consideration	Date of completion of payment of consideration	Number of Shares as of the Latest Practicable Date	Average cost per Share <sup>(1)</sup>	Interests held in our Company immediately before the completion of the	Interests held in our Company immediately after the completion of the	Discount to the estimated value of the H Shares <sup>(3)</sup>
								Introduction and the Privatization	Introduction and the Privatization <sup>(2)</sup>	
26. . .	Wenzhou Zhenrui	July 15, 2021	RMB2,387,497	RMB168.30 million	March 25, 2021	3,702,481	45.46	0.80%	0.64%	31.59%
27. . .	Changsheng Yingkang	July 15, 2021	RMB709,298	RMB50.00 million	April 15, 2021	1,099,965	45.46	0.24%	0.19%	31.59%
28. . .	Dongguan Kejin	July 15, 2021	RMB1,418,596	RMB100.00 million	April 20, 2021	2,199,929	45.46	0.47%	0.38%	31.59%
29. . .	Dongguan Biotechnology	July 15, 2021	RMB1,418,596	RMB100.00 million	April 22, 2021	2,199,929	45.46	0.47%	0.38%	31.59%
30. . .	Dongguan Science City	July 15, 2021	RMB4,255,788	RMB300.00 million	April 23, 2021	6,599,787	45.46	1.42%	1.14%	31.59%
31. . .	Yinyuan Power	July 15, 2021	RMB709,298	RMB50.00 million	April 26, 2021	1,099,965	45.46	0.24%	0.19%	31.59%
32. . .	Daxie Hansheng	July 15, 2021	RMB1,418,596	RMB100.00 million	May 11, 2021	2,199,929	45.46	0.47%	0.38%	31.59%
33. . .	Shunyin Industry Financing	July 15, 2021	RMB1,418,596	RMB100.00 million	May 19, 2021	2,199,929	45.46	0.47%	0.38%	31.59%
34. . .	Wenzheng Changxing	July 15, 2021	RMB764,623	RMB53.90 million	May 13, 2021	1,185,761	45.46	0.26%	0.21%	31.59%

## HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

	Pre-Listing Investors	Date of capital increase/equity transfer agreement	Subscription amount of registered capital	Consideration	Date of completion of payment of consideration	Number of Shares as of the Latest Practicable Date	Average cost	Interests	Interests	Discount to the estimated value of the H Shares <sup>(3)</sup>
							per Share <sup>(1)</sup>	held in our Company immediately before the completion of the Introduction and the Privatization	held in our Company immediately after the completion of the Introduction and the Privatization <sup>(2)</sup>	
								(RMB)		
35. . .	Guiyang Development Fund	July 15, 2021	RMB709,298	RMB50.00 million	May 25, 2021	1,099,965	45.46	0.24%	0.19%	31.59%
36. . .	Yidu Guotong	July 26, 2021	RMB1,418,596	RMB100.00 million	March 5, 2021	2,199,929	45.46	0.47%	0.38%	31.59%
37. . .	Qianhai Xizheng	July 26, 2021	RMB1,418,596	RMB100.00 million	July 5, 2021	2,199,929	45.46	0.47%	0.38%	31.59%
38. . .	CICC SAIC	July 26, 2021	RMB2,127,894	RMB150.00 million	June 29, 2021	3,299,894	45.46	0.71%	0.57%	31.59%
39. . .	Zhuhai Kangpu	December 10, 2021	RMB2,709,518	RMB191.00 million	December 16, 2021	4,201,864	45.46	0.91%	0.73%	31.59%
40. . .	CCB Investment	December 10, 2021	RMB4,255,790	RMB300.00 million	December 9, 2021	6,599,790	45.46	1.42%	1.14%	31.59%
41. . .	Hangzhou Zhonghe	December 23, 2022	RMB360,034	RMB30.00 million	March 28, 2023	558,333	53.73	0.12%	0.10%	19.14%

*Notes:*

1. The average cost per Share paid by the Pre-Listing Investors is calculated based on the investment amounts made by these investors divided by the number of Shares they actually hold as of the Latest Practicable Date.
2. The interests held by the Pre-Listing Investors in this column was calculated based on the number of Shares held by the Pre-Listing Investors as of the Latest Practicable Date, divided by the number of Shares in issue immediately after the completion of the Introduction and the Privatization.
3. The estimated value of the H Shares was approximately RMB66.45 as concluded in the valuation report appended to the 3.5 Announcement.

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## HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

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### 2. Key terms of the Pre-Listing Investment

Use of Proceeds from the Pre-Listing Investment . . . . .	<p>All the proceeds from the Pre-Listing Investment shall be used for expansion and operation of our business, including commencement of our medicine R&amp;D operation and replenishment of working capital.</p> <p>As of the Latest Practicable Date, the proceeds from the Pre-Listing Investment had been fully utilized.</p>
Strategic benefit brought to our Group by the Pre-Listing Investment . . . . .	<p>At the time of Pre-Listing Investment, the Directors believed that our Company will benefit from the additional capital brought by the investment made by the Pre-Listing Investors and their knowledge and experience.</p>
Basis of determination of paid consideration . . . . .	<p>The considerations were determined after arm's length negotiation between the parties with reference to the status and prospects of our business development, the pre-investment valuation of our Company and/or the valuation of the entire shareholders' interest of our Company made by the independent valuers. Please refer to "Major changes in shareholding and corporate form of our Company" in this section for further details.</p>
Lock-up period . . . . .	<p>Pursuant to applicable PRC laws and regulations, within one year following the Listing Date, the Pre-Listing Investors shall not dispose of any Shares held by them.</p>

### 3. Special rights granted to the Pre-Listing Investors

According to the shareholder agreement entered into among our then Shareholders on December 10, 2021 (the "**2021 Shareholder Agreement**"), the Pre-Listing Investors (except for Hangzhou Zhonghe) are entitled to certain special rights, including rights of first refusal for additional registered capital, transfer restrictions, pre-emptive rights, co-sale rights, liquidation preferences, anti-dilution rights, redemption rights, drag-along rights, right to be informed and other corporate governance rights. Under the 2021 Shareholder Agreement, the Pre-Listing Investors may exercise their redemption rights against our Company, Dongguan HEC Pharmaceutical, Dongguan HEC Generic Drug, Dongguan HEC Biopharmaceutical, Dongguan HEC Medicine, US HEC, Germany HEC and Hong Kong HEC (collectively, our "**Important Subsidiaries**"), Ms. Guo and Mr. Zhang (collectively, our "**Actual Controllers**") and Yichang HEC Research, Shenzhen HEC Industrial, Yidu Shuaixinwei, Yidu Junjiafang, Yidu Yingwenfang and Yidu Fangwenwen (collectively, our "**Founding Shareholders**").



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## HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

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In March 2022, in preparation of the conversion of our Company into a joint stock limited company, each of the Pre-Listing Investors (except for Hangzhou Zhonghe, which only invested in our Company in December 2022) provided a confirmation in writing to our Company and our Important Subsidiaries, pursuant to which the Pre-Listing Investors confirmed that they had waived their redemption rights under the 2021 Shareholder Agreement against our Company and the Important Subsidiaries, which had no redemption obligation ab initio. On March 14, 2022, our Company held a Shareholders' meeting, at which all the then Shareholders (including all Pre-Listing Investors save for Hangzhou Zhonghe) unanimously passed a resolution to reaffirm their agreement to this waiver. On December 23, 2022, Hangzhou Zhonghe entered into a joining agreement pursuant to the 2021 Shareholder Agreement (including its subsequent amendments), under which Hangzhou Zhonghe became entitled to all the special rights granted to the Pre-Listing Investors under the 2021 Shareholder Agreement, except for the redemption rights against our Company and the Important Subsidiaries.

On December 11, 2024, our Company, our Actual Controllers, our Important Subsidiaries, and all existing Shareholders jointly entered into a supplemental agreement (the **"Supplemental Shareholder Agreement"**) pursuant to which the Pre-Listing Investors agreed that the redemption rights against our Actual Controllers and our Founding Shareholders shall be automatically terminated upon the first submission of the listing application. Upon the earlier of (i) our Company voluntarily withdraws its listing application; or (ii) our Company's listing application being rejected or returned by the relevant stock exchange, the redemption rights so terminated will be reinstated and restated from the day following such withdrawal, rejection or return of the listing application. Except for the redemption rights, all other special rights of the Pre-Listing Investors will be automatically terminated pursuant to the Supplemental Shareholder Agreement immediately upon the completion of a qualified listing of our Company (which includes the Listing).

Our PRC Legal Advisor is of the view that the redemption rights granted to the Pre-Listing Investors under the 2021 Shareholder Agreement had been fully terminated on December 11, 2024 based on the following grounds: (a) the redemption rights against our Company and the Important Subsidiaries were effectively terminated in March 2022 by the written confirmations provided by the Pre-Listing Investors and the unanimous resolution passed at the Shareholders' meeting held on March 14, 2022, pursuant to which all the Pre-Listing Investors (except for Hangzhou Zhonghe) agreed to waive their redemption rights under the 2021 Shareholder Agreement against our Company and the Important Subsidiaries; (b) all the Pre-Listing Investors entered into the Supplemental Shareholder Agreement, explicitly agreeing to terminate the redemption rights against our Actual Controllers and our Founding Shareholders as of the date our Company submitted the first listing application; (c) according to the provisions of the Supplemental Shareholder Agreement, it became valid and effective upon execution by all parties involved; and (d) all the Pre-Listing Investors duly signed the Supplemental Shareholder Agreement. Since the confirmations issued in March 2022 and the Supplemental Shareholder Agreement pertain to the termination of redemption rights against distinct parties, there is no conflict between the two.

#### 4. Compliance with the guideline regarding Pre-Listing Investments

As the Listing will be more than 120 clear days after the completion of the Pre-Listing Investments; and the special rights granted to the Pre-Listing Investors, as disclosed in the above paragraph headed “3. Special rights granted to Pre-Listing Investors” shall cease to be effective and be discontinued upon the Listing (save for the redemption rights which shall be automatically terminated upon the first submission of the listing application as described above), the Sole Sponsor confirms that the Pre-Listing Investments complies with the relevant requirements under Chapter 4.2 of the Guide for New Listing Applicants.

#### 5. Information about the Pre-Listing Investors

The background of our Pre-Listing Investors is set out below:

1. Dongyang Guangsheng is a limited liability partnership established under the PRC laws and is principally engaged in corporate management business, the general partner of which is Dongyang Xiaoka Investment Management Co., Ltd.\* (東陽小咖投資管理有限公司). Dongyang Xiaoka Investment Management Co., Ltd. is a company established under the PRC laws with limited liability and is ultimately controlled by Zhang Yanyang (張艷陽). As of the Latest Practicable Date, Dongyang State Owned Assets Investment. Co., Ltd.\* (東陽市國有資產投資有限公司), the limited partner of Dongyang Guangsheng, held 99.9% interests of Dongyang Guangsheng. Dongyang State Owned Assets Investment. Co., Ltd. is a company established under the PRC laws with limited liability, which is ultimately controlled by Office of Dongyang State-owned Assets Supervision and Administration\* (東陽市國有資產監督管理辦公室). As of the Latest Practicable Date, Dongyang Guangsheng directly held 2.93% of our total issued Shares. To the knowledge of our Directors, Dongyang Guangsheng is an Independent Third Party.
2. Advanced Manufacturing is a limited partnership established under the laws of the PRC and is principally engaged in equity investment, the general partner of which is Guangdong Advanced Manufacturing Industry Investment Private Equity Fund Management Co., Ltd.\* (廣東先進製造產業投資私募基金管理有限公司). Guangdong Advanced Manufacturing Industry Investment Private Equity Fund Management Co., Ltd. is a company established under the laws of the PRC with limited liability and is ultimately controlled by the State-owned Assets Supervision and Administration Commission of Guangdong Province\* (廣東省國有資產監督管理委員會). As of the Latest Practicable Date, Guangdong Hengjian Investment Holdings Co., Ltd.\* (廣東恆健投資控股有限公司), the limited partner of Advanced Manufacturing, held 99.99% interest in Advanced Manufacturing. Guangdong Hengjian Investment Holdings Co., Ltd. is a company established under the laws of the PRC with limited liability and is wholly owned by the State-owned Assets Supervision and Administration Commission of Guangdong Province. As of the Latest Practicable Date, Advanced Manufacturing directly held approximately 2.85% of our total issued Shares. To the knowledge of our Directors, Advanced Manufacturing is an Independent Third Party.

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3. Cinda Asset is a joint stock limited company established under the laws of the PRC and is principally engaged in distressed asset management and financial services, the shares of which are listed on the Stock Exchange (stock code: 01359) and are ultimately controlled by Ministry of Finance. As of the Latest Practicable Date, Cinda Asset directly held approximately 2.21% of our total issued Shares. To the knowledge of our Directors, Cinda Asset is an Independent Third Party.
4. Xingsheng Dongyan is a limited partnership established under the laws of the PRC and is principally engaged in equity investment and merger and acquisition activities. Ningbo Meishan Free Trade Zone Yuansheng Investment Management Co., Ltd.\* (寧波梅山保稅區遠晟投資管理有限公司) is a company established under the laws of the PRC with limited liability and is the general partner of Xingsheng Dongyan. Ningbo Meishan Free Trade Zone Yuansheng Investment Management Co., Ltd. is ultimately controlled by Industrial Bank Co., Ltd.\* (興業銀行股份有限公司) (“**Industrial Bank**”) through Industrial Guoxin Asset Management Co., Ltd.\* (興業國信資產管理有限公司) (“**Industrial Guoxin Asset Management**”). The shares of Industrial Bank are listed on the Shanghai Stock Exchange (stock code: 601166) and the Finance Department of Fujian Province is its single largest shareholder. As of the Latest Practicable Date, Industrial Guoxin Asset Management, the limited partner of Xingsheng Dongyan, held approximately 99.99% interest in Xingsheng Dongyan. As of the Latest Practicable Date, Xingsheng Dongyan directly held approximately 2.09% of our total issued Shares. To the knowledge of our Directors, Xingsheng Dongyan is an Independent Third Party.
5. Orient Asset is a joint stock limited company established under the laws of the PRC and is principally engaged in the financial asset management, whose approximately 71.55% equity interest is held and controlled by the Ministry of Finance. The equity interest of Orient Asset is held respectively as to 16.39% by the National Council for Social Security Fund of the PRC\* (全國社會保障基金理事會), as to 5.64% by China Telecommunications Corporation\* (中國電信集團有限公司), which is wholly owned by the SASAC, as to 4.40% by China Reform Capital Corporation Ltd.\* (國新資本有限公司) and as to 2.02% by Shanghai Electric Group Company Limited\* (上海電氣集團股份有限公司) (its shares are listed on the Shenzhen Stock Exchange (stock code: 601727) and the Stock Exchange (stock code: 02727) and ultimately controlled by the Shanghai State-owned Assets Supervision and Administration Commission). As of the Latest Practicable Date, Orient Asset directly held approximately 2.06% of our total issued Shares. To the knowledge of our Directors, Orient Asset is an Independent Third Party.

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## HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

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6. Jiaxing Jiayu Equity Investment Partnership (L.P.)\* (嘉興嘉鈺股權投資合夥企業(有限合伙)) (“**Jiaxing Jiayu**”) is a limited partnership established under the laws of the PRC and is principally engaged in equity investments and mergers and acquisitions. Hangzhou Luohua Private Equity Fund Management Co., Ltd. (杭州灝華私募基金管理有限公司) is a company established under the PRC laws with limited liability and is the general partner of Jiaxing Jiayu, ultimately controlled by Chen Kun (陳堃), who is an Independent Third Party.

As of the Latest Practicable Date, Jiaxing Jiayu had a total of six limited partners, all were Independent Third Parties. Among them, Fu Xuan (付璿) held approximately 42.64% interests in Jiaxing Jiayu and the other five limited partners held an aggregate of approximately 57.11% interests in Jiaxing Jiayu. To the best of our Directors’ knowledge, information and belief, the limited partners of Jiaxing Jiayu are independent of each other. As of the Latest Practicable Date, Jiaxing Jiayu directly held approximately 1.90% of our total issued Shares. To the knowledge of our Directors, Jiaxing Jiayu is an Independent Third Party.

7. CCB Investment is a company established under the laws of the PRC with limited liability and is principally engaged in convertible bond and related business in China. CCB Investment is wholly-owned by China Construction Bank Corporation\* (中國建設銀行股份有限公司) (“**CCB**”), the shares of which are listed on the Stock Exchange (stock code: 939) and the Shanghai Stock Exchange (stock code: 601939). As of the Latest Practicable Date, CCB Investment directly held approximately 1.42% of our total issued Shares. To the knowledge of our Directors, CCB Investment is an Independent Third Party.

8. Zhuhai Kangyang Management Consulting Partnership (L.P.)\* (珠海康陽管理諮詢合夥企業(有限合伙)) (“**Zhuhai Kangyang**”) is a limited partnership established under the laws of the PRC and is principally engaged in investment and management consulting. The general partner of Zhuhai Kangyang is Shenzhen Jingchuang Zhizao Enterprise Management Partnership (L.P.)\* (深圳精創智造企業管理合夥企業(有限合伙)) (“**Shenzhen Zhizao**”). Shenzhen Zhizao is a limited partnership established under the laws of the PRC and is ultimately jointly controlled by Li Jianguang (李建光), Niu Kuiguang (牛奎光) and Wang Jingbo (王靜波), who are all Independent Third Parties.

As of the Latest Practicable Date, Zhuhai Kangyang had one limited partner, namely Shenzhen Harmony Growth Phase III Technology Development Equity Investment Fund Partnership L.P.\* (深圳和諧成長三期科技發展股權投資基金合夥企業(有限合伙)) (“**Harmony Growth**”), holding approximately 99.99% of the partnership share in Zhuhai Kangyang. Harmony Growth is a limited partnership established under the laws of the PRC, the general partner of which is Shenzhen Zhizao.

As of the Latest Practicable Date, Zhuhai Kangyang directly held approximately 1.42% of our total issued Shares. To the knowledge of our Directors, Zhuhai Kangyang is an Independent Third Party.

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9. Yuan Zhimin (袁志敏) is a PRC natural person who directly held approximately 1.42% of our total issued Shares as of the Latest Practicable Date. To the knowledge of our Directors, Yuan Zhimin is an Independent Third Party.
10. Dongguan Songshan Lake Science City Investment Co., Ltd.\* (東莞松山湖科學城投資有限公司) (“**Dongguan Science City**”) is a company established under the laws of the PRC with limited liability, and is principally engaged in investment and management. It is indirectly wholly-owned by the Dongguan Municipal Government through the Management Committee of Dongguan Songshan Lake High-tech Industrial Development Zone\* (東莞松山湖高新技術產業開發區管理委員會). As of the Latest Practicable Date, Dongguan Science City directly held approximately 1.42% of our total issued Shares. To the knowledge of our Directors, Dongguan Science City is an Independent Third Party.
11. Gongqingcheng Jianyi is a limited partnership established under the laws of the PRC and is principally engaged in equity investment. Qiu Jun (邱俊), an Independent Third Party, is the general partner of Gongqingcheng Jianyi. As of the Latest Practicable Date, Gongqingcheng Jianyi had a total of four limited partners, all were Independent Third Parties. Among them, Huitianze Investment Co., Ltd.\* (匯天澤投資有限公司) (ultimately controlled by Dong Zhengqing (董正青), an Independent Third Party) held approximately 86.26% interests in Gongqingcheng Jianyi and the other three limited partners held an aggregate of approximately 10.54% interests in Gongqingcheng Jianyi. To the best of our Directors’ knowledge, information and belief, the limited partners of Gongqingcheng Jianyi are independent of each other. As of the Latest Practicable Date, Gongqingcheng Jianyi directly held approximately 1.23% of our total issued Shares. To the knowledge of our Directors, Gongqingcheng Jianyi is an Independent Third Party.
12. Huzhou Rongrui Equity Investment Partnership (L.P.)\* (湖州融睿股權投資合夥企業(有限合夥)) (“**Huzhou Rongrui**”) is a limited partnership established under the laws of the PRC and is principally engaged in equity investment, the general partner of which is Ruyuan Shancheng Shuidu Woodwork Co., Ltd.\* (乳源山城水都木製品有限公司) (“**Shancheng Shuidu**”). Shancheng Shuidu is a company established under the laws of the PRC with limited liability, in which Shenzhen Shibi’an Investment Co., Ltd.\* (深圳事必安投資有限公司) (“**Shenzhen Shibi’an**”) held 85.25% equity interests. Shenzhen Shibi’an is in turn owned as to 67.86% and 32.14% by Yuan Lingbin (袁靈斌) and Li Xiaohong (厲小紅), each being an Independent Third Party. As of the Latest Practicable Date, Huzhou Rongrui had one limited partner, namely, Shenzhen Shibi’an, holding 99.58% interest in Huzhou Rongrui.

As of the Latest Practicable Date, Huzhou Rongrui directly held approximately 1.08% of our total issued Shares. To the knowledge of our Directors, Huzhou Rongrui is an Independent Third Party.



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13. Zhuhai Kangpu is a limited partnership established under the laws of the PRC and is principally engaged in equity investment and management through private equity funds, the general partner of which is Zhuhai Maijike Investment Management Co., Ltd.\* (珠海邁吉刻投資管理有限公司) (“**Zhuhai Maiji**”). Zhuhai Maiji is a company established under the laws of the PRC with limited liability and is ultimately indirectly held as to approximately 34%, 32.7% and 33.3% equity interests by Niu Kuiguang (牛奎光), Wang Jingbo (王靜波) and Lin Dongliang (林棟樑), respectively, each being an Independent Third Party. As of the Latest Practicable Date, Zhuhai Kangpu had six limited partners, all were Independent Third Parties, and no limited partner held more than 30% interests in Zhuhai Kangpu. To the best of our Directors’ knowledge, information and belief, the limited partners of Zhuhai Kangpu are independent of each other. As of the Latest Practicable Date, Zhuhai Kangpu directly held approximately 0.91% of our total issued Shares. To the knowledge of our Directors, Zhuhai Kangpu is an Independent Third Party.
14. Wenzhou Zhenrui Equity Investment Partnership (L.P.)\* (溫州臻瑞股權投資合夥企業(有限合夥)) (“**Wenzhou Zhenrui**”) is a limited partnership established under the laws of the PRC and is principally engaged in equity investment and management, the general partner of which is Shanghai Yijia Private Equity Management Co., Ltd.\* (上海億嘉私募基金管理有限公司) (“**Shanghai Yijia**”). Shanghai Yijia is a company established under the laws of the PRC with limited liability and is held as to 68%, 15%, 8%, 6% and 3% equity interests by Lin Gongyi (林公義), Wu Bing (吳兵), Teng Jing (滕靜), Xu Gongbo (徐恭波) and Dai Zhiye (戴智業), respectively. As of the Latest Practicable Date, Wenzhou Zhenrui had a total of ten limited partners, all were Independent Third Parties, and no limited partner held more than 30% interests in Wenzhou Zhenrui. To the best of our Directors’ knowledge, information and belief, the limited partners of Wenzhou Zhenrui are independent of each other. As of the Latest Practicable Date, Wenzhou Zhenrui directly held approximately 0.80% of our total issued Shares. To the knowledge of our Directors, Wenzhou Zhenrui is an Independent Third Party.
15. CICC SAIC is a limited partnership established under the laws of the PRC and is principally engaged in equity investment and management, the general partners of which are CICC Capital Management Co., Ltd.\* (中金資本運營有限公司) (“**CICC Capital**”) and Shanghai SAIC Hengxu Investment Management Co., Ltd.\* (上海上汽恒旭投資管理有限公司) (“**SAIC Hengxu**”). CICC Capital is a company established under the laws of the PRC with limited liability and wholly-owned by China International Capital Corporation Limited\* (中國國際金融股份有限公司) (its shares are listed on Shanghai Stock Exchange (stock code: 601995) and the Stock Exchange (stock code: 03908)). SAIC Hengxu is a company established under the laws of the PRC with limited liability and is ultimately controlled by Lu Yongtao (陸永濤), who is an Independent Third Party.

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As of the Latest Practicable Date, CICC SAIC had a total of six limited partners, all were Independent Third Parties. Among them, Qingdao SAIC Innovative Upgrade Equity Investment Fund Partnership (L.P.)\* (青島上汽創新升級產業股權投資基金合夥企業(有限合夥)) (“**Qingdao SAIC**”) held approximately 72% interests in CICC SAIC, Huzhou CICC Shangyuan Equity Investment Partnership (L.P.)\* (湖州中金上源股權投資合夥企業) (“**Huzhou CICC**”) held approximately 7.2% interest in CICC SAIC and the other four limited partners held an aggregate of approximately 20.5% interests in CICC SAIC. Qingdao SAIC is a limited partnership established under the laws of the PRC, of which approximately 99.63% interests are held by SAIC Motor Corporation Limited\* (上海汽車集團股份有限公司) (its shares are listed on Shanghai Stock Exchange (stock code: 600104)), and is ultimately controlled by Shanghai Municipal State-owned Assets Supervision and Administration Commission\* (上海市國有資產監督管理委員會). The general partner of Huzhou CICC is CICC Private Equity Management Co., Ltd.\* (中金私募股權投資管理有限公司), which is in turn a wholly-owned subsidiary of China International Capital Corporation Limited\* (中國國際金融股份有限公司) (its shares are listed on Shanghai Stock Exchange (Stock Code: 601995) and the Stock Exchange (Stock Code: 03908)). China International Capital Corporation Hong Kong Securities Limited, our Sole Sponsor, is also an indirectly wholly-owned subsidiary of China International Capital Corporation Limited. To the best of our Directors’ knowledge, information and belief, except for the abovementioned, other limited partners of CICC SAIC are independent of each other. As of the Latest Practicable Date, CICC SAIC directly held approximately 0.71% of our total issued Shares. To the knowledge of our Directors, CICC SAIC is an Independent Third Party.

16. Shenzhen Xinshi Xinxing Industry Merger and Acquisition Equity Investment Fund Partnership (L.P.)\* (深圳信石信興產業併購股權投資基金合夥企業(有限合夥)) (“**Xinshi Xinxing**”) is a limited partnership established under the laws of the PRC and is principally engaged in equity investment and management, the general partners of which are Cinda Kunpeng (Shenzhen) Equity Investment Management Co., Ltd.\* (信達鯤鵬(深圳)股權投資管理有限公司) (“**Cinda Kunpeng**”) and Cinda Capital Management Co., Ltd.\* (信達資本管理有限公司). Xinshi Xinxing is managed by Cinda Kunpeng, which is the sole executive partner of Xinshi Xinxing, and Cinda Capital Management Co., Ltd. does not execute the business of Xinshi Xinxing. Cinda Kunpeng is a company established under the laws of the PRC with limited liability, which is ultimately controlled by Sino-Rock Investment Management Company Limited\* (漢石投資管理有限公司) (“**Sino-Rock Investment**”). Sino-Rock Investment is a company incorporated in Hong Kong under the laws of Hong Kong, principally engaged in asset management and investment. Cinda Capital Management Co., Ltd. is a company established under the laws of the PRC with limited liability, which is indirectly controlled by Cinda Asset. As of the Latest Practicable Date, Xinshi Xinxing had a total of four limited partners, all were Independent Third Parties. Among them, Cinda Asset held approximately 48% interests in Xinshi Xinxing and the other three limited partners held an aggregate of 50% interests in Xinshi Xinxing. To the best of our Directors’ knowledge, information and belief, the limited partners of Xinshi Xinxing are independent of each other. As of the Latest Practicable Date, Xinshi Xinxing directly held approximately 0.70% of our total issued Shares. To the knowledge of our Directors, Xinshi Xinxing is an Independent Third Party.



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17. Dongguan Municipal Guanzhiguang Equity Investment Partnership (L.P.)\* (東莞市莞之光股權投資合夥企業(有限合夥)) (“**Guanzhiguang**”) is a limited partnership established under the laws of the PRC and is principally engaged in equity investment and management, the general partner of which is Dongguan Jinkong Equity Investment Fund Management Co., Ltd.\* (東莞金控股權投資基金管理有限公司) (“**Dongguan Jinkong Fund**”). Dongguan Jinkong Fund is a company established under the laws of the PRC with limited liability, is wholly-owned by Dongguan Financial Holdings Group Co., Ltd.\* (東莞金融控股集團有限公司) and is ultimately controlled by Dongguan Municipal State-owned Assets Supervision and Administration Commission\* (東莞市國有資產監督管理委員會). As of the Latest Practicable Date, Guanzhiguang had a total of three limited partners, namely Dongguan Municipal Innovative Investment Development Partnership (L.P.)\* (東莞市創新投資發展合夥企業(有限合夥)), Guangdong Jinxin Capital Investment Co., Ltd.\* (廣東金信資本投資有限公司) and Dongguan Municipal Hongshang Capital Investment Co., Ltd.\* (東莞市宏商資本投資有限公司) and each held approximately 60.39%, 29.7% and 9.9% interests of Guanzhiguang, respectively. To the best of our Directors’ knowledge, information and belief, except that Dongguan Municipal Innovative Investment Development Partnership (L.P.) and Guangdong Jinxin Capital Investment Co., Ltd. are both ultimately controlled by Dongguan Municipal State-owned Assets Supervision and Administration Commission, other limited partners of Guanzhiguang are independent of each other. As of the Latest Practicable Date, Guanzhiguang directly held approximately 0.47% of our total issued Shares. To the knowledge of our Directors, Guanzhiguang is an Independent Third Party.
18. Dongguan Science & Technology Innovative Finance Group Co., Ltd.\* (東莞科技創新金融集團有限公司) (“**Dongguan Kejin**”) is a company established under the laws of the PRC with limited liability, principally engaged in investment and investment advisory business, and is wholly-owned by Dongguan Municipal State-owned Assets Supervision and Administration Commission. As of the Latest Practicable Date, Dongguan Kejin directly held 0.47% of our total issued Shares. To the knowledge of our Directors, Dongguan Kejin is an Independent Third Party.
19. Dongguan Municipal Biotechnology Industry Investment Co., Ltd.\* (東莞市生技產業投資有限公司) (“**Dongguan Biotechnology**”) is a company established under the laws of the PRC with limited liability and is principally engaged in industry investment business. Dongguan Biotechnology is indirectly and wholly owned by Dongguan Songshan Lake Hi-tech Technology Industry Development Management Committee\* (東莞松山湖高新技術產業開發區管理委員會), which is in turn a local office of the Dongguan government and holds such equities on behalf of the Dongguan government. As of the Latest Practicable Date, Dongguan Biotechnology directly held 0.47% of our total issued Shares. To the knowledge of our Directors, Dongguan Biotechnology is an Independent Third Party.

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20. Ningbao Daxie Hansheng Enterprise Management Co., Ltd.\* (寧波大榭漢勝企業管理有限公司) (“**Daxie Hansheng**”) is a company established under the laws of the PRC with limited liability and is principally engaged in corporate management and advisory business. Daxie Hansheng is respectively held as to 50% interests by Bao Liming (鮑立明) and Shen Limin (沈利民), each being an Independent Third Party. As of the Latest Practicable Date, Daxie Hansheng directly held 0.47% of our total issued Shares. To the knowledge of our Directors, Daxie Hansheng is an Independent Third Party.
21. Guangdong Shunyin Industry Financing Investment Co., Ltd.\* (廣東順銀產融投資有限公司) (“**Shunyin Industry Financing**”) is a company established under the laws of the PRC with limited liability and is principally engaged in investment in various industries, investment management, investment consulting and asset management, and its equity interests are jointly held by 22 shareholders. Among which, Ningbo Meishan Free Trade Port Zone Yuechen Investment Management Co., Ltd.\* (寧波梅山保稅港區樾宸投資管理有限公司) (a wholly-owned subsidiary of Midea Construction (Hong Kong) Limited\* (美的建業(香港)有限公司)), Guangdong Fuhua Mechanical Equipment Manufacturing Co., Ltd.\* (廣東富華機械裝備製造有限公司) (which is ultimately controlled by Fuwa Mechanical Engineering (HK) Company Limited\* (富華工程機械(香港)有限公司)), Guangdong Shunxu Investment Management Co., Ltd.\* (廣東順旭投資管理有限公司) (which is ultimately controlled by Lu Chuqi (盧礎其), an Independent Third Party), Guangdong Liansu Technology Industrial Co., Ltd.\* (廣東聯塑科技實業有限公司) (a wholly-owned subsidiary of Liansu Group Company Limited\* (聯塑集團有限公司)) and Foshan Municipal Shunde District Xinhaibang Enterprise Management Co., Ltd.\* (佛山市順德區信海邦企業管理有限公司) (which is ultimately controlled by Wu Zhizheng (伍志徵), an Independent Third Party) held 15%, 15%, 15%, 10% and 10% equity interests of Shunyin Industry Financing, respectively, and the remaining 35% equity interests are held by 17 shareholders, each holding no more than 5% equity interests of Shunyin Industry Financing. As of the Latest Practicable Date, Shunyin Industry Financing directly held 0.47% of our total issued Shares. To the knowledge of our Directors, Shunyin Industry Financing is an Independent Third Party.
22. Yidu Guotong is a company established under the laws of the PRC with limited liability and is principally engaged in infrastructure construction and management and the operation and management of state-owned assets. Yidu Guotong is held as to 83.67%, 10.80% and 5.53% equity interests by Yidu Municipal State-owned Assets Investment and Operation Holding Group Co., Ltd.\* (宜都市國有資產投資運營控股集團有限公司) (“**Yidu State-owned Assets Investment**”), China Development Bank Development Fund Co., Ltd.\* (國開發展基金有限公司) (“**China Development Fund**”) and China Agricultural Development Key Construction Fund Co., Ltd.\* (中國農發重點建設基金有限公司) (“**Agricultural Development Fund**”), respectively. Yidu State-owned Assets Investment is a company established under the laws of the PRC with limited liability and is wholly-owned by Yidu Municipal

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State-owned Assets Supervision and Administration Bureau\* (宜都市國有資產監督管理局). China Development Fund is a company established under the laws of the PRC with limited liability and is wholly-owned by China Development Bank\* (國家開發銀行), an Independent Third Party. Agricultural Development Fund is a company established under the laws of the PRC with limited liability and is wholly-owned by Agricultural Development Bank of China\* (中國農業發展銀行), an Independent Third Party. As of the Latest Practicable Date, Yidu Guotong directly held 0.47% of our total issued Shares. To the knowledge of our Directors, Yidu Guotong is an Independent Third Party.

23. Qianhai Xizheng is a limited partnership established under the laws of the PRC and is principally engaged in equity investment and management, the general partner of which is Shenzhen Qianhai Everbright Investment Management Co., Ltd.\* (深圳前海光大金控投資管理有限公司) (“**Qianhai Everbright**”). Qianhai Everbright is a company established under the laws of the PRC with limited liability and is ultimately controlled by the State Council. As of the Latest Practicable Date, Qianhai Everbright had a total of two limited partners, namely Shaoguan Municipal Jincui Investment Group Co., Ltd.\* (韶關市金財投資集團有限公司) (“**Shaoguan Jincui**”) and Shaoguan Municipal City Investment Development Group Co., Ltd.\* (韶關市城市投資發展集團有限公司) (“**Shaoguan City Investment**”), which held approximately 75.47% and 22.64% interests of Qianhai Xizheng, respectively. Each of Shaoguan Jincui and Shaoguan City Investment is a limited liability company established under the laws of the PRC, each of which is held as to 90% and 10% equity interests by Shaoguan Municipal State-owned Assets Supervision and Administration Commission\* (韶關市國有資產監督管理委員會) and Department of Finance of Guangdong Province\* (廣東省財政廳), respectively. As of the Latest Practicable Date, Qianhai Xizheng directly held 0.47% of our issued Shares. To the knowledge of our Directors, Qianhai Xizheng is an Independent Third Party.
24. Shenzhen Dicheng is a limited partnership established under the laws of the PRC and is principally engaged in equity investment and management, the general partner of which is Shenzhen Municipal Wenzheng Asset Management Co., Ltd.\* (深圳市穩正資產管理有限公司) (“**Shenzhen Wenzheng**”), holding 0.01% interest in Shenzhen Dicheng. Shenzhen Wenzheng is a company established under the laws of the PRC with limited liability and is ultimately controlled by Xiong Qiangbo (熊強波). As of the Latest Practicable Date, Shenzhen Dicheng had a total of 16 limited partners, all were Independent Third Parties. Among them, Lv Luyao (呂露瑤) held 37% interests in Shenzhen Dicheng, while the remaining 62.99% interests of Shenzhen Dicheng were held by other limited partners. To the best of the Directors’ knowledge, information and belief, the limited partners of Shenzhen Dicheng are independent of each other. As of the Latest Practicable Date, Shenzhen Dicheng directly held 0.46% of our total issued Shares. To the knowledge of our Directors, Shenzhen Dicheng is an Independent Third Party.

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25. Qinzhi Kanghong is a limited partnership established under the laws of the PRC and is principally engaged in venture investment, equity investment and investment advisory business, the general partner of which is Shenzhen Qianhai Qinzhi International Capital Management Co., Ltd.\* (深圳前海勤智國際資本管理有限公司) (“**Qianhai Qinzhi**”). Qianhai Qinzhi is a company established under the laws of the PRC with limited liability and is ultimately controlled by Tang Dajie (湯大傑), an Independent Third Party. As of the Latest Practicable Date, Qinzhi Kanghong had a total of seven limited partners, all were Independent Third Parties. Among them, Shenzhen Shibi'an and Chen Juncao (陳鈞操) held 61.59% and 10.10% interests in Qinzhi Kanghong, respectively, while the remaining 24.22% interests of Qinzhi Kanghong were held by five limited partners, each holding no more than 10% interests. To the best of the Directors' knowledge, information and belief, the limited partners of Qinzhi Kanghong are independent of each other. As of the Latest Practicable Date, Qinzhi Kanghong directly held 0.45% of our total issued Shares. To the knowledge of our Directors, Qinzhi Kanghong is an Independent Third Party.
26. Mige Investment is a limited partnership established under the laws of the PRC and is principally engaged in equity investment and management, the general partner of which is Xie Jiasheng (謝佳勝), an Independent Third Party, holding 66.4% interest in Mige Investment. As of the Latest Practicable Date, Mige Investment had a total of 11 limited partners, all were Independent Third Parties and held an aggregate of 33.6% interests in Mige Investment, each holding no more than 10% interests. To the best of the Directors' knowledge, information and belief, the limited partners of Mige Investment are independent of each other. As of the Latest Practicable Date, Mige Investment directly held 0.42% of our total issued Shares. To the knowledge of our Directors, Mige Investment is an Independent Third Party.
27. Guangzhou Yuanshi No. 1 Venture Investment Partnership (L.P.)\* (廣州源石壹號創業投資合夥企業(有限合夥)) (“**Yuanshi No. 1**”) is a limited partnership established under the laws of the PRC and is principally engaged in equity investment and management, the general partner of which is Guangdong Yuanshi Equity Investment Fund Management Co., Ltd.\* (廣東源石股權投資基金管理有限公司) (“**Guangdong Yuanshi**”). Guangdong Yuanshi is a company established under the laws of the PRC with limited liability and is ultimately controlled by Yang Yanfeng (楊燕峰), an Independent Third Party. As of the Latest Practicable Date, Yuanshi No. 1 had a total of 17 limited partners, all were Independent Third Parties, and no limited partner held more than 30% interests in Yuanshi No. 1. To the best of the Directors' knowledge, information and belief, the limited partners of Yuanshi No. 1 are independent of each other. As of the Latest Practicable Date, Yuanshi No. 1 directly held 0.33% of our total issued Shares. To the knowledge of our Directors, Yuanshi No. 1 is an Independent Third Party.

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28. Xingsheng Guangchuang is a limited partnership established under the laws of the PRC and is principally engaged in equity investment and management, the general partner of which is Ningbao Meishan Bonded Port Area Yuancheng Investment Management Co., Ltd.\* (寧波梅山保税港區遠晟投資管理有限公司) (“**Yuancheng Investment**”). Yuancheng Investment is a company established under the laws of the PRC with limited liability and is ultimately controlled by Industrial Bank through Industrial Guoxin Asset Management. As of the Latest Practicable Date, Xingsheng Guangchuang had one limited partner, namely Industrial Guoxin Asset Management, which held 99.98% interests of Xingsheng Guangchuang. As of the Latest Practicable Date, Xingsheng Guangchuang directly held 0.28% of our total issued Shares. To the knowledge of our Directors, Xingsheng Guangchuang is an Independent Third Party.
29. Zhuji Wolun Jingfu Equity Investment Partnership (L.P.)\* (諸暨沃侖景富股權投資合夥企業(有限合夥)) (“**Wolun Jingfu**”) is a limited partnership established under the laws of the PRC and is principally engaged in equity investment and management, the general partners of which are Shanghai Wolun Investment Management Co., Ltd.\* (上海沃侖投資管理有限公司) (“**Shanghai Wolun**”) and Aoyang (Shanghai) Private Equity Fund Management Co., Ltd.\* (傲洋(上海)私募基金管理有限公司) (“**Aoyang Fund**”), with Shanghai Wolun as its fund manager. Shanghai Wolun is a company established under the laws of the PRC with limited liability and is ultimately controlled by Gu Liang (顧亮), an Independent Third Party. Aoyang Fund is a company established under the laws of the PRC with limited liability and is held as to 41%, 29%, 20% and 10% equity interests by Gan Qian (淦謙), Chen Dehu (陳德虎), Wu Gang (吳剛) and GiHo Group Co., Ltd.\* (傑豪集團有限公司), respectively, who are all Independent Third Parties. As of the Latest Practicable Date, Wolun Jingfu had a total of eight limited partners, all were Independent Third Parties, and no limited partner held more than 30% interests in Wolun Jingfu. To the best of the Directors’ knowledge, information and belief, the limited partners of Wolun Jingfu are independent of each other. As of the Latest Practicable Date, Wolun Jingfu directly held 0.28% of our total issued Shares. To the knowledge of our Directors, Wolun Jingfu is an Independent Third Party.
30. Cuiheng New Era is a limited partnership established under the laws of the PRC and is principally engaged in equity investment and management, the general partners of which are Zhuhai Hengqin Cuiheng Asset Management Center (L.P.)\* (珠海橫琴翠亨資產管理中心(有限合夥)) (“**Hengqin Cuiheng**”) and Yan Min (嚴敏), an Independent Third Party. Hengqin Cuiheng is a limited partnership established under the laws of the PRC, the general partner of which is Pan Fangzhou (潘方舟), an Independent Third Party, and the limited partners of which are Yan Min and Li Weitang (李偉堂) (an Independent Third Party), who held 77.5% and 17.5% interests of Hengqin Cuiheng, respectively. Hengqin Cuiheng is ultimately controlled by Yan Min, an Independent Third Party. As of the Latest Practicable Date, Cuiheng New Era had a total of six limited partners, all were Independent Third Parties. Among them, Sun Lianhe (孫聯合) held 33.06% interests in Cuiheng New Era, and the other



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five limited partners held an aggregate of 54.53% interests in Cuiheng New Era. To the best of our Directors' knowledge, information and belief, the limited partners of Cuiheng New Era are independent of each other. As of the Latest Practicable Date, Cuiheng New Era directly held 0.26% of our total issued Shares. To the knowledge of our Director, Cuiheng New Era is an Independent Third Party.

31. Shenzhen Wenzheng Changxing Venture Capital Enterprise (L.P.)\* (深圳市穩正長興創業投資企業(有限合夥)) (“**Wenzheng Changxing**”) is a limited partnership established under the laws of the PRC and is principally engaged in equity investment and management, the general partner of which is Shenzhen Wenzheng, holding 0.02% interest in Wenzheng Changxing. As of the Latest Practicable Date, Wenzheng Changxing had a total of 18 limited partners, all were Independent Third Parties, and no limited partner held more than 30% interests in Wenzheng Changxing. To the best of our Directors' knowledge, information and belief, the limited partners of Wenzheng Changxing are independent of each other. As of the Latest Practicable Date, Wenzheng Changxing directly held approximately 0.26% of our total issued Shares. To the knowledge of our Directors, Wenzheng Changxing is an Independent Third Party.
32. Hunan Xingxiang Jiacheng Private Equity Investment Fund Partnership (L.P.) (湖南興湘佳誠私募股權投資基金合夥企業(有限合夥))\* (“**Xingxiang Jiacheng**”) is a limited partnership established under the laws of the PRC and principally engaged in equity investment and management, the general partner of which is Hunan Xingxiang Emerging Industries Investment Fund Management Co., Ltd.\* (湖南興湘新興產業投資基金管理有限公司) (“**Hunan Xingxiang**”). Hunan Xingxiang is a company established under the laws of the PRC with limited liability and is ultimately controlled by the State-owned Assets Supervision and Administration Commission of Hunan Province\* (湖南省國有資產監督管理委員會). As of the Latest Practicable Date, Xingxiang Jiacheng had two limited partners, namely Guiyang Zhongtian Jiachuang Investment Co., Ltd.\* (貴陽中天佳創投資有限公司) (“**Guiyang Zhongtian**”) and Hunan Xingxiang Emerging Industry Investment Fund Partnership (L.P.)\* (湖南興湘新興產業投資基金合夥企業(有限合夥)) (“**Xingxiang Investment**”), which held approximately 49.99% and 49.01% interest in Xingxiang Jiacheng, respectively. Guiyang Zhongtian is a limited liability company established under the PRC law and is a subsidiary of Zhongtian Financial Group Company Limited\* (中天金融集團股份有限公司), the shares of which are listed on the National Equities Exchange and Quotations (stock code: 400174) and ultimately controlled by Luo Yuping (羅玉平). Xingxiang Investment is a limited partnership established under the laws of the PRC and ultimately controlled by the State-owned Assets Supervision and Administration Commission of Hunan Province. To the best of our Directors' knowledge, information and belief, the limited partners of Xingxiang Jiacheng are independent of each other. As of the Latest Practicable Date, Xingxiang Jiacheng directly held approximately 0.24% of our total issued Shares. To the knowledge of our Directors, Xingxiang Jiacheng is an Independent Third Party.

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33. Zaozhuang Changsheng Yingkang Equity Investment Management Partnership (L.P.)\* (棗莊常勝英康股權投資管理合夥企業(有限合夥)) (“**Changsheng Yingkang**”) is a limited partnership established under the laws of the PRC and is principally engaged in equity investment and management, the general partner of which is Wang Jianying (王建英), an Independent Third Party, holding approximately 87.83% interest in Changsheng Yingkang. As of the Latest Practicable Date, the remaining 12.17% interests in Changsheng Yingkang were held by three limited partners (all Independent Third Parties). To the best of our Directors’ knowledge, information and belief, the limited partners of Changsheng Yingkang are independent of each other. As of the Latest Practicable Date, Changsheng Yingkang directly held approximately 0.24% of our total issued Shares. To the knowledge of our Directors, Changsheng Yingkang is an Independent Third Party.
34. Ruyuan Yao Autonomous County Yinyuan Electric Power Group Co., Ltd.\* (乳源瑤族自治縣銀源電力集團有限公司) (“**Yinyuan Electric Power**”) is a limited liability company established under the laws of the PRC and is principally engaged in the production and supply of tap water and electricity, and is held by Ruyuan Yao Autonomous County Jinyao City Management Investment Co., Ltd.\* (乳源瑤族自治縣金瑤城市經營投資有限公司) and Ruyuan Yao Autonomous County Fuliuyan Country Revitalization Co., Ltd.\* (乳源瑤族自治縣富麗源鄉村振興有限公司) as to 67.7% and 32.3% of its equity interests, respectively. Ruyuan Yao Autonomous County Jinyao City Management Investment Co., Ltd. is a limited liability company established under the PRC law, and is wholly-owned by Ruyuan Yao Autonomous County Public Assets Management Center\* (乳源瑤族自治縣公共資產管理中心), a public institution in Ruyuan Yao Autonomous County, Shaoguan City, which is responsible for assisting in the management of government-invested equity. Ruyuan Yao Autonomous County Fuliuyan Country Revitalization Co., Ltd. is wholly-owned by Ruyuan Yao Autonomous County Mingyuan State-owned Assets Co., Ltd.\* (乳源瑤族自治縣明源國有資產有限公司), which is in turn wholly-owned by the People’s Government of Ruyuan Yao Autonomous County. As of the Latest Practicable Date, Yinyuan Electric Power directly held approximately 0.24% of our total issued Shares. To the knowledge of our Directors, Yinyuan Electric Power is an Independent Third Party.
35. Guiyang SME Development Fund (L.P.)\* (貴陽中小企業發展基金(有限合夥)) (“**Guiyang Development Fund**”) is a limited partnership established under the laws of the PRC and is principally engaged in equity investment and management, the general partner of which is Guiyang Venture Capital Co., Ltd.\* (貴陽市創業投資有限公司). Guiyang Venture Capital Co., Ltd. is a company established under the laws of the PRC with limited liability and is ultimately controlled by the State-owned Assets Supervision and Administration Commission of Guiyang\* (貴陽市國有資產監督管理委員會). As of the Latest Practicable Date, Guiyang Development Fund had a total of four limited partners, all were Independent Third Parties. Among them, Guiyang Industrial Control Capital Co., Ltd.\* (貴陽產控資本有限公司) (which is ultimately controlled by State-owned Assets Supervision and Administration



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Commission of Guiyang) and Guiyang Industrial and Information Industry Development Guidance Fund Co., Ltd.\* (貴陽市工業和信息化產業發展引導基金有限公司) (which is ultimately controlled by State-owned Assets Supervision and Administration Commission of Guiyang) held approximately 76.92% and 6.38% interests in Guiyang Development Fund, respectively, and the other two limited partners held an aggregate of 15.38% interests in Guiyang Development Fund. To the best of our Directors' knowledge, information and belief, except for Guiyang Industrial Control Capital Co., Ltd. and Guiyang Industrial and Information Industry Development Guidance Fund Co., Ltd., both of which are ultimately controlled by State-owned Assets Supervision and Administration Commission of Guiyang, the other limited partners of Guiyang Development Fund are independent of each other. As of the Latest Practicable Date, Guiyang Development Fund directly held approximately 0.24% of our total issued Shares. To the knowledge of our Directors, Guiyang Development Fund is an Independent Third Party.

36. Shenzhen Jiahui Chuanglong Investment Enterprise (L.P.)\* (深圳市佳匯創隆投資企業(有限合夥)) (“**Jiahui Chuanglong**”) is a limited partnership established under the laws of the PRC and is principally engaged in equity investment and management, the general partner of which is Hainan Jiarong Private Equity Management Co., Ltd.\* (海南嘉榮私募基金管理有限公司), which is in turn ultimately controlled by Xue Xiangling (薛向陵), an Independent Third Party. As of the Latest Practicable Date, Jiahui Chuanglong had two limited partners, namely, Dongguan Qingyao Investment Partnership (L.P.)\* (東莞市青藥投資合夥企業(有限合夥)) (“**Dongguan Qingyao**”) and Guangdong Qingwei Investment Development Co., Ltd.\* (廣東青為投資發展有限公司) (“**Guangdong Qingwei**”), holding 96.93% and 3.05% interest in Jiahui Chuanglong, respectively. The general partner of Dongguan Qingyao is Guangdong Qingwei, which is in turn ultimately controlled by Wang Yan (王嬾), an Independent Third Party. As of the Latest Practicable Date, Jiahui Chuanglong directly held approximately 0.22% of our total issued Shares. To the knowledge of our Directors, Jiahui Chuanglong is an Independent Third Party.
37. Jiaxing Aomin Equity Investment Partnership (L.P.)\* (嘉興傲旻股權投資合夥企業(有限合夥)) (“**Jiaxing Aomin**”) is a limited partnership established under the laws of the PRC and is principally engaged in equity investment and management, the general partner of which is Aoyang (Shanghai) Private Equity Fund Management Co., Ltd.\* (傲洋(上海)私募基金管理有限公司) (“**Aoyang Shanghai**”). Aoyang Shanghai is a company established under the laws of the PRC with limited liability and is ultimately controlled by Gan Qian (淦謙), an Independent Third Party. As of the Latest Practicable Date, Jiaxing Aomin had a total of 24 limited partners, all were Independent Third Parties, and no limited partner held more than 30% interests in Jiaxing Aomin. To the best of our Directors' knowledge, information and belief, the limited partners of Jiaxing Aomin are independent of each other. As of the Latest Practicable Date, Jiaxing Aomin directly held approximately 0.20% of our total issued Shares. To the knowledge of our Directors, Jiaxing Aomin is an Independent Third Party.

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38. Jiaying Ximian is a limited partnership established under the laws of the PRC and is principally engaged in equity investment and management, the general partner of which is Shenzhen Qianzi Wealth Management Co., Ltd.\* (深圳市綫子財富管理有限公司) (“**Shenzhen Qianzi**”). Shenzhen Qianzi is a company established under the laws of the PRC with limited liability and is ultimately controlled by Wu Manping (吳蔓萍), an Independent Third Party. As of the Latest Practicable Date, Jiaying Ximian had a total of 22 limited partners, all were Independent Third Parties, and no limited partner held more than 30% interests in Jiaying Ximian. To the best of our Directors’ knowledge, information and belief, the limited partners of Jiaying Ximian are independent of each other. As of the Latest Practicable Date, Jiaying Ximian directly held approximately 0.14% of our total issued Shares. To the knowledge of our Directors, Jiaying Ximian is an Independent Third Party.
39. Hangzhou Zhonghe is a limited partnership established under the laws of the PRC and is principally engaged in equity investment and management, the general partner of which is Zhonghe Guoxin (Hangzhou) Private Equity Fund Management Co., Ltd.\* (中合國信(杭州)私募基金管理有限公司) (“**Zhonghe Guoxin**”). Zhonghe Guoxin is a company established under the laws of the PRC with limited liability and is ultimately controlled by the National Information Center\* (國家信息中心) (i.e. the National E-Government Extranet Management Center\* (國家電子政務外網管理中心) is a public institution directly managed by the China Development and Reform Commission). As of the Latest Practicable Date, Hangzhou Panchuang Construction Materials Co., Ltd.\* (杭州磐創建築材料有限公司), the sole limited partner of Hangzhou Zhonghe, held 98% interest in Hangzhou Zhonghe. Hangzhou Panchuang Construction Materials Co., Ltd. is a company established under the laws of the PRC with limited liability and is wholly-owned by HOPE FAITH HOLDING LIMITED, which is a company incorporated in Hong Kong and an Independent Third Party. As of the Latest Practicable Date, Hangzhou Zhonghe directly held approximately 0.12% of our total issued Shares. To the knowledge of our Directors, Hangzhou Zhonghe is an Independent Third Party.
40. Pingxiang Junyuan Tongchuang Enterprise Management Center (L.P.)\* (萍鄉市君源同創企業管理中心(有限合夥)) (“**Junyuan Tongchuang**”) is a limited partnership established under the laws of the PRC and is principally engaged in equity investment and management, the general partner of which is Shenzhen Dongfang Junyuan Asset Management Limited\* (深圳東方君源資產管理有限公司) (“**Oriental Junyuan**”). Oriental Junyuan is a company established under the laws of the PRC with limited liability and is wholly-owned by Yu Qike (俞淇科), an Independent Third Party. As of the Latest Practicable Date, Junyuan Tongchuang had a total of four limited partners, all were Independent Third Parties. Among them, Pingxiang Xiangyu Junyuan Enterprise Management Center (L.P.)\* (萍鄉市湘裕君源企業管理中心(有限合夥)) held approximately 71.43% interests in Junyuan Tongchuang, and the other three limited partners held an aggregate of approximately 23.80% interests in Junyuan Tongchuang. Pingxiang Xiangyu Junyuan Enterprise Management Center (L.P.) is a limited partnership established under the laws of the PRC and is

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ultimately controlled by the Pingxiang State-owned Assets Supervision and Administration Commission\* (萍鄉市國有資產監督管理委員會). To the best of our Directors' knowledge, information and belief, the limited partners of Junyuan Tongchuang are independent of each other. As of the Latest Practicable Date, Junyuan Tongchuang directly held approximately 0.09% of our total issued Shares. To the best knowledge of our Directors, Junyuan Tongchuang is an Independent Third Party.

41. Xinquanxin is a limited partnership established under the laws of the PRC and is principally engaged in equity investment and management, the general partner of which is Zhang Liang (張亮), an Independent Third Party, holding 42.84% interest in Xinquanxin. As of the Latest Practicable Date, Xinquanxin had a total of 19 limited partners, all were Independent Third Parties, and no limited partner held more than 30% interests in Xinquanxin. To the best of our Directors' knowledge, information and belief, the limited partners of Xinquanxin are independent of each other. As of the Latest Practicable Date, Xinquanxin directly held approximately 0.01% of our total issued Shares. To the knowledge of our Directors, Xinquanxin is an Independent Third Party.

### PRINCIPAL SUBSIDIARIES OF OUR COMPANY

As of the Latest Practicable Date, our Company has four branches and 79 subsidiaries. Among them, the following subsidiaries are important to us in terms of financial results, business performance and qualifications:

Name of subsidiary	Place of incorporation/ establishment	Date of incorporation/ establishment	Percentage of equity interest held by our Company as of the Latest Practicable Date	Principal business
Shenzhen HEC Testing . . .	The PRC	February 28, 2014	100%	Product quality inspection
Dongguan HEC Biopharmaceutical . . . .	The PRC	March 21, 2019	100%	R&D and transfer of biosimilar drugs and new biologic drugs
Dongguan HEC Generic Drug . . . . .	The PRC	March 21, 2019	100%	Generic drug research and production
HEC CJ Pharm . . . . .	The PRC	August 8, 2001	51.41% <sup>(1)</sup>	Drugs production, wholesale, retail and import and export
Dongguan Yangzhikang. . .	The PRC	August 24, 2018	51.41% <sup>(2)</sup>	R&D, production and sales of drugs and biological products

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Name of subsidiary	Place of incorporation/ establishment	Date of incorporation/ establishment	Percentage of equity interest held by our Company as of the Latest Practicable Date	Principal business
Guangdong HEC Biopharmaceutical . . . .	The PRC	February 10, 2017	51.41% <sup>(2)</sup>	R&D, production and sales of drugs and biologics
Yichang HEC Medical . . .	The PRC	July 8, 2005	51.41% <sup>(2)</sup>	Drugs wholesale, retail and import and export
Yichang HEC Pharmaceutical . . . . .	The PRC	February 28, 2018	51.41% <sup>(2)</sup>	Drugs production, wholesale and import and export
Yichang HEC Medical Technology . . .	The PRC	September 10, 2019	51.41% <sup>(2)</sup>	Pharmaceutical information consultation, analysis and investigation and pharmaceutical market promotion
Dongguan HEC Medical . .	The PRC	January 10, 2017	51.41% <sup>(2)</sup>	R&D, production and sales of chemical raw material drugs and chemical preparations
Hong Kong HEC . . . . .	Hong Kong	August 25, 2020	100%	Pharmaceutical sales
Germany HEC . . . . .	Germany	December 22, 2009	90% <sup>(3)</sup>	Import, export and distribution of pharmaceutical products, intermediates, and active pharmaceutical ingredients
US HEC . . . . .	USA	November 1, 2011	100%	Import, promotion, and sales of drugs

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### Notes:

- (1) As of the Latest Practicable Date, the HEC CJ Pharm H Shares are listed on the Stock Exchange (stock code: 1558). Our Company controls an aggregate of 51.41% equity interest in HEC CJ Pharm, and HEC CJ Pharm's remaining 2.48%, 0.046% and 46.064% equity interests are held by Guangdong HEC Technology, the other core connected persons of our Company and public HEC CJ Pharm H Shareholders, respectively. To the best knowledge of our Company after due inquiry, the other core connected persons of our Company (the "**Other Core Connected Persons**") include: (i) Mr. Tang Xinfa, our non-executive Director; (ii) Mr. Li Shuang, Mr. Wang Danjin, Mr. Jiang Juncai and Mr. Li Xuechen, each of whom is a director of HEC CJ Pharm (the "**Relevant HEC CJ Pharm Directors**"); and (iii) Mr. Wang Shengchao and Mr. Luo Zhonghua, each of whom is a supervisor of HEC CJ Pharm (the "**Relevant HEC CJ Pharm Supervisors**"). As of the Latest Practicable Date, Mr. Tang Xinfa, the Relevant HEC CJ Pharm Directors and the Relevant HEC CJ Pharm Supervisors held approximately 0.015%, 0.021% and 0.010% equity interest in HEC CJ Pharm, respectively.
- (2) These subsidiaries are wholly-owned subsidiaries of HEC CJ Pharm; and
- (3) The remaining 10% equity interest in Germany HEC is held by Guenther, an Independent Third Party. Guenther has passed away and the probate process in relation to his estate (including the equity interest in Germany HEC) is still ongoing as of the Latest Practicable Date to determine the heirs of Guenther.

## ACQUISITIONS AND DISPOSALS DURING THE TRACK RECORD PERIOD

During the Track Record Period and up to the Latest Practicable Date, we did not engage in any material acquisitions, disposals or mergers.

## STRUCTURE OF THE INTRODUCTION AND THE PRIVATIZATION

Our Company has made the Privatization Proposal to privatize HEC CJ Pharm by way of merger by absorption in accordance with the PRC Company Law, other applicable PRC laws, Hong Kong laws, the Takeovers Code and the Listing Rules. On May 10, 2024, our Company and HEC CJ Pharm entered into the Merger Agreement, pursuant to which our Company and HEC CJ Pharm have agreed to implement the Merger subject to the terms and conditions of the Merger Agreement. The principal terms and conditions of the Merger Agreement are as follows:

**Parties** . . . . . our Company; and HEC CJ Pharm

**Overview of the Merger** . . . . . Subject to the terms and conditions of the Merger Agreement and the requirements of the PRC Company Law, the Takeovers Code, the Listing Rules, the Articles and the articles of association of HEC CJ Pharm, the Merger will be implemented by our Company merging HEC CJ Pharm by way of merger by absorption, namely:

- (1) Our Company will issue H Shares as consideration to acquire the Share Exchange HEC CJ Pharm H Shares held by the Share Exchange Shareholders;

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## HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

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- (2) Our Company will apply to the Stock Exchange for the listing of, and permission to deal in, the H Shares by way of introduction;
- (3) HEC CJ Pharm will be delisted from the Stock Exchange; and
- (4) The Share Exchange Shareholders will become Shareholders.

After completion of the Merger, our Company will assume all assets, liabilities, interests, businesses, employees, contracts and all other rights and obligations of HEC CJ Pharm and HEC CJ Pharm will be eventually deregistered in the PRC. All domestic shares of HEC CJ Pharm held by our Company (representing all domestic shares of HEC CJ Pharm in issue) and all HEC CJ Pharm H Shares held by our Company and through its subsidiary will be cancelled after completion of the Merger.

**Consideration** . . . . . Pursuant to the Merger Agreement, conditional upon the fulfillment (or waiver, as applicable) of the Pre-Conditions, the Conditions to effectiveness and the Conditions to implementation set out in the paragraphs headed “*Pre-Conditions to the Merger Agreement becoming effective*”, “*Conditions to effectiveness*” and “*Conditions to implementation*” below, the Share Exchange Shareholders will be entitled to receive from our Company:

For every Share Exchange	
HEC CJ Pharm	0.263614
H Share cancelled . . . . .	new H Share

Application will be made to the Stock Exchange for H Shares to be listed and traded on the Stock Exchange by way of introduction.

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**Pre-Conditions to the Merger Agreement becoming effective. . . . .**

The Merger Agreement is subject to the fulfilment of the following pre-conditions, namely,

- (1) the approval, filing or registration (if applicable) with or by (a) NDRC (if applicable); (b) the Ministry of Commerce of the PRC (if applicable) and (c) SAFE (if applicable), and such other applicable governmental approvals in respect of the Merger having been obtained. Subject to confirmation from SAFE, the approval, filing or registration with or by SAFE in (c) above may be applicable to the Merger and/or if any HEC CJ Pharm H Shares held by a Dissenting Shareholder (if any) will be acquired by our Company with funds remitted from the PRC to Hong Kong;
- (2) the approval or filing by or with the Listing Committee of the Stock Exchange, the Department of International Cooperation of the CSRC and such other competent authorities which are necessary for the listing (by way of introduction) of, and permission to deal in, the H Shares on the Stock Exchange pursuant to the Listing; and
- (3) approval by the shareholders meeting of our Company of the Merger in accordance with the PRC Laws and the Articles (the “**Pre-Conditions**”).

The above Pre-Conditions are not waivable. If any of the Pre-Conditions is not fulfilled by the Long-stop Date, the Merger Agreement will not become effective and will be automatically terminated.

**Conditions to effectiveness . . .**

After the Pre-Conditions are fulfilled, the Merger Agreement shall become effective upon fulfillment of all of the following conditions (none of which is capable of being waived) (the “**Conditions to effectiveness**”):



- (1) the passing of special resolution(s) by a majority of not less than two-thirds of the votes cast by way of poll by the HEC CJ Pharm Shareholders present and voting in person or by proxy at the HEC CJ Pharm EGM to approve the Merger under the Merger Agreement in accordance with the articles of association of HEC CJ Pharm and PRC Laws. Our Company and any parties acting in concert are not required to abstain from voting in respect of the Merger at the HEC CJ Pharm EGM under the PRC Company Law. Each of the Relevant HEC CJ Pharm Directors and the Relevant HEC CJ Pharm Supervisors intends, with respect of their own beneficial shareholdings in HEC CJ Pharm, to vote in favor of the Merger at the HEC CJ Pharm EGM. HEC CJ Pharm Shares held by members of the CICC group acting in the capacity of an exempt principal trader connected with our Company or HEC CJ Pharm will not be voted at the HEC CJ Pharm EGM in accordance with the requirements of Rule 35.4 of the Takeovers Code; and
- (2) the passing of special resolution(s) by way of poll approving the Merger under the Merger Agreement at the HEC CJ Pharm H Shareholders' Class Meeting to be convened for this purpose, provided that: (a) approval is given by at least 75% of the votes attaching to the HEC CJ Pharm H Shares held by the Independent HEC CJ Pharm H Shareholders that are cast either in person or by proxy; and (b) the number of votes cast against the resolution is not more than 10% of the votes attaching to all HEC CJ Pharm H Shares held by the Independent HEC CJ Pharm H Shareholders. Our Company and any parties acting in concert (including Guangdong HEC Technology and Mr. Tang Xinfu) will abstain from voting at the HEC CJ Pharm H Shareholders' Class Meeting for the purpose of satisfying the requirements under Rule 2.10 of the Takeovers Code. Each of the Relevant HEC CJ Pharm Directors and the Relevant HEC CJ Pharm Supervisors intends, with respect of their own beneficial shareholdings in HEC CJ Pharm, to vote in favor of the Merger at the HEC CJ Pharm H Shareholders' Class Meeting.

If the above Conditions to effectiveness are not fulfilled by the Long-stop Date, the Merger Agreement may be terminated by either party. Please also refer to the paragraph headed “*Termination*” in this section.

**Conditions to implementation .** After the Merger Agreement becomes effective upon fulfilment of the Pre-Conditions and all the Conditions to effectiveness, the implementation of the Merger shall be subject to the following conditions being fulfilled (the “**Conditions to implementation**”, together with the Conditions to effectiveness, collectively, the “**Conditions**”):

- (1) there being no material breach of the representations, warranties or undertakings given by our Company in the Merger Agreement on the Delisting Date which has a material adverse impact on the Merger;
- (2) there being no material breach of the representations, warranties or undertakings given by HEC CJ Pharm in the Merger Agreement on the Delisting Date which has a material adverse impact on the Merger;
- (3) there being no law, restriction or prohibition of any governmental authority or any judgment, decision or adjudication of any court on the Delisting Date which restricts, prohibits or terminates the Merger; and
- (4) the necessary approval or filing for the listing (by way of introduction) of, and the permission to deal in, the H Shares on the Stock Exchange pursuant to the Listing under Pre-Condition (2) not having been withdrawn and remain valid.

HEC CJ Pharm shall be entitled to waive Condition (1) above and our Company shall be entitled to waive Condition (2) above. Conditions (3) and (4) above are not capable of being waived. If the above Conditions to implementation are not fulfilled or if applicable, waived, by the Long-stop Date, the Merger Agreement may be terminated by the relevant party as detailed in the paragraph headed “*Termination*” in this section.

**Right of a Dissenting****Shareholder . . . . .**

According to the PRC Company Law and the Articles, any Dissenting Shareholder may by written notice request HEC CJ Pharm to acquire its HEC CJ Pharm H Shares at a “fair price”.

If any Dissenting Shareholder exercises its right, the HEC CJ Pharm, our Company (if so elected by the HEC CJ Pharm) or any other third party designated by the HEC CJ Pharm may acquire the HEC CJ Pharm H Shares held by that Dissenting Shareholder at a “fair price”. For the avoidance of doubt, Dissenting Shareholders that do not exercise or invalidly exercise this right would retain their HEC CJ Pharm H Shares and participate in the Share Exchange.

If HEC CJ Pharm designates a third party to acquire such HEC CJ Pharm H Shares held by that Dissenting Shareholder, any HEC CJ Pharm H Shares so acquired by the designated third party will be exchanged into the H Shares according to the Share Exchange Ratio, which will be held by the designated third party after the Share Exchange. Upon completion of the acquisition of such HEC CJ Pharm H Shares by the designated third party from the Dissenting Shareholder, the Dissenting Shareholder shall not be entitled to make any further request to our Company, HEC CJ Pharm and/or any other HEC CJ Pharm Shareholders who voted in favour of the shareholders’ resolutions of HEC CJ Pharm in respect of the Merger Agreement, the Merger and the relevant arrangements, nor shall such Dissenting Shareholder have the right to exchange its HEC CJ Pharm H Shares into H Shares.

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## HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

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As of the Latest Practicable Date, North & South Brother Pharma is expected to be designated by HEC CJ Pharm to acquire the HEC CJ Pharm H Shares from any Dissenting Shareholder that elects to have its HEC CJ Pharm H Shares to be acquired at a “fair price”. To the best knowledge of our Directors after making due and careful enquiries, North & South Brother Pharma is an Independent Third Party, considering that (1) North & South Brother Pharma is not a connected person of our Company nor an associate of connected persons of our Company; (2) the acquisition of any HEC CJ Pharm H Shares from any Dissenting Shareholder by North & South Brother Pharma shall be financed by its own source of funds; (3) North & South Brother Pharma and its ultimate beneficial owners are not accustomed to take instructions from any core connected person of our Company; (4) North & South Brother Pharma and its ultimate beneficial owners have not entered into any acting-in-concert arrangements with our Company or any of its core connected persons; (5) North & South Brother Pharma cannot exercise significant influence on the decisions of our Company or any of our core connected persons; and (6) North & South Brother Pharma shall be the legal and beneficial owner of any HEC CJ Pharm H Shares so acquired from Dissenting Shareholders and H Shares so acquired pursuant to the Share Exchange.

**Termination** . . . . . Subject to the requirements of the Takeovers Code and the regulatory requirements of the SFC and the Stock Exchange, the Merger Agreement may be terminated before the implementation of the Merger in any of the following circumstances:

- (1) by either our Company or HEC CJ Pharm, if

- (i) any competent governmental authority issues any order, decree, ruling or take any other actions which permanently restricts, impedes or otherwise prohibits the Merger and which is final, binding and not capable of being appealed (both our Company and HEC CJ Pharm shall use reasonable endeavors to procure the withdrawal of such order, decree, ruling or action); or
  - (ii) the Conditions to effectiveness not having been fulfilled on or before the Long-stop Date;
- (2) by our Company, if HEC CJ Pharm commits a material breach of the representations, warranties and undertakings under the Merger Agreement or any other agreement related to the Merger which has a material adverse impact on the Merger and such breach is not remedied by HEC CJ Pharm within 30 days following written notice from our Company; or
- (3) by HEC CJ Pharm, if our Company commits a material breach of the representations, warranties and undertakings under the Merger Agreement or any other agreement related to the Merger which has a material adverse impact on the Merger and such breach is not remedied by our Company within 30 days following written notice from HEC CJ Pharm.

In addition, as set out in the paragraph headed “*Pre-Conditions to the Merger Agreement becoming effective*”, the Merger Agreement will be automatically terminated if any of the Pre-Conditions is not fulfilled by the Long-stop Date.

As of the date of this Listing Document, our Company has obtained the filing notice from the NDRC in respect of the Merger on March 11, 2025, and has been informed that the approval from the Ministry of Commerce of the PRC and SAFE is not applicable to the Merger. Our Company has completed the filing with the CSRC for the Listing on June 16, 2025, and received a letter from the Stock Exchange approving in principle the listing of the H Shares on the Stock Exchange on June 27, 2025. Our Company has also obtained the approval by the shareholders meeting of our Company of the Merger in accordance with the PRC Laws and the Articles on December 11, 2024. Accordingly, all the Pre-Conditions have been fulfilled. Save for the disclosed, all of the above Conditions remain to be outstanding.

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## HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

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The Share Exchange Ratio was determined on commercial basis on arm's length terms after taking into account, among other things:

- (a) the theoretical value of the H Shares under the Merger for each Share Exchange HEC CJ Pharm H Share, which is attractive for the Share Exchange Shareholders and represents a higher premium rate compared to the value of the shares being offered as consideration in previous transactions involving privatization and listing by way of introduction in Hong Kong;
- (b) the historical performance of our Company and HEC CJ Pharm;
- (c) the current and historical market price levels of HEC CJ Pharm and the historical and current trading multiples of certain of the respective comparable companies of HEC CJ Pharm;
- (d) the business potential of our Group after the Merger takes effect and the potential benefits of the Introduction and the Merger for the Share Exchange Shareholders; and
- (e) the fact that the H Shares are being offered as consideration under the Merger and that following completion of the Introduction and the Merger, HEC CJ Pharm will be merged into our Company and thus, the Share Exchange Shareholders will be able to continue to participate in the performance of HEC CJ Pharm directly.

For more details on the valuation of our H Shares, please refer to the valuation report appended to the Composite Document (Appendix II to the Composite Document).

The Privatization and the Listing will not proceed if the Merger is not approved or lapses or does not become unconditional for any reason, and the Merger is conditional upon obtaining the necessary approvals and/or having made the necessary filings for the listing (by way of introduction) of, and permission to deal in, our H Shares on the Stock Exchange pursuant to the Listing. On June 16, 2025, the CSRC issued a notification on our Company's completion of the CSRC filing procedures for the Listing. As advised by our PRC Legal Advisor, our Company has completed the filing procedures with the CSRC as required under the Trial Measures in relation to the Listing. As of the Latest Practicable Date, we have applied to the Listing Committee for the listing of, and permission to deal in, the H Shares to be issued pursuant to the Privatization and the Listing.

**Warning: The implementation of the Privatization Proposal (including the effectiveness of the Merger Agreement) is subject to the Conditions set out above being fulfilled or waived, as applicable, and therefore the Privatization Proposal may or may not be implemented and the Merger Agreement may or may not become effective. Shareholders and potential investors of our Company and HEC CJ Pharm should therefore exercise caution when dealing in the securities of our Company and HEC CJ Pharm. Persons who are in doubt as to the action they should take should consult their stockbroker, bank manager, solicitor or other professional advisers.**

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## HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

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### *Expected events in relation to the Privatization Proposal subsequent to the date of this Listing Document*

Subsequent to the issuance of the Listing Document, the key milestone events and dates in relation to the Privatization Proposal are set out below:

HEC CJ Pharm EGM will be held for the HEC CJ Pharm Shareholders to consider and if thought fit, approve the Merger Agreement, the Merger and the relevant arrangements . . . . . 9:00 a.m. on Monday, July 21, 2025

HEC CJ Pharm H Shareholders' Class Meeting will be held for the HEC CJ Pharm H Shareholders to consider and if thought fit, approve the Merger Agreement, the Merger and the relevant arrangements . . . . . 9:30 a.m. on Monday, July 21, 2025 or immediately after the conclusion of the HEC CJ Pharm EGM or any adjournment thereof on Monday, July 21, 2025

Expected date for all Conditions to effectiveness to be satisfied and for the Merger Agreement to become effective . . . . . Monday, July 21, 2025

Latest date and time for dealings in HEC CJ Pharm H Shares . . . . . 4:10 p.m. on Tuesday, July 29, 2025

Share Exchange Record Date . . . . . Monday, August 4, 2025

Expected date and time of withdrawal of listing of HEC CJ Pharm H Shares . . . . . 4:00 p.m. on Tuesday, August 5, 2025

Latest date for the Share Exchange . . . . . Thursday, August 7, 2025

Dealings in the H Shares on the Stock Exchange expected to commence at . . . . . 9:00 a.m. on Thursday, August 7, 2025

Expected date for all Conditions to implementation to be satisfied (or waived, as applicable) . . . . . Thursday, August 7, 2025



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## HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

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For details of the expected timetable, please refer to the section headed “Expected Timetable” in this Listing Document. The timetable as set out above and in the section headed “Expected Timetable” are subject to changes, and further announcement(s) will be made in the event there is any change.

### THE PREVIOUS INITIAL PUBLIC OFFERING APPLICATION

In July 2023, to explore the opportunity of establishing a capital market platform in the A-share market in the PRC, we entered into a tutoring agreement for the initial public offering (the “**Tutoring Agreement**”) with China International Capital Corporation Limited (“**CICC**”), to receive guidance from CICC, a qualified sponsor of A-share listing. On July 25, 2023, CICC, on behalf of our Company, submitted the preliminary tutoring filing (上市前輔導備案) to the CSRC Guangdong office.

Considering our strategic decision to privatise HEC CJ Pharm through a merger by absorption and pursue a listing of our H Shares on the Stock Exchange by way of introduction, our Company has decided to proceed with the Listing on an international platform. This approach will enable us to gain future access to foreign capital and attract a broader investor base. As of the Latest Practicable Date, our Company did not submit A-share listing application to the CSRC or the relevant stock exchanges in the PRC, and did not receive any comments or inquiries from the CSRC or the relevant stock exchanges in the PRC.

The Directors confirm that (a) there was no disagreement between our Company and the professional parties involved in the previous A-share listing attempt; and (b) there are no material matters or unresolved issues relating to our Company’s previous A-share listing attempt that need to be brought to the attention of the Stock Exchange. Based on the independent due diligence conducted by the Sole Sponsor, the Sole Sponsor is not aware that (a) there was any disagreement between the Company and the professional parties involved in the previous A-share listing attempt; or (b) there are any material matters or unresolved issues relating to the Company’s previous A-share listing attempt that need to be brought to the attention of the Stock Exchange.

### EMPLOYEE INCENTIVE SCHEME

In order to incentivise our Directors, Supervisors, senior management and core employees for their contributions to our Group and to attract and retain suitable personnel to our Group, we established Yidu Fangwenwen and Yidu Yingwenfang as employee incentive platforms in China, and in June 2023, we adopted the Employee Incentive Scheme. See “Appendix VI — Statutory and General Information — D. Employee Incentive Scheme” in this Listing Document for further details.

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## HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

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### COMPLIANCE WITH LAWS AND REGULATIONS

As of the Latest Practicable Date, the establishment, equity transfer and change in registered capital of our Company had been properly and legally completed in compliance with applicable laws and regulations.

As advised by our PRC Legal Advisor, as of the Latest Practicable Date, our Company had obtained relevant approvals or confirmations for its establishment and subsequent equity transfers and registered capital changes in all material respects, and had registered or filed with the relevant competent authorities in accordance with the relevant PRC laws and regulations. As of the Latest Practicable Date, the establishment of our Company and subsequent equity transfers and changes in registered capital were valid and legally binding.

### PUBLIC FLOAT

Rule 8.08(1)(a) of the Listing Rules requires there to be an open market in the securities for which listing is sought. This normally means that at least 25% of the issuer's total issued share capital must at all times be held by the public. None of the Domestic Shares (including Domestic Shares held by the Pre-Listing Investors) will be treated as part of the public float of our Company. All H Shares to be issued to the Share Exchange Shareholders (excluding the H Shares that will be issued to Guangdong HEC Technology, Mr. Tang Xinfu, the Relevant HEC CJ Pharm Directors and the Relevant HEC CJ Pharm Supervisors) will be counted towards the public float. It is expected that upon Listing, the total number of listed H Shares of our Company held by the public represents 18.53% of the total number of issued Shares of our Company. We have applied to the Stock Exchange to request the Stock Exchange to exercise its discretion under Rule 8.01(1)(d) of the Listing Rules, and the Stock Exchange has granted our Company a waiver from strict compliance with the requirements of Rule 8.08(1)(a) of the Listing Rules, pursuant to which the minimum percentage of our H Shares from time to time held by the public shall be the higher of (1) 18.53% and (2) such percentage of H Shares to be held by the public immediately upon completion of the Introduction and the Privatization. For details of the relevant waiver, please refer to "Waivers from Strict Compliance with the Listing Rules — Public Float" in this Listing Document.

[illegible]

Notes:

- \* Individuals/entities marked with an asterisk “\*” are our Controlling Shareholders. In addition, our Controlling Shareholders also include Dongguan HEC Industrial and Zhejiang HEC Health.
- (1) Ruyuan Shuaicai Investment is a limited partnership established under the laws of the PRC and its general partner is Mr. Zhang. The limited partners of Ruyuan Shuaicai Investment are Hu Zhidong, Wei Cailiang and Zhou Lin, who are Independent Third Parties.
- (2) Zhang Hongwei is an Independent Third Party.
- (3) Ruyuan Yao Autonomous County Xinwei Investment Service Partnership (G.P.)\* (乳源瑶族自治县新伟投资服务合伙企业(普通合伙)) (“**Ruyuan Xinwei Investment**”) is a general partnership established under the laws of the PRC. Ruyuan Xinwei Investment’s partners are Lu Yuxin, Zhang Hongwei, Zhu Yingwei, Deng Xinhua and Tang Xinfu (executive partner). Save for Zhu Yingwei and Tang Xinfu who are our non-executive Directors, the other partners are Independent Third Parties.
- (4) Ruyuan Yao Autonomous County Yangzhiguang Industrial Development Co., Ltd.\* (乳源瑶族自治县阳光实业发展有限公司) (“**Ruyuan Yangzhiguang**”) is owned as to 80.52% by Ruyuan Yao Autonomous County Jingwei Industrial Development Co., Ltd.\* (乳源瑶族自治县景伟实业发展有限公司) (“**Ruyuan Jingwei Industrial**”), which is in turn owned as to 99.82% and 0.18% by Li Shangjun and Zhang Tianbao, each an Independent Third Party.
- (5) Yichang HEC Medicine is owned as to 53.73% by Zhejiang HEC Health, 22.13% by North & South Brother Pharma (ultimately wholly-owned by Mo Kit, an Independent Third Party), 10.56% by Shenzhen HEC Industrial, 6.55% by Yichang HEC Research, 5.75% by Dongguan HEC Industrial and 1.28% by Hubei Hanshen Yangguang Biopharmaceutical Industrial Investment Fund (L.P.)\* (湖北瀚桑阳光生物医药产业投资基金(有限合伙)) (ultimately controlled by Tu Ran (涂然), an Independent Third Party).
- (6) Linzhi Bayi District Gaoyuanzhiguang Investment Co., Ltd.\* (林芝市巴宜区高原之光投资有限公司) (“**Linzhi Bayi Gaoyuanzhiguang**”) is a limited company established under the laws of the PRC, which is wholly-owned by He Xin, an Independent Third Party.
- (7) and (12) Yidu Shuaixinwei and Yidu Junjiafang are the share incentive plan platforms of our Company at the shareholder level, and Mr. Zhang is the sole general partner of these platforms. Mr. Zhang holds 29.77% interest in Yidu Shuaixinwei and 88.04% interest in Yidu Junjiafang, respectively. Yidu Shuaixinwei has a total of eight limited partners, with their names and approximate percentage of interest in Yidu Shuaixinwei listed as follows: Zhang Hongwei (15.07%), Zhu Yingwei (15.07%), Deng Xinhua (15.07%), Lu Yuxin (15.07%), Hu Zhidong (3.62%), Wei Cailiang (3.01%), Zhou Lin (3.01%) and Ms. Guo (0.30%). Save for Zhu Yingwei who is our non-executive Director and Ms. Guo who is our Controlling Shareholder, the other limited partners of Yidu Shuaixinwei are Independent Third Parties. Yidu Junjiafang has a total of ten limited partners, with their names and approximate percentage of interest in Yidu Junjiafang listed as follows: Wang Mingxing (1.55%), Zhang Wei (1.40%), Zheng Hongshu (1.29%), Wang Changyong (1.24%), Wang Jing (1.24%), Zhai Jianfeng (1.16%), Pan Yangjun (1.16%), Chen Junhao (1.09%), Pan Sanxiong (0.93%) and Ms. Guo (0.89%). Save for Ms. Guo who is our Controlling Shareholder, the other limited partners of Yidu Junjiafang are Independent Third Parties.

- (8) The shares of Guangdong HEC Technology are listed on the Shanghai Stock Exchange (stock code: 600673), and as of the Latest Practicable Date, Shenzhen HEC Industrial and its parties acting in concert, namely, Yichang HEC Medicine, Ruyuan Yangzhiguang Aluminum, Ruyuan HEC Enterprise Management, Shenzhen NewFoxon and Suzhou Fenghe directly and indirectly control approximately 52.69% interests in Guangdong HEC Technology. Ruyuan Yangzhiguang Aluminum is owned as to 40.11% by Ruyuan Yangzhiguang (ultimately controlled by Li Shangjun, an Independent Third Party and a merchant), 27.57% by Zhejiang Zheshang Industrial Finance Holdings Co., Ltd.\* (浙江浙商產融控股有限公司) (ultimately controlled by Fu Yunsong (傅雲松) and Fang Lingya (方凌雅), each an Independent Third Party), 17.10% by North & South Brother (HK), and 15.22% by Ruyuan HEC Industrial. Ruyuan HEC Enterprise Management is owned as to 77.03% by Ruyuan Xinwei Investment (ultimately controlled by Tang Xinfa, our non-executive Director), 10.23% by Ruyuan Yao Autonomous County Zhilin Investment Service Partnership (G.P.)\* (乳源瑤族自治縣志林投資服務合夥企業(普通合夥)) (ultimately controlled by Hu Zhidong (胡志東), an Independent Third Party), 7.90% by Ruyuan Yao Autonomous County Mingrong Investment Service Partnership (L.P.)\* (乳源瑤族自治縣明榮投資服務合夥企業(有限合夥)) (ultimately controlled by Zhang Zhiming (張志明), an Independent Third Party), and 4.83% by Ruyuan Yao Autonomous County Weiming Investment Service Partnership (L.P.)\* (乳源瑤族自治縣維明投資服務合夥企業(有限合夥)) (ultimately controlled by Wang Mingxing (王明星), an Independent Third Party). Shenzhen NewFoxon is a fund managed by Shenzhen NewFoxon Investment Co., Ltd.\*, which is owned as to 55% by Guangzhou Fusheng Investment Co., Ltd.\* (廣州復昇投資有限公司) (ultimately controlled by Ding Xungang (丁訓剛), an Independent Third Party and a merchant), 40% by Ding Xungang and 5% by Zhan Chu (詹礎) (an Independent Third Party). Suzhou Fenghe's general partner is Suzhou Industrial Park Tiantinghui Enterprise Management Co., Ltd.\* (蘇州工業園區天庭輝企業管理有限公司), holding 0.5% interest in Suzhou Fenghe, and is wholly-owned by Liu Sheng (劉聖) (an Independent Third Party and a merchant). Suzhou Fenghe has five limited partners, namely, Liu Sheng, Sun Yuzhou (孫雨舟), Ding Hai (丁海), Feng Xiaowei (馮小偉) and Fang Jie (方杰), holding 49.5%, 15%, 15%, 10% and 10% interest in Suzhou Fenghe, respectively, and each an Independent Third Party. According to the acting in concert arrangements made among Shenzhen HEC Industrial, Yichang HEC Medicine, Ruyuan HEC Enterprise Management, Ruyuan Yangzhiguang Aluminum, Shenzhen Newfoxon and Suzhou Fenghe, the parties acting in concert with Shenzhen HEC Industrial agreed to fully defer their voting rights towards Guangdong HEC Technology to Shenzhen HEC Industrial. Since Shenzhen HEC Industrial is held as to 42.34%, 27.01% and 30.66% by Ruyuan Yuneng Electric, Shaoguan Xinyuneng Industrial and Ruyuan Xinjing Technology, respectively, Shaoguan Xinyuneng Industrial is owned as to 58% and 42% by Ruyuan Yuneng Electric and Ruyuan Xinjing Technology, respectively, and Ruyuan Yuneng Electric and Ruyuan Xinjing Technology are ultimately controlled by Ms. Guo and Mr. Zhang. Guangdong HEC Technology is ultimately jointly controlled by Ms. Guo and Mr. Zhang.
- (9) Dongyang City Caitong Renyao Equity Investment Partnership (L.P.)\* (東陽市財通仁藥股權投資合夥企業(有限合夥)) ("Caitong Renyao")'s general partner is Zhejiang Caitong Capital Investment Co., Ltd.\* (浙江財通資本投資有限公司), which is a wholly-owned subsidiary of Caitong Securities Co., Ltd.\* (財通證券股份有限公司), whose shares are listed on the Shanghai Stock Exchange (stock code: 601108) and are ultimately controlled by the Zhejiang Provincial Department of Finance. The limited partner of Caitong Renyao is Dongyang City State-owned Assets Investment Co., Ltd. (東陽市國有資產投資有限公司), which is owned as to 90% by Dongyang City State-owned Assets Supervision and Administration Office (東陽市國有資產監督管理辦公室) and 10% by Zhejiang Financial Development Co., Ltd. (浙江省財務開發有限責任公司) (which is wholly owned by Zhejiang Provincial Department of Finance).
- (10) and (11) Yidu Yingwenfang and Yidu Fangwenwen are our Group's employee incentive platforms. For details of the Employee Incentive Scheme, please refer to "Appendix VI - Statutory and General Information - D. Employee Incentive Scheme."
- (13) For further details of the Pre-listing Investors, please refer to the "Pre-listing Investment" of this section.
- (14) As of the Latest Practicable Date, our Company has 79 subsidiaries in total, among which 50 subsidiaries are owned indirectly by our Company through HEC CJ Pharm.
- (15) Guenther is an Independent Third Party, save for his shareholding in Germany HEC. Guenther has passed away and the probate process in relation to his estate (including the equity interest in Germany HEC) is still ongoing as of the Latest Practicable Date to determine the heirs of Guenther.
- (16) US HEC is an indirect wholly-owned subsidiary of our Company.

- (17) On October 25, 2023, Shenzhen HEC Industrial pledged 42,988,226 Shares (representing approximately 9.27% of our issued Shares as of the Latest Practicable Date) to Industrial Bank Co., Ltd. Shenzhen Branch as collateral to guarantee a loan in the principal amount of RMB870 million for a period of five years ending on June 25, 2028.
- (18) On March 8, 2024, our Company and Hong Kong HEC entered into an equity transfer agreement, pursuant to which the transfer of rights and obligations attached to the 25.71% equity interest in HEC CJ Pharm from Hong Kong HEC to our Company has completed on March 8, 2024. As of the Latest Practicable Date, Hong Kong HEC remains the legal owner of the 25.71% equity interest in HEC CJ Pharm, as the register of members of HEC CJ Pharm has yet to be updated.





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*Notes:*

- (1) to (17) Please refer to “the shareholding structure of our Company immediately prior to the completion of the Introduction and the Privatization” for further details.
- (18) According to the PRC Company Law and the Articles of Association, any Dissenting Shareholder may by written notice request HEC CJ Pharm to acquire the HEC CJ Pharm H Shares held thereby at a “fair price”, and HEC CJ Pharm or a party designated by HEC CJ Pharm may acquire the HEC CJ Pharm H Shares held by that Dissenting Shareholder. As at the Latest Practicable Date, North & South Brother Pharma, an Independent Third Party, is expected to be designated by HEC CJ Pharm to acquire the HEC CJ Pharm H Shares from any Dissenting Shareholder that elects to have their HEC CJ Pharm H Shares to be acquired at a “fair price”. The percentage of Shares held by H Share public shareholders immediately following the completion of the Introduction and the Privatization shall include H Shares held by North & South Brother Pharma obtained through the Share Exchange, if any.
- (19) HEC CJ Pharm will be deregistered after all its assets, liabilities, interests, businesses, employees, contracts and all other rights and obligations have been assumed by our Company in accordance with relevant laws and regulations.
- (20) Other Core Connected Persons consist of (i) Mr. Tang Xinfu, our non-executive Director, who will hold approximately 34,375 H Shares exchanged from 130,400 HEC CJ Pharm H Shares he held as of the Latest Practicable Date; (ii) Mr. Li Shuang, Mr. Wang Danjin, Mr. Jiang Juncui and Mr. Li Xuechen, each of whom is a director of HEC CJ Pharm, who will hold approximately 17,609, 17,714, 17,609 and 1,054 H Shares exchanged from 66,800, 67,200, 66,800 and 4,000 HEC CJ Pharm H Shares they held respectively as of the Latest Practicable Date; and (iii) Mr. Wang Shengchao and Mr. Luo Zhonghua, each of whom is a supervisor of HEC CJ Pharm, who will hold approximately 8,435 and 17,609 H Shares exchanged from 32,000 and 66,800 HEC CJ Pharm H Shares they held respectively as of the Latest Practicable Date.

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## **BENEFITS OF THE INTRODUCTION AND THE PRIVATIZATION**

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The Directors believe that the completion of the Merger and the Listing benefits both Share Exchange Shareholders and the Company and marks a significant milestone in the development of the Company. The Merger and the Listing represent an opportunity for Share Exchange Shareholders to become shareholders of the Enlarged SLP Group, and will benefit the Company and Share Exchange Shareholders in the following aspects:

### **BENEFITS OF THE MERGER AND THE LISTING TO THE COMPANY**

We plan to further integrate with HEC CJ Pharm to become a comprehensive pharmaceutical company driven by independent R&D with integrated capacities in R&D, production and commercialization, further capitalizing on the economies of scale and synergies to unleash greater growth potential.

**Through the Merger, the Enlarged SLP Group will become an integrated pharmaceutical company engaging in R&D, production and commercialization of pharmaceutical products, and consolidate its position as a comprehensive pharmaceutical company**

Before the completion of the Merger, as a result of the non-compete agreement between HEC CJ Pharm and SLP, there is a clear division of business between HEC CJ Pharm and SLP. SLP is responsible for the pharmaceutical R&D and overseas sales, while HEC CJ Pharm is responsible for the domestic commercialization of pharmaceutical products. HEC CJ Pharm currently does not have a strong in-house R&D system, and its revenue and profits are mainly generated from the sales of its major product, Kewei (oseltamivir phosphate). Its product structure is relatively simple and its channels for acquiring new products are limited. Through the full integration of SLP's and HEC CJ Pharm's businesses, the Enlarged SLP Group will promote the vertically integrated operation and management of pharmaceutical R&D, production and commercialization. By combining SLP's R&D capability and robust drug pipeline and HEC CJ Pharm's strong nationwide sales network, the Enlarged SLP Group will benefit from the synergy of the Merger. HEC CJ Pharm will reduce its dependence on its major products with the Enlarged SLP Group's diverse and robust drug pipeline, achieve long-term sustainable growth, expand its market value, and consolidate its position as a comprehensive pharmaceutical company.

### **Integrating domestic and overseas sales channels to build an extensive sales network**

Before the completion of the Merger, as a result of the non-compete agreement and to avoid competition between HEC CJ Pharm and SLP, HEC CJ Pharm was solely responsible for the commercialization of pharmaceutical products in China, while SLP was solely responsible for the pharmaceutical R&D and overseas sales. After years of development, HEC CJ Pharm has formed a large domestic sales network in the PRC, while SLP has built an extensive sales network which covers eight jurisdictions and regions including but not limited to the United States, Germany, and the United Kingdom. SLP has established an independent brand with good reputation and formed certain sales capabilities. By combining the sales channels of HEC CJ Pharm and SLP, the Enlarged SLP Group will form a fully-integrated extensive sales network. As a result, the Enlarged SLP Group can carry out its business operations with more

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## **BENEFITS OF THE INTRODUCTION AND THE PRIVATIZATION**

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flexibility and respond to the unmet medical demands for different pharmaceutical products without being subject to the constraints of the non-compete agreement, and provide its diverse and robust pipeline of pharmaceutical products to both domestic and overseas markets in the future, which our Directors believe is essential for the creation of a global pharmaceutical company and the enhancement of our market position and influence.

### **Improving overall corporate efficiency for long-term sustainable and resilient growth**

Under the current management arrangement, the review chain of major business decision-making processes is long and requires the approval from both HEC CJ Pharm and SLP. It also takes a long time to complete the approval process for connected transactions for HEC CJ Pharm. As a result, strategic opportunities for product development may be missed. After completion of the Merger, the businesses of HEC CJ Pharm and SLP will be integrated to optimize the management structure, shorten the business decision-making process, improve the management operation efficiency and integrate the R&D systems, production facilities and sales networks, thus achieving long-term sustainable and resilient growth.

### **BENEFITS OF THE MERGER AND THE LISTING TO THE SHARE EXCHANGE SHAREHOLDERS**

Our Directors believe that the Enlarged SLP Group will be an attractive investment opportunity for the Share Exchange Shareholders. Upon completion of the Merger, the Share Exchange Shareholders may continue to invest in HEC CJ Pharm (as part of the Enlarged SLP Group) which will be equipped with excellent commercialization capabilities; they may also benefit from the potential synergy that may be achieved as a result of the Merger. Apart from the greater capital market potential of the investment target, the Share Exchange Shareholders will also directly receive immediate cash benefits by way of Special Dividend of HK\$1.50 per Share to be distributed by HEC CJ Pharm, thus enabling the Share Exchange Shareholders to realize a certain level of capital return from their investment. As we do not need to raise capital in connection with the Listing, the proposed transaction will be less exposed to capital market volatility. In summary, our Directors believe that the overall transaction structure is in the interests of the Share Exchange Shareholders and that the long-term benefits to the Share Exchange Shareholders include the following:

### **Our integrated in-house R&D system and our R&D platform that covers the complete drug development cycle enabling us to achieve long-term value creation**

In order to drive the long-term sustainable development of HEC CJ Pharm, in addition to maintaining the revenue growth from the existing pharmaceutical products, HEC CJ Pharm also needs to build a robust product pipeline and continue to introduce new products to ensure long-term growth. SLP has strong pharmaceutical R&D capabilities in the PRC, and has established an integrated in-house R&D system and an R&D platform that covers the complete development cycle of chemical drugs and biologics. It has in-house and systematic R&D capabilities, enabling rapid commercialization of our drugs under development.

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## **BENEFITS OF THE INTRODUCTION AND THE PRIVATIZATION**

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Leveraging its R&D platforms, SLP has established a diverse and robust product pipeline in three major therapeutic areas with huge unmet clinical needs, and has formed differentiated development paths in each R&D field: (1) its pipeline of anti-infective drugs covers indications such as hepatitis B, hepatitis C, influenza, and acute respiratory infection; (2) in the field of chronic diseases, SLP has built a strong diabetes drug portfolio, and is continuing to expand product lines to cover respiratory diseases such as pulmonary fibrosis, pulmonary hypertension, chronic obstructive pulmonary disease, and asthma, and is gradually expanding to metabolic disorders such as gout and obesity and neuropsychiatric disorders; (3) its oncology pipeline focuses on the treatment of solid tumor and blood cancers (hematological malignancy) utilizing technologies such as precise targeting.

Through this integration, the Share Exchange Shareholders will become the shareholders of the Enlarged SLP Group, and benefit from the R&D results produced by its R&D platforms focusing on the three key therapeutic areas. The Enlarged SLP Group will achieve a virtuous cycle in respect of its business model of integrated R&D, production and commercialization focusing on innovative new drugs, while continue to be involved in modified new drugs, generic drugs and biosimilars. The Enlarged SLP Group's major products will continuously generate strong cash flow to support R&D investment, and its strong R&D capabilities will further strengthen its product portfolio and expand its market shares, which will be conducive to sustainable business growth and long-term value creation.

### **Eliminating connected transactions, improving operational efficiency and expanding economies of scale**

Under the current shareholding structure, SLP and HEC CJ Pharm are required to comply with their non-compete agreement and the connected transaction requirements under the Listing Rules. After the completion of the Merger, the Enlarged SLP Group will be able to complete the integration of R&D, manufacturing and commercialization, resulting in a more streamlined and efficient decision-making process, which enables it to respond to market demands more rapidly and with more reasonable commercial arrangements. In addition, after the Merger, the Enlarged SLP Group will be able to utilize the combined supply chain system and manufacturing bases, which will significantly reduce the number of continuing connected transactions between the SLP and HEC CJ Pharm, as well as the restrictions from non-compete agreement. This is expected to further reduce procurement and manufacturing costs, thereby enhancing management efficiency, lowering overall operating expenses, maximizing cooperation synergies, and achieving economies of scale.

### **Enhancing overall performance in the capital market**

Firstly, prior to the implementation of the Merger, HEC CJ Pharm does not have an independent R&D system, and its capital market valuation was at a low level. After completion of the Merger, the Enlarged SLP Group will become a comprehensive pharmaceutical enterprise integrating R&D, production and commercialization, as well as a listed entity with a complete business chain, which will enhance investors' market confidence in the Enlarged SLP Group.

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## **BENEFITS OF THE INTRODUCTION AND THE PRIVATIZATION**

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Secondly, HEC CJ Pharm will significantly reduce the number of continuing connected transactions that it involves, and the restrictions from non-compete agreement, which will be beneficial in reducing its administrative and compliance costs, thus boosting overall business performance.

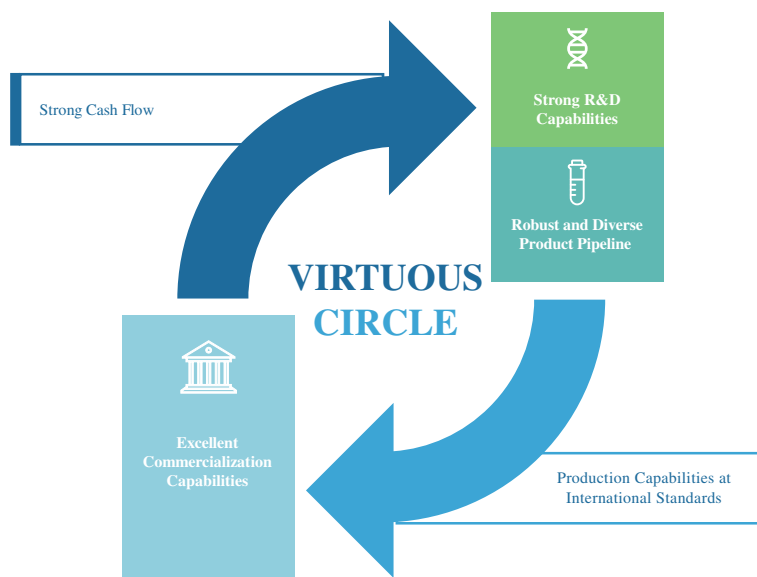
Thirdly, prior to the implementation of the Merger, HEC CJ Pharm's sources of business revenue and profits were relatively concentrated. After completion of the Merger, the Enlarged SLP Group will have stronger R&D capabilities and a more diverse drug pipeline to respond to changing market competition, which will increase its long-term investment value. The above changes will also make the Enlarged SLP Group more attractive to investors.

In summary, after the Merger becomes unconditional and upon completion of the Listing, the Enlarged SLP Group will become a comprehensive pharmaceutical enterprise integrating R&D, production and sales, with reduced management and compliance costs, and a steady and continuous growth in its revenue and profits, all of which will enhance the Enlarged SLP Group's overall performance in the capital market.

**OVERVIEW**

We are a vertically integrated pharmaceutical company engaging in research and development, production and commercialization of pharmaceutical products with a focus on innovative drugs and are also involved in modified new drugs, generic drugs and biosimilars. With over two-decade of experience since our inception in 2003, we have built independent research and development platforms, production facilities that meet the international standards and a comprehensive sales network. We strategically focus on therapeutic areas of infectious diseases, chronic diseases and oncology. We are a market leader in the oseltamivir phosphate market in China in terms sales value in 2024. In 2024, our oseltamivir phosphate products, including our top-selling product, Kewei, accounted for 54.8% of the entire oseltamivir phosphate market in China. During the Track Record Period, sales of oseltamivir phosphate accounted for 81.2%, 86.9% and 64.2% of our revenue for the years ended December 31, 2022, 2023 and 2024, respectively. Most of the oseltamivir phosphate revenue was generated from Kewei (oseltamivir phosphate), our top-selling product. We also generated revenue from sales of chronic disease treatment drugs in the amount of RMB517.3 million, RMB580.7 million and RMB1,067.7 million for the years ended December 31, 2022, 2023 and 2024, respectively, accounting for 13.6%, 9.1%, 26.6% of our total revenue for the same period, respectively. Driven by our in-house research and development, we have developed a diverse and robust product portfolio. As of the Latest Practicable Date, we had 150 approved drugs in various countries and regions, including China, the United States and Europe. As of the Latest Practicable Date, we also had more than 100 drugs in the pipeline, including 49 Class I innovative drug candidates in China, among which one innovative drug candidate was under the NMPA's review for launching and ten innovative drug candidates were in Phases II or III clinical trials. As of the Latest Practicable Date, we have successfully developed and launched three Class I innovative drugs and applied for launching one Class I innovative drug through our in-house research and development in China. The value and potential of our drug portfolio have been recognized by our international industry peers, particularly highlighted by the overseas exclusive license agreement we entered into with one of our international partners in respect of our product candidate HEC88473. As a result of our extensive pipeline of anti-infective drugs, we were approved by the Ministry of Science and Technology of the PRC to establish a State Key Laboratory of Anti-Infective Drug Development.

We have managed to create a virtuous circle in respect of our business model through our integrated capabilities in research and development, production and commercialization. Our strong research and development and production capabilities have facilitated the successful commercialization of our products. The strong operating cash flow generated by the sales of our products then allows us to continue to invest in our research and development, production and marketing. Through this virtuous circle, we are able to continuously advance our innovative research and development capabilities, which is essential for us to further strengthen our product portfolio and expand our market shares, eventually leading to our sustainable business growth and maintaining long-term competitive advantage.







We have developed comprehensive and integrated in-house research and development capabilities. We have more than 1,100 research and development personnels which consist of scientists with extensive work experience gained in multinational pharmaceutical companies and pharmaceutical talents with rich experience in research and development. Core members of the team, including Dr. Zhang Yingjun (張英俊博士), Dr. Gu Baohua (谷保華博士), Dr. Ye Qunrui (葉群瑞博士) and Dr. Cai Xiaoli (蔡曉莉醫學博士), have industry insights and drug research and development experience. Our research and development platforms cover the full cycle of the development of chemical drugs and biologics. We also possess advanced technologies such as AIDD, small nucleic acid, ADC, PROTAC and specific antibody. We are also committed to applying AI technology across all stages of drug research and development, having established advanced AI-driven models to enhance our innovation capabilities. We have continued to invest in research and development during the Track Record Period. Our strong in-house research and development capabilities have translated into a diverse and robust drug pipeline, and enable us to efficiently advance our drugs under development to commercialization. We have completed Phase I clinical trials for four new drugs in the United States and Australia as of the Latest Practicable Date. We submitted the BLA for our biosimilar, Insulin Glargine, to the U.S. FDA in December 2023, and have been actively addressing the U.S. FDA's requests for additional information to facilitate the approval process. We are expected to become the first PRC pharmaceutical company to sell Insulin Glargine in the United States, which has received the U.S. FDA approval for an exemption from Phase III clinical trial.


We have a diverse and robust product portfolio in our strategically focused therapeutic areas, including infectious diseases, chronic diseases, and oncology. The following table sets forth our drug portfolio comprising some of our major drugs and drug candidates:



## Drug Portfolio

Therapeutic Area	Product Name	Classification <sup>(a)</sup>	Target	Indications	Drug Highlights	Clinical Trial or Sale Region	Pre-clinical	Phase I	Phase II	Phase III	NDA/BLA	Launch
Infectious Diseases 	Dongwei'en (Emitasvir Phosphate)	1	NS5A	Hepatitis C	The rate of SVR12 reaches 99.5%	China						
	Dong'antai (Nefasvir Phosphate)*	1	NS5A	Hepatitis C	Domestic in-house R&D combination treatment regimen for pan-genotypic treatment	China						
	Dong'anjiang (Enocofosvir)*	1	NS5B	Hepatitis C		China						
	Dong'andi (Morphothiadine Mesylate)	1	HBV capsid	Hepatitis B	Leading clinical trial progress in China	China						
	Dong'anrui (Freethiadine)	1	HBV capsid	Hepatitis B	Improved antiviral activity	China						
	HECN30227	1	HBV RNA	Hepatitis B	Improved in vitro and in vivo activity	China						
	HEC191834	1	TLR8	Hepatitis B	High selectivity, high distribution to the liver	China						
	Five Insulins <sup>(1)</sup>	3.3	IR	Diabetes	Advanced production process, quality similar to the RLD	China						
	Dongjiantang (Oloripilfosin) <sup>(2)</sup>	1	SGLT-2	Diabetes	Best urinary glucose excretion in 24 hours	China						
	Guangjianyou (Insulin glargine (U.S.)) <sup>(3)</sup>	3.3	IR	Diabetes	Potential to enter U.S. market	China & U.S.						
Chronic Diseases 	Guangjianbao (HEC38473) <sup>(4)</sup>	1	GLP-1/FGF21	Diabetes, Obesity, NASH	Advanced R&D progress	China & Australia						
	Dongjiandi (Vinfendone Hydrochloride) <sup>(5)</sup>	1	-	IPF	Better anti-fibrotic effects and safety profile	China & U.S.						
	Dongjiansheng (HEC53856) <sup>(6)</sup>	1	HIF-PHD	Renal anemia	Better safety profile	China						
	Dongtongshen (Mitizodone Phosphate)	1	5-HT <sub>1A</sub> , 5-HT <sub>1B</sub>	Depression	Multi-target synergistic mechanism	China						
	Dongjiangang (HEC95468)	1	sGC	PAH	Steady blood pressure-lowering effect	China						
	Dongjianshun (HEC93077)	1	XO/URAT1	Gout	Leading clinical trial progress of dual-target inhibitor in China	China						
	Dongjianyuan (HEC96719) <sup>(7)</sup>	1	FXR	NASH	Leading clinical trial progress among FXR drug candidates for NASH in China	China & Australia						
	HEC169584 <sup>(8)</sup>	1	THR-β	NASH	High hepatic targeting	China						
	Dongtongshun (HEC137076)	1	5-HT <sub>1f</sub>	Migraine	High blood-brain barrier penetration	China						
	Amlodipine Besylate Granules <sup>(9)</sup>	2.2	CCB	Hypertension, Coronary heart disease	Targeting patients with hypertension and stroke who have swallowing difficulties and pediatric patients with hypertension	China						
Oncology 	HECB1502201	2.2, 2.4	P-CABs	Peptic ulcer bleeding	Better control over gastric pH	China						
	HECB1701301	2.1, 2.2	NMDA	AD	Drug compliance improvement	China						
	HEC007	1	GLP-1/GCG/GIP	Obesity	Potent weight reduction, improved blood lipids and fatty liver condition	China						
	Dongningchun (Clitfinib Besylate) <sup>(10)</sup>	1	FLT3	AML	High selectivity, significant efficacy	China						
	Dongningguan (Larotinib Mesylate)	1	EGFR	ESCC	Excellent clinical efficacy	China						
	Dongningsheng (HEC53856)	1	HIF-PHD	CIA	Better safety profile	China						
	Dongningda (HEC169096)	1	RET	Tumors	Effective against resistance to selective RET inhibitor	China						
	HEC201625	1	PD-L1	Tumors	Oral small molecule tumor immuno-therapy	China						

 Overseas clinical trial

 Licensing/co-development

Notes:

- \* Following NMPA approval, we plan to sell Dong'anlai (Netasvir Phosphate) and Dong'anjiang (Encofosbuvir) in China under the brand names Dongweizhuo (東衛卓®) and Dongyinghe (東英賀®), respectively.
- (1) Our five insulin products include (i) Human Insulin Injection, (ii) Mixed Protamine Human Insulin Injection (30R), (iii) Insulin Glargine Injection, (iv) Insulin Aspart Injection, and (v) Insulin Aspart 30 Injection.
  - (2) Based on its Phase I clinical trial results and our predication of the effective dose for its Phase III clinical trial by using population pharmacokinetics and exposure-response (E-R) models, we applied to and received approval from the CDE for an exemption from the Phase II clinical trial to directly conduct the Phase III clinical trial.
  - (3) We have been collaborating with Lannett to develop Insulin Glargine Injection for the U.S. market. As a biosimilar, we are generally required to conduct Phase I and Phase III clinical trials. We applied to the U.S. FDA for an exemption from Phase III clinical trial, and we have received the U.S. FDA approval for this exemption. The approval allowed us to submit the BLA for our Insulin Glargine Injection to the U.S. FDA in December 2023 without conducting Phase III clinical trial.
  - (4) We also completed Phase I clinical trial in Australia and entered into an exclusive license and commercialization agreement with Apollo Therapeutics Group Limited in November 2024.
  - (5) We also completed Phase I clinical trial in the U.S.
  - (6) HEC53856 has two indications, namely renal anemia and CIA.
  - (7) We also completed Phase I clinical trial in Australia.
  - (8) HEC169584, a THR- $\beta$  agonist drug candidate for the treatment of NASH, is the first new small molecule drug candidate developed by our AIDD laboratory. We have submitted the IND application for HEC169584 in September 2024. We obtained its clinical trial approval in December 2024.
  - (9) We have completed its bioequivalence study and submitted its NDA in November 2024.
  - (10) Based on its Phase I clinical trial results, we applied to and received approval from the CDE for an exemption from the Phase II clinical trial to directly conduct the Phase III clinical trial. On November 25, 2024, we entered into an exclusive commercialization collaboration agreement with HEC CJ Pharm and Shenyang Sunshine Pharmaceutical Co., Ltd.
  - (11) In China, drugs are classified by the NMPA into Class 1 as innovative (chemical/biological) drugs that have never been marketed worldwide, Class 2 as modified new drugs comprising sub-classes 2.1 (drugs containing optical isomers, esters, salts or other derivatives of known active ingredients), 2.2 (drugs with new dosage forms, formulation processes or routes of administration), 2.3 (new compound preparations of known active ingredients) and 2.4 (drugs for new indications) and Class 3.3 as biosimilars. In other jurisdictions, these drugs may be classified differently based on their respective regulatory frameworks.

As of the Latest practicable Date, we have 150 approved drugs and more than 100 drug candidates in the pipeline. The table below sets forth a breakdown of our approved drugs and drug candidates by therapeutic area and geographic area as of the Latest Practicable Date.

	Innovative Drugs		Biosimilar Drugs		Modified New Drugs		Generic Drugs					Other overseas countries
	Approved drugs	Drug candidates	Approved drugs	Drug candidates	Drug candidates	Drug candidates	Approved drugs	Drug candidates	Approved drugs	Drug candidates		
	China <sup>(1)</sup>	China <sup>(2)</sup>	China	China	China	U.S.	E.U.					
Therapeutic area												
Anti-infective drugs . . .	3	9	0	0	0	26	5	10	0	9	1	2 <sup>(3)</sup>
Chronic disease treatment drugs . . .	0	23	5	7	9	40	19	24	3	20	0	1 <sup>(4)</sup>
Oncology and other diseases . . . . .	0	17	0	0	0	5	8	3	0	2	0	0
Total . . . . .	3	49	5	7	9	71	32	37	3	31	1	3

Note 1: We are conducting clinical trials for our Chinese innovative drugs concurrently in other countries. Such concurrent clinical trials include the following: (i) we completed Phase I clinical trial in Australia for Guangjianbao (HEC88473); (ii) we are conducting clinical trials in the U.S. for Dongjiandi (Yinfenidone Hydrochloride) and have completed Phase I clinical trial; and (iii) we are conducting clinical trials for Dongjianyuan (HEC96719) in Australia and have completed Phase I clinical trial in Australia.

Note 2: We have also submitted the BLA for our Insulin Glargine Injection to the U.S. FDA in December 2023.

Note 3: Our generic drugs Moxifloxacin Hydrochloride Tablet has obtained approval in Malaysia and Clarithromycin Tablet has obtained approval in South Africa.

Note 4: Our Entacapone Tablet has obtained approval in Malaysia.

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## BUSINESS

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As of December 31, 2024, we had two production bases located in Songshan Lake, Dongguan, Guangdong province, the PRC, and Yidu, Hubei province, the PRC, with a total area of over 1,300 mu. Our production bases are built in compliance with international standards and our Songshan Lake base has obtained GMP certifications from the United States, the European Union and China. Our production facilities cover the entire pharmaceutical production process in respect of formulations, forming a well-coordinated production system. We are capable of manufacturing pharmaceuticals in a variety of dosage forms, including tablets, capsules, granules, and dry suspensions. Our Yidu production facility has obtained PRC GMP certification, and recently passed the inspection conducted by the U.S. FDA in May 2024. Our Yidu production base is the largest Kewei (oseltamivir phosphate) production base in the PRC.

We have an extensive sales network in China. As of the Latest Practicable Date, we had promoted and sold a total of 48 drugs in China. Our sales and distribution network spans 32 provinces, municipalities and autonomous regions, and nearly 300 prefecture-level cities in China. Our sales and distribution network covers over 2,500 Class III hospitals, 9,600 Class II hospitals and 89,000 Class I hospitals, large-scale national or regional pharmacy chains and other medical institutions, allowing us to maximize our reach of the market in China. We also actively participate in national medical insurance negotiations in respect of our innovative drugs, and as a result, one of our Class I innovative drugs had been included in the NRDL as of December 31, 2024. In terms of overseas markets, we have been expanding in the U.S. and Europe for several years. Our overseas sales network covers eight countries and regions including the United States, Germany, and the United Kingdom. Our products have gained a good reputation in overseas markets and we have built sales capabilities in local markets.

We have been selected as one of the Top 20 companies in the “China Drug Research and Development Comprehensive Strength Ranking” (中國藥品研發綜合實力排行榜) released by Yaozhi.com (藥智網), a well-known healthcare industry data provider in China, for seven consecutive years from 2017 to 2023. This ranking is based on a comprehensive evaluation of drug approvals, R&D investment, clinical trial progress and patent portfolio. We have also been ranked among the tier-one group of the “Top 100 Chinese Pharmaceutical Innovators” (中國醫藥創新企業100強) issued by Healthcare Executive Magazine (E藥經理人), a reputable business magazine for the healthcare industry in China, for five consecutive years from 2019 to 2023. This ranking assesses companies based on innovation foundation, process and outcomes, with key indicators including the number of granted patents, patent citations, clinical trials and approved innovative drugs. In August 2024, we received a first-class award of Guangdong Science and Technology Award (廣東省科技進步一等獎) granted by the People’s Government of Guangdong Province in recognition of our contributions to scientific and technological advancement.

### OUR COMPETITIVE STRENGTHS

**We are a pharmaceutical company with vertically integrated capabilities in research and development, production and commercialization of pharmaceuticals, ranking first in the PRC in terms of the sales revenue of antiviral drugs for the past five years**

Our in-house innovation and research and development capabilities are the driving force and core competency for our long-term development. We have rich experience in engaging in in-house research and development of innovative drugs. We have established a large and professional research and development team consisting of over 1,100 employees. Our in-house research and development platforms cover the entire research and development process of chemical drugs and biologics. We are among the top PRC pharmaceutical companies in terms of the number of innovative drugs under clinical development. We have successfully developed and launched three Class I innovative drugs and applied for launching for one Class I innovative drug through our in-house research and development.

Expanding our international footprint is a key strategy for our business development. According to the Frost & Sullivan Report, we have commercialized pharmaceutical formulation overseas and one of the PRC pharmaceutical companies with the largest number of overseas approvals. With our Fingolimod capsule, a U.S. FDA approved first generic drug, we have become the first PRC pharmaceutical company that successfully challenged the patent of a novel drug in the U.S.. We have also been conducting overseas clinical trials and have completed Phase I clinical trials for four new drugs in the United States and Australia, two of which have obtained FDA Orphan Drug Designation. We received FDA clearance of IND application in respect of HEC88473 in February 2024 and entered into an exclusive license and commercialization agreement for HEC88473 with Apollo Therapeutics Group Limited in November 2024. According to the Frost & Sullivan Report, we were one of the only two PRC pharmaceutical companies to develop insulin products for the U.S. market as of the Latest Practicable Date. According to the Frost & Sullivan Report, we ranked 16th among the top 30 pharmaceutical companies in the world and 1st among PRC pharmaceutical companies in terms of approved generic drugs from May 2018 to May 2019.

We have an extensive nationwide sales and distribution network, which has been a key driver for our business growth. As of December 31, 2024, we had 1,884 dedicated sales and marketing personnels spanning 32 provinces, municipalities and autonomous regions across China covering over 2,500 Class III hospitals, 9,600 Class II hospitals and 89,000 Class I hospitals, large-scale national or regional pharmacy chains and other medical institutions. In addition, our overseas sales network covers eight countries and regions, and we maintain long-term partnerships with world-renowned pharmaceutical companies which provide a solid foundation for continuous expansion of our business overseas. We had 70 drugs approved overseas, including 36 in the United States and 31 in Europe as of December 31, 2024. Our Clarithromycin Tablets and its Sustained-Release Tablets accounted for more than 21% and 87% of the market share in the United States in 2022, respectively, while our Azithromycin Tablets ranked first in terms of market share for the Azithromycin market in Germany for the

period between 2018 and 2022 according to the Frost & Sullivan Report. The large number of overseas approvals we have obtained helps us to further improve our overseas market position, strengthen our product supply chain, and expand our market size.

We have also built production bases and quality management systems based in the PRC, which have obtained international GMP certifications, and help us to produce high-quality drugs in an efficient and sustainable manner and safeguard the commercialization of our products.

Our outstanding commercialization capabilities have helped us maintain our position as the number one pharmaceutical company in terms of antiviral drugs sales revenue in the PRC for the past five years from 2018 to 2022 according to the Frost & Sullivan Report and steadily increase our overseas sales. As of the Latest Practicable Date, we had promoted and sold 48 drugs in the PRC and 21 of our drugs had been the winning bids in connection with the centralized tender with respect to medicine procurement by the PRC authorities including five insulin products which have become a reliable source for our revenue. Kewei (oseltamivir phosphate), as our major product and the top brand of oseltamivir phosphate, ranked first in the PRC in terms of cumulative oseltamivir phosphate shipments and production volume over a period of five years between 2019 and 2023, according to the Frost & Sullivan Report. The sales revenue for Insulin Glargine and Dongweien (emtasvir phosphate) grew 426% and 276%, respectively, in 2023 when compared to 2022. As of December 31, 2024, we had commercialized five insulin products for sale in the Chinese market all of which have won the national VBP scheme tenders, and expected greater sales growth for our insulin product series.

We have managed to create a virtuous circle in respect of our business model through our integrated capabilities in research and development, production and commercialization. Our strong research and development and production capabilities have facilitated the successful commercialization of our products. The strong operating cash flow generated by the sales of our products not only funds our daily operations, but also allows us to continue to invest in our research and development, production and marketing. Through this virtuous circle, we are able to continuously advance our innovative research and development capabilities, which is essential for us to further strengthen our product portfolio and expand our market shares, eventually leading to our sustainable business growth and maintaining long-term competitive advantage.

### **We have established a diverse and robust pipeline of innovative drug candidates with commercialization potential**

We strategically focus on the research and development of innovative drugs in the therapeutic areas of infectious diseases, chronic diseases and oncology. The research and development of our drug candidates in the pipeline is primarily driven by our in-house R&D. As of the Latest Practicable Date, we had a diverse and robust pipeline of 49 Class I innovative drug candidates in China, mainly comprising (i) one Class I innovative drug candidate, for which we have submitted the NDA to the NMPA, and (ii) ten Class I innovative drug candidates in Phase II or Phase III clinical trials. We believe our diverse and robust pipeline of I

innovative drug candidates enables us not only to maintain a competitive edge in the research and development area among the PRC pharmaceutical companies but also to support our sustainable growth. Clinical drug development involves a lengthy and expensive process and uncertain outcome. For the risk associated with our clinical trial development, please see “Risk Factors — We rely substantially on the success of our drug candidates, some of which are in preclinical or clinical development stage, as well as our ability to identify additional drug candidates. If we are unable to successfully identify new drug candidates, complete clinical development, obtain regulatory approval and commercialize our drug candidates, or experience significant delays in doing so, our business will be materially harmed.”

***Established domestic R&D capabilities for anti-infective drugs***

Relying on our State Key Laboratory of Anti-Infective Drug Development, we have been continuously focusing on research and development on multiple indications for viral and bacterial infections, which has further enhanced our position in the therapeutic area of infectious diseases. As of the Latest Practicable Date, our anti-infective Class I innovative drugs primarily focused on the treatment of hepatitis C as well as hepatitis B, and mainly comprised (i) three Class I innovative drugs for the treatment of hepatitis C, which have been approved by the NMPA for launching, and (ii) one Class I innovative drug candidate that we have been developing in-house for the treatment of hepatitis B in Phase III clinical trial.

***Hepatitis C.*** We have one commercialized Class I innovative drug for the treatment of genotype-specific chronic hepatitis C and two approved Class I innovative drugs for the treatment of pan-genotypic chronic hepatitis C. Our Dongweien (emitasvir phosphate) is a domestic in-house R&D Class I innovative drug for the treatment of genotype 1 chronic hepatitis C, which has been approved for launching and included in the NRDL in China. The combination treatment of Dongweien (emitasvir phosphate) and Sofosbuvir achieved an SVR12 of 99.5% against genotype 1 chronic hepatitis C patients. We also have two approved Class I innovative anti-HCV drugs, namely Dong’antai (Netanasvir Phosphate) and Dong’anqiang (Encofosbuvir), which were approved by the NMPA for launching in China in February 2025 and March 2025, respectively. We are currently scaling up production and finalizing our market launch preparations, with sales expected to begin in July 2025. In parallel, we are preparing to initiate negotiations with national medical insurance authorities in December 2025, and we anticipate that our products will be included in the NRDL starting in January 2026. Our combination treatment regimen of Netanasvir Phosphate and Encofosbuvir is a domestic in-house R&D combination treatment regimen for pan-genotypic chronic hepatitis C, which achieved an SVR12 of 95.0% against pan-genotypic chronic hepatitis C patients. According to the Frost & Sullivan Report, the total number of patients diagnosed with chronic hepatitis C in China was 2.6 million in 2023 and is expected to increase to 2.8 million and 3.1 million in 2026 and 2030, respectively.



***Hepatitis B.*** We have established a pipeline of innovative drug candidates with various mechanism of actions for the treatment of hepatitis B. We have one Class I innovative anti-HBV drug candidate in Phase III clinical trial, namely Dong'andi (Morphothiadine Mesylate). According to the Frost & Sullivan Report, Morphothiadine Mesylate was the only anti-HBV capsid inhibitor in Phase III clinical trial in China and had the leading clinical trial progress in China as of the Latest Practicable Date. Morphothiadine Mesylate was also the world's first oral small molecule drug for the treatment of chronic hepatitis B, which has been clinically validated to significantly inhibit hepatitis B virus surface antigen, according to the Frost & Sullivan Report. We also have one Class I innovative drug with Phase I clinical trial completed, namely Freethiadine, which also targets anti-HBV capsid inhibitor. In addition to anti-HBV capsid inhibitor drug candidates, we also have two Class I innovative drug candidates, which might be possible to functionally cure chronic hepatitis B through combination therapy. For example, we plan to submit the IND application for HECN30227 in 2025, which is a small nucleic acid drug. In addition, our HEC191834 is a TLR8 agonist drug candidate, which is also in preclinical stage. According to the Frost & Sullivan Report, the total number of patients diagnosed with chronic hepatitis B in China was 19.1 million in 2023 and is expected to increase to 23.2 million and 31.9 million in 2026 and 2030, respectively. According to the Frost & Sullivan Report, the market size of anti-HBV drugs in China reached RMB9.9 billion in 2023 and is expected to increase to RMB16.7 billion and RMB43.4 billion in 2026 and 2030, respectively.

***A diverse and near-commercial pipeline of innovative drug candidates for the treatment of chronic diseases***

As of the Latest Practicable Date, our chronic disease treatment innovative drug candidates primarily focused on the treatment of metabolic diseases such as diabetes, obesity and NASH, as well as respiratory system diseases, and neuropsychiatric diseases, and mainly comprised (i) one Class I innovative drug candidate that we have been developing in-house and for which we have submitted the NDA to the NMPA, (ii) six Class I innovative drug candidates that we have been developing in-house in Phase II or III clinical trials, (iii) two Class I innovative drug candidates for which we have been approved for clinical trials, and (iv) one Class I innovative drug candidate for which the IND application has been submitted.

***Diabetes.*** We have established a comprehensive product portfolio and drug pipeline, covering chemical drugs and biologics, for the treatment of diabetes. Our Dongjiantang (Ologliflozin) is a Class I innovative SGLT-2 inhibitor drug candidate that we have been developing in-house for the treatment of type 2 diabetes and for which we have submitted the NDA to the NMPA in December 2023. Our Guangjianbao (HEC88473) is a Class I innovative dual-targeted (GLP-1/FGF21) biological drug candidate with three intended indications including type 2 diabetes, which we have been developing in-house in Phase II. According to the Frost & Sullivan Report, HEC88473 was the first GLP-1/FGF21 dual agonist drug candidate to enter the clinical stage and had the leading R&D progress among all GLP-1/FGF21 dual agonist drug candidates in the world as of the Latest Practicable Date. According to the Frost & Sullivan Report, the market size of diabetes drugs in China reached RMB67.6 billion in 2023 and is expected to increase to RMB90.3 billion and RMB122.3 billion in 2026 and 2030, respectively.

***Respiratory system diseases.*** We have established a diverse drug pipeline for the treatment of respiratory system diseases. Dongjiandi (Yinfenidone Hydrochloride) is a Class I innovative drug candidate for the treatment of IPF in Phase II clinical trial. We completed Phase I clinical trials for Yinfenidone Hydrochloride in China and the U.S. and Yinfenidone Hydrochloride was also granted Orphan Drug Designation in the U.S. We have been conducting its Phase II clinical trial in China and have obtained its interim analysis data. We have also received its Phase III clinical trial approval from the Center for Drug Evaluation (CDE). In addition, we also have (i) one Class I innovative drug candidate for the treatment of pulmonary arterial hypertension, namely Dongjianqiang (HEC95468), and (ii) four modified new drugs for the treatment of COPD and asthma, namely Tiotropium Bromide Inhaler, Tiotropium Bromide and Olodaterol Inhaler, and two other modified inhalers. According to the Frost & Sullivan Report, the market size of respiratory system disease drugs in China was RMB82.1 billion in 2023 and is expected to increase to RMB103.7 billion and RMB123.9 billion in 2026 and 2030, respectively.

***Expanding the innovative drug pipeline with multiple treatment technologies for oncology***

We aim to achieve significant clinical benefits by using multiple treatment technologies, such as precise targeting and ADC to establish a wide coverage of the product candidates. As of the Latest Practicable Date, our oncology drug candidates mainly comprised (i) two Class I innovative drug candidates that we have been developing in-house in Phase III clinical trials, (ii) one Class I innovative drug candidate that we have been developing in-house in Phase II clinical trial, (iii) one Class I innovative drug candidate that we have been developing in-house in Phase I clinical trial and (iv) one Class I innovative drug candidate that we have been developing in-house in pre-clinical trial. We expect our oncology drug candidates in our pipeline to bring new business growth opportunities to us, thereby enhancing our market competitiveness.

Our Dongningchun (Clifutinib Besylate) is a Class I innovative drug candidate that we have been developing in-house for the treatment of AML in Phase III clinical trial. According to the Frost & Sullivan Report, Clifutinib Besylate was the first domestic in-house R&D highly selective FLT3 inhibitor drug candidate that has entered Phase III clinical trial. According to the Frost & Sullivan Report, the market size of AML drugs in China was RMB0.3 billion in 2023 and is expected to increase from RMB1.0 billion in 2026 to RMB3.5 billion in 2030, with a CAGR of 36.8%. Our Dongningguan (Larotinib Mesylate) is a Class I innovative drug candidate that we have been developing in-house in Phase III clinical trial for the treatment of esophageal squamous cell carcinoma, a type of esophagus cancer. According to the Frost & Sullivan Report, Larotinib Mesylate was the first small molecule targeted therapeutic drug for the treatment of esophageal cancer in China that entered Phase III clinical trial. According to the Frost & Sullivan Report, the number of incidence of esophagus cancer in China was 231.0 thousand in 2023 and the number of new cases of esophagus cancer is expected to increase to 252.3 thousand and 280.5 thousand in 2026 and 2030, respectively.

**We have built comprehensive in-house research and development capabilities and have created independent research and development platforms and technologies that cover the entire drug development cycle for both chemical drugs and biologics**

Since our inception, we have been committed to developing innovative drugs with clinical advantages. We have been continuously improving our research and development platforms and enhancing our research and development capabilities. We have built independent research and development platforms and technologies for the entire cycle of drug development from early drug discovery to commercialization and production. We are equipped with full-cycle research and development platforms for both chemical drugs and biologics. In addition, we are committed to applying AI technology across all stages of drug research and development, having established multiple advanced AI-driven models to enhance our innovation capabilities. We obtained the clinical trial approval for HEC169584 in December 2024, a THR- $\beta$  agonist drug candidate for the treatment of NASH, which is the first new small molecule drug candidate developed by our AIDD laboratory. Please see “— Chronic Diseases — Product Candidate — HEC169584” for details. By integrating every step in the drug research and development process effectively, we achieve seamless operation to support efficient drug research and development. The comprehensive and integrated drug discovery and development process has become our significant advantage.

With respect to innovative chemical drugs, the focus of our in-house research and development has been on the Class I innovative drugs and we have established an early-stage drug research and development platform which drives our early-stage drug development. We have 18 years’ research and development experience in respect of Class I innovative drugs and are one of the first companies in China conducting research and development of Class I innovative drugs. As of December 31, 2024, our early-stage drug discovery team comprised of over 200 research personnels, with some of the team members previously holding senior positions and having been involved in drug discovery at multinational pharmaceutical companies and research institutes. They have expertise in various research areas including biology, medicinal chemistry, drug metabolism and pharmacokinetics and translational medicine. Our team has excellent experience in molecular design and optimization, which has also become a core competency in our innovative drug research and development. As of December 31, 2024, more than 100 of our compound patents had been collected and reported by Daily Drug News, demonstrating our industry-recognized pharmaceutical design capabilities. At the same time, our rapid molecule structural design and optimization capabilities facilitate the protection of our core intellectual property rights as well as breaking through the patent protection barriers of our competitors. As of the Latest Practicable Date, we had successfully developed and launched three Class I innovative drugs, applied for launching one Class I innovative drug and had over 25 candidate molecules in various stages of clinical trials. According to the statistics from Insight and Yaozhi.com (藥智網), we ranked third in China with 42 Class I chemical drug application numbers from 2016 to 2019, and were in the top 10 in the China’s Chemical Drug Research and Development Strength List (“中國化藥研發實力排行榜”) for five consecutive years.

In connection with our research and development of biologics, we have established comprehensive platforms for the development of recombinant proteins and antibodies products. As of December 31, 2024, our team had over 160 employees and were guided by experts with extensive experience in the research and development of biologics. Regarding our diabetes products, we can fully self-develop and commercialize a wide range of insulin products and GLP-1 biosimilars. As of December 31, 2024, we had commercialized five insulin products in the Chinese market and expected to receive FDA approval in respect of our Insulin Glargine in 2025. In addition, we also focus on metabolism and oncology. We have the world's first GLP-1/FGF21 dual-target candidate that has entered the Phase II clinical trial stage, as well as anti-tumor projects including dual (multi) antibodies and ADC.

In terms of modified new drug R&D platform, we have core design platforms for soft mist inhalation, long-acting injections, oral sustained-release and pre-formulation drug. As a result of our innovation in formulation technology, we submitted our first modified new drug NDA application in November 2024, and one modified new drug of ours is about to enter Phase III clinical trial.

We have established robust in-house clinical development capabilities, with a team of over 200 employees located in eight offices across China. Their specialties cover clinical medicine, clinical operations, data management, biostatistics, clinical pharmacology, drug safety and other functions, covering all major aspects of clinical development. We are capable of completing Phase I, II, and III clinical trials of Class I innovative drugs in-house efficiently with high standards. As of December 31, 2024, our clinical development team had undertaken a total of 111 Phase I, II, and III clinical trials and 205 bioequivalence trials, and supported our clinical development of more than 20 innovative drugs. The trials were conducted in places including the United States, Australia, China and other countries. We also partner with clinical research centers located across the PRC, and work with nearly 300 clinical trial institutions in China and overseas and more than 920 of their specialized departments to conduct our clinical trials. Our clinical development team have accumulated profound experience in the design of clinical trials and operational management in respect of multiple indications, and have rich experience in dealing with regulatory authorities, and thereby have been playing an important role in advancing our clinical development plans towards successful commercialization.

Our core technologies, drugs and drugs under development are protected by a comprehensive patent portfolio. As of December 31, 2024, we had filed a total of 2,446 invention patent applications, including 382 PCT applications, 1,131 PRC domestic invention applications and 933 overseas applications, among which, a total of 1,401 invention patents have been granted by the relevant patent authorities, including 746 in the PRC and 655 overseas. The scope of our patents covers new drug compounds, protein molecular structures, manufacturing processes, usage and preparation formulation. We believe our patents provide solid and long-term protection for our technologies, drugs and drugs under development. As a result of our extensive research and development achievements, we have been awarded with multiple national awards and approved to establish multiple state-level research institutions, including the establishment of the State Key Laboratory of Anti-Infective Drug Development approved by the Ministry of Science and Technology of the PRC, the National Intellectual

Property Model Enterprise (“國家知識產權示範企業”) by the National Intellectual Property Administration of the PRC, and a postdoctoral research workstation. According to the Frost & Sullivan Report, we ranked first among PRC pharmaceutical companies in terms of the number of patents published and the number of authorized patent announcements in China from January 1, 2014 to December 31, 2023, and we ranked 79th in the world and 10th in China in terms of the number of public invention patent applications for the global biomedical-industry in 2023.

**We have an extensive nationwide sales and distribution network in China**

We maintain an extensive sales and distribution network in China, which, combined with our proven commercialization capabilities, have been among the key drivers for the continuous growth of our revenues. Through close cooperation with our local partners, we have established stable sales and distribution networks, providing customers with easy access to our products and high-quality after-sales services.

In the PRC market, we have a nationwide product sales and distribution network. Our sales team has 1,918 sales professionals and our sales coverage spans 32 provinces, municipalities and autonomous regions across China, and nearly 300 prefecture-level cities in China. The domestic sales team is divided into (i) our pediatric line represented by our top-selling product, Kewei (oseltamivir phosphate), (ii) our chronic disease line focusing on our insulin series products, (iii) our innovative drug line represented by our hepatitis C drug Emitasvir, and (iv) our VBP and other market channels line represented by our Esomeprazole Magnesium Enteric-Coated Capsules. All of our sales lines showed strong growth in sales in 2023. As of the Latest Practicable Date, we had promoted and sold a total of 48 drugs in China. Our sales network covers over 2,500 Class III hospitals, 9,600 Class II hospitals and 89,000 Class I hospitals, large-scale national or regional pharmacy chains and other medical institutions, allowing us to maximize our reach of the market in China. We also actively participate in national medical insurance negotiations in respect of our innovative drugs, and as a result, one of our Class I innovative drugs had been included in the NRDL as of December 31, 2024. In overseas markets, our overseas sales network spans across eight countries including the United States, Germany and the United Kingdom.

**We have an advanced production and supply chain system in China, and our production bases fully comply with international GMP standards.**

We currently have two production bases in Songshan Lake, Dongguan, Guangdong province, the PRC, and Yidu, Hubei province, the PRC, occupying a total area of more than 1,300 mu. These production bases cover the entire production chain of formulations. Our Songshan Lake production base is an advanced factory in China producing solid chemical formulation and biologics. It has obtained GMP certifications from the United States, the European Union and China, including recently passing EU GMP audit conducted by National Office for Health and Social Affairs of Germany in November 2023, GMP inspection by the U.S. FDA in March 2024, and a GMP compliance check by the Guangdong Provincial Drug Administration in January 2025. Its annual production capacity of chemical drugs reaches 1.8

billion tablets/capsules. A large-scale biologics facility that complies with international GMP standards is expected to be completed in 2026, equipped with production lines for cell, E coli fermentation and yeast fermentation as planned, which will provide solid support for the commercialization of our biologics under development. Our Songshan Lake base currently manufactures our main products including Esomeprazole Enteric-Coated Capsules, Moxifloxacin Hydrochloride Tablets and Clarithromycin Tablets. Our Yidu production base has obtained Chinese GMP certification, and it produces a wide range of insulin products, solid dosage forms and freeze-dried powder injections. The dosage forms include tablets, capsules, granules, dry suspensions and freeze-dried powder injections. As of December 31, 2024, our Yidu production base was the largest production base of oseltamivir phosphate formulation in the PRC and can also produce a wide range of insulin products ranging from the second to fourth generation, with an annual production capacity of over 15 million injections. We have already expanded its maximum annual insulin production capacity from 18 million injections in 2023 to 100 million injections in 2024. As of December 31, 2024, the annual theoretical production capacity of the Yidu chemical solid formulation production facility had passed 3.5 billion tablets/capsules, 1.6 billion granule packets and 4.5 million vials of freeze-dried powder injections.

Our production bases adopt a comprehensive quality management system to ensure that the quality of our products meets the highest standards. We strictly comply with the quality standards such as GMP issued by relevant regulatory authorities, and have passed multiple audits conducted by these regulators. These audits included rigorous reviews of our production facilities, production processes, quality control measures and raw materials. Our goal is to provide our customers with safe, reliable and quality products which comply with relevant regulatory requirements. We are committed to continuously improving and enhancing our quality management system to ensure customer satisfaction and compliance with the requirements of regulatory authorities.

We provide a reliable supply of Kewei (oseltamivir phosphate) for the Chinese national drug reserve. Over the years, we have demonstrated strong and high-standard production capabilities in response to the outbreak of influenza in China. We have advanced facilities and high production standards, which comply with stringent quality management systems such as GMP. Our team are experienced and able to quickly adjust production plans to ensure the continuity and stability of oseltamivir phosphate supply. We have the ability to provide reliable supply for the national drug reserve.

**We have an experienced team with a proven track record, which enables our business to grow in the future**

Our research and development team has an excellent track record of developing innovative drugs, having successfully launched one innovative drug onto the market, advanced three innovative drugs to the NMPA's review for launching in China and progressed dozens of independently-discovered drug candidates to the clinical research stage. Consisting of scientists with extensive working experience in multinational pharmaceutical companies and key talents with rich practical experience in research and development, our research and development team have deep understanding and profound experience in various aspects of drug research and development, providing strong support for our product development. As of



December 31, 2024, our research and development team has over 1,100 employees working in the areas of early drug discovery and evaluation, pharmaceutical development, clinical development, regulatory affairs and quality assurance. Their experience and qualifications span across chemistry, pharmaceutical formulation, analysis, biology, pharmacology and clinical medicine.

Our research and development team are led by our Chairman, Dr. Zhang Yingjun (張英俊博士), who is a renowned scientist in the field of innovative chemical drugs and previously served as the person in charge of the National Major Scientific and Technological Special Project for “Significant New Drugs Development”. He is currently serving as deputy director of the State Key Laboratory of Anti-Infective Drug Development, a member of the National Pharmaceutical Chemistry Committee and a senior member of the Pharmaceutical Chemistry Committee of Guangdong Province. Dr Zhang oversees our strategic planning and drug development, and has led the development in respect of more than 50 Class I innovative drugs. Dr Zhang, as the first author, received a first-class award of Guangdong Science and Technology Award (廣東省科技進步一等獎) in 2024. He has more than 15 years of experience in drug development and company management, and deep knowledge in the fields of infectious diseases, chronic diseases, and oncology. Dr. Zhang has made significant contributions to our research and development and the research platforms. Our core research and development team also includes Dr. Zhang Ji (張霽博士), Dr. Gu Baohua (谷保華博士), Dr. Ye Qunrui (葉群瑞博士), Dr. Liang Shaoqin (梁紹勤博士), and Dr. Cai Xiaoli (蔡曉莉博士). They have held senior positions at renowned pharmaceutical companies and research institutions, such as Pfizer, BMS, GlaxoSmithKline, Novartis and the University of Pennsylvania. They have been involved in drug discovery and development across various fields. Their expertise covers areas including drug synthesis and process chemistry, biology, immunology, antibody screening, clinical medicine and operation, and have profound insights and extensive experience in all aspects of drug development.

Our management team hold comprehensive expertise in all aspects of the management of a pharmaceutical company. They have academic and/or professional backgrounds in pharmacology, finance and law, and each member has at least ten years of relevant experience in the pharmaceutical industry or corporate management. The management team have a solid track record in managing the research and development, manufacture, and commercialization of pharmaceuticals products. Under their leadership, we have managed to attract a large number of outstanding employees to join us. The team’s expertise and experience provide strong support for our research and development and operations, driving our continuous growth and success in the pharmaceutical industry.



### OUR STRATEGIES

We aim to continue to solidify our market leadership in our strategically focused therapeutic areas. We plan to implement the following strategies to achieve our goal:

**We will focus on upgrading our key research and development platforms and further strengthening our diverse and robust drug pipeline in order to achieve sustainable growth**

We will continue to invest in our own research and development platforms and focus on advanced pharmaceutical research and development technologies including small nucleic acid drugs, AIDD and ADCs. With respect to the small nucleic acid technology, we will focus on building an integrated platform for early-stage drug design, synthesis, characterization, and purification by initially focusing on hepatitis B as the key therapeutic area and gradually expanding into other chronic diseases. In respect of AIDD, we plan to build an in-house AI models based on our extensive research and development data and use the AI models to design new molecules for potential drug candidates and predict the druggability of our drug candidates. We have submitted the IND application for HEC169584 in September 2024 and obtained its clinical trial approval in December 2024, which is our first new small molecule drug candidate discovered through AIDD. In the ADC field, we will focus on developing new technological platforms including linkers, toxins, and conjugation methods. We plan to apply these advanced technologies in drug research and development, continuously exploring innovative drug treatment methods, and providing patients with safer and more effective treatment options.

We remain committed to providing patients with high-quality and affordable drugs. We strategically focus on the research and development of drugs targeting therapeutic areas with significant unmet medical needs. We are committed to advancing the clinical trials of our existing clinical-stage drugs under development while further strengthening our diverse and robust drug pipeline covering a deeper and broader range of therapeutic areas.

In the field of infectious diseases, we plan to leverage our research work conducted in our State Key Laboratory of Anti-Infective Drug Development to continue to develop broad-spectrum anti-infective drugs by leveraging new technologies such as high-throughput screening, computer-aided drug screening and design and combined chemical synthesis. In the field of diabetes, we already have a comprehensive portfolio covering mainstream insulin products and a diverse and robust pipeline of multiple innovative drug candidates including both chemical drugs and biologics. We plan to gradually expand our pipeline into comprehensive diabetes management medications, including weight loss, heart and renal protection and metabolic improvement. In the field of oncology, we plan to focus our research and development investments on the treatment of cancers which are prevalent in the PRC such as gastrointestinal cancer. By leveraging our research and development platforms, we will accelerate the development of oncology innovative drugs and create our competitive advantage in this area.

We plan to upgrade our manufacturing facilities by promoting the intelligent manufacture of drugs and by digitalizing and automating our production process. Furthermore, we plan to adopt a drug traceability system, in order to achieve end-to-end traceability of drugs. We believe such a system will improve the quality and safety of our production process and provide us with reliable data support. Ultimately, these measures will enhance our production efficiency, reduce costs and help us deliver high-quality drugs to our customers.

**We plan to accelerate our expansion into global markets and strive to become an international pharmaceutical company**

We are a company with a global perspective and international operational capabilities. We have extensive overseas experience in terms of research and development, commercialization and operation and have established a global sales network across major international markets.

Our overseas sales network covers eight countries and regions including the United States, Germany and the United Kingdom. In the future, we plan to expand our overseas sales network to Africa and Latin America, forming sales capacities covering both developed and developing countries.

We plan to implement the following strategies to expand our overseas market. Firstly, we will boost international sales of our existing drugs manufactured in China, in particular, our drugs with EU and U.S. approvals. We believe we can increase the overseas sales of our existing products by leveraging our existing drug production, quality management capabilities and supply chain systems that meet international standards. Secondly, we plan to build up our international capabilities in research and development, product registration, clinical trials, and commercialization with a focus on advancing clinical trials of drugs under development with unmet demands, clinical value and competitive advantages in the overseas markets. Thirdly, we will continue to seek opportunities for collaboration with multinational pharmaceutical companies to enhance our position in the international pharmaceutical market.

We plan to strengthen our global research and development system by building international research and development platforms and improving our overseas clinical trial capabilities. We will actively seek and deepen collaboration with our international strategic partners to jointly develop international research and development projects. Through technology transfer and knowledge sharing, we plan to acquire technologies and patents to enhance the competitiveness of our drug products. For our drugs under development at clinical stage, we will focus on advancing cooperation with multinational companies to fully exploit the commercial value of such drugs under development. Secondly, we plan to strengthen our market research process to gain a deeper understanding of the demands of overseas markets and the competitive market environment so that we can better identify the target products which cater to the relevant market demand. At the same time, we will strengthen our brand-building and marketing in overseas markets to increase the visibility and recognition of our products globally.

The recent U.S.-China trade tensions have led to the introduction of high tariffs on a host of goods trading between the two countries. The trade tensions between the two countries have been rising and there is a possibility that the extent and scale of trade restrictions between the two countries be escalated if the U.S. and China fail to reach any agreement to settle the issues. There is no assurance as to how the U.S.-China trade tensions might develop or whether there will be any changes to the scope and extent of goods that are or will be being subject to such export controls, sanctions, tariffs, or new trade policies introduced by the two countries. We cannot predict the implications of the ongoing U.S.-China trade tensions and the resulting impact on our industry and the global economy. We believe the U.S.-China trade tensions have no material impact on our business as we primarily source our raw materials from India, Switzerland and the United Kingdom and our overseas sales only represented 1.6%, 0.8% and 3.4% of our total revenue for 2022, 2023 and 2024, respectively.

**We plan to strengthen our brand recognition and accelerate the commercialization of our approved drugs**

We plan to continue to strengthen our brand recognition in the global markets. We are the number one PRC pharmaceutical company in terms of antiviral drug sales in the PRC for the past five years, our brands in relation to our antiviral products have been widely recognized in the industry and among our patients according to the Frost & Sullivan Report. Building on our existing achievements, we will continue to enhance the brand recognition of our company and our major products through promoting public awareness and standardized treatment processes for relevant diseases. We plan to partner with large e-commerce platforms to sell our major products through them, aiming to increase our brand exposure directly to consumers. In addition, we will actively participate in international industry exhibitions and further develop cooperative relationships with global customers and partners.

We plan to increase our marketing efforts to promote the sales of our existing drugs on the market. In respect of our hepatitis C drugs, we plan to work with PRC healthcare authorities to facilitate national policies regarding elimination of hepatitis C. With respect to our diabetes drugs, we plan to enhance our marketing efforts by conducting more market education to improve doctors' understanding and knowledge of our diabetes products. We also plan to implement sales strategies specifically tailored to different regions to improve market recognition of our brand and to drive product sales growth.

We plan to accelerate the global commercialization of our approved drugs. In the domestic market, we plan to promote the sales of our generic drugs through a combination of various marketing approaches, including in-hospital prescriptions, out-of-hospital retail, and agency sales. We will expand the coverage and distribution network of products through new retail channels, such as large and medium-sized chain pharmacies and major e-commerce platforms, thereby increasing the sales volume and market share of our drugs. In overseas markets, we will launch one to three drugs each year. By enriching our product portfolio and strengthening marketing efforts, we aim to further enhance our competitive advantage in overseas markets.

### **We plan to attract and develop global pharmaceutical talents by establishing a human resources system that facilitates and incentivizes career development**

We attach great importance to the training and development of our young generation of scientists. We plan to help our research and development staff reach their full innovative potential and grow their professional skills by (i) establishing a comprehensive training and development system, (ii) encouraging inter-departmental collaboration and knowledge sharing, (iii) supporting innovative projects and scientific research activities, and (iv) implementing effective evaluation and promotion systems.

We highly value the recruitment of international research and development talents. We plan to recruit high-performance individuals with outstanding professional skills from multi-cultural backgrounds. Through partnerships with top universities, professional institutions and talent search agencies, we plan to identify potential candidates with a global perspective and outstanding track-record in the relevant fields. We offer competitive compensation and development opportunities to global research and development talents who meet our requirements. We will also provide a wide range of on-board training and a mentoring program to new joiners to help them adapt to our corporate culture and connect with other colleagues.

### **We plan to actively seek and work with global strategic partners**

We will identify strategic opportunities through internal and external communication. Firstly, we will continue to maintain and expand our relationships with reputable research institutions, leading universities and key laboratories around the world. We plan to collaborate with these organizations and jointly develop cutting-edge scientific research projects and innovative technology to grow our research and development capabilities. Secondly, we will also strengthen our cooperation with renowned pharmaceutical companies to achieve mutual benefits through shared marketing channels, brand influence and sales resources. Thirdly, we plan to promote the license-in and license-out cooperations with our strategic partners to enhance domestic and overseas technology transfer. By obtaining the intellectual property rights of advanced technologies and products and transferring our intellectual property rights to our partners through licensing arrangements, we will deepen our cooperation with key research organizations and renowned companies, better integrate the competitive strengths of all parties, improve product layout and proactively meet the clinical medication needs of patients.

## **OUR PRODUCTS AND PRODUCT CANDIDATES**

### **Our Existing Product Portfolio**

Our existing product portfolio focuses on the therapeutic areas of infectious diseases and chronic diseases, mainly comprising the following major products: (i) five major anti-infective drugs, including our top-selling product, Kewei (oseltamivir phosphate), one Class I innovative

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drug developed in-house, Dongweien (emitasvir phosphate), and three other major anti-infective generic drugs, and (ii) nine major products for the treatment of chronic diseases, including five insulin products and four other major chronic disease treatment generic drugs. Sales of our major products accounted for 92.6%, 95.4% and 84.9% of our total revenue for the years ended December 31, 2022, 2023 and 2024, respectively.

During the Track Record Period, we generated a significant portion of our revenue from sales of anti-infective drugs. In 2022, 2023 and 2024, our revenue from sales of anti-infective drugs was RMB3,242.5 million, RMB5,745.8 million and RMB2,797.6 million, respectively, accounting for 85.0%, 90.0% and 69.6% of our total revenue for the same periods, respectively. During the Track Record Period, we also generated a moderate portion of our revenue from sales of drugs for the treatment of chronic diseases.

The following table sets forth a breakdown of our revenue from sales of drugs by therapeutic areas for the periods indicated:

Year ended December 31,						
	2022		2023		2024	
<i>(RMB in thousands, except for percentages)</i>						
Anti-infective						
drugs . . . . .	3,242,508	85.0%	5,745,811	90.0%	2,797,632	69.6%
Chronic disease						
treatment						
drugs . . . . .	517,258	13.6%	580,743	9.1%	1,067,707	26.6%
Others <sup>(1)</sup> . . . . .	53,800	1.4%	59,062	0.9%	153,566	3.8%
Total . . . . .	<u>3,813,566</u>	<u>100.0%</u>	<u>6,385,616</u>	<u>100.0%</u>	<u>4,018,905</u>	<u>100.0%</u>

*Note:*

- (1) Others comprise (i) revenue from sales of drugs that were not anti-infective drugs or chronic disease treatment drugs, mainly including tadalafil and sildenafil, (ii) transfer and license fee we received pursuant to the HEC88473 Agreement with Apollo, and to a lesser extent, (iii) rental revenue generated from the leasing of fixed assets and (iv) revenue from the disposal of surplus construction materials.

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The following table sets forth the sales of our major products, which contributed an important portion of our revenue during the Track Record Period or are expected to contribute to our future growth, in absolute amounts and as percentages of our total revenue for the periods indicated:

			Year ended December 31,					
Therapeutic area	Major products	Indication	2022		2023		2024	
			(RMB in thousands, except for percentages)					
Anti-infective drugs . . . . .	Oseltamivir Phosphate <sup>(1)</sup>	Influenza	3,097,403	81.2%	5,546,118	86.9%	2,580,704	64.2%
	Clarithromycin	Infections caused by clarithromycin sensitive bacteria	52,293	1.4%	41,875	0.7%	43,146	1.1%
	Moxifloxacin Hydrochloride Tablets	Infections caused by sensitive bacteria	33,434	0.9%	47,516	0.7%	48,214	1.2%
	Emitasvir Phosphate Capsules	Hepatitis C	10,816	0.3%	40,665	0.6%	89,486	2.2%
	Levofloxacin Tablets	Infections caused by sensitive bacteria	25,771	0.7%	29,778	0.5%	27,566	0.7%
	Subtotal <sup>(3)</sup>		3,219,718	84.4%	5,705,952	89.4%	2,789,116	69.4%
Chronic disease treatment drugs . . . . .	Benzbromarone Tablets	Hyperuricemia	98,424	2.6%	94,968	1.5%	109,534	2.7%
	Esomeprazole Magnesium Enteric-Coated Capsules	Stomach acid related diseases	89,734	2.4%	92,274	1.5%	206,187	5.1%
	Telmisartan Tablets	Hypertension	62,922	1.6%	77,980	1.2%	110,281	2.7%
	Insulin Injections <sup>(2)</sup>	Diabetes	12,420	0.3%	69,449	1.1%	136,688	3.4%
	Olmesartan Medoxomil Tablets	Hypertension	44,433	1.2%	42,540	0.7%	59,405	1.5%
	Subtotal <sup>(4)</sup>		307,933	8.1%	377,211	5.9%	622,095	15.5%
Total major products			3,527,650	92.6%	6,083,163	95.4%	3,411,211	84.9%

*Note:*

- (1) Our oseltamivir phosphate products mainly include Kewei granule, Kewei capsule, Yangjiantai capsule products. For revenue generated by our main oseltamivir phosphate products, please refer to “— Sales, Marketing and Distribution — Our Oseltamivir Phosphate Products and the Reasons for the Fluctuation of the Sales of Our Oseltamivir Phosphate Products during the Track Record Period” for detail. During the Track

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Record Period, we also generated small amount of revenue from (i) the sales of dry suspension form of oseltamivir phosphate in the amount of nil, RMB6.0 million and RMB3.5 million for 2022, 2023 and 2024, respectively and (ii) the sales of 30 mg and 45 mg oseltamivir phosphate capsules which in aggregate generated revenue in the amount of nil, RMB763.5 thousands, RMB33.1 thousands for 2022, 2023 and 2024, respectively.

- (2) Our insulin products include (i) Human Insulin Injection, (ii) Mixed Protamine Human Insulin Injection (30R), (iii) Insulin Glargine Injection, (iv) Insulin Aspart Injection, and (v) Insulin Aspart 30 Injection. Mixed Protamine Human Insulin Injection (30R) was approved for sale in 2023 and we started generating revenue from its sales in 2024. For details of our five insulin products, please see “— Chronic Diseases — Diabetes — Commercialized Products — Insulins in China.”
- (3) In 2022, 2023 and 2024, our five major anti-infective products (Oseltamivir Phosphate, Clarithromycin, Moxifloxacin Hydrochloride Tablets, Emitasvir Phosphate Capsules and Levofloxacin Tablets) contributed 99.3%, 99.3% and 99.7% of our revenue from sales of anti-infective products for the same periods, respectively. The remaining revenue from sales of anti-infective products in 2022, 2023 and 2024 was contributed by six, four and six other anti-infective products, respectively.
- (4) In 2022, 2023 and 2024, our nine major chronic disease treatment products (namely Benzbromarone Tablets, Esomeprazole Magnesium Enteric-Coated Capsules, Telmisartan Tablets, five Insulin Injections and Olmesartan Medoxomil Tablets) contributed 59.5%, 65.0% and 58.3% of our revenue from sales of chronic disease treatment products for the same periods, respectively. The remaining revenue from sales of chronic disease treatment products in 2022, 2023 and 2024 was contributed by 20, 22 and 27 other chronic disease treatment products, respectively.

Kewei (oseltamivir phosphate), an anti-influenza drug, is our top-selling product. In 2022, 2023 and 2024, our revenue from sales of Oseltamivir Phosphate was RMB3,097.4 million, RMB5,546.1 million and RMB2,580.7 million, respectively, accounting for 95.5%, 96.5% and 92.3% of our revenue from sales of anti-infective products for the same periods, respectively, and accounting for 81.2%, 86.9% and 64.2% of our total revenue for the same periods, respectively.

The table below sets forth a breakdown of the revenue derived from our oseltamivir phosphate products by dosage form for the years indicated:

	Year ended December 31,					
	2022		2023		2024	
	RMB'000	% of total	RMB'000	% of total	RMB'000	% of total
Oseltamivir phosphate (capsule) . . . . .	512,252	16.5	715,576	12.9	395,676	15.3
Oseltamivir phosphate (granule) . . . . .	2,585,151	83.5	4,824,592	87.0	2,181,509	84.6
Oseltamivir phosphate (dry suspension) . . . . .	—	—	5,950	0.1	3,520	0.1
Total . . . . .	<u>3,097,403</u>	<u>100</u>	<u>5,546,118</u>	<u>100</u>	<u>2,580,705</u>	<u>100</u>



The following table sets forth the selected information of our major products in major dosage forms, which contributed an important portion of our revenue during the Track Record Period or was expected to contribute to our future growth, as of the Latest Practicable Date.

Therapeutic Area	Major Product	Classification	Indication	Major Dosage Form	Year of First Inclusion in NRDL <sup>(2)</sup>	Inclusion in National Essential Drug List (2018 Version) <sup>(3)</sup>	VBP Scheme <sup>(4)</sup>	In-house R&D/License-in Patents
Infectious diseases . . . . .	Kewei (Osetlamivir Phosphate Capsules/Granules) 可威® (磷酸奥司他韦胶囊/颗粒)	Capsules: Class VI active chemical drug <sup>(1)</sup>	Influenza	Capsules: 75 mg per capsule	2006, Part B	Yes	No <sup>(6)</sup>	Licensed-in patents until the expiry of the relevant patents in March 2024
		Granules: Class V active chemical drug <sup>(1)</sup>		Granules: 15 mg per sachet	2008, Part B	Yes	Provincial <sup>(7)</sup> 2023: six provinces 2024: 20 provinces 2025: 23 provinces	Licensing-in patents until the expiry of the patents in April 2026
	Dongwei'en (Emitasvir Phosphate Capsules) 東衛恩® (磷酸依米他韋膠囊)	Class I chemical drug – innovative drug	Hepatitis C	0.1g per capsule	2022, Part B	No	No	In-house R&D
	Clarithromycin Tablets (克拉霉素片) <sup>(5)</sup>	Class IV chemical drug – generic drug	Infections caused by clarithromycin-sensitive bacteria	250 mg/500 mg per tablet	2004, Part B	Yes	National: 2020-2023 Provincial <sup>(7)</sup> 2024: four provinces 2025: four provinces	In-house R&D

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Therapeutic Area	Major Product	Classification	Indication	Major Dosage Form	Year of First Inclusion in NRDL <sup>(2)</sup>	Inclusion in National Essential Drug List (2018 Version) <sup>(3)</sup>	VBP Scheme <sup>(4)</sup>	In-house R&D/License-in Patents
	Levofloxacin Tablets (左氧氟沙星片) <sup>(5)</sup>	Class IV chemical drug – generic drug	Infections caused by sensitive bacteria	250 mg/500 mg per tablet	2018, Part A	Yes	National: 2021-2024 Provincial <sup>(7)</sup> 2025: 17 provinces	In-house R&D
	Moxifloxacin	Class IV chemical drug – generic drug	Infections caused by sensitive bacteria	400 mg per tablet	2018, Part B	Yes	National: 2020-2023 Provincial <sup>(7)</sup> 2023: four provinces 2024: 20 provinces 2025: 20 provinces	In-house R&D
	Hydrochloride Tablets (鹽酸莫西沙星片) <sup>(5)</sup>							
Chronic diseases . . . . .	Human Insulin Injection (Yibilin R) (人胰島素注射液 (宜必霖R))	Class III biological drug – biosimilar drug	Diabetes	3 ml: 300 IU (prefilled pen-type)	2020, Part A	Yes	National: 2021-2024; 2024-2027	In-house R&D
	Mixed Protamine Human Insulin Injection (30R) (Yibilin 30) (精蛋白人胰島素混合注射液(30R)(宜必霖30®))	Class III biological drug – biosimilar drug	Diabetes	3 ml: 300 IU (prefilled pen-type)	2023, Part A	Yes	National: 2024-2027	In-house R&D
	Insulin Glargine Injection (Yibigan) (甘精胰島素注射液(宜必甘®))	Class III biological drug – biosimilar drug	Diabetes	3 ml: 300 IU (prefilled pen-type)	2021, Part B	Yes	National: 2021-2024; 2024-2027	In-house R&D

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Therapeutic Area	Major Product	Classification	Indication	Major Dosage Form	Year of First Inclusion in NRDL <sup>(2)</sup>	Inclusion in National Essential Drug List (2018 Version) <sup>(3)</sup>	VBP Scheme <sup>(4)</sup>	In-house R&D/License-in Patents
	Insulin Aspart Injection (門冬胰島素注射液)	Class III biological drug – biosimilar drug	Diabetes	3 ml: 300 IU (prefilled pen-type)	2022, Part B	No	National: 2024-2027	In-house R&D
	Insulin Aspart 30 Injection (門冬胰島素30注射液)	Class III biological drug – biosimilar drug	Diabetes	3 ml: 300 IU (prefilled pen-type)	2022, Part B	No	National: 2024-2027	In-house R&D
	Ertongshu (Benzbromarone Tablets) 爾同舒® (苯溴馬隆片)	Class IV active chemical drug <sup>(1)</sup>	Hyperuricemia	25 mg/50 mg per tablet	2004, Part B	Yes	Provincial <sup>(7)</sup> 2025: two provinces	In-house R&D
	Oumeining (Telmisartan Tablets) 歐美寧® (替米沙坦片)	Class II active chemical drug <sup>(1)</sup>	Hypertension	40 mg/80 mg per tablet	2004, Part B	No	National: 2021-2024 Provincial <sup>(7)</sup> 2025: eight provinces	In-house R&D
	Esomeprazole Magnesium Enteric-Coated Capsules (艾司奧美拉唑鎂腸溶膠囊)	Class III chemical drug – generic drug	Stomach acid related diseases	20 mg per capsule	2020, Part B	No	National: 2021-2024 Provincial <sup>(7)</sup> 2025: 17 provinces	In-house R&D
	Olmesartan Medoxomil Tablets (奧美沙坦酯片) <sup>(5)</sup>	Class IV chemical drug – generic drug	Hypertension	20 mg/40 mg per tablet	2019, Part B	No	National: 2020-2023 Provincial <sup>(7)</sup> 2023: four provinces 2024: 22 provinces 2025: 22 provinces	In-house R&D

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*Notes:*

- (1) This drug was registered before the implementation of the new registration classification of chemical drugs and its classification remains the same upon its re-registration.
- (2) The NRDL comprises Part A and Part B. Patients purchasing pharmaceuticals included in Part A of the NRDL are entitled to reimbursement of the entire amount of the purchase price, while patients purchasing pharmaceuticals included in Part B of the NRDL are required to pay a deductible amount and obtain reimbursement for the remainder of the purchase price. The amount of the deductible differs from region to region in the PRC. The market demand for our drugs is sensitive to the coverage of the NRDL. Please see “Risk Factors — Risks Relating to Our Business and Industries — If our products are removed or excluded from national, provincial or other government sponsored medical insurance programs or the National Essential Drug List, our operation, revenue and business prospects in relation to the affected products could be materially and adversely affected.”

In 2022, 2023 and 2024, we had 65, 66 and 66 drugs included in the NRDL, contributing RMB3,693.7 million, RMB6,251.0 million and RMB3,817.6 million in revenue, respectively. Revenue from NRDL drugs decreased significantly from RMB6,251.0 million in 2023 to RMB3,817.6 million in 2024, primarily due to a decrease in the sales volume of Kewei (oseltamivir phosphate). For further details of the decrease in Kewei’s sales volume, see “Business — Sales, Marketing and Distribution — Our Oseltamivir Phosphate Products and the Reasons for the Fluctuation of the Sales of Our Oseltamivir Phosphate Products during the Track Record Period.” Some of the drugs included in the NRDL were also sold through the national and provincial VBP schemes during the Track Record Period.

- (3) The current version of National Essential Drug List is promulgated by the NHC and National Administration of Traditional Chinese Medicine pursuant to the Notice on the Issuance of National Essential Drug List (2018 Version) (關於印發《國家基本藥物目錄(2018年版)》的通知) on September 30, 2018, which became effective on November 1, 2018. The National Essential Drug List is a list of essential medicines designated by the Chinese government to ensure equitable access to healthcare at fair prices. The market demand for our drugs is also sensitive to the coverage of the National Essential Drug List. Please see “Risk Factors — Risks Relating to Our Business and Industries — If our products are removed or excluded from national, provincial or other government sponsored medical insurance programs or the National Essential Drug List, our operation, revenue and business prospects in relation to the affected products could be materially and adversely affected.”
- (4) The VBP scheme aims to achieve a lower price of pharmaceuticals and medical devices center on medical products with mature, high-volume clinical usage and sufficient market competition through a competitive bidding process for large-volume procurement. The VBP scheme has been rolled out at both national and provincial levels. For details of the differences of the national and provincial VBP schemes, see “Regulatory Environment — Principal Regulatory Provisions — Laws and Regulations on Drug Supply — VBP of Drugs in “4+7 Cities” and Nationwide.”

In 2022, 2023 and 2024, we sold 20, 25 and 34 drugs through the national and provincial VBP schemes, contributing RMB341.3 million, RMB946.7 million and RMB1,756.2 million in revenue, respectively. Revenue from VBP scheme drugs increased steadily during the Track Record Period, primarily driven by the increasing number of drugs included in the national and provincial VBP schemes and the increasing number of provinces procuring our Kewei (Oseltamivir Phosphate Granules) through the provincial VBP scheme. Some of the drugs sold through the national and provincial VBP schemes were also included in the NRDL.

- (5) This drug has also been sold overseas. For details of our sales overseas, please see “— Sales, Marketing and Distribution — Sales Outside the PRC.”
- (6) We also sell oseltamivir phosphate capsules in 75 mg doses under the brand Yangjiantai (陽健泰®). Yangjiantai was approved for sale in China in 2022 and was included in the NRDL (Part B) and the National Essential Drug List in the same year. It was also included in the national VBP scheme in 2022 and the cycle is expected to end in 2025. We intend to submit bids for Yangjiantai to be included in the provincial VBP scheme after 2025. During the Track Record Period, Kewei accounted for 99.9%, 99.4% and 96.5% and Yangjiantai accounted for 0.1%, 0.5% and 3.4% of our total sales of oseltamivir phosphate for 2022, 2023 and 2024, respectively. Given the relatively small revenue contribution from Yangjiantai and the fact that we do not plan to conduct large-scale marketing to promote the brand, we do not expect our overall financial and business performance will be significantly impacted by whether Yangjiantai is included in the national VBP scheme or not.
- (7) Represents the number of provinces that procured our products through the provincial VBP scheme in the corresponding year, with the figure for 2025 reflecting the status as of the Latest Practicable Date.

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The following tables set forth the sales volume, average selling price and gross profit margin of our major products and top 10 revenue-generating products for each year during the Track Record Period.

While the majority of the top 10 revenue-generating products during the Track Record Period are our major products, a few products are not recognized as our major products, primarily due to their limited future growth potential. Our major products refer to those that contributed an important portion of our revenue during the Track Record Period or are expected to contribute to our future growth. Linagliptin Tablets remained in the top 10 revenue-generating products from 2022 to 2024, but it is not recognized as a major product, primarily because we did not succeed in its bid for inclusion in the national VBP scheme in 2024, and we anticipate that its provincial VBP scheme will not begin until 2027 after the completion of its current three-year national procurement cycle, leading to limited future growth potential.

No.	Product name	Indication	Dosage form	For the year ended December 31, 2022		
				Sales volume	Average selling price <sup>(1)</sup>	Gross profit/(loss) margin <sup>(2)</sup>
				('000 units)	(RMB/unit)	(%)
1 . . .	Kewei (Oseltamivir Phosphate Capsules)*	Influenza	75 mg per capsule	66,356.3	7.65	89.1
	Kewei (Oseltamivir Phosphate Granules)*		15 mg per sachet	818,073.0	2.98	83.4
	Kewei (Oseltamivir Phosphate Granules)		25 mg per sachet <sup>(9)</sup>	43,715.2	3.30	74.3
	Yangjiantai (Oseltamivir Phosphate Capsules)		75 mg per capsule	5,479.1	0.86	(0.9) <sup>(4)</sup>
2 . . .	Linagliptin Tablets	Diabetes	tablet (pills)	19,012.8	5.35	94.0
3 . . .	Benzbromarone Tablets*	Hyperuricemia	tablet (pills)	79,102.9	1.24	85.0
4 . . .	Esomeprazole Magnesium Enteric-Coated Capsules*	Stomach acid related diseases	capsule (pills)	40,188.1	2.23	59.4
5 . . .	Telmisartan Tablets*	Hypertension	tablet (pills)	152,124.3	0.41	38.5
6 . . .	Clarithromycin*	Infections caused by clarithromycin sensitive bacteria	tablet (pills)	70,179.9	0.75	25.5
7 . . .	Olmesartan Medoxomil Tablets*	Hypertension	tablet (pills)	84,674.5	0.52	61.4
8 . . .	Moxifloxacin Hydrochloride Tablets*	Infections caused by sensitive bacteria	tablet (pills)	17,410.4	1.92	37.7
9 . . .	Tadalafil Tablets	Erectile dysfunction	tablet (pills)	33,426.2	0.90	57.4
10 . .	Levofloxacin Tablets*	Infections caused by sensitive bacteria	tablet (pills)	25,816.6	1.00	50.6
	Insulin Injections* <sup>(3)</sup>	Diabetes	injection (prefilled pen-type)	199.3	62.31	(297.3) <sup>(5)</sup>
	Emitasvir Phosphate Capsules*	Hepatitis C	capsule (pills)	212.4	50.91	67.7

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No.	Product name	Indication	Dosage form	For the year ended December 31, 2023		
				Sales volume	Average selling price <sup>(1)</sup>	Gross profit/(loss) margin <sup>(2)</sup>
				( '000 units)	(RMB/unit)	(%)
1 . . .	Kewei (Oseltamivir Phosphate Capsules)*	Influenza	75 mg per capsule	84,212.4	8.13	91.4
	Kewei (Oseltamivir Phosphate Granules)*		15 mg per sachet	1,439,643.3	3.22	85.4
	Kewei (Oseltamivir Phosphate Granules)		25 mg per sachet <sup>(9)</sup>	48,873.5	4.01	81.8
	Yangjiantai (Oseltamivir Phosphate Capsules)		75 mg per capsule	26,905.5	1.09	17.0
	Kewei (Oseltamivir Phosphate Others)		30 mg per capsule, 45 mg per capsule and 0.36 g per sachet of dry suspension	1,745.4	4.23	18.8
2 . . .	Benzbromarone Tablets*	Hyperuricemia	tablet (pills)	72,084.2	1.32	86.8
3 . . .	Esomeprazole Magnesium Enteric-Coated Capsules*	Stomach acid related diseases	capsule (pills)	43,773.6	2.11	58.3
4 . . .	Telmisartan Tablets*	Hypertension	tablet (pills)	191,504.9	0.41	50.2
5 . . .	Insulin Injections* <sup>(3)</sup>	Diabetes	injection (prefilled pen-type)	1,169.7	59.37	(62.4) <sup>(5)</sup>
6 . . .	Linagliptin Tablets	Diabetes	tablet (pills)	10,997.3	5.16	93.8
7 . . .	Moxifloxacin Hydrochloride Tablets*	Infections caused by sensitive bacteria	tablet (pills)	23,742.5	2.00	30.5
8 . . .	Olmesartan Medoxomil Tablets*	Hypertension	tablet (pills)	83,263.5	0.51	64.0
9 . . .	Clarithromycin*	Infections caused by clarithromycin sensitive bacteria	tablet (pills)	66,458.4	0.63	14.6
10 . .	Emitasvir Phosphate Capsules*	Hepatitis C	capsule (pills)	800.9	50.77	73.7
	Levofloxacin Tablets*	Infections caused by sensitive bacteria	tablet (pills)	30,283.2	0.98	60.5

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No.	Product name	Indication	Dosage form	For the year ended December 31, 2024		
				Sales volume	Average selling price <sup>(1)</sup>	Gross profit/(loss) margin <sup>(2)</sup>
				('000 units)	(RMB/unit)	(%)
1 . . .	Kewei (Oseltamivir Phosphate Capsules)*	Influenza	75 mg per capsule	47,628.3	6.44	90.0
	Kewei (Oseltamivir Phosphate Granules)*		15 mg per sachet	735,522.2	2.97	86.4
	Yangjiantai (Oseltamivir Phosphate Capsules)		75 mg per capsule	79,001.3	1.11	41.7
	Kewei (Oseltamivir Phosphate Others)		30 mg per capsule, 45 mg per capsule and 0.36 g per sachet of dry suspension	173.8	25.95	51.6
2 . . .	Esomeprazole Magnesium Enteric-Coated Capsules*	Stomach acid related diseases	capsule (pills)	87,403.3	2.36	89.5 <sup>(6)</sup>
3 . . .	Linagliptin Tablets	Diabetes	tablet (pills)	35,672.2	5.28	95.0
4 . . .	Insulin Injections* <sup>(3)</sup>	Diabetes	injection (prefilled pen-type)	4,066.6	33.61 <sup>(7)</sup>	(13.7) <sup>(5)</sup>
5 . . .	Telmisartan Tablets*	Hypertension	tablet (pills)	269,733.1	0.41	47.9
6 . . .	Benzbromarone Tablets*	Hyperuricemia	tablet (pills)	85,947.7	1.27	84.7
7 . . .	Emitasvir Phosphate Capsules*	Hepatitis C	capsule (pills)	1,763.6	50.74	76.5
8 . . .	Olmesartan Medoxomil Tablets*	Hypertension	tablet (pills)	115,616.2	0.51	70.3
9 . . .	Rivaroxaban Tablets	Thrombosis	tablet (pills)	531,912.3	0.11	53.1
10 . .	Moxifloxacin Hydrochloride Tablets*	Infections caused by sensitive bacteria	tablet (pills)	27,982.7	1.72	49.0
	Clarithromycin*	Infections caused by clarithromycin sensitive bacteria	tablet (pills)	83,902.8	0.51	1.1 <sup>(8)</sup>
	Levofloxacin Tablets*	Infections caused by sensitive bacteria	tablet (pills)	30,176.4	0.91	69.9

**Notes:**

- \* It refers to our major products, which contributed an important portion of our revenue during the Track Record Period or are expected to contribute to our future growth.



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- (1) Average selling price is calculated by dividing revenue by sales volume which includes sales through VBP and non-VBP.
- (2) The gross profit margin is calculated based on sales generated from both VBP and non-VBP.
- (3) Our insulin products include (i) Human Insulin Injection, (ii) Mixed Protamine Human Insulin Injection (30R), (iii) Insulin Glargine Injection, (iv) Insulin Aspart Injection, and (v) Insulin Aspart 30 Injection. Mixed Protamine Human Insulin Injection (30R) was approved for sale in 2023 and we started generating revenue from its sales in 2024.
- (4) The gross loss margin of Yangjiantai (Oseltamivir Phosphate Capsules) in 2022 was due to high unit costs, primarily driven by low sales volume and small-scale manufacturing.
- (5) The gross loss margin of our Insulin Injections during the Track Record Period was due to high unit costs, resulting from low utilization rates of the Insulin Injection production line. However, gross loss margin improved during each year of the Track Record Period due to a decrease in manufacturing costs per unit, as we benefitted from economies of scale resulting from the increased production capacity of our Insulin Injections.
- (6) The increase in gross profit margin of Esomeprazole Magnesium Enteric-Coated Capsules in 2024 was primarily due to the higher sales volume, which helped reduce per-unit costs by spreading fixed amortization across more units, along with the increase in the average selling price.
- (7) The decrease in average selling price of our Insulin Injections was due to three out of the five insulin products being included in the national VBP scheme starting in 2024.
- (8) The decrease in gross profit margin of Clarithromycin in 2024 was due to the decrease in the average selling price, resulting from the increased sales volume of Clarithromycin Tablets (250 mg and 500 mg) driven by the VBP scheme.
- (9) We stopped selling Kewei (Oseltamivir Phosphate Capsules) (25 mg) since 2024.

During the Track Record Period, we manufactured and mainly sold drugs in China. Meanwhile, some of our major generic drugs for the treatment of infectious diseases and chronic diseases such as Clarithromycin, Levofloxacin, Moxifloxacin Hydrochloride and Olmesartan Medoxomil were also approved for sale overseas. For details of our sales outside China, please see “— Sales, Marketing and Distribution — Sales Outside the PRC.” During the Track Record Period, we also conducted R&D collaboration projects with overseas partners. Please see “— Research and Development — Collaboration and Licensing Agreements” for further details. In 2022, 2023 and 2024, our overseas revenue from sales of drugs and license fee generated from overseas R&D collaboration projects was RMB60.4 million, RMB49.7 million and RMB138.4 million, respectively.

**Infectious Diseases**

According to the Frost & Sullivan Report, the market size of anti-infective drugs in China reached RMB190.3 billion in 2023 and is expected to increase to RMB204.5 billion and RMB221.5 billion in 2026 and 2030, respectively.

Our existing anti-infective product portfolio mainly includes (i) our top-selling product, Kewei (oseltamivir phosphate), for the treatment of influenza, (ii) one innovative drug developed in-house, Dongweien (emitasvir phosphate), for the treatment of hepatitis C, and (iii) three generic drugs for the treatment of infections caused by sensitive bacteria, namely Clarithromycin, Levofloxacin and Moxifloxacin Hydrochloride. In 2022, 2023 and 2024, our revenue from sales of anti-infective drugs was RMB3,242.5 million, RMB5,745.8 million and RMB2,797.6 million, respectively, accounting for 85.0%, 90.0% and 69.6% of our total revenue for the same periods, respectively.

In 2022, 2023 and 2024, our revenue from sales of Oseltamivir Phosphate accounted for a significant portion of our revenue from sales of anti-infective products for the same periods, respectively. Our anti-infective product portfolio excluding Oseltamivir Phosphate has also established itself as a stable cash flow generator with consistent revenue growth. In 2022, 2023 and 2024, our revenue from sales of our major anti-infective drugs (Oseltamivir Phosphate, Clarithromycin, Moxifloxacin Hydrochloride Tablets, Emitasvir Phosphate Capsules and Levofloxacin Tablets) excluding Oseltamivir Phosphate was RMB122.3 million, RMB159.8 million and RMB208.4 million, respectively, representing a CAGR of 30.5% from 2022 to 2024. Key drugs including Emitasvir Phosphate, Clarithromycin, Levofloxacin and Moxifloxacin Hydrochloride have been included in the NRDL, with the latter three further succeeding in VBP schemes at national and provincial levels, demonstrating strong market acceptance. To increase the sales of Emitasvir Phosphate, we plan to cooperate with health authorities such as the National Health Commission of the People's Republic of China to conduct education campaigns on hepatitis C to identify and target more hepatitis C patients. To ramp up the sales of Clarithromycin, Levofloxacin and Moxifloxacin Hydrochloride, we plan to further expand their provincial VBP schemes to cover more provinces. We also plan to strengthen hospital-to-retail integration via partnerships with leading pharmacy chains, converting in-hospital prescriptions into sustainable retail channel growth. This dual approach enhances patient accessibility to affordable treatment while maintaining operational efficiency across distribution networks.

### *Influenza*

According to the Frost & Sullivan Report, the market size of anti-influenza drugs (excluding traditional Chinese medicines) in China was RMB6.7 billion in 2024 and is expected to increase to RMB10.1 billion and RMB11.6 billion in 2026 and 2030, respectively.

*Commercialized Product — Kewei (Oseltamivir Phosphate Granules/Capsules) 可威® (磷酸奥司他韦颗粒/胶囊)*



Kewei (Oseltamivir Phosphate Granules/Capsules), our top-selling product, is an anti-influenza drug. According to the Frost & Sullivan Report, our Kewei (oseltamivir phosphate) ranked first in the Chinese oseltamivir phosphate market, and our oseltamivir phosphate products had a market share of 54.8% in 2024, and accounted for 38.5% of the Chinese anti-influenza drug market in terms of sales revenue in 2024. Oseltamivir Phosphate targets neuraminidase, an enzyme on the surface of influenza viruses.

Kewei (oseltamivir phosphate) has been mainly sold in the dosage forms of capsules and granules in China. We have been manufacturing and selling Oseltamivir Phosphate Capsules in China since June 2006 after obtaining the right to use certain patents relating to oseltamivir phosphate. Our Oseltamivir Phosphate Capsules, typically sold in 75 mg doses, are primarily used for the prevention and treatment of influenza in adults. In November 2008, we introduced Oseltamivir Phosphate Granules specifically designed for the treatment of influenza in children. Our Oseltamivir Phosphate Granules, typically sold in 15 mg doses, are primarily used for the prevention and treatment of influenza in children over one year of age. The granule formulation allows for accurate dosing, and each sachet of 15 mg dose maintains its effectiveness and safety over time, making it safer and more convenient for children.

During the Track Record Period, Kewei (oseltamivir phosphate) contributed a significant portion of our revenue. In 2022, 2023 and 2024, our revenue from sales of Oseltamivir Phosphate was RMB3,097.4 million, RMB5,546.1 million and RMB2,580.7 million,

respectively, accounting for 95.5%, 96.5% and 92.3% of our revenue from sales of anti-infective products for the same periods, respectively, and accounting for 81.2%, 86.9% and 64.2% of our total revenue for the same periods, respectively.

The sales of Kewei (oseltamivir phosphate) are subject to seasonality, with peak demand occurring during the winter-spring flu seasons in China (typically November through March), when influenza activity reaches its highest levels. Conversely, during periods of low influenza activity, particularly summer months (June through August), demand for Kewei (oseltamivir phosphate) experiences declines. According to the World Health Organization (WHO), influenza viruses are classified into four types: Type A, Type B, Type C, and Type D. Among them, Type A and Type B influenza viruses circulate widely among humans and are the primary causative virus of seasonal influenza epidemics. During the Track Record Period, the flu outbreaks in China are mostly caused by Type A or Type B influenza viruses and oseltamivir phosphate has been proven to be effective against both Type A or Type B influenza viruses. Please refer to “Risk Factors — Risks Relating to Our Business and Industries — Our revenue and business prospects currently depend on Kewei (oseltamivir phosphate). If we are unable to maintain the sales volumes, pricing levels and profit margins of Kewei, our revenue and business prospects could be materially and adversely affected.” for further details.

### Product Advantages

- ***Efficacy and convenience.*** Oseltamivir Phosphate has a proven clinical efficacy and is currently one of the most widely used anti-influenza drugs in China. Among all anti-influenza drugs available in China, Oseltamivir Phosphate stands out as the only neuraminidase inhibitor available in an oral formulation, offering the convenience of both treatment and prevention.
- ***High safety and good compliance.*** Oseltamivir Phosphate is the preferred choice for treating influenza in children. For children over one year of age, Oseltamivir Phosphate Granules can be accurately administered in multiples of 15 mg per sachet, simplifying the complex dispensing process associated with other pediatric formulations and enhancing the convenience and accuracy of medication for children.
- ***Low drug resistance.*** The risk of drug resistance is low during the clinical application of Oseltamivir Phosphate and Oseltamivir Phosphate is recommended as a daily anti-influenza medication.

### Market Opportunities and Competitive Landscape

Oseltamivir Phosphate has been recommended by various international and PRC guidelines for the treatment of influenza. Oseltamivir Phosphate was listed as an “essential medicine” in the World Health Organization (WHO) Model List of Essential Medicines and was also recommended by the U.S. Centers for Disease Control as one of the key antiviral medicines for the treatment of influenza and the treatment of avian influenza viruses, including H5N1. In China, Oseltamivir Phosphate was recommended as the first-line antiviral drug for the treatment of influenza in a number of clinical practice guidelines, including the Expert Consensus on Antiviral Treatment of Influenza in Adults (《成人流行性感胃抗病毒治療專家共識》), Expert Consensus on Emergency Treatment of Influenza in Adults (2022 Edition) (《成人流行性感胃診療規範急診專家共識(2022版)》), and Expert Consensus on Diagnosis and Treatment of Influenza in Children (2020) (《兒童流感診斷與治療專家共識(2020年版)》). According to the Frost & Sullivan Report, the sales revenue of drugs sold under the generic name of oseltamivir phosphate reached RMB4.7 billion in 2024, accounting for 70.3% of the anti-influenza drug market in China in terms of sales revenue for the same period.

We were among the first few PRC pharmaceutical companies to secure the right to use key patents relating to the oseltamivir phosphate, granting us a first-mover advantage in the manufacturing and selling Oseltamivir Phosphate Capsules in the PRC. The key patents relating to the oseltamivir phosphate were licensed from a Switzerland-based global pharmaceutical company that holds the rights to certain patents relating to oseltamivir phosphate (an Independent Third Party, the “**Oseltamivir Phosphate Licensor**”), under a licensing agreement with Shenzhen HEC Industrial, one of our controlling shareholders. The oseltamivir phosphate licensing agreement was first signed in 2006 and had been renewed, remaining valid until the expiration of the last patent among the licensed patents in March 2024 (the “**Oseltamivir Phosphate Licensing Agreement**”). The licenses under the Oseltamivir Phosphate Licensing Agreement covered several key patents relating to oseltamivir phosphate compound and oseltamivir phosphate synthetic process for manufacturing oseltamivir phosphate API and Oseltamivir Phosphate Capsules. The key patents relating to oseltamivir phosphate compound began to expire in August 2017, with the final key patent relating to oseltamivir phosphate synthetic process expired in March 2024. Despite the expiry of the initial patents in August 2017, the in-licensing arrangement with the Oseltamivir Phosphate Licensor remained necessary due to the continued validity of the Oseltamivir Phosphate Licensing Agreement until the expiration of the last patent in March 2024. Under the terms of the Oseltamivir Phosphate Licensing Agreement, Shenzhen HEC Industrial has been granted the right to manufacture and sell oseltamivir phosphate API and Oseltamivir Phosphate Capsules in the PRC, and we were irrevocably and royalty-free authorized to exercise such rights in the PRC pursuant to a separate sublicense agreement between Shenzhen HEC Industrial and our Company. The license from the Oseltamivir Phosphate Licensor to Shenzhen HEC Industrial was non-exclusive and included a royalty fee arrangement based on the sales amount of our oseltamivir phosphate API and Oseltamivir Phosphate Capsules, which was directly paid to the Oseltamivir Phosphate Licensor by us.

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## BUSINESS

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We believe the expiry of the patent in March 2024 does not have any material negative impact on our business for the following reasons:

- (i) The key patents under the Oseltamivir Phosphate Licensing Agreement relating to oseltamivir phosphate compound began to expire in August 2017, with the final patent relating to oseltamivir phosphate synthetic process which is used in the manufacturing the of oseltamivir phosphate products expired in March 2024. Despite the expiry of the initial patents in August 2017, the in-licensing arrangement with the Oseltamivir Phosphate Licensor remained necessary due to the continued validity of the Oseltamivir Phosphate Licensing Agreement until the expiration of the last patent in March 2024. Since 2017, other pharmaceutical companies have been producing and selling oseltamivir phosphate capsule products by using different oseltamivir phosphate manufacturing processes. As a result, our oseltamivir phosphate capsule drug has been competing with other oseltamivir phosphate producers since 2017.
- (ii) The expiry of oseltamivir phosphate patent in 2017 had no material impact on the sales of our Kewei products during the period from 2016 to 2019 mainly because (i) the patent on our Kewei granules will not expire until 2026 and (ii) our competitors on Kewei capsules were relatively small with limited production capacity and small market share during the period from 2016 to 2019 and therefore, we did not face intensive competitions from those competitors during such period. We believe that the patent expiry in March 2024 doesn't have a major impact on the competitive landscape for oseltamivir phosphate capsule as it is not a patent necessary for the other oseltamivir phosphate producers for oseltamivir phosphate production and according to Frost & Sullivan, the number of oseltamivir phosphate capsule producers in the PRC remained stable before and after the expiry of such patent in March 2024.
- (iii) During the period from 2016 to 2019, being the period from one year before to two years after the year when the patents in connection with oseltamivir phosphate started to expire in 2017, our sales of oseltamivir phosphate increased rapidly and the average selling prices for our oseltamivir phosphate products remained relatively stable which shows the expiry of patents relating to oseltamivir phosphate does not have a material impact on our business.
- (iv) The drop of our revenue in 2024 as compared with our revenue in 2023 was mainly caused by the decrease in sales volume of our oseltamivir phosphate products as a result of (a) a drop in influenza incidence in China in 2024 as compared to that of 2023; (b) an increase in the sales volume of oseltamivir phosphate capsules sold in public hospitals through the VBP scheme which coupled with the drop in influenza incidence in China in 2024, further reduced the clinical demand for our Kewei from the public hospitals. For a detailed analysis on the reasons for the drop of our revenue in 2024, please see "Business — Sales, Marketing and Distribution — Our



Oseltamivir Phosphate Products and the Reasons for the Fluctuation of the Sales of Our Oseltamivir Phosphate Products during the Track Record Period”; and (c) increasingly intense competition oseltamivir phosphate is facing from other types of anti-influenza drugs.

The patents relating to Oseltamivir Phosphate Granules were originally developed by the Poisons and Drugs Research Office of the Medical Science Academy of the PRC People’s Liberation Army (中國人民解放軍軍事醫學科學院毒物藥物研究所), a research institute primarily focused on research and development of antiviral drugs (an Independent Third Party, the “**Poisons and Drugs Research Office**”). We became acquainted with the Poisons and Drugs Research Office through our participation in an oseltamivir phosphate research program in 2004. The patents relating to Oseltamivir Phosphate Granules were first exclusively licensed to us in 2006 under a written agreement, which was set to expire on June 8, 2015 with a royalty fee arrangement based on the consumption of oseltamivir phosphate API used in granule production. These patents were subsequently transferred to us in May 2015, with a royalty fee arrangement based on the sales amount of Oseltamivir Phosphate Granules, effective until the expiry of the relevant patents in April 2026. This arrangement was adopted as the consideration for the transfer, with the transfer fee structured as post-sale royalty payments to reduce the financial burden of a one-time lump-sum payment. The Poisons and Drugs Research Office agreed to the transfer in recognition of our commitment to researching and developing anti-viral drugs as well as our strong sales network and promotional capabilities. The transfer in 2015 was also a strategic move to ensure our long-term use and avoid uncertainties on renewing the licensing agreement after the expiry of the initial licensing agreement for Oseltamivir Phosphate Granules in the PRC. The current patents relating to Oseltamivir Phosphate Granules are valid until April 2026.

We can still manufacture and sell Oseltamivir Phosphate in the form of capsule and granules after the expiry of patents relating to Oseltamivir Phosphate Capsules and Granules. We do not consider the expiry of such patents to have a material impact on our business in the short to medium term. According to the Frost & Sullivan Report, our Kewei (oseltamivir phosphate) ranked first in the Chinese oseltamivir phosphate market, and our oseltamivir phosphate products had a market share of 54.8% in 2024, and accounted for 38.5% of the Chinese anti-influenza drug market in terms of sales revenue in 2024. According to the Frost & Sullivan Report, we ranked first in the PRC in terms of cumulative oseltamivir phosphate production volume over a period of five years from 2019 to 2023, we ranked first in the PRC in terms of cumulative oseltamivir phosphate shipments over a period of five years from 2019 to 2023, and we had the largest scale of oseltamivir phosphate production facilities in the PRC in terms of floor area in 2023. As the number one PRC pharmaceutical company in terms of anti-viral drug sales in the PRC, our brands in relation to our anti-viral products have been widely recognized in the industry and among our patients according to the Frost & Sullivan Report. Over a decade of development and continued efforts, we have also established a comprehensive oseltamivir phosphate production line in China with a supply chain system from starting materials to finished formulations. Our Yidu production base is the largest Kewei (oseltamivir phosphate) production base in the PRC. Leveraging on our outstanding brand recognition and production capacity, we believe that Kewei (oseltamivir phosphate) will



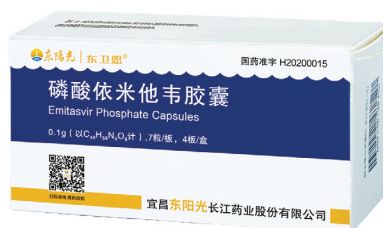
continue to have significant competitive advantages over competitor products in the Chinese anti-influenza drug market. In 2023, Kewei (oseltamivir phosphate) was listed on the brand list of the “2023 Health Industry Brand List of the Health Industry (International) Ecological Conference (健康產業(國際)生態大會2023健康產業品牌榜)” and the “Hospital Terminal of China’s Pharmaceutical Brands (中國醫藥品牌榜醫院終端)”. It also won the “Award for Single Product with the Most Collaborative Value for Chinese Pharmacy Chains (中國連鎖藥店最具合作價值單品獎)” and the for the third time, the “Gold Award of the Health Industry (International) Ecological Conference (健康產業(國際)生態大會金獎)”.

### *Hepatitis C*

According to the Frost & Sullivan Report, the total number of patients diagnosed with chronic hepatitis C in China was 2.6 million in 2023 and is expected to increase to 2.8 million and 3.1 million in 2026 and 2030, respectively. The PRC government has announced policies such as the Work Plan for the Elimination of Public Health Hazards of Hepatitis C (2021-2030) (《消除丙肝公共衛生危害行動工作方案(2021-2030年)》) to improve hepatitis C diagnosis and treatment. This will drive the growth of the anti-hepatitis C drug market in China. Before the DAAs for hepatitis C were approved for launching in China, hepatitis C was predominantly treated with a combination of Interferon and Ribavirin. With the launch of DAAs that have high sustained virologic response (“SVR”) in the Chinese market, the cure rate of hepatitis C has been greatly improved. According to the Guidelines for Prevention and Treatment of Hepatitis C (2022 Edition) (《丙型肝炎防治指南(2022年版)》) (the “**2022 Guidelines**”), the Interferon-free pan-genotypic regimen is the preferred treatment recommendation, achieving over 90% SVR in HCV-infected individuals with known primary genotypes and sub-genotypes. The application of the pan-genotypic regimen can reduce pre-treatment testing and in-treatment monitoring, making it more suitable for the treatment and management of chronic HCV infections.

We have one commercialized Class I innovative drug for the treatment of genotype-specific chronic hepatitis C and two approved Class I innovative drugs for the treatment of pan-genotypic chronic hepatitis C. During the Track Record Period, we mainly manufactured and sold one Class I innovative anti-HCV drug developed in-house, namely Dongweien (emitasvir phosphate). We also have two approved Class I innovative anti-HCV drugs, namely Dong’antai (Netanasvir Phosphate) and Dong’anqiang (Encofosbuvir), which were approved by the NMPA for launching in China in February 2025 and March 2025, respectively. For details, see “— Our Product Pipeline — Infectious Diseases — Approved Product — The Combination Treatment Regimen of Dong’antai (Netanasvir Phosphate Capsules) and Dong’anqiang (Encofosbuvir Tablets) (磷酸奈坦司韋膠囊/艾考磷布韋片聯用治療方案).”

*Commercialized Product — Dongweien (Emitasvir Phosphate Capsules) 東衛恩® (磷酸依米他韋膠囊)*



Dongweien (Emitasvir Phosphate Capsules) is a domestic in-house R&D Class I innovative drug for the treatment of genotype 1 chronic hepatitis C, which is an inhibitor targeting HCV NS5A, capable of inhibiting HCV assembly and replication.

Dongweien was approved by the NMPA for launching in China in December 2020 and included in the NRDL in January 2022.

Emitasvir Phosphate combined with Sofosbuvir has shown a high clinical cure rate in Phase II and III trials, achieving an SVR12 of 99.5% (424/426) in patients with chronic genotype 1 HCV in China. The effectiveness of Dongweien is not affected by factors like baseline NS5A resistance, gender, or age. It also has a strong safety profile and is suitable for individuals with special health conditions. Based on clinical trial results, Emitasvir Phosphate has been proven to be effective and safe for patients with varying degrees of kidney dysfunction or mild to moderate liver dysfunction. As of the Latest Practicable Date, Dongweien has been recommended by the Guidelines for Prevention and Treatment of Hepatitis C (2022 Edition) (《丙型肝炎防治指南(2022年版)》).

We sell Dongweien in capsule form. Each capsule contains 0.1g of Emitasvir Phosphate (calculated as C<sub>49</sub>H<sub>58</sub>N<sub>8</sub>O<sub>6</sub>). In 2022, 2023 and 2024, our revenue from sales of Dongweien was RMB10.8 million, RMB40.7 million and RMB89.5 million, respectively, representing a CAGR of 187.6% from 2022 to 2024.

### ***Other Commercialized Products for Infectious Diseases***

During the Track Record Period, in addition to Oseltamivir Phosphate and Emitasvir Phosphate, we also manufactured and sold three major anti-infective generic drugs (namely Clarithromycin, Levofloxacin and Moxifloxacin Hydrochloride for the treatment of infections caused by sensitive bacteria) in terms of revenue contribution during the Track Record Period. In 2022, 2023 and 2024, our revenue from sales of these three major anti-infective generic drugs was RMB111.5 million, RMB119.3 million and RMB118.9 million, respectively, accounting for 3.4%, 2.1% and 4.3% of our revenue from sales of anti-infective products for the same periods, respectively, and accounting for 2.9%, 1.9% and 3.0% of our total revenue for the same periods, respectively.

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The following table sets forth the selected information of the three major anti-infective generic drugs that we sold during the Track Record Period.

Product name	Product image	Brief description
Clarithromycin Tablets (克拉霉素片) . . . . .		Clarithromycin is a macrolide antibiotic. This medicine is used to treat certain bacterial infections, such as pneumonia (a lung infection), bronchitis (infection of the tubes leading to the lungs), and infections of the ears, sinuses, skin, and throat. It is also used to treat and prevent disseminated Mycobacterium avium complex (MAC) infection. It is used in combination with other medications to eliminate H. pylori, a bacterium that causes stomach ulcers.
Levofloxacin Tablets (左氧氟沙星片) . . . . .		Levofloxacin is a quinolone antibiotic. This medicine is used to treat certain infections such as pneumonia, and kidney, prostate, and skin infections. Levofloxacin is also used to prevent anthrax in people who may have been exposed to anthrax germs in the air and treat and prevent plague.
Moxifloxacin Hydrochloride Tablets (盐酸莫西沙星片) . . . . .		Moxifloxacin is a quinolone antibiotic. This medicine is used to treat certain infections caused by bacteria such as pneumonia, and skin, and abdominal (stomach area) infections. It is also used to prevent and treat plague, including pneumonic and septicemic plague.

**Chronic Diseases**

According to the Medium- and Long-Term Plan for the Prevention and Treatment of Chronic Diseases in China (2017-2025) (《中國防治慢性病中長期規劃(2017-2025)》) promulgated by the PRC government, chronic diseases account for 86.6% of total deaths of all diseases and the related costs for treatment of chronic disease accounts for over 70% of the total costs for treatment of all diseases, indicating significant prospects in the drug market for the treatment of chronic diseases.

Our commercialized chronic disease treatment drugs primarily focuses on the treatment of diabetes, hyperuricemia, hypertension and stomach acid related disease, including five insulin products and four major generic drugs. In 2022, 2023 and 2024, our revenue generated from sales of chronic disease treatment drugs was RMB517.3 million, RMB580.7 million and RMB1,067.7 million, accounting for 13.6%, 9.1% and 26.6% of our total revenue for the same periods, respectively. For details of our five insulin products, please see “— Diabetes — Commercialized Products — Insulins in China.” For details of the four major generic drugs, namely Benzbromarone, Telmisartan, Olmesartan Medoxomil and Esomeprazole Magnesium, for the treatment of hyperuricemia, hypertension and stomach acid related disease in the therapeutic areas of chronic diseases that we sold during the Track Record Period, please see “— Other Commercialized Products for Chronic Diseases.”

Our chronic disease treatment drug portfolio has also witnessed consistent revenue growth during the Track Record Period. In 2022, 2023 and 2024, our revenue from sales of chronic disease treatment drugs was RMB517.3 million, RMB580.7 million and RMB1,067.7 million, respectively, representing a CAGR of 26.8% from 2022 to 2024. All our major chronic disease treatment drugs have been included in the NRDL and VBP schemes at either national or provincial levels. With all of our five insulin products being included in the national VBP scheme, we expect their sales growth will continue, which will further drive revenue growth of our chronic disease treatment drugs. To ramp up the sales of our major chronic disease treatment drugs, we plan to leverage on the advantage that our insulin products have already entered value-based procurement at the national level to expand their coverage across regions. We also plan to strengthen hospital-to-retail integration by collaborating with leading pharmacy chains to ensure our drugs can be easily accessed outside of hospital. Furthermore, we plan to enhance medical education through national and regional workshops, including our Discover HEC (“走進東陽光”) program, to promote our brand image. For details of our Discover HEC program, see “— Sales, Marketing and Distribution.”

***Diabetes***

According to the Frost & Sullivan Report, the global market of diabetes drugs reached US\$92.8 billion in 2023 and is expected to increase to US\$112.8 billion and US\$132.6 billion in 2026 and 2030, respectively. In China, the market size of diabetes drugs reached RMB67.6 billion in 2023 and is expected to increase to RMB90.3 billion and RMB122.3 billion in 2026 and 2030, respectively. The current treatment regimen for diabetes often involves a combination of lifestyle changes and medication, with the goal of managing blood glucose levels and preventing complications. Medications mainly include traditional oral drugs, insulin and its analogs, GLP-1 receptor agonists, and SGLT-2 inhibitors. Even though new diabetes drugs such as GLP-1 drugs and SGLT-2 drugs are relatively new to the China's diabetes drug market, they had rapid growth over the past years. For details of the diabetes drug market, please see "Industry Overview — Overview of the Metabolic Diseases Drug Market in China — Overview of the Diabetes Drug Market."

Our commercialized products for the treatment of diabetes include five insulin products and several oral drugs. As of the Latest Practicable Date, we have also established a comprehensive drug pipeline for the treatment of diabetes, including (i) one innovative drug candidate (namely Dongjiantang (Ologliflozin)), for which we have submitted the NDA to the NMPA, (ii) two insulins (namely Guangjianyou (Insulin Glargine Injection) and Guangjiantan (Insulin Aspart Injection)) that we have been developing in collaboration with Lannett in the U.S., (iii) one innovative dual-targeted GLP-1/FGF21 drug candidate (namely Guangjianbao (HEC88473)) in Phase II clinical trial, (iv) two insulin analogs (namely Guangjianda (Insulin Degludec Injection) and Guangjianshu (Insulin Degludec/Insulin Aspart Injection)) for which we submitted the BLAs to the NMPA in January and June 2025, respectively, and (v) two GLP-1 receptor agonists (namely Liraglutide Injection and Guang Jian Cheng (Dulaglutide Injection)) in clinical trials. We started the R&D of biosimilars at an early stage and we are capable of industrializing a wide range of insulins and in-house R&D of GLP-1 receptor agonists, according to the Frost & Sullivan Report. We believe our diverse drug portfolio and comprehensive drug pipeline for the treatment of diabetes could enhance our competitive advantages and have the potential to satisfy the unmet medical needs for various diabetes drugs in China. For details, see "— Our Product Pipeline — Chronic Diseases — Approved Product — The Combination Treatment Regimen of Dong'antai (Netanasvir Phosphate Capsules) and Dong'anqiang (Encofosbuvir Tablets) (磷酸蔡坦司韋膠囊/艾考磷布韋片聯用治療方案)."

***Commercialized Products — Insulins in China***




According to the Frost & Sullivan Report, the market size of insulin and its analogs in China reached RMB18.3 billion in 2023. Despite the current dominance of overseas pharmaceutical companies in the insulin market in China, a clear trend towards PRC substitution is emerging.

We have a wide range of insulin products, covering the most widely used mealtime insulin, premixed insulin, and basal insulin. Clinically, our products can cater to the medication needs of various patient subgroups and accommodate the prescribing habits of different physicians, including combinations of premixed, long-acting, and intensified insulin regimens.



We had five insulin products sold in China, namely (i) Human Insulin Injection, (ii) Mixed Protamine Human Insulin Injection (30R), (iii) Insulin Glargine Injection, (iv) Insulin Aspart Injection, and (v) Insulin Aspart 30 Injection. Mixed Protamine Human Insulin Injection (30R) was approved for sale in 2023 and we started generating revenue from its sales in 2024. In 2022, 2023 and 2024, our revenue from sales of our insulin products was RMB12.4 million, RMB69.4 million and RMB136.7 million, respectively, accounting for 2.4%, 12.0% and 12.8% of our revenue from sales of chronic disease treatment products for the same periods, respectively, representing a CAGR of 231.8% from 2022 to 2024.

All of our five insulin products have been included in the national VBP schemes as of the Latest Practicable Date, and we expect the sales revenue of our insulin products will further increase. In addition, we believe our diverse drug portfolio for the treatment of diabetes will also enhance our insulin products' competitive advantages in the insulin and its analogs market in China.

The following table sets forth the selected information of our five insulin products, including insulin and its analog:

Product name	Product image	Brief description
Human Insulin Injection (Yibilin R) (人胰岛素注射液(宜必霖R)) . . . . .		This product is a short-acting insulin for the treatment of hyperglycemia caused by type 1 and type 2 diabetes.
Mixed Protamine Human Insulin Injection (30R) (Yibilin 30) (精蛋白人胰岛素混合注射液(30R)(宜必霖30®)) . . . .		This product is a dual-action insulin formulation designed for the treatment of diabetes, consisting of 30% soluble human insulin and 70% protamine human insulin, providing both short-acting and intermediate-acting insulin. It effectively controls after meal blood glucose and fasting blood glucose.
Insulin Glargine Injection (Yibigan)(甘精胰岛素注射液(宜必甘®)) . . . . .		This product is a long-acting insulin analog used to regulate blood glucose levels in patients with type 1 and type 2 diabetes. It is administered subcutaneously once daily at a consistent time.

## BUSINESS

Product name	Product image	Brief description
Insulin Aspart Injection (門冬胰島素注射液) . . .		This product is a rapid-acting insulin analog used to control high blood glucose in adults and children with diabetes. It is typically used in combination with a longer-acting insulin.
Insulin Aspart 30 Injection (門冬胰島素30 注射液) . . . . .		This product is a mixed insulin formulation that contains 30% soluble insulin aspart, a rapid-acting insulin, and 70% protamine-crystallised insulin aspart, an intermediate-acting insulin. This product can be used as a standalone treatment for type 2 diabetes.

### *Other Commercialized Products for Chronic Diseases*

During the Track Record Period, in addition to the five biosimilar insulins, we also manufactured and sold four major generic drugs for the treatment of chronic diseases (namely Benzbromarone, Telmisartan, Esomeprazole Magnesium and Olmesartan Medoxomil) in terms of revenue contribution during the Track Record Period. In 2022, 2023 and 2024, our revenue from sales of the above four generic drugs for the treatment of chronic diseases was RMB295.5 million, RMB307.8 million and RMB485.4 million, respectively, accounting for 57.1%, 52.0% and 45.5% of our revenue from sales of chronic disease treatment products for the same periods, respectively, and accounting for 7.7%, 4.8% and 12.1% of our total revenue for the same periods, respectively.

The following table sets forth the selected information of the four major generic drugs for the treatment of chronic diseases that we sold during the Track Record Period.

Product name	Product image	Brief description
Ertongshu (Benzbromarone Tablets) 爾同舒® (苯溴馬隆片) . . . . .		Benzbromarone is used for the treatment of excess uric acid in blood (hyperuricemia), which could often lead to gout.



## BUSINESS

Product name	Product image	Brief description
Oumeining (Telmisartan Tablets) 歐美寧® (替米沙坦片) . . . . .		Telmisartan is used for the treatment of high blood pressure (hypertension) and works by relaxing blood vessels to help reduce blood pressure. Telmisartan is an angiotensin II receptor antagonist used for the treatment and prevention of hypertension.
Esomeprazole Magnesium Enteric-Coated Capsules (艾司奥美拉唑 镁肠溶胶囊) . . . . .		Esomeprazole is mainly used for the treatment of stomach acid related disease. Esomeprazole is a second-generation proton pump inhibitor, which is derived from omeprazole and has better safety profile. The drug is also used to treat gastroesophageal reflux disease, eradicating helicobacter pylori in combination with appropriate antibacterial therapies, and in patients requiring continuous non-steroidal anti-inflammatory drugs treatment.
Olmesartan Medoxomil Tablets (奥美沙坦酯片) .		Olmesartan is used for the treatment of hypertension. Olmesartan is an angiotensin receptor blocker. Olmesartan may be used alone or in combination with other antihypertensive agents.

### Our Product Pipeline

As of the Latest Practicable Date, we had a diverse and robust pipeline of 49 Class I innovative drug candidates in the therapeutic areas of infectious diseases, chronic diseases and oncology in China. The research and development of our drug candidates in the pipeline is primarily driven by our in-house R&D. Our major innovative drug candidates mainly comprise (i) one Class I innovative drug candidate, for which we have submitted the NDA to the NMPA, and (ii) ten Class I innovative drug candidates in Phase II or Phase III clinical trials. For details of each of our major innovative drug candidates and their status, please see “— Overview.” As of the Latest Practicable Date, we also had around 10 modified new drugs under development and around 20 generic drugs under development, respectively. Our modified new drugs under development mainly target indications such as hypertension, coronary heart disease, peptic

ulcer bleeding, Alzheimer’s disease, COPD and asthma in the therapeutic area of chronic diseases. Meanwhile, our generic drugs under development mainly target indications such as influenza in the therapeutic area of infectious diseases, and diabetes, gastroesophageal reflux disease, adjunctive treatment of major depressive disorder in adults and treatment of schizophrenia in adults in the therapeutic area of chronic diseases. For details of our major modified new drugs under development, please see “— Other Innovative and Modified New Drugs under Development for Chronic Diseases.”

### **Infectious Diseases**

As of the Latest Practicable Date, we also had two approved Class I innovative anti-HCV drugs, namely Dong’antai (Netanasvir Phosphate) and Dong’anqiang (Encofosbuvir), which were approved by the NMPA for launching in China in February 2025 and March 2025, respectively. In addition, as of the Latest Practicable Date, we had a pipeline of four major Class I innovative drug candidates that we have been developing in-house in the therapeutic area of infectious diseases, including (i) one innovative drug candidate (namely Dong’andi (Morphothiadine Mesylate)) in Phase III clinical trial, (ii) one Class I innovative drug candidate with Phase I clinical trial completed (namely Freethiadine), and (iii) two Class I innovative drug candidates (namely HECN30227 and HEC191834) in preclinical stages.

*Approved Product — The Combination Treatment Regimen of Dong’antai (Netanasvir Phosphate Capsules)\* and Dong’anqiang (Encofosbuvir Tablets)\* (磷酸奈坦司韋膠囊/艾考磷布韋片聯用治療方案)*

Netanasvir Phosphate Capsules and Encofosbuvir Tablets are two approved Class I innovative drugs that we have developed in-house for the treatment of pan-genotypic chronic hepatitis C. Netanasvir Phosphate is an NS5A inhibitor, capable of inhibiting HCV assembly and replication. Encofosbuvir is an NS5B polymerase nucleoside analog inhibitor, part of the DAAs used in the treatment of pan-genotypic chronic HCV.

We have submitted the NDA to the NMPA for the combination treatment regimen of Netanasvir Phosphate and Encofosbuvir in August 2023. Netanasvir Phosphate and Encofosbuvir were approved by the NMPA for launching in China in February 2025 and March 2025, respectively. Netanasvir Phosphate and Encofosbuvir made their debut on March 29, 2025 at the 2025 Asian Pacific Association for the Study of the Liver (2025年亞太肝病學會年會). We are currently scaling up production and finalizing our market launch preparations, with sales expected to begin in July 2025. In parallel, we are preparing to initiate negotiations with national medical insurance authorities in December 2025, and we anticipate that our products will be included in the NRDL starting in January 2026. We plan to leverage our well-established sales channels for anti-infective drugs to expand its coverage for our anti-hepatitis C drugs. We plan to collaborate with health authorities, such as the National Health

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\* Following NMPA approval, we plan to sell Dong’antai (Netanasvir Phosphate) and Dong’anqiang (Encofosbuvir) in China under the brand names Dongweizhuo (東衛卓®) and Dongyinghe (東英賀®), respectively.

Commission, to promote educational activities on hepatitis C to locate and target more HCV patients. Furthermore, introducing the combination treatment regimen of Netanasvir Phosphate and Encofosbuvir for the treatment of pan-genotypic chronic hepatitis C will enable our treatment regimen to cover more HCV genotypes, meeting the diverse needs of patients and broadening the treatment population. The combination treatment regimen of Netanasvir Phosphate and Encofosbuvir also received support from the National Major Scientific and Technological Special Project for “Significant New Drugs Development”.

The combination treatment regimen of Netanasvir Phosphate and Encofosbuvir has high cure rates for genotypes 1, 2, 3, and 6 HCV. Phase II/III clinical trials showed an overall SVR12 of 95.0% (420/442) in patients treated with this regimen. This regimen does not include protease inhibitors, which lowers the risk of potential drug-drug interactions and makes it suitable for patients with compensated liver cirrhosis.

### ***Hepatitis B***

According to the Frost & Sullivan Report, the total number of patients diagnosed with chronic hepatitis B in China was 19.1 million in 2023 and is expected to increase to 23.2 million and 31.9 million in 2026 and 2030, respectively. According to the Frost & Sullivan Report, the market size of anti-HBV drugs in China reached RMB9.9 billion in 2023 and is expected to increase to RMB16.7 billion and RMB43.4 billion in 2026 and 2030, respectively. As of the Latest Practicable Date, the treatment of HBV mainly involved two major categories of drugs, namely Interferon and nucleoside analogs. Interferon requires injection and has a low response rate and severe side effects, resulting in insufficient patient compliance. Even though nucleoside analogs can be administered orally and effectively reduce HBV DNA titers, they are ineffective in reducing HBsAg and have issues such as drug resistance and recurrence after treatment. Therefore, anti-HBV drugs targeting the core proteins have become a key focus in current research on HBV treatment.

Based on the latest scientific insights, we have established a pipeline of innovative drug candidates with various mechanism of actions for the treatment of hepatitis B. As of the Latest Practicable Date, we had one major Class I innovative anti-HBV drug candidate in Phase III clinical trial, namely Dong’andi (Morphothiadin Mesylate), an anti-HBV capsid inhibitor. We also had one Class I innovative drug with Phase I clinical trial completed, namely Freethiadine. Freethiadine is another anti-HBV capsid inhibitor that we have been developing in-house and it has shown improved antiviral activity in pre-clinical studies. In addition, we have two Class I innovative drug candidates, which might be possible to functionally cure chronic hepatitis B through combination therapy, mainly including (i) one Class I innovative drug candidate in preclinical stage, namely HECN30227, which is a small nucleic acid drug targeting HBV RNA and inhibiting HBsAg and for which we plan to submit the IND application in 2025, and (ii) one Class I innovative drug candidate in preclinical stage, namely HEC191834, which is a TLR8 agonist simulating the immune system. In pre-clinical studies, HECN30227 has shown improved in vitro and in vivo activity and HEC191834 has shown high selectivity and high

distribution to the liver. We believe our diverse pipeline of anti-HBV drug candidates could enhance our competitive advantages and have the potential to satisfy the unmet medical needs for the treatment of chronic hepatitis B.

*Product Candidate — Dong'andi (Morphothiadine Mesylate Capsules) (甲磺酸莫非賽定膠囊)*

Morphothiadine Mesylate, also known as GLS4 or Morphothiadine, is a Class I innovative drug candidate that we have been developing in-house for the treatment of chronic hepatitis B. Morphothiadine Mesylate is an anti-HBV capsid inhibitor.

We have obtained approval from CDE to commence Phase III clinical trial for Morphothiadine Mesylate. Morphothiadine Mesylate also received support from the National Major Scientific and Technological Special Project for “Significant New Drugs Development”. According to the Frost & Sullivan Report, Morphothiadine Mesylate was the only anti-HBV capsid inhibitor in Phase III clinical trial in China and had the leading clinical trial progress in China as of the Latest Practicable Date. Morphothiadine Mesylate was also the world’s first oral small molecule drug for the treatment of chronic hepatitis B, which has been clinically validated to significantly inhibit the hepatitis B virus surface antigen, according to the Frost & Sullivan Report.

Morphothiadine Mesylate has demonstrated strong clinical efficacy. In a phase II trial, patients who received the combination therapy (combination of Morphothiadine Mesylate and nucleoside analogs) showed better performance in various efficacy indicators (including HBsAg, HBV pgRNA and HBcrAg) than patients who received the nucleotide analogs alone. Combination therapy continued to be superior in terms of efficacy in patients who have received nucleoside therapy. The combination treatment has also shown a good safety profile and is well tolerated by patients. Morphothiadine Mesylate also works by targeting the cccDNA, which is crucial for the virus’s ability to reproduce.

### **Chronic Diseases**

As of the Latest Practicable Date, we also had a pipeline of eleven major Class I innovative drug candidates that we have primarily been developing in-house in the therapeutic area of chronic diseases, including (i) one Class I innovative drug candidate (namely (Dongjiantang Olorigliflozin)), for which we have submitted the NDA to the NMPA; (ii) one Class I innovative drug candidate (namely Dongjiandi (Yinfenidone Hydrochloride)) in phase III clinical trial; (iii) five Class I innovative drug candidates (namely Guangjianbao (HEC88473), Dongjianqiang (HEC95468), Dongtongshen (Mitizodone Phosphate), Dongjianshun (HEC93077) and Dongjianyuan (HEC96719)) in Phase II clinical trials, (iv) one Class I innovative drug candidate (namely Dongtongshun (HEC137076), a drug candidate targeting 5-HT<sub>1f</sub> for the treatment of migraine, which has demonstrated high ability to cross the blood-brain barrier in pre-clinical studies) in Phase I clinical trial, (v) one Class I innovative drug candidate (namely Dongningsheng (HEC53856), a drug candidate target HIF-PHD for the treatment of renal anemia and CIA) which has finished its Phase Ic clinical trial for renal anemia and has conducted the Phase II clinical trial for CIA, (vi) one Class I

innovative drug candidate (namely HEC169584, a THR-agonist drug candidate for the treatment of NASH), for which we obtained clinical trial approval in December 2024; and (vii) one Class I innovative drug candidate (namely HEC007, a GLP-1/GIP/GCG triple-target agonist drug candidate for the treatment of obesity), for which we submitted the IND application in January 2025 and obtained clinical trial approval in April 2025.

In addition, we have been cooperating with Lannett, a U.S. pharmaceutical company, to develop two insulins (namely Guangjianyou (Insulin Glargine Injection) and Guangjiantan (Insulin Aspart Injection)) for the U.S. market.

Furthermore, we also had a pipeline of modified new drugs and generic drugs in different stages of development, mainly targeting peptic ulcer bleeding, Alzheimer's disease, COPD, asthma, diabetes, gastroesophageal reflux disease, adjunctive treatment of major depressive disorder in adults and treatment of schizophrenia in adults. For details of our major modified new drugs under development in the therapeutic area of chronic diseases, please see “— Other Innovative and Modified New Drugs under Development for Chronic Diseases.”

*Product Candidate — Guangjianyou (Insulin Glargine Injection) and Guangjiantan (Insulin Aspart Injection) in the U.S.*

According to the Frost & Sullivan Report, the market size of diabetes drugs in the U.S. reached USD40.4 billion in 2023 and is expected to reach USD52.0 billion in 2030. In 2023, the sales of insulin and its analogs accounted for approximately 20% of the diabetes drug market in the U.S.

As of the Latest Practicable Date, we have been collaborating with Lannett to develop two insulins, namely Insulin Glargine Injection and Insulin Aspart Injection, for the U.S. market. We are one of the only two PRC pharmaceutical companies that are developing Insulin Glargine Injection for the U.S. market. We completed a pivotal Phase I clinical trial for our Insulin Glargine Injection. We submitted the BLA for our Insulin Glargine Injection to the U.S. FDA in December 2023. Since then, we have been actively responding to the U.S. FDA's requests for additional information to facilitate the approval process. Based on the current review progress and our understanding of the U.S. FDA's general review timeframe for BLA applications, we expect to receive BLA approval for our Insulin Glargine Injection in the first half of 2026. We believe that our Insulin Glargine Injection has the potential to become the first insulin to be approved for launching in the U.S., which has received the U.S. FDA approval for an exemption from Phase III clinical trial. We have also submitted a Pre-IND consultation to the U.S. FDA for Insulin Aspart Injection. We also aim to submit the BLA for our Insulin Aspart Injection to the U.S. FDA around the end of 2025 and expect to receive its BLA approval around the end of 2026. Following BLA approval, in order to ensure successful market entry, we plan to establish partnerships with insurance companies, long-term care facilities, rehabilitation centers and chain pharmacies to enhance market penetration and strengthen our brand presence among the end-users. For details of our cooperation with the U.S. pharmaceutical company on insulins in the U.S., please see “— Research and Development — Collaboration and Licensing Agreements — Collaboration with Lannett.”

The Phase I clinical trial for the U.S. marketing application of Insulin Glargine Injection was based on a clinical trial conducted overseas. The trial results have confirmed that both the pharmacokinetic similarity and the pharmacodynamic similarity between our Insulin Glargine Injection and the U.S. RLD. Insulin production is complex, but we operate multiple production lines that work well together, helping to keep production costs low.

*Product Candidate — Dongjiantang (Ologliflozin Capsules) (奥洛格列净胶囊)*

Type 2 diabetes is the predominant form of diabetes in China. According to the Frost & Sullivan Report, the total number of type 2 diabetes patients in China was 137.0 million in 2023 and is expected to increase to 144.3 million and 150.5 million in 2026 and 2030, respectively. SGLT-2 inhibitor is a type of innovative antidiabetic medication that can lower the renal glucose threshold and promote urinary glucose excretion, thus reducing blood glucose levels. In addition, SGLT-2 inhibitors can also effectively reduce the risk of cardiovascular diseases and have a protective effect on the kidneys. According to the Frost & Sullivan Report, the market size of SGLT-2 inhibitors in China reached RMB10.5 billion in 2023 and is expected to increase to RMB20.0 billion and RMB27.5 billion in 2026 and 2030, respectively.

Ologliflozin, a Class I innovative drug candidate that we have been developing in-house, is an SGLT-2 inhibitor.

We submitted the NDA to the NMPA for Ologliflozin in December 2023 and expect to receive approval in 2025. Following NMPA approval, we will conduct targeted medical promotion conferences and expert seminars to demonstrate Ologliflozin's clinical advantages, supported by clinical trial results. We will also consider its combination sales with our other products for the treatment of diabetes, such as insulin products, to provide comprehensive treatment solutions that will meet diverse patient needs. In addition, we will explore new indications for Ologliflozin, such as specific types of metabolic syndrome, to broaden its application scope. In terms of pricing strategy, we will balance research and development as well as manufacturing costs with therapeutic value to set a market-competitive price to ensure its accessibility. Furthermore, we will actively pursue its inclusion in the NRDL through negotiations with health insurance departments. Ologliflozin also received support from the National Major Scientific and Technological Special Project for "Significant New Drugs Development". We believe our Ologliflozin could not only treat type 2 diabetes but also have benefits of improving cardiovascular diseases and the potential to reduce the risk of chronic kidney diseases.

In addition to its glucose-lowering effects, Ologliflozin effectively regulates lipid metabolism and protect the pancreas during long-term use. Moreover, when combined with other diabetes medications that act through different mechanisms, Ologliflozin complements their effects, enhancing the lowering of blood sugar. Ologliflozin demonstrated comprehensive and sustained glucose-lowering effects in two Phase III clinical trials. After 24 weeks of treatment, the 50mg and 20mg monotherapy groups of Ologliflozin reduced the primary efficacy endpoint HbA1c by 1.01% and 0.94%, respectively, compared to placebo. Compared to other SGLT2 inhibitors with statistically significant 2-hour postprandial plasma



glucose data (mainly from Chinese patients), Olorigliflozin exhibited better reductions in both fasting plasma glucose and 2-hour postprandial plasma glucose. It also brings a greater effect on weight loss and lowering of systolic blood pressure. In terms of safety, Olorigliflozin demonstrated a good safety profile, with fewer gastrointestinal side effects, lower rates of urinary tract infections compared to the placebo group, and no adverse reactions related to hypovolemia.

*Product Candidate — Guangjianbao (HEC88473 Injection)*

As public awareness regarding obesity control and treatment intensifies, the obesity drug market is experiencing exponential growth, with high demand observed for anti-obesity drugs such as Semaglutide and Tirzepatide. Meanwhile, NASH remains an area devoid of approved treatment options in China, with many drugs currently in clinical trials demonstrating limited efficacy. According to the Frost & Sullivan Report, the total number of patients with NASH in China reached 42.5 million in 2023 and is expected to increase to 47.2 million and 54.9 million in 2026 and 2030, respectively. As of the Latest Practicable Date, the U.S. FDA has only approved one drug for the treatment of NASH with moderate to advanced scarring fibrosis.

HEC88473, a Class I innovative dual-targeted (GLP-1/FGF21) biological drug candidate that we have been developing in-house, is a long-acting fusion protein injection. HEC88473 can simultaneously activate GLP-1 and FGF receptors, which can synergistically lower blood glucose levels, reduce body weight and improve lipid metabolism. Compared to currently marketed GLP-1 receptor agonists (“**GLP-1RAs**”), GLP-1/FGF21 dual-targeted agonist exhibits advantages in blood glucose reduction and weight loss, as well as effectively mitigating NASH. HEC88473 has the potential to concurrently target three indications, namely type 2 diabetes, NASH and obesity. According to the Frost & Sullivan Report, HEC88473 was the first GLP-1/FGF21 dual targeted agonist drug candidate to enter the clinical stage and it is leading the R&D progress of the dual agonist class globally.

As of the Latest Practicable Date, we completed Phase I clinical trials for HEC88473 in China and Australia. The multi-dose escalation Phase I clinical trial in China was conducted in patients with type 2 diabetes co-existing with fatty liver disease, assessing the safety and preliminary efficacy of HEC88473 in this type of patients. Moreover, we have been conducting Phase II clinical trial for type 2 diabetes in China to evaluate the efficacy and safety of HEC88473 in treating subjects who have type 2 diabetes and have enrolled all the subjects for Phase II clinical trials. Concurrently, we have submitted the IND application for NASH to the U.S. FDA and have received its clearance. We have entered into an exclusive overseas license and commercialization agreement with Apollo Therapeutics Group Limited in November 2024, demonstrating the global development and commercialization of HEC88473. Please see “— Research and Development — Collaboration and Licensing Agreements — Licensing Agreement with Apollo” for further details.

HEC88473 offers stable blood sugar control, promotes weight loss, improves blood lipid levels, and shows promise in improving NASH and fibrosis, offering broad metabolic benefits. Phase I clinical trial in China indicated that HEC88473 is safe and well-tolerated at single



doses ranging from 0.5 mg to 62.9 mg and multiple doses from 5.1 mg to 68.0 mg. Study results supported the use of once-weekly dosing. In a 5-week trial with patients who have type 2 diabetes and fatty liver, HEC88473 showed strong effects in lowering blood sugar and reducing liver fat. It resulted in significant reductions in HbA1c, fasting blood glucose, and liver fat content.

*Product Candidates — Liraglutide Injection and Guang Jian Cheng (Dulaglutide Injection)*

In addition to insulins, our biosimilar pipeline for diabetes also extends to the field of GLP-1RAs. As of the Latest Practicable Date, we had two GLP-1RAs under development, namely Liraglutide Injection and Dulaglutide Injection, for which we completed Phase III clinical trial and Phase I clinical trial, respectively.

Phase III clinical trial results for our Liraglutide Injection have shown that our Liraglutide Injection is therapeutically equivalent to the original Liraglutide Injection (Victoza®), with comparable safety profiles, similar immunogenicity and pharmacokinetics.

Phase I clinical trial results for our Dulaglutide Injection have shown that the pharmacokinetics, safety, and immunogenicity of our Dulaglutide Injection are similar to that of the original Dulaglutide Injection (Trulicity®) in healthy subjects.

***Respiratory System Diseases***

According to the Frost & Sullivan Report, the global market of respiratory system disease drugs reached US\$94.6 billion in 2023 and is expected to increase to US\$119.5 billion and US\$137.6 billion in 2026 and 2030, respectively. In China, the market size of respiratory system disease drugs reached RMB82.1 billion in 2023 and is expected to increase to RMB103.7 billion and RMB123.9 billion in 2026 and 2030, respectively.

As of the Latest Practicable Date, we have established a diverse drug pipeline for the treatment of respiratory system disease, mainly including (i) one Class I innovative drug candidate for the treatment of idiopathic pulmonary fibrosis (IPF) in Phase III clinical trial, namely Dongjiandi (Yinfenidone Hydrochloride Tablets), (ii) one Class I innovative drug candidate for the treatment of pulmonary arterial hypertension in Phase II/III clinical trial, namely Dongjianqiang (HEC95468 tablets), (iii) four modified new drugs for the treatment of COPD and asthma, namely Tiotropium Bromide Inhaler, in Phase I clinical trial, Tiotropium Bromide and Olodaterol Inhaler in preclinical stage and for which we plan to submit the IND application in 2025, and two other modified inhalers in formulation development stage. We also had one Class I innovative in-house R&D drug candidate for the treatment of IPF, namely HEC68498. We completed Phase I clinical trial for HEC68498 in the U.S. and HEC68498 was granted Orphan Drug Designation in the U.S.

*Product Candidate — Dongjiandi (Yinfenidone Hydrochloride Tablets) (鹽酸伊非尼酮片)*

According to the Frost & Sullivan Report, the total number of IPF patients in China was 164.3 thousand in 2023 and such number is expected to increase to 231.1 thousand and 339.2 thousand in 2026 and 2030, respectively. According to the Frost & Sullivan Report, the market size of pulmonary fibrosis drugs in China reached RMB1.5 billion in 2023 and is expected to increase to RMB2.7 billion and RMB3.2 billion in 2026 and 2030, respectively. As of the Latest Practicable Date, there were only two drugs for the treatment of IPF (namely Pirfenidone and Nintedanib) available in the world, which had also been approved for sale in China. However, they had a high frequency of side effects (such as gastrointestinal intolerance, phototoxicity, and hepatotoxicity), which may lead to treatment interruption. Therefore, there is an urgent need for safer and more effective IPF treatment drugs. Even though there were numerous drugs candidates for the treatment of IPF in clinical trials in China, their efficacy and safety still needed to be verified.

Yinfenidone Hydrochloride (HEC585) is a Class I innovative drug candidate that we have been developing in-house for the treatment of IPF.

As of the Latest Practicable Date, we completed its Phase I clinical trial in China and the U.S., the results of which have shown that Yinfenidone Hydrochloride has a long half-life, and could be administered once a day. In August 2017, Yinfenidone was granted Orphan Drug Designation in the U.S., making it eligible for preferential policies for approval and pricing in the U.S. Moreover, we have been conducting Phase II clinical trial in China to evaluate its efficacy and safety and have received its Phase III clinical trial approval from the CDE based on Phase II interim analysis data. Given the extensive overlap between the sales channels for approved pulmonary fibrosis drugs in China and our existing sales network for Oseltamivir Phosphate Capsules, we plan to leverage our existing sales network and integrate it with sales channels used for Oseltamivir Phosphate Capsules to achieve market penetration for Yinfenidone Hydrochloride following the NMPA approval. We also plan to explore its sales channels such as Direct-to-Patient (DTP) pharmacies and online hospitals to expand its reach and enhance its brand recognition. Yinfenidone Hydrochloride also received support from the National Major Scientific and Technological Special Project for “Significant New Drugs Development”.

Compared to Pirfenidone, a drug for the treatment of IPF with limited efficacy, Yinfenidone Hydrochloride may exert its anti-fibrotic effects through multiple pathways, making its mechanism distinct. In vitro studies have shown that it is 200-500 times more potent than Pirfenidone in anti-fibrotic activity. Preclinical studies also demonstrated its ability to reduce pulmonary fibrosis, slow disease progression, and alleviate damage and inflammation in the lungs, all with a much lower dose compared to Pirfenidone. Additionally, Yinfenidone Hydrochloride offers a once-daily dosing regimen, unlike Pirfenidone, which requires three doses a day. Clinical trials have shown that it has a better safety profile, with no serious liver enzyme abnormalities, phototoxicity, or severe indigestion side effects. Preliminary data from Phase II trials indicated that Yinfenidone Hydrochloride has demonstrated better anti-fibrotic

effects compared to Pirfenidone. In addition, we will consider conducting its overseas Phase II clinical trials and we are seeking overseas collaboration opportunities to promote its global development and commercialization.

*Product Candidate — Dongjianqiang (HEC95468 Tablets)*

HEC95468, a Class I innovative drug candidate that we have been developing in-house in Phase II/III clinical trial, is the second generation of soluble guanylate cyclase (sGC) stimulator for the treatment of pulmonary arterial hypertension (PAH). HEC95468 exhibited favorable pharmacokinetic properties, posed a low risk of drug-drug interaction, and had a long half-life. It could be administered once daily for pulmonary hypertension indications, and it could achieve a steady blood pressure-lowering effect. Although the PAH drug market has experienced rapid growth in recent years, there are still many patients whose clinical needs cannot be met. According to the Frost & Sullivan Report, the total number of patients with PAH in China was 85.3 thousand in 2023 and is expected to increase to 94.1 thousand in 2030.

***Other Innovative and Modified New Drugs under Development for Chronic Diseases***

As of the Latest Practicable Date, in addition to diabetes and respiratory system diseases, our key innovative drug candidates in the therapeutic area of chronic diseases also targeted indications such as depression, NASH, gout and hyperuricemia.

*Product Candidate — Dongtongshen (Mitizodone Phosphate Tablets) (磷酸咪替佐酮片)*

Mitizodone Phosphate (HEC113995) is a Class I innovative anti-depressant drug candidate that we have been developing in-house. It has a multi-target synergistic mechanism of action. Compared to Vilazodone (a drug for the treatment of depression), Mitizodone has better in vivo and in vitro activity and better safety. Phase I clinical results have shown that its pharmacokinetic properties met expectations, and it had good safety and tolerability. We are currently conducting its Phase II clinical trial. According to the Frost & Sullivan Report, the total number of patients with depression in China was 31.3 million in 2023 and is expected to increase to 32.5 million and 33.9 million in 2026 and 2030, respectively. According to the Frost & Sullivan Report, the market size of anti-depressant drugs in China reached RMB10.8 billion in 2023 and is expected to increase to RMB12.0 billion and RMB14.2 billion in 2026 and 2030, respectively.

*Product Candidate — Dongjianyuan (HEC96719 Tablets)*

HEC96719, a Class I innovative drug candidate that we have been developing in-house, is a farnesoid X receptor (FXR) agonist for the treatment of NASH. HEC96719 had the leading clinical trial progress among FXR agonist drug candidates in China as of the Latest Practicable Date. Non-clinical studies indicated that HEC96719 has shown good anti-NASH and anti-fibrosis effects in both in vivo and in vitro drug efficacy experiments. It had good drug absorption, safety, and druggability. Based on non-head-to-head comparisons, the safety window of HEC96719 was more than 60 times, which was better than that of obeticholic acid

(< 5 times) and Tropifexor (< 4 times), both of which were drugs with the same target. We completed Phase I clinical trials in China and Australia as well as the Phase IIa clinical trial in NASH patients in China. Phase I clinical trial results have shown that HEC96719 with low to medium doses have demonstrated good safety and tolerability, and a strong regulatory effect on both pharmacodynamics indicators, which is better than drug candidates with the same targets. Phase IIa clinical trial results have also shown the clinical efficacy met expectations. According to the Frost & Sullivan Report, the total number of patients with NASH in China was 42.5 million in 2023 and is expected to increase to 47.2 million and 54.9 million in 2026 and 2030, respectively.

*Product Candidate — HEC169584 Capsules*

HEC169584 is our first Class I innovative drug candidate developed in-house by our AIDD laboratory. HEC169584 is a THR- $\beta$  agonist for the treatment of NASH. We utilize our HEC GEN model, a molecular fragment generation model based on sparse graph attention neural networks, to identify the small molecule, HEC169584. Pre-clinical studies have demonstrated that HEC169584 exhibits high in vitro activity on THR- $\beta$  cells, which is better than that of the positive control drug, Resmetirom, the first FDA-approved drug for NASH in 2024. We obtained its clinical trial approval in December 2024.

*Product Candidate – Dongjianshun (HEC93077 Tablets)*

HEC93077, a Class I innovative drug candidate that we have been developing in-house, is a XO/URAT1 dual-target inhibitor for the treatment of gout and hyperuricemia. HEC93077 had the leading clinical trial progress among XO/URAT1 dual-target inhibitor drug candidates in China as of the Latest Practicable Date. Compared to single-target drugs, HEC93077 effectively reduced blood uric acid levels by targeting both the production and excretion of uric acid. Preliminary data from Phase I clinical trial results have shown that it had a good uric acid-lowering effect and a good safety profile. During the Track Record Period, we have manufactured and sold Benzbromarone Tablets and Febuxostat Tablets for the treatment of gout and hyperuricemia. HEC93077 is an important drug candidate to supplement our pipeline for gout and hyperuricemia. According to the Frost & Sullivan Report, the total number of patients with hyperuricemia in China was 188.6 million in 2023 and is expected to increase to 231.6 million in 2030, and the total number of patients with gout in China was 40.7 million in 2023 and is expected to increase to 50.4 million in 2030.

As of the Latest Practicable Date, we also had a drug pipeline of modified new drugs to enrich our chronic disease treatment products, mainly targeting hypertension, coronary heart disease, peptic ulcer bleeding and Alzheimer's disease.

*Product Candidate - Amlodipine Besylate Granules (苯磺酸氨氯地平颗粒)*

Amlodipine Besylate Granules is a modified new drug for the treatment of hypertension and coronary heart disease for which we submitted its NDA to the NMPA in November 2024. Following NMPA approval, we plan to prioritize its inclusion in the NRDL and implement

combination sales strategies with our existing commercialized drugs for the treatment of hypertension. These initiatives will focus on expanding distribution through outpatient pharmacies affiliated with major children's hospitals to enhance accessibility for children with hypertension. Amlodipine Besylate is a third-generation calcium channel blockers (CCB). Comparing with Amlodipine Besylate Tablets, it targets (i) patients with hypertension and stroke who have swallowing difficulties, and (ii) pediatric patients with hypertension.

*Product Candidate — HECB1502201 (Vonoprazan Fumarate Injection) (富馬酸伏諾拉生注射液)*

HECB1502201 (Vonoprazan Fumarate Injection) is a modified new drug under development in-house for the treatment of peptic ulcer bleeding. It reduced gastric acid secretion by blocking an enzyme in the stomach that leads to the production of stomach acid. Compared to the original tablet formulation Vocinti® (Vonoprazan Fumarate Tablets), HECB1502201 could meet the clinical needs of patients with peptic ulcer bleeding that oral formulations cannot address, including high-risk patients who cannot take oral medications due to severe conditions, and patients who require a rapid increase in gastric pH for quick hemostasis. We completed Phase II clinical trial for HECB1502201 and will commence its Phase III clinical trial. Phase I clinical trial results have shown that HECB1502201 had better control over gastric pH compared to PPI injections. Its acid suppression capability was better than that of Esomeprazole Sodium Injection. It also exhibited full efficacy from the first dose and demonstrated good nocturnal acid control.

*Product Candidate — HECB1701301 (Long-acting Intramuscular Injection) (長效肌肉注射劑)*

HECB1701301 (Long-acting Intramuscular Injection) is a modified new drug under development in-house for the maintenance treatment of moderate to severe Alzheimer's disease (AD). It is a long-acting intramuscular injection that has been modified from a once or twice daily oral formulation to an injection administered at least once every week. This modification improved drug compliance and avoided fluctuations in clinical indicators caused by patients missing doses, thus enhancing treatment efficacy. We are currently conducting Phase I clinical trial for HECB1701301.

*Product Candidate – HEC007*

HEC007 is a GLP-1/GCG/GIP triple-target fusion protein for the treatment of obesity independently developed by us. Pre-clinical in vitro and in vivo studies have shown that the weight loss effect of HEC007 is superior to that of the existing marketed drug Tirzepatide, indicating great competitive potential in the field of obesity treatment. HEC007 also has favorable pharmacokinetic properties, meeting the once-weekly dosing requirements for humans. In the in vivo toxicology study, HEC007 was shown to be well tolerated with a large safety window. Therefore, HEC007 has promising druggability and is expected to bring a new treatment option for obese patients. We submitted the IND application for HEC007 in China in January 2025 and obtained its clinical trial approval in April 2025.

**Oncology**

According to the Frost & Sullivan Report, the market size of oncology drugs in China reached RMB269.0 billion in 2023 and is expected to increase to RMB398.5 billion and RMB581.7 billion in 2026 and 2030, respectively.

As of the Latest Practicable Date, our oncology drug candidates were still at various clinical trial stages. As of the Latest Practicable Date, we had a pipeline of four key innovative drug candidates that we have been developing in-house in the therapeutic area of oncology, including (i) two Class I innovative drug candidates (namely Dongningchun (Clifutinib Besylate) and Dongningguan (Larotinib Mesylate)) in Phase III clinical trials, (ii) one Class I innovative drug candidate (namely Dongningsheng (HEC53856)) for its indication on chemotherapy-induced anemia in Phase II clinical trial, (iii) one Class I innovative drug candidate (namely Dongningda (HEC169096)) in Phase I clinical trial. HEC169096 targets the rearranged during transfection (“RET”) proto-oncogene and is for the treatment of tumors. HEC169096 is also capable of suppressing the resistance mutants to other selective RET inhibitors, and (iv) one Class I innovative drug candidate (namely HEC201625), which is under pre-clinical study stage. HEC201625 is a oral small-molecule PD-L1 inhibitor for tumor immuno-therapy.

***Product Candidate — Dongningchun (Clifutinib Besylate Tablets) (苯磺酸克立福替尼片)***

According to the Frost & Sullivan Report, the number of new cases of AML in China was 29.1 thousand in 2023 and the number of new cases of AML is expected to increase to 30.4 thousand and 32.2 thousand in 2026 and 2030, respectively. According to the Frost & Sullivan Report, the market size of AML drugs in China was RMB0.3 billion in 2023 and is expected to increase from RMB1.0 billion in 2026 to RMB3.5 billion in 2030, with a CAGR of 26.9%. As of the Latest Practicable Date, there was only one FLT3 inhibitor drug (namely Gilteritinib) for the treatment of AML that had been approved for sales in China.

Clifutinib Besylate (HEC73543), a Class I innovative drug candidate that we have been developing in-house, is a second-generation, highly selective FLT3 inhibitor for the treatment of AML with a positive FLT3-ITD mutation.

According to the Frost & Sullivan Report, Clifutinib Besylate was the first domestic in-house R&D highly selective FLT3 inhibitor drug candidate that has entered Phase III clinical trial. The CDE has granted us the permission to submit the interim analysis of surrogate endpoints of its CR/CRh rate in the Phase III clinical trial for a conditional NDA and we plan to submit it to the NMPA in 2026 and expect to commercialize Clifutinib Besylate in 2027. Clifutinib Besylate also received support from the National Major Scientific and Technological Special Project for “Significant New Drugs Development”. On November 25, 2024, we entered into an exclusive commercialization collaboration agreement with HEC CJ Pharm and Shenyang Sunshine Pharmaceutical Co., Ltd. Please see “— Collaboration and Licensing Agreements — Collaboration with 3SBIO” for further details. We believe Clifutinib Besylate has a large market potential with the growth of the AML drugs market in China.



The novel design in structure of Clifutinib Besylate retained anti-tumor activity while enhancing selectivity, reducing off-target risks. It has also improved pharmacokinetic profiles with good oral absorption and metabolic stability. Importantly, it diminished hERG-related issues of the lead compound and minimized cardiotoxicity. Pre-clinical studies showed Clifutinib Besylate has low drug-drug risk interactions. In Phase I clinical trial in China for Clifutinib Besylate as a monotherapy in patients with relapsed/refractory AML, 26 subjects with FLT3-ITD(+), TKD(-) relapsed/refractory AML were enrolled in the 40 mg dose group. The CR rate was 11.5% (3/26), the CRc rate was 53.8% (14/26), and the CR/CRh rate was 23.1% (6/26). Based on non-head-to-head comparisons, in subjects who had only undergone first-line treatment and had a positive FLT3 mutation, we believe Clifutinib Besylate recorded higher CR/CRh rates (30.8% vs. 22.6% and 11%) compared to that of Gilteritinib (a drug targeting FLT3 for the treatment of AML) and Quizartinib (a drug candidate targeting FLT3). But Clifutinib Besylate is still subject to validation in large-scale subjects. In terms of safety, according to the latest publicly available non-head-to-head data, Clifutinib Besylate had good tolerance to non-hematological toxicity (such as elevated transaminase) and had a lower risk of QT interval prolongation than Quizartinib. As of the Latest Practicable Date, we have been conducting a Phase III clinical trial in China for evaluating Clifutinib Besylate as a monotherapy in patients with relapsed/refractory AML, and a Phase Ib/II clinical trial for investigating the combination of Clifutinib Besylate with chemotherapeutic drugs in newly diagnosed AML patients.

***Product Candidate – Dongningguan (Larotinib Mesylate Capsules) (甲磺酸萊洛替尼膠囊)***

Larotinib Mesylate, a Class I innovative drug candidate that we have been developing in-house, is used for the treatment of ESCC, a type of esophagus cancer. According to the Frost & Sullivan Report, Larotinib Mesylate was the first small molecule targeted therapeutic drug for the treatment of esophageal cancer in China that entered Phase III clinical trial. Larotinib Mesylate is characterized by its rich target tissue distribution concentration and excellent clinical efficacy as demonstrated in early clinical trials. We are currently conducting Phase III clinical trial for Larotinib Mesylate. Larotinib Mesylate also received support from the National Major Scientific and Technological Special Project for “Significant New Drugs Development”. According to the Frost & Sullivan Report, the number of new cases of esophagus cancer in China was 231.0 thousand in 2023 and the number of new cases of esophagus cancer is expected to increase to 252.3 thousand and 280.5 thousand in 2026 and 2030, respectively.

***Product Candidate — Dongningsheng (HEC53856 Tablets)***

HEC53856, a Class I innovative drug candidate of HIF-PHD inhibitor, is used for the treatment of the indication on CIA in patients with non-myeloid malignancies. Completed clinical and non-clinical trial results have shown that the safety profile of HEC53856 was better than that of Roxadustat (a drug targeting HIF-PHD for the treatment of anemia), based on non-head-to-head comparison. HEC53856 had no adverse reactions associated with increased heart rate in healthy subjects, and the risk of thrombosis was reduced. HEC53856 also has the additional benefit of lowering cholesterol. In addition, the effectiveness of



HEC53856 is not affected by food intake or renal insufficiency, making it a more flexible and suitable treatment option for patients with renal insufficiency. We are currently conducting the Phase II clinical trial for HEC53856 based on our in-house R&D for chemotherapy-related anemia. Phase II clinical trial is a single-art, open and multi-center trial to evaluate the efficacy of HEC53856 in approximately 72 patients with chemotherapy-related anemia. The primary endpoint of the trial is the largest change from baseline in Hb after 15 weeks of treatment. According to the Frost & Sullivan Report, the number of new cancer cases in China was 4.9 million in 2023 and is expected to increase to 5.2 million and 5.6 million in 2026 and 2030, respectively. The proportion of solid tumor patients undergoing chemotherapy treatment was more than 60%, of which around 50% of patients have concurrent moderate to severe anemia that needs treatment. The current treatment methods are mainly blood transfusion and recombinant human erythropoietin with iron agents, and there are unmet medical needs for the treatment of chemotherapy-related anemia.

#### ***Product Candidate — HEC201625***

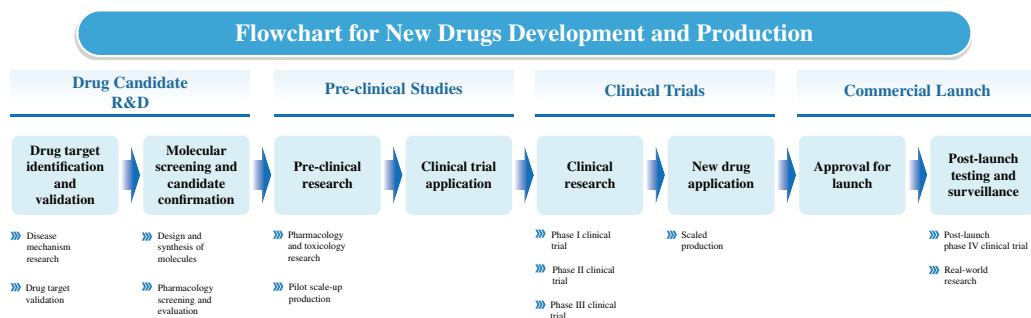
HEC201625 is an oral small-molecule PD-L1 inhibitor with high activity and specificity. Pre-clinical research data shows that HEC201625 exhibits anti-tumor activity comparable to, or even stronger, than PD-L1 antibodies in multiple humanized immune reconstitution tumor models. The pharmacokinetics across various animal species are favorable, with high in vitro and in vivo safety profiles, and it exhibits good drug-like properties. HEC201625 in combination with chemotherapy or VEGF monoclonal antibodies result in enhanced therapeutic synergistic effects. At current stage, several antibodies have been approved to market globally, but there is still an unmet clinical need in the small molecule market. We plan to submit the IND application in the second half of 2025. According to the Frost & Sullivan Report, the global immuno-oncology therapies market has reached US\$ 60.6 billion in 2023 and is expected to reach US\$104.5 billion and US\$201.1 billion in 2026 and 2030, respectively.

## **RESEARCH AND DEVELOPMENT**

### **Overview**

We are a Chinese pharmaceutical company driven by independent research and development. In-house original research and innovation have always been our core strategy. Focusing on three key therapeutic areas, including infectious diseases, chronic diseases, and oncology, we are committed to developing products with breakthrough potential. We continue to improve and develop our research and development platform and enhance our research and development capabilities, and have built a complete set of technology systems for the entire cycle of drug development from early drug discovery to commercialization and manufacture. We are equipped with full-cycle research and development platforms for both chemical drugs and biologics. We are committed to applying AI technology across all stages of drug research and development, having established multiple advanced AI-driven models to enhance our innovation capabilities and development efficiency. Our research and development activities are generally in connection with our existing product portfolios and future products in our pipeline. Our core technologies are also protected by a comprehensive patent portfolio. As of

December 31, 2024, we applied for a total of 2,446 invention patents and have been granted a total of 1,401 in China and overseas. Set out below is a flow chart that demonstrates the key stages of drug development and production.



### *Research and Development Pipeline*

We have a full-cycle drug development platform and in-house research and development capabilities which are leading in China, with a focus on innovative drugs and are also involved in modified new drugs, generic drugs and biosimilars. We have created a diverse and robust pipeline portfolio with broad and deep indication coverage through differentiated molecular design and comprehensive technology platforms. Our targets include globally pioneered and validated targets, which can support our continuous launch of commercial products. As of the Latest Practicable Date, we have 150 approved drugs in various countries and regions, including China, the United States and Europe. As of the Latest Practicable Date, we also had more than 100 drug candidates in the pipeline, including 49 Class I innovative drug candidates in China. As of the Latest Practicable Date, we have successfully developed and launched three Class I innovative drugs and applied for launching one Class I innovative drug through our in-house research and development in China. Our diverse and robust drug pipeline not only secures our position in the domestic pharmaceutical research and development sector, but also helps us to maintain our sustainable development and growth momentum. In terms of the layout of our pipeline, we focus on three major therapeutic areas, namely infectious disease, chronic disease and oncology, which have all created different competitive advantages for us. For information about our core research and development pipeline, please see “— Research and Development — Overview”.

We have established an independent and comprehensive innovative drug development system that covers innovative drug target validation, molecular design and optimization, preclinical drug evaluation, pharmaceutical development, clinical studies, and innovative drug approval applications, with the ability to commercialize rapidly. We have built three core platforms focusing on chemical drugs discovery, biologics research and development and innovative formulation technologies, which serve as the foundation for our drug discovery and development in order to respond to medical needs in key areas. In order to further facilitate the rapid discovery of candidate molecules, we continue to improve our technology platforms. We have built advanced technology platforms such as AIDD, small nucleic acids, PROTAC, ADC

and specific antibodies, which empower the research and development of innovative drugs and enhance innovation. We have strong core competencies in terms of the technological sophistication and comprehensiveness of our technology platforms.

#### ***Our Core Research and Development Team***

Our research and development team has created notable competitive advantages for us in both innovation and execution capabilities, laying a solid foundation for the efficient advancement of our research projects. Our research and development team is led by our Chairman, Dr. Zhang Yingjun (張英俊博士), who is a renowned scientist in the field of innovative chemical drugs and previously served as the person in charge of the National Major Scientific and Technological Special Project for “Significant New Drugs Development”. He is currently serving as executive deputy director of the State Key Laboratory for New Anti-Infective Drugs Development, a member of the National Pharmaceutical Chemistry Committee, a senior member of the Pharmaceutical Chemistry Committee of Guangdong Province and was recognized as one of the Technology Innovation for Middle-Aged and Young Professionals (創新人才推進計劃中青年科技創新領軍人才) by the Ministry of Science and Technology of the PRC. Dr. Zhang oversees our strategic planning and drug development, and has led the research process in respect of more than 50 Category 1 innovative drugs. Dr. Zhang, as the first author, received a first-class award of Guangdong Science and Technology Award (廣東省科技進步一等獎) in 2024. He has more than 15 years of experience in drug development and company management, and deep knowledge in the fields of infectious diseases, chronic diseases, and oncology. Dr. Zhang, as the first inventor, successfully led our team to launch the first independently-developed new anti-hepatitis C drug Dongweien (東衛恩®) onto the Chinese market and develop two other innovative drugs which are currently at the review stage of NMPA for launching in China. In addition, under his leadership, we have created more than 20 new candidate molecules which have advanced to clinical trial stage, completed overseas Phase I clinical trial for three innovative drugs and created a highly competitive innovative drug product line. Dr. Zhang has applied for more than 1,200 patents, among which, 140 were PCT patents, over 800 were authorized and 250 were granted to Dr. Zhang as the first inventor. Dr. Zhang has made significant contributions to our research and development and the research platforms. For further details, please see “Directors, Supervisors and Senior Management” in this Listing Document.

Dr. Zhang Ji (張霽博士) is the chief scientist of our drug synthesis and process chemistry department and a member of the Academic Committee of the State Key Laboratory for New Anti-infective Drugs Development. He served as the person in charge of the National Major Scientific and Technological Special Project for “Significant New Drugs Development” and was recognized by the Overseas High-Level Talent Recruitment Programs (「海外高層次人才引進計劃」) by the PRC government. He has 25 years of working experience in pharmaceutical industry including experiences in the U.S. multinational pharmaceutical companies, such as Abbott/AbbVie, Pfizer and Bristol-Myers Squibb, and he served as the head of the green chemical pharmaceuticals department at Pfizer. Dr. Zhang has been successively responsible for the early research and development and late-stage development of dozens of new clinical drugs, as well as the process innovation and scale-up production of multiple drugs. He has

accumulated extensive experience in innovative drug research and development and achieved excellent research results. As a result, Dr. Zhang is able to rapidly scale up laboratory technology to industrial production. He is also familiar with the U.S. FDA-related pharmaceutical regulations, ICH Guidelines, intellectual property management and patent law.

Dr. Gu Baohua (谷保華博士) is the chief scientist of our pharmacology department and has more than 25 years of experience in the field. He was a core member of the respiratory system innovative drug development team of Guangdong Province, China, (「廣東省呼吸系統創新藥物研發團隊」) and has previously worked for international pharmaceutical companies, including GSK and Novartis, assisting them in drug development. He has scientific research experience from a number of research institutions at several prestigious universities in the United States. His experience spans across areas such as virus, molecular biology, biochemistry and immunology. Dr. Gu was also engaged in the development of new anti-hepatic fibrosis and anti-tumor drugs. In our Company, Dr. Gu is responsible for work relating to molecular biology research and clinical translation, and led our major products, including Morphothiadin Mesylate Capsules, the new anti-HBV drug, and Yinfenidone Hydrochloride Tablets, the innovative drug for idiopathic pulmonary fibrosis. He is also responsible for general scientific research for our drug development, including biological mechanism research and pharmacological research.

Dr. Ye Qunrui (葉群瑞博士) is our chief scientist of research and development on macromolecular drugs. Dr. Ye was a postdoctoral fellow at the Dana-Farber Cancer Institute of Harvard Medical School, with several years of research experience at the University of Pennsylvania and the Children's Hospital of Philadelphia. He was previously also an Ernst-Hardon Foundation-sponsored researcher at the University of Zurich, Switzerland, and was recognized as a young scholar in organ transplantation by the American Society of Transplantation (AST) in 2002. Dr. Ye has deep experience in the fields of oncology and viral infections treatment and pathological research of certain viruses. He is responsible for coordinating the research and clinical development of multiple pipelines for tumors. Dr. Ye's pipeline for solid tumor rapid CAR-T has already entered into the stage of pre-clinical research.

Dr. Cai Xiaoli (蔡曉莉醫學博士) is our chief medical officer, who has over three decades' experience in the fields of basic medical science and pharmaceutical clinical research and development in leading Chinese and U.S. institutes including Rockefeller University, Chinese Academy of Medical Sciences Fuwai Hospital and Jiangsu Hengrui Pharmaceuticals Co., Ltd.. Dr. Cai was an executive member of the Clinical Trial Professional Committee of the Chinese Pharmacological Society (「中國藥理學會臨床試驗專業委員會常務委員」). With her extensive overseas experience, Dr. Cai is able to manage our clinical development strategy with international perspective.

Our research and development team has an excellent track record of developing innovative drugs, having successfully launched two innovative drug onto the market, advanced two innovative drugs to the NMPA's review for launching in China and dozens of independently-discovered drug candidates to the clinical research stage. Consisting of scientists with extensive working experience in multinational pharmaceutical companies and

key talents with rich practical experience in research and development, our research and development team have deep understanding and profound experience in various aspects of drug research and development, providing strong support for our product development. As of December 31, 2024, our research and development team has over 1,100 employees working in the areas of early drug discovery and evaluation, pharmaceutical development, clinical development, regulatory affairs and quality assurance. Their experience and qualifications span across chemistry, pharmaceutical formulation, analysis, biology, pharmacology and clinical medicine. To incentivize our core research and development staff to stay with our Company and continue to contribute, we have set up equity and non-equity technology rewards for employees who make outstanding contributions to research and development, technology upgrades and product optimization. Nevertheless, the loss of any core research and development employee may hinder the development and commercialization of our major products. In order to minimize the impact of the loss of these technical employees on us, we have entered into confidentiality agreements with all research and development employees and signed confidentiality agreements that contain stricter confidentiality obligations with our core research and development employees. We also enter into non-compete agreements with our core research and development employees when they leave our Company, and have also established a strict work handover process to ensure that all confidential documents remain with our Company.

#### **Drug Discovery and Non-clinical Development**

Our drug discovery platform is established to design and modify differentiated candidate molecules with high clinical value for efficient clinical development, thereby enriching our pipeline and playing a fundamental role in addressing clinical needs. As of December 31, 2024, our drug discovery team comprised of over 200 employees, including medicinal chemists, AI research scientists, biologists and immunologists, over 60% of whom hold master's or doctoral degrees, with core members having an average of over ten years of experience in the relevant field. Members of our core drug discovery team also play important roles in molecular design and management of research projects, with some of them having previously held senior positions and having been involved in drug discovery at multinational pharmaceutical companies and research institutes. They hold work experience in various disease areas and expertise in biology, medicinal chemistry, drug metabolism and pharmacokinetics and translational medicine, which supports our product development. We have been engaged in the advancement of drugs under development for more than 15 years and have independently developed our own products in the pipeline, successfully commercialized two innovative drug, advanced two innovative drugs onto the registration stage and more than 25 small and large molecules with independent intellectual property rights onto the clinical trial stage, including four brand new molecules onto the overseas clinical trial stage.

Our non-clinical research platform mainly relies on expertise in pharmacology, pharmacokinetics and toxicology to facilitate the rapid advancement of projects and guide our clinical design. We have established a comprehensive and systematic non-clinical pharmacodynamic evaluation system for drugs, which is capable of reliably constructing more than 100 internationally recognized disease models. This system facilitates the transformation from pharmacological efficacy and biomarkers experiments to clinical trials, as well as

subsequently use the clinical results to guide non-clinical pharmacological efficacy and biomarker studies. Additionally, our established pharmacokinetic and non-clinical safety evaluation platforms efficiently meet our drug screening and evaluation needs, thereby helping us to efficiently screen clinical candidate compounds. Our non-clinical research team consists of over 50 members, more than 60% of whom hold master's or doctoral degrees.

We have set up a state-of-the-art drug discovery and non-clinical research laboratory which adheres to the international standards, occupying a floor area of over 5,000 square metres, to support our in-house development of innovative drugs. The drug discovery and non-clinical research laboratory is owned by our controlling shareholder and another entity owned by our ultimate controlling shareholder. We operate and own the R&D centres in our Yidu and Songshan Lake base respectively which primarily focus on manufacturing related research and development.

### **CMC Development**

We adhere to the belief that quality originates from meticulous design, and thus, adopt a scientific approach in formulating prescriptions and process routes. Our pharmaceutical development team comprises over 400 members equipped with extensive expertise in process optimization, analytical method development, quality standard formulation, and technology transfer. Key technology platforms have been systematically established for active pharmaceutical ingredients, encompassing metal catalysis, biocatalysis, and prodrug design, alongside seven essential technology platforms for quality research. These include liquid-phase method development, impurity analysis, structural elucidation, preparative separation, gas phase-based toxin detection, elemental and ionic impurity detection, and in-process control testing. Additionally, within the solid-state drug development team, a comprehensive solid-state chemical drug research platform has been established, featuring four modules: solid-state form screening, solid-state property evaluation, crystallographic process development and optimization, and solid-state property testing. Meanwhile, multiple formulation development technology platforms have also been established. All these technology platforms enable us to promptly address clinical and industrial requirements, providing solutions for intricate and unique demands.

### **Clinical Development**

We have a strong clinical research team, which is located in several clinical centers based in Beijing, Shanghai, Guangzhou, Dongguan, Nanjing, Chengdu, Wuhan and Changchun. As of December 31, 2024, we had over 200 staff in the clinical development team, over 70 of whom have more than 10 years of clinical development experience, doctoral degrees or clinical medicine backgrounds. Our clinical research team has been playing an important role in advancing our clinical development plans towards successful commercialization. The team is responsible for formulating clinical development strategies, designing clinical trial protocols, conducting clinical trial, monitoring drug safety and clinical trial quality control. The core competencies of the clinical research team in the development field include clinical development plan determination, clinical trial plan design, project management and monitoring



of clinical operation, project quality control, clinical pharmacology, medical writing, drug safety alert. As of December 31, 2024, our clinical development team had undertaken 111 phase I, II or III clinical trials and 205 bioequivalence trials, with trial sites located in the United States, Australia, China and other Asian countries. The team's clinical trials involve nearly 300 clinical trial institutions and more than 900 professional departments of medical institutions in China and abroad. In particular, the team has accumulated deep experience in the design and operation management of clinical trials for diabetes and hepatitis C diseases, and has extensive experience in communicating with regulatory agencies.

### AI and Research and Development

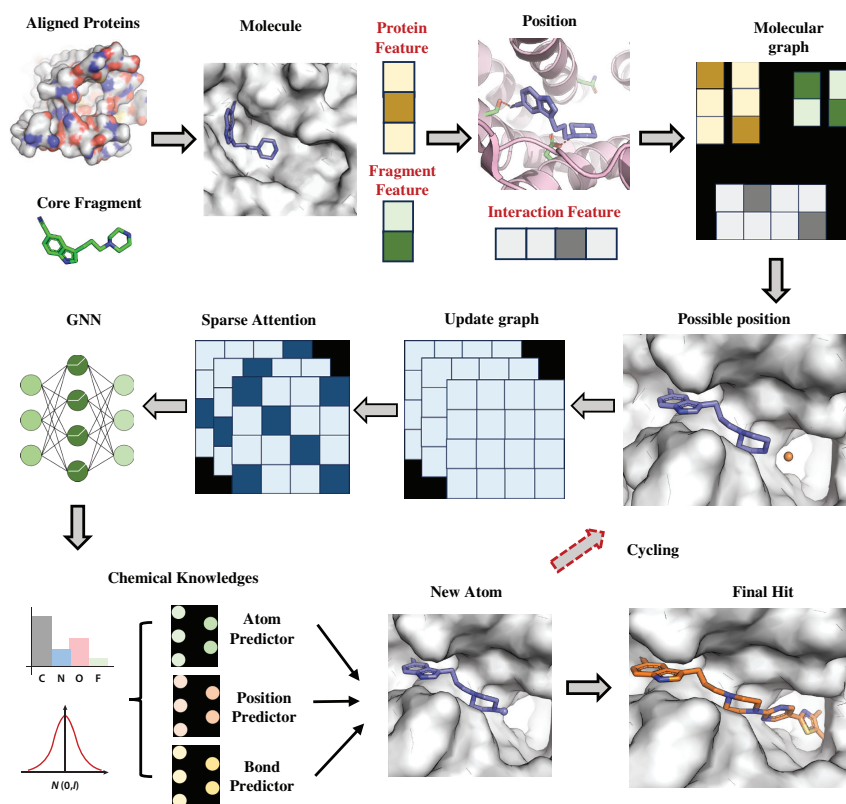
We are committed to applying AI technology across all stages of drug research and development, having established multiple advanced AI-driven models to enhance R&D efficiency and innovation capabilities. Through these AI-driven models, we are continuously advancing the development of innovative drugs to meet global market demands for new treatments.

- ***Molecular Screening Platform.*** This platform integrates a virtual database of billions of molecules with a proprietary database of novel structural molecular entities, enabling us to conduct rapid molecular searches and obtain target molecules in seconds. The platform's key functionalities include: (i) Simplified Molecular Input Line Entry System (SMILES) Drawing: generating detailed two-dimensional (2D) and three-dimensional (3D) structural diagrams from user-input SMILES, allowing for intuitive observation of molecular stereochemistry, spatial arrangement, and intermolecular interactions, thereby aiding drug design and molecular optimization, (ii) Structural Data Visualization: this technology provides three-dimensional visualization of small molecules and protein structures, facilitating our understanding of the relationship between molecular structure and function, (iii) Data Download: we can access detailed information about compounds and proteins, including chemical properties and biological activity, which assists us in predicting pharmacokinetics and evaluating drug efficacy, (iv) Similarity Calculation and Search: this technology quantifies structural similarities between molecules, aiding us in the prediction of biological activity and swiftly locating compounds structurally similar to target molecules within vast molecular libraries, thus accelerating the drug discovery and optimization process, and (v) Molecular Docking: this technique enhances our understanding of interactions between small molecules and biological macromolecules, revealing mechanisms of action and assessing binding affinity, which is crucial for predicting the activity and selectivity of biomolecules.
- ***Molecular Generation Platform.*** Utilizing deep learning technology, this platform generates molecules with specific pharmacological characteristics by learning from existing compound datasets. Its advantages include rapid screening of potential candidate molecules while optimizing their physicochemical properties, target affinity, and pharmacokinetic characteristics to enhance research and development



efficiency. Our research and development team has developed a molecular generation model based on Graph Neural Networks (GNN), exploring multi-target drug development by analyzing interactions between specific fragments across multiple target proteins. This approach significantly narrows the chemical space that needs to be screened. The generation process relies on deep characterization of target protein surfaces and ligand molecules to ensure that generated molecules exhibit drug-like properties and target compatibility. As illustrated below, the model employs surface-based molecular graphs to convert proteins and ligands into input matrices recognizable by neural networks, learning key interaction features between ligands and proteins through a sparse attention mechanism. Subsequently, GNNs combined with embedded chemical knowledge determine the atomic structure of generated fragments. This platform organically combines chemical knowledge with sparse attention mechanisms to ensure that generated molecules possess rational chemical structures, high target affinity, as well as favorable pharmacokinetic properties and biological activity.

### The working process of Molecular Generation Platform



- **Pharmacokinetic Property Prediction Platform.** We leverage machine learning and deep learning technologies to establish AI-assisted pharmacokinetic models. These models utilize advanced computational methods and databases to help researchers predict drug absorption, distribution, metabolism, and excretion processes across different species. They can also forecast in vivo concentration-time curves for drugs,

reducing reliance on experimental data while providing in-depth insights into pharmacokinetic properties. Our pharmacokinetic property prediction platform is a user-friendly, rapid, and accurate online tool that supports users in uploading their datasets to train customized AI models for pharmacokinetic property predictions.

- ***Retrosynthetic Analysis Platform.*** This platform employs machine learning algorithms to analyze extensive public and internal chemical reaction data, identifying relationships between molecular structures and reaction patterns. It intelligently disassembles target molecules to generate feasible precursor structures traceable back to viable starting materials. Based on this analysis, the platform can recommend appropriate reaction conditions to optimize experimental operability while integrating forward reaction prediction functions that evaluate potential products at each reaction step, identifying possible by-products and impurities. Utilizing heuristic search algorithms, the platform selects the most economical and operable synthetic routes, demonstrating significant potential in molecular design within pharmaceutical chemistry and materials science. Key applications supported by this platform include automated retrosynthetic design, reaction condition recommendations, and forward reaction predictions, allowing for rapid analysis and prediction of compound synthesis pathways while effectively expanding the diversity of reaction route designs. Additionally, it possesses capabilities for retrosynthetically disassembling complex molecular structures, enhancing flexibility and innovation in compound design. This technology has been efficiently applied within our drug development system.

## **Collaboration and Licensing Agreements**

### **Collaboration with 3SBIO**

On November 25, 2024, we entered into an exclusive commercialization collaboration agreement (the “**Clifutinib Agreement**”) with HEC CJ Pharm and Shenyang Sunshine Pharmaceutical Co., Ltd. (“**3SBIO**”). Under this agreement, we aim to jointly develop and commercialize an oral formulation with selective inhibition of FLT-3 (“**Clifutinib**”) for sale in the mainland China market. Clifutinib can be used for the treatment of AML with a positive FLT3-ITD mutation. 3SBIO is a leading biotechnology company headquartered in Shenyang, China, with extensive experience in the research, development, production, and marketing of biopharmaceutical products, and has over thirty pharmaceutical products for sale on the market. By partnering with 3SBIO, we believe that their expertise and capabilities in the commercialization and marketing of hematology pharmaceutical products will significantly promote the commercialization of Clifutinib.

***Rights and obligations of the parties.*** Subject to the terms and conditions of the Clifutinib Agreement and during the term of the agreement, we grant 3SBIO exclusive, non-transferable, and sublicensable commercialization rights in mainland China in respect of Clifutinib targeting monotherapy for FLT3-ITD mutation in relapsed/refractory acute myeloid leukemia (“**Indication 1**”) and newly diagnosed acute myeloid leukemia with FLT3-ITD

mutation. We will continue to conduct clinical trials for Clifutinib that were initiated prior to the signing of the Clifutinib Agreement and bear associated costs, and will also be responsible for advancing the drug registration application process for Clifutinib in mainland China, including obtaining authorization for market sale and meeting regulatory requirements as the Marketing Authorization Holder. Unless otherwise stipulated in the agreement, we are responsible for protecting the intellectual property rights associated with Clifutinib, including taking legal action against infringements and bearing related costs. 3SBIO is responsible for all commercialization activities related to Clifutinib in the mainland China market, including but not limited to channel management, market development, customer management and services, and government affairs.

***Joint management committee.*** The joint management committee consists of three to four representatives appointed by each party who possess relevant expertise. The number of representatives appointed by each party must be the same. The responsibilities of the joint management committee include comprehensive oversight, management of the execution of the Clifutinib Agreement, regular review of 3SBIO's marketing plans and market entrance strategies, discussion and communication regarding Clifutinib's research and development progress, clinical trial results, and marketing authorization plans. Furthermore, the joint management committee is responsible for supervising product manufacture and supply chain management, monitoring drug safety, and developing patient assistance programs as necessary.

***Sublicense.*** Under the Clifutinib Agreement, we grant 3SBIO ordinary, non-transferable rights with multiple levels of sublicensing that is necessary for the commercialization of Clifutinib in mainland China. This authorization is solely for 3SBIO or its affiliates and/or subcontractors to fulfill its obligations under the Clifutinib Agreement. 3SBIO or its affiliates and/or subcontractors are not permitted to use it for any other purpose.

***Licensing fees.*** During the Track Record Period, we received an upfront payment of RMB60 million in accordance with the terms of the Clifutinib Agreement and are expected to receive development, regulatory and commercial milestone payments over the term of the agreement. The development and regulatory milestone payments are contingent upon achieving agreed research milestones and obtaining specific regulatory approvals. Commercial milestone payments are contingent upon achieving agreed annual net sales in mainland China. We agree to pay 3SBIO a monthly promotional service fee following Clifutinib's first commercial sale that creates sales revenue, which is calculated based on actual sales revenue of that month minus relevant expenses multiplied by the agreed service fee rate (a mid-to-high range double-digit percentage depending on the amount of the actual sales revenue of that month minus relevant expenses). If we fail to obtain authorization for market sale in respect of Clifutinib targeting Indication 1 within the specified timeframe under the Clifutinib Agreement, 3SBIO has the right to terminate this agreement and request a refund of all payments 3SBIO made to us except for the upfront payment.

***Term and termination.*** The Clifutinib Agreement becomes effective upon signing and remains valid until the end of the fifteenth full calendar year following the first commercial sale of Clifutinib ("**Initial Term**"). Upon expiration of the Initial Term, both parties will

negotiate in good faith regarding renewal, and if there are no significant breaches or major market changes during this period, the agreement can be renewed for five-year terms. Both parties have the right to terminate the agreement due to a material breach by the other party that remains unremedied.

We understand that 3SBIO is an Independent Third Party.

### **Licensing Agreement with Apollo**

On November 6, 2024, we entered into an exclusive development and commercialization license agreement (the “**HEC88473 Agreement**”) with Apollo Therapeutics Group Limited (“**Apollo**”), a portfolio biopharmaceutical company headquartered in the United Kingdom, and Apollo AP60 Limited (“**AP60**”), an affiliate of Apollo. Under this agreement, we grant an exclusive license to AP60 for the development, manufacture and commercialization of the GLP-1/FGF21 dual agonist HEC88473 (the “**HEC88473**”) for all uses outside the Greater China Region (the “**ROW**”). HEC88473 can simultaneously activate GLP-1 and FGF receptors, which can synergistically lower blood glucose levels, reduce body weight and improve lipid metabolism. We entered into the HEC88473 Agreement with Apollo to leverage their unique expertise in expanding the GLP-1/FGF21 dual agonist HEC88473 into new indications, while benefiting from their international clinical resources and project management experience. This collaboration aims to accelerate the development and commercialization of HEC88473 in the international markets, which complements our development and commercialization efforts in the PRC market.

***Rights and obligations of the parties.*** During the term of the HEC88473 Agreement, we grant AP60 an exclusive license in respect of our patent rights and know-how that are necessary or useful to the exploitation of HEC88473 or related products, to develop, manufacture, commercialize and otherwise exploit HEC88473 and related products for all uses in ROW. In addition, subject to AP60’s written request and our approval in each instance, we agree to grant AP60 a non-exclusive license to manufacture or to have manufactured HEC88473 and related products in the Greater China Region for the sole purpose of developing, commercializing and otherwise exploiting HEC88473 or related products by or on behalf of AP60, its affiliates and sublicensees in the ROW. Subject to the terms of the HEC88473 Agreement, AP60 will have sole control over the development of HEC88473 and related products for all uses in the ROW at its own cost and expense, and we will have sole control over the development of HEC88473 and related products for all uses in the Greater China Region at our own cost and expense. For details on our research and development activities in respect of HEC88473, please see “Business — Our Products and Product Candidates — Diabetes — Product Candidate — Guangjianbao (HEC88473 Injection)”.

***Ownership of intellectual property.*** During the term of the HEC88473 Agreement, any know-how (and patent rights that cover such know-how) developed, conceived, or reduced to practice solely by or on behalf of AP60, any of its affiliates or sublicensees shall be solely owned by AP60, and any know-how (and patent rights cover such know-how) developed,

conceived, or reduced to practice solely by or on behalf of us or any of our affiliates or licensees shall be solely owned by us. Any intellectual property that is jointly discovered, conceived, or reduced to practice by us and AP60 shall be jointly owned by both parties on an equal and undivided basis.

**Sublicense.** AP60 may grant sublicenses of the rights we granted to AP60 under the HEC88473 Agreement to any of its affiliates or to any third party, including to any subcontractor to the extent such sublicense is necessary for such subcontractor to satisfy its obligations. If AP60 intends to grant sublicense to a China-based biopharma company, such sublicense must be subject to our approval (not to be unreasonably withheld, conditioned or delayed).

**Licensing fees.** As part of the HEC88473 Agreement, we are entitled to receive up to US\$938 million in payments, including an upfront cash payment of US\$12 million and development, regulatory and commercial milestone payments of up to US\$926 million, over the term of the HEC88473 Agreement. During the Track Record Period, we received an upfront payment of US\$12 million and recognized revenue of US\$11 million in 2024 in accordance with the terms of the HEC88473 Agreement and the performance obligation that our Group had fulfilled. The development milestone payments are contingent upon reaching defined research stages. The regulatory milestone payments are contingent upon obtaining certain regulatory approvals. The commercial milestone payments are contingent upon reaching defined annual sales thresholds across major markets. Separately, if and when HEC88473 is successfully commercialized in the ROW, we may, during the term of the HEC88473 Agreement, receive royalties ranging from high single to low double-digit percentages based on net sales in the ROW.

**Term and termination.** The HEC88473 Agreement shall remain effective until terminated or expired as specified in the agreement. The term of the HEC88473 Agreement is from the date of signing of the HEC88473 Agreement to at least ten years following the date of the first commercial sale. AP60 may terminate the HEC88473 Agreement in its entirety or on a country-by-country basis, at its sole discretion and for any or no reason at any time by providing 90 days' advance written notice of such termination to us. Each party has the right to terminate the agreement due to a material breach by the other party that is not remedied or due to bankruptcy.

We understand that Apollo and AP60 are Independent Third Parties.

### **Collaboration with Lannett**

On November 21, 2019, we entered into a collaboration and license agreement with Lannett Company Inc. ("**Lannett**"), to jointly develop Insulin Glargine for the treatment of Type 1 and Type 2 diabetes and sale in the U.S. market (the "**Glargine Agreement**"). On February 5, 2021, we entered into another collaboration and license agreement with Lannett, to jointly develop Insulin Aspart for the treatment of Type 1 and Type 2 diabetes and sale in the U.S. market (the "**Aspart Agreement**"). Lannett is a generic drug company in the United

States and manufactures and distributes over 70 generic drug products in the United States through retail and non-retail channels. Lannett possess a robust team of experts to support development and approval of biosimilar insulins for the US market, which could help us to expedite the development and commercialization of our Insulin Glargine and Insulin Aspart projects. Leveraging its well-established sales channels within the United States, Lannett can help to improve our success rate in securing new business contracts and facilitate the acceleration of market penetration of our products.

***Rights and obligations of the parties.*** Under the Glargine Agreement and the Aspart Agreement, we are responsible for, and have the sole decision-making authority for the following matters: (a) developing and commercializing Insulin Glargine and Insulin Aspart (other than the variable dose, multi-dose disposal injection drug delivery device (“**Insulin Pen**”)) in all countries in the world other than the United States, (b) the development activities in the United States that are assigned to us under the development plans in each of the Glargine Agreement and the Aspart Agreement, including pre-clinical research, approval documentation, approval maintenance and potential patent litigation, and (c) manufacturing of Insulin Glargine and Insulin Aspart, subject to certain terms of the Glargine Agreement and the Aspart Agreement respectively. Lannett is responsible for, and has the sole decision-making authority for the following matters: (a) the development activities in the United States that are assigned to Lannett under the development plans in each of the Glargine Agreement and the Aspart Agreement, including clinical research and commercialization of Insulin Glargine, Insulin Aspart as well as the Insulin Pen in the United States; and (b) development of Insulin Pen in the United States.

***Sublicense.*** Each party has the right to grant sublicenses to its affiliates and third parties who are engaged by that party to carry out development, manufacturing or commercialization activities provided the party has notified the other party in writing of such sublicense under the Glargine Agreement or the Aspart Agreement.

***Ownership of intellectual property.*** With respect to the intellectual properties and inventions discovered, developed, generated, or invented jointly by us and Lannett in the course of the development and commercialization process of Insulin Glargine and Insulin Aspart, both parties should own such intellectual property rights jointly on the basis of each party having an undivided interest and shall be deemed to be controlled by each party (“**Joint Inventions**”). Without the other party’s consent, each party shall have the right to individually use the Joint Inventions and right to non-exclusively license, or sell or otherwise transfer its interest in such Joint Inventions to its affiliates. Subject to the terms of the relevant agreement(s) and with the other party’s prior written consent, each party also has the right to exclusively license the Joint Inventions to any third party, or sell or otherwise transfer its interests in the Joint Inventions to a third party. All intellectual properties and inventions discovered, developed, generated or invented solely by a party shall be owned exclusively by that party. All intellectual properties and patents regarding Insulin Pen discovered or developed pursuant to the collaboration shall be owned exclusively by Lannett.



***Profit/loss and cost sharing.*** Under the Glargine Agreement, we will bear the development costs incurred by us to conduct activities set out in the development plan while Lannett will pay up to US\$32,000,000 pursuant to the development plan, and both parties shall equally share the reasonable direct costs incurred by either party or their affiliates for the development activities related to Insulin Glargine solely in the United States in accordance with the terms and conditions of the agreement subject to certain exceptions. Under the Aspart Agreement, we will bear the development costs incurred by us to conduct activities set out in the development plan while Lannett will pay up to US\$32,000,000 development costs upon achieving certain development milestone, and each party shall individually bear the reasonable direct costs incurred by it or its affiliates for the development activities related to Insulin Aspart solely in the United States in accordance with the terms and conditions of the agreement subject to certain exceptions. In respect of the operational profits or losses arising from the development and commercialization of Insulin Glargine and Insulin Aspart in the United States, each party shall be entitled to or bear fifty percent (50%) of the operational profits or losses from the initiation of the profit or loss sharing or development cost sharing until the earlier of (i) the tenth anniversary of the first commercial sale, or (ii) termination of the relevant agreement, provided that we can meet the minimum supply requirements under the corresponding agreement. If the relevant agreement remains in effect after the tenth anniversary of the first commercial sale, then from the tenth anniversary of the first commercial sale until the earlier of (i) the fifteenth anniversary of the first commercial sale, or (ii) the termination of the relevant agreement, we shall be entitled to or bear sixty percent (60%) of the operational profits or losses, while Lannett shall be entitled to or bear forty percent (40%) of the operational profits or losses, provided that we can meet the minimum supply requirements under the relevant agreement. During the Track Record Period, there was no cost sharing and we generated no income under the Glargine Agreement and the Aspart Agreement. The cost sharing arrangements under the Glargine Agreement and the Aspart Agreement are only related to some specific development activities for the U.S. market and are subject to a number of exceptions (i.e. costs specifically designated to a party). As of the Latest Practicable Date, our Insulin Glargine and Insulin Aspart were still mainly in the development stage in China, as a result, no cost sharing occurred during the Track Record Period.

***Term and termination.*** The Glargine Agreement is effective from the date of signing until the fifteenth anniversary of the first commercial sale of Insulin Glargine, and the Aspart Agreement is effective from the date of signing until the fifteenth anniversary of the first commercial sale of Insulin Aspart. After the expiration of the initial terms, both agreements will automatically renew every three years unless either party notifies the other party that it intends to terminate the corresponding Agreement with at least 12 months' prior written notice or the relevant agreement is terminated pursuant to other terms in that agreement. Both parties have the right to terminate the relevant agreement due to the other party's failure to rectify a material breach or bankruptcy.

***Supply agreement.*** A supply agreement, the form of which is attached as appendix to the Aspart Agreement, was entered into between Lannett and us on February 5, 2021 ("**Supply Agreement**"). Under the Supply Agreement, Lannett or its affiliates will purchase from us, and we or our affiliates will manufacture and supply to Lannett, Insulin Aspart during the term of



the Supply Agreement. The supply of Insulin Aspart will be at the price set out in the Supply Agreement, which was set based on the relevant market price with the price decreasing if the amount of Insulin Aspart to be purchased by Lannett increases, as amended by both parties from time to time. Lannett will order Insulin Aspart by sending purchase orders to us in accordance with the shipping instructions set forth in the Supplier Agreement, which will also specify the delivery date. Lannett will provide us with a minimum lead-time of twelve weeks on all purchase orders. We agree to deliver the Insulin Aspart on the delivery date DDP (Incoterms 2010) to such U.S. location as may be designated by Lannett from time to time. Lannett shall pay each invoice within ninety calendar days of the applicable delivery date, and payments shall be made to us by check or wire transfer to the bank account designated by us. Insulin Aspart products accepted by us as not meeting the applicable requirements from the FDA or another applicable regulatory authority and/or the product specifications agreed by both parties, or which is determined by the independent third party laboratory not to meet such requirements and/or the product specifications, shall be returned by Lannett to us, or disposed of, as directed by us and at our sole cost and expense. The term of the Supply Agreement shall terminate upon the expiration or termination of the Aspart Agreement.

We understand that Lannett is an independent third party.

### **Relationships with CROs**

In line with industry practice, we work with reputable CROs to manage and execute our clinical trials in China, United States, Australia and India. The primary research and development processes which are delegated to CROs include bioanalytical testing, data management and statistical analysis, subject recruitment, site management organization services, logistics, and warehousing. When we select CROs, we consider a number of factors, including their professional qualifications, their experience and industry reputation. We make sure that all CROs that we work with must comply with all applicable laws and regulations as well as follow our protocols to ensure that all clinical trial results are accurate and authentic.

When conducting pre-clinical formal toxicology experiments, the CROs commissioned by us strictly abide by the requirements of current Good Laboratory Practices (GLPs) and carry out necessary documentation, quality control and data management. In this way, we can ensure that our trial results are reliable, repeatable and traceable, and a sound scientific basis is provided for the research and development and regulatory filings in respect of our drugs under development. All formal clinical studies for the purpose of regulatory filings of our drugs under development conducted by the CROs commissioned by us are conducted in strict accordance with current GCP, principles and relevant ethical requirements of the Declaration of Helsinki of the World Medical Congress, and clinical trials are conducted in compliance with clinical trial protocols and data management procedures. Meanwhile, regular internal and external audits we conduct continuously improve CROs' quality management system and ensure compliance with the corresponding regulatory requirements.

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All of our animal experiments are conducted through CROs that have animal experiment qualification and comply with the regulations on the husbandry and use of laboratory animals.

Our agreement with the CRO typically contains these key terms:

- **Description of Services.** As stipulated in our master agreement or work order, the CROs provides us with the specified service related to drug development.
- **Term.** The service of the CRO must be completed within a prescribed time limit at an acceptable quality.
- **Payment.** Our payment to the CRO must be made pursuant to a mutually agreed schedule.
- **Risk allocation.** The party shall indemnify the other party for damages caused by its negligence, carelessness, willful negligence or material breach of the master agreement or work order.

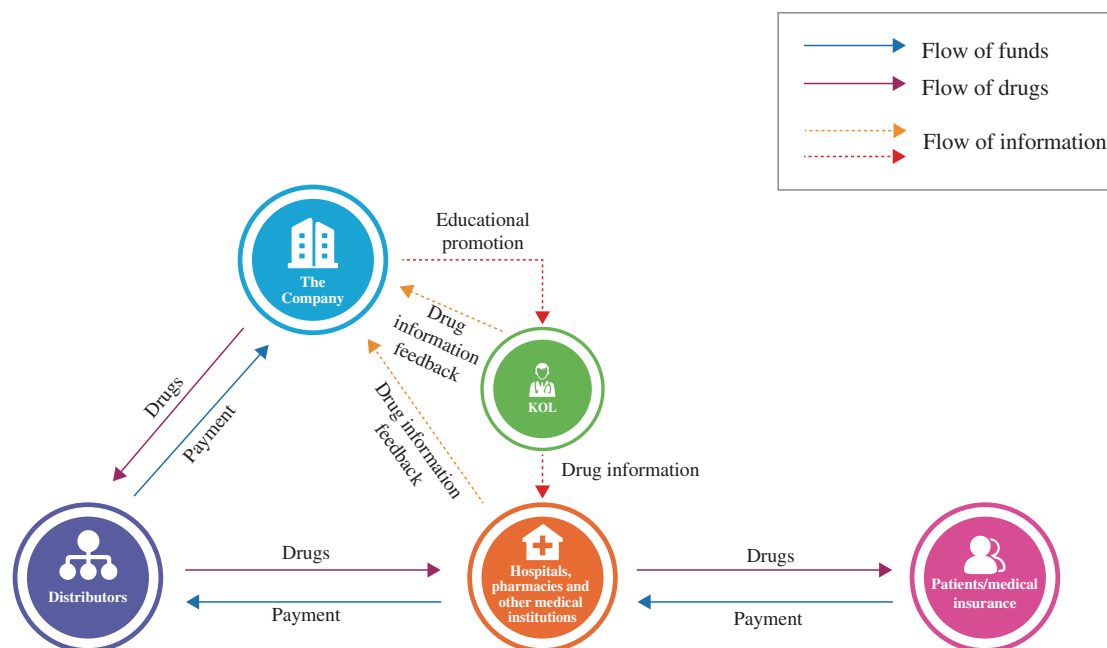
## SALES, MARKETING AND DISTRIBUTION

Our approach to generating demand for our products is based on two central strategies: promotional activities and strengthening and optimizing our distribution network. We promote our drugs primarily through our in-house sales and marketing team, which interacts with KOLs as well as other healthcare professionals through educational promotion activities. We believe our educational promotion activities enhance healthcare professionals' knowledge about the relevant therapeutic areas, as well as their understanding of the usage, clinical efficacy and other features of our products.

We sell our products primarily to GSP-certified third-party distributors, which distribute our products to hospitals, other medical institutions and pharmacies in the PRC. All distributors engaged by the Company are offline distributors. As of December 31, 2024, we have 1,884 employees engaged in our marketing and educational promotion activities, covering 32 provinces, cities and autonomous regions and nearly 300 prefecture-level cities in the PRC. As of December 31, 2024, we had 610 third-party distributors conducting sales, marketing and distribution activities within the PRC. Our GSP-certified third-party distributors are located throughout the PRC, which enables us to deepen our market penetration and expand our coverage of hospitals, pharmacies and other medical institutions throughout the PRC. We believe that this approach optimizes the allocation of our sales, marketing and distribution resources in an effective manner.

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The diagram below illustrates the general relationships among us, third-party distributors, KOLs, hospitals and other medical institutions, pharmacies and end-users of our products in the PRC in connection with sales, marketing and distribution of our drugs in the PRC.



We consider medical experts to be KOLs. We engaged a total of 137 medical experts as our KOLs during the Track Record Period. We choose to work with KOLs based on their professional qualifications, previous qualifications as well as academic standing and recognition within the relevant therapeutic area. We promote our pharmaceutical products primarily through our in-house sales and marketing team. The KOLs only participate in our educational promotion activities. We do not hire KOLs to sell our products. During the Track Record Period, we did not generate any revenue from KOLs' sales activities. As advised by our PRC Legal Advisor, we were not subject to any fines or penalties due to violation of relevant PRC laws and regulations in connection with our educational promotion activities during the Track Record Period and up to the Latest Practicable Date.

During the years ended December 31, 2022, 2023 and 2024, revenue generated in the PRC was RMB3,753.2 million, RMB6,335.9 million, and RMB3,880.5 million, respectively, representing 98.4%, 99.2%, and 96.6% of our revenue for the respective years. The remaining portion of our revenue are from sales to our overseas customers. Please see “— Sales, Marketing and Distribution — Sales outside the PRC” for further details.

During the Track Record Period and up to the Latest Practicable Date, we had not: (i) received any material complaints from our customers in relation to our products, (ii) been subject to any general or specific product recalls in respect of our products, or (iii) been subject to any product liability claim or experienced any product quality issue.

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Our sales and marketing department is responsible for developing our overall sales and marketing strategies. The sales and marketing department establishes our marketing strategies for each of our products through its research and analysis of the competitive positioning of our products and coordinates the various other departments involved in our marketing and promotion activities. Our sales and marketing department is organized by therapeutic areas and geographical regions. As of the Latest Practicable Date, we had marketed and sold a total of 48 drugs in China. Our sales and marketing team covers over 2,500 Class III hospitals, 9,600 Class II hospitals, 89,000 Class I hospitals, large-scale national or regional pharmacy chains and other medical institutions. Our sales and marketing department is also responsible for preparing marketing strategies for our future products, including market research and planning, allocation of marketing resources and pricing strategy. Going forward, as our product portfolio expands, we intend to increase the number of our sales and marketing staff, including developing specialist teams for our major products. We believe that with the support and central oversight given by our management team in our headquarters and the execution of our sales and marketing strategies by our local branches, we are able to seamlessly implement overall brand strategies through educational promotion activities and professional marketing.

We conduct educational promotion activities for doctors and other medical practitioners to educate them on our products and, at the same time, receive feedback from them on our products and our competitors' products. We consider this to be a two-way communication process that allows us to educate hospital management, doctors and other medical practitioners on the benefits and uses of our products, while also allowing us to understand their concerns regarding our products, and other similar products in the market. We also seek to understand their perception of the effectiveness of our products in the treatment and prevention of the relevant diseases or conditions compared to other products and also to demonstrate to them why our products should be prescribed for the relevant diseases and conditions. We believe that educational promotion activities raise the awareness of our product portfolio among doctors and other medical practitioners, which would in turn increase the use of our products by patients and thereby strengthen our brand awareness among the general public. Within the PRC, we regularly work with educational promotion organizations and third-party promoters and collaborate with KOLs for the purposes of marketing and promotion of our products. We consider physicians and other healthcare professionals to be KOLs based on their professional qualifications, previous qualifications as well as academic standing and recognition within the relevant therapeutic area. As of the Latest Practicable Date, we had marketed and sold a total of 48 drugs in China.

We have implemented internal control policies to ensure KOL's educational promotional activities comply with applicable laws and regulations, which includes internal control policies including (i) prohibiting inflation of the number of participants or days involved in the educational promotional events in order to give the KOLs larger reimbursement or excessive lecture fees; (ii) requiring our manager of the promotional activities to confirm the content of the activity with KOLs to facilitate the subsequent settlement; and (iii) conducting internal reviewing of educational promotional activities and if any violations are found, the relevant managers will be subject to internal disciplinary action.

In addition to our educational promotion activities, we have launched the “Discover HEC” program (“走進東陽光”) to build stronger connections with KOLs and business partners. Through this program, we regularly invite experts and partners to visit our Yidu production base. These visits include facility tours, academic workshops and in-depth discussions, giving participants a clear view of our operations and R&D capabilities. We believe this program helps promote academic exchange, enhance our professional reputation and increase brand awareness.

### **Centralized Tender Process and VBP Schemes**

In general, under PRC laws and regulations, the procurement of most pharmaceutical products by non-profit medical institutions established by the PRC government at the county level or higher and state-owned enterprises (including state-controlled enterprises) has to be conducted through a centralized tender process, including public bidding, invitational bidding and direct procurement. Pursuant to these centralized tender processes, pharmaceutical manufacturers of relevant products are invited to submit their bids to the local government or its designated institution that runs the tender process through public bidding. The tender selection for each drug product is conducted on the basis of comprehensive evaluation through regulatory authorities reviewing the materials submitted by pharmaceutical manufacturers, including the product quality, product price, service and the pharmaceutical manufacturer’s reputation. Medical institutions then select one or more winning pharmaceutical manufacturers to supply the medicine by placing orders with the relevant pharmaceutical product distributors. For details on centralized tender process and VBP schemes, see “Regulatory Environment — Principal Regulatory Provisions — Laws and Regulations on Drug Supply — Drug Purchases by Hospitals” and “— VBP of Drugs in “4+7 Cities” and Nationwide.”

During the Track Record Period, we participated in 12 national-level VBP scheme tenders and 166 provincial-level VBP scheme tenders. The relevant bidding projects may involve a number of our products and the average success rate on an annual basis for each of our national and provincial-level tenders during the Track Record Period was about 66.7% and 67.5%, respectively. During the years ended December 31, 2022, 2023 and 2024, with respect to national-level tenders, we participated in three tenders, one tender and eight tenders, respectively, with the average success rate being approximately 66.7%, 100.0% and 62.5%, respectively. During the years ended December 31, 2022, 2023 and 2024, with respect to provincial-level tenders, we participated in 50 tenders, 60 tenders and 56 tenders, respectively, with the average success rate being approximately 60.0%, 68.3% and 73.2%, respectively. The fluctuation in the success rates of our tenders is primarily attributable to variations in VBP schemes, different selection rules, and our product-specific bidding strategies.

**Our Oseltamivir Phosphate Products and the Reasons for the Fluctuation of the Sales of Our Oseltamivir Phosphate Products during the Track Record Period*****Overview of our oseltamivir phosphate products***

We currently sell most of our oseltamivir phosphate products, including granules and capsules, under the brand of Kewei (可威®) and a relatively small amount of oseltamivir phosphate capsules under the brand Yangjiantai (陽健泰®). During the Track Record Period, Kewei (including granules (primarily for children) and capsules (primarily for adults)) accounted for 99.9%, 99.4% and 96.5% and Yangjiantai (only in capsule form) accounted for 0.1%, 0.5% and 3.4% of our total sales of oseltamivir phosphate for 2022, 2023 and 2024, respectively. As the provincial VBP schemes had been implemented on Kewei granules since 2023, we mainly sell Kewei granules to public hospitals through provincial VBP schemes or to public hospitals, pharmacies and other medical institutions outside of VBP schemes. Our Kewei capsules have not been included in any national or provincial VBP schemes. Our Yangjiantai capsules have been included in national VBP schemes since 2022. We believe those two oseltamivir phosphate brands enable us to meet the demand of different types of end users of oseltamivir phosphate, with Yangjiantai focusing on meeting the demand of public hospitals through VBP schemes, as well as retail users who are price conscious, and Kewei focusing on meeting the demand of users who are willing to pay a price premium for high-end branded drugs. We are actively marketing and promoting sales of Kewei while we spend less marketing effort on Yangjiantai as its sales are mainly generated through VBP scheme. We mainly sold three types of oseltamivir phosphate products during the Track Record Period, namely (i) oseltamivir phosphate granule under the brand Kewei with a revenue of RMB2,585.2 million, RMB4,824.6 million and RMB2,181.5 million for 2022, 2023 and 2024, respectively, representing 83.5%, 87.0% and 84.6% of our total revenue from oseltamivir phosphate products, respectively; (ii) oseltamivir phosphate capsule under the brand Kewei with a revenue of RMB507.6 million, RMB684.9 million and RMB307.0 million for 2022, 2023 and 2024, respectively, representing 16.4%, 12.3% and 11.9% of our total revenue from oseltamivir phosphate products, respectively; and (iii) oseltamivir phosphate capsule under the brand Yangjiantai with a revenue of RMB4.7 million, RMB29.2 million and RMB87.7 million for 2022, 2023 and 2024, respectively, representing 0.1%, 0.5% and 3.4% of our total revenue from oseltamivir phosphate products, respectively.

***Key factors affecting the sales of our oseltamivir phosphate products during the Track Record Period***

Our revenue increased by 67.4% from RMB3,813.6 million in 2022 to RMB6,385.6 million in 2023 and then decreased by 37.1% to RMB4,018.9 million in 2024. The fluctuation of our revenue during the Track Record Period was mainly affected by our revenue generated from our oseltamivir phosphate products. The following are the key factors affecting the sales of our oseltamivir phosphate products during the Track Record Period.

*1. The fluctuation of flu incidence*

The flu incidence affects the demand for our oseltamivir phosphate products. As a result, our revenue generated from the sales of oseltamivir phosphate products fluctuated with flu incidence in China and our revenue fluctuation was generally in line with our competitors during the Track Record Period. The increase in flu incidence in China in 2023 and the subsequent drop in flu incidence in China in 2024 were the main reason for the increase in our oseltamivir phosphate revenue in 2023 and the decrease in our oseltamivir phosphate revenue in 2024, respectively. According to Frost & Sullivan, there were 2.5 million, 12.5 million and 8.6 million new influenza cases reported in China in 2022, 2023 and 2024, respectively, based on the Statistical Report on China's Healthcare Development. According to Frost & Sullivan, the PRC's anti-influenza drug market increased by 150.0% from RMB4.4 billion in 2022 to RMB11.0 billion in 2023 due to the significant influenza outbreaks in 2023 and dropped by 39.1% from RMB11.0 billion in 2023 to RMB6.7 billion in 2024 due to lack of significant influenza outbreaks and the resulting lower flu incidence in 2024.

For our oseltamivir phosphate granules (Kewei) product (15mg) ("**Kewei granules**"), as we are a market leader in terms of sales volume of and revenue derived from the sales of oseltamivir phosphate granules, holding over 99% of the market share in the PRC of oseltamivir phosphate granules during the Track Record Period, flu incidence affects the sales of our kewei granules mainly by affecting the market demand for our Kewei granules, which in turn affects the sales volume of our Kewei granules. As a result, whether the provincial VBP schemes had been implemented and the number of provinces which implemented provincial VBP on Kewei granules have no material impact on the aggregate sales volume of Kewei granule for both VBP and non-VBP sales. Our strong market position for Kewei granules is also reflected by the gross profit margin for our Kewei granules, which remained stable at 85.6% and 88.3% for 2023 and 2024, respectively, even though the number of provinces which had implemented the provincial VBP scheme on Kewei granules increased from six in 2023 to 20 in 2024.

For our oseltamivir phosphate capsules (Kewei) product ("**Kewei capsules**"), as there has not been any VBP schemes implemented on Kewei capsules, we cannot sell our Kewei capsules to public hospitals through VBP schemes under normal conditions, and we can only sell Kewei capsules to public hospitals outside of the VBP schemes. However, as explained in more detail in factor 3 below, in a year when there is a sudden spike of flu incidence which causes a shortage of oseltamivir phosphate capsules in the public hospitals, we will be able to sell our Kewei capsules to public hospitals.

*2. The average selling price of Kewei granules*

Our Kewei granules accounted for 83.5%, 87.0% and 84.6% of our total revenue from oseltamivir phosphate products for 2022, 2023 and 2024, respectively. As a result, the average selling prices has a significant impact on our revenue.

During the Track Record Period, the inclusion of Kewei granules in the provincial VBP schemes resulted in a reduction in the average selling price of Kewei granules due to the reduction of sales opportunities to hospitals outside of the VBP scheme at a higher



average selling price. In 2024, the price under the provincial VBP schemes for a package of 15mg\*10 sachets of Kewei granules was set at RMB40.95, while the listing price on the government platform for the same pack of Kewei granules outside the provincial VBP scheme was set at RMB45.68. The provincial VBP scheme has been implemented for Kewei granules since 2023. A total of six provinces implemented the provincial VBP schemes on Kewei granules in 2023, and a total of 20 provinces had implemented provincial VBP schemes for Kewei granules by the end of 2024. We believe the impact of the provincial VBP schemes being implemented on the price of Kewei granules is relatively mild, as we are a market leader in terms of sales volume of and revenue derived from the sales of oseltamivir phosphate granules, holding over 99% of the market share of oseltamivir phosphate granules in the PRC during the Track Record Period, and accordingly, there is less competitive pressure on our pricing.

In addition to the impact of VBP schemes on our average selling price of Kewei granules, the average selling price of Kewei granules is also impacted by whether it is sold to Kewei pharmacy distributors or general distributors which distribute it to hospitals. PRC hospitals procure Kewei granules from general distributors but not from Kewei pharmacy distributors. The average selling price for Kewei granules sold to Kewei pharmacy distributors in general is lower than the average selling price for Kewei granules sold to general distributors which distribute it to hospitals, as we give bigger sales rebates to our Kewei pharmacy distributors to compensate for their marketing and promotion activities as compared with that for the general distributors which distribute the drug to hospitals, either in or outside of the VBP scheme. As a result, even though the average selling price for our Kewei granules has been negatively impacted by its inclusion in the VBP scheme, the average selling price for our Kewei granules under the VBP schemes (which are mainly distributed through general distributors) is still higher as compared with the average selling price of Kewei granules outside of the VBP schemes (which are distributed through both general distributors and Kewei pharmacy distributors). During the Track Record Period, the average selling price for our Kewei granules under the VBP schemes was RMB3.3 and RMB3.4 for 2023 and 2024, respectively, as compared with the average selling price of Kewei granules outside of the VBP schemes of RMB3.2 and RMB2.7 for 2023 and 2024, respectively.

The overall average selling price of Kewei granules (15 mg) decreased by 7.8% from RMB3.22 in 2023 to RMB2.97 in 2024, which negatively impacted our revenue from 2023 to 2024. Such decrease was primarily due to the decrease in the average selling price of Kewei granules (15 mg) through non-VBP schemes from RMB3.2 for 2023 to RMB2.7 for 2024. The sales of our Kewei granules (15 mg) through non-VBP scheme include (i) the sales to general distributors which distribute Kewei granules (15 mg) to public hospitals and other medical institutions through non-VBP scheme, and (ii) the sales to Kewei pharmacy distributors which distribute to pharmacies. The decrease in the average selling price of Kewei granules (15 mg) through non-VBP schemes from RMB3.2 for 2023 to RMB2.7 for 2024 was primarily caused by the fact that the proportion of Kewei granules (15 mg) sold to Kewei pharmacy distributors which distribute to pharmacies as a percentage of all Kewei granules (15 mg) sold through non-VBP increased in 2024, which caused the average selling price for Kewei granules (15 mg) to drop in 2024 as the

average selling price for Kewei granules (15 mg) sold to Kewei pharmacy distributors in general is lower than the average selling price for Kewei granules (15 mg) sold to general distributors which distribute it to hospitals and other medical institutions through non-VBP schemes.

*3. The purchase Kewei capsule product outside of VBP scheme*

According to Frost & Sullivan, the PRC public hospitals generally determine the annual amounts of drugs they procure under the VBP scheme according to their estimates of the clinical demand for such drugs every year, and the public hospitals generally make purchases of such drugs every month according to the annual order subject to any additional purchases. The public hospitals usually make such estimates by referencing the historical purchase amount of the drug and relevant disease incidence in the previous year. In cases where there is a higher-than-expected outbreak of flu season and oseltamivir phosphate capsules procured by the public hospitals through VBP scheme is not sufficient to meet the patients' demand, the public hospitals will purchase extra oseltamivir phosphate capsules including our Kewei capsules from the market. In 2023, the PRC public hospitals made such purchases of Kewei capsules from the market due to the spike in the flu incidence. We believe that our competitive advantage in production capacity of oseltamivir phosphate allows us to benefit from such sudden demand from public hospitals, as we are better positioned than our competitors to ramp up our production quickly to meet such sudden demand.

The PRC public hospitals increased the procurement amount for oseltamivir phosphate capsules through the VBP scheme in 2024, as there was a significant outbreak of influenza in China and the resulting spike in patients' demand of oseltamivir phosphate capsules in 2023. However, the demand for oseltamivir phosphate capsules was not as high as originally expected due to the lack of significant influenza outbreaks in 2024. As a result, there was less demand to purchase oseltamivir phosphate capsules from the market as the amount of oseltamivir phosphate capsules the public hospitals purchased through the VBP scheme was sufficient to meet patients' demand.

*4. Competition from other anti-influenza drugs*

Increasingly intense competition from other types of anti-influenza drugs negatively affected our revenue generated from oseltamivir phosphate products during the Track Record Period. According to Frost & Sullivan, peramivir and baloxavir marboxil, which accounted for 8.6% and 5.4% of the PRC's anti-influenza drug market in 2023, respectively, were able to increase their market shares to 12.4% and 10.8% in 2024, respectively. In addition, our competitors within the oseltamivir phosphate market, such as Company A and Company B, also increased their market share from 16.3% and 3.9% in 2023 to 21.2% and 4.9% in 2024, respectively. If we cannot maintain our market share for our oseltamivir phosphate products in the future, it will have a negative impact on our business performance and financial position. Please see "Risk Factors — Our revenue and business prospects currently depend on Kewei (oseltamivir phosphate). If we are unable to maintain the sales volumes, pricing levels and profit margins of Kewei, our revenue and business prospects could be materially and adversely affected." for details.

*The impact of fluctuations of flu incidence on our customers' procurement plans for oseltamivir phosphate drugs included in or excluded from the VBP schemes*

We mainly sell Kewei in granule form and capsule form. During the Track Record Period, Kewei granules represented 83.5%, 87.0% and 84.6% of our total oseltamivir phosphate sales for 2022, 2023 and 2024, respectively. Kewei capsules represented 16.4%, 12.4% and 11.9% of our total oseltamivir phosphate sales for 2022, 2023 and 2024, respectively.

Product	Dosage	Type	2022				2023				2024						
			Sales Volume ( <i>'000 units</i> )	Proportion of Total Sales (%)	Revenue (RMB <i>'000</i> )	Proportion of Revenue (%)	ASP (RMB/unit)	Sales Volume ( <i>'000 units</i> )	Proportion of Total Sales (%)	Revenue (RMB <i>'000</i> )	Proportion of Revenue (%)	ASP (RMB/unit)	Sales Volume ( <i>'000 units</i> )	Proportion of Total Sales (%)	Revenue (RMB <i>'000</i> )	Proportion of Revenue (%)	ASP (RMB/unit)
oseltamivir phosphate granule (Kewei)	15mg per sachet	VBP ( <i>note 1</i> )	NA	NA	NA	NA	127,827	8.9	424,289	9.2	3.3	260,412	51.9	896,822	41.1	3.4	
		Non-VBP ( <i>note 2</i> )	818,073	100	2,441,015	100	3.0	1,311,816	91.1	4,204,310	90.8	3.2	473,110	48.1	1,284,687	58.9	2.7
	Sub-total	818,073	100	2,441,015	100	NA	1,439,643	100	4,628,599	100	NA	735,522	100	2,181,509	100	NA	
	Non-VBP ( <i>note 2</i> )	43,716	100	144,137	100	3.3	48,874	100	195,994	100	4.0	NA	NA	NA	NA	NA	
oseltamivir phosphate capsule (Kewei)	75mg per capsule	Non-VBP ( <i>note 2</i> )	66,356	100	507,554	100	7.7	84,212	100	684,910	100	8.1	47,628	100	306,950	100	6.4
oseltamivir phosphate capsule (Yangjiantai)	75mg per capsule	VBP ( <i>note 1</i> )	5,479	100	4,698	100	0.9	18,534	68.9	15,893	54.4	0.9	52,515	66.5	45,548	51.9	0.9
		Non-VBP ( <i>note 2</i> )	NA	NA	NA	NA	8,371	31.1	13,335	45.6	1.6	26,486	33.5	42,189	48.1	1.6	
		Sub-total	5,479	100	4,698	100	NA	26,905	100	29,228	100	NA	79,001	100	87,737	100	NA
Total revenue for VBP					4,698	0.2			440,182	7.9				942,370	36.6		
Total revenue for non-VBP					3,092,706	99.8			5,098,549	92.1				1,633,827	63.4		
Total revenue ( <i>note 4</i> )					3,097,404	100			5,538,731	100				2,576,197	100		

*Note 1:* Once the drug enters the VBP scheme for a province: (1) all sales to public hospitals in such province will be under the VBP scheme at the VBP scheme price, whether under the initial procurement or a subsequent top up of demand for the drug; (2) the price of the drug sold to public hospitals in the province will follow that applicable for the provincial VBP scheme, regardless of whether the sales are made in the initial procurement under the provincial VBP scheme or under further purchases by public hospitals in the province beyond the initial procurement under the VBP scheme.

*Note 2:* The Non-VBP sales include the sales to public hospitals and other medical institutions in the provinces which have not implemented VBP schemes and the sales to pharmacies.

*Note 3:* We have stopped selling oseltamivir phosphate granule (Kewei) 25mg since 2024 due to the lack of market demand for the products.

*Note 4:* The total revenue primarily includes revenue from the sales of our Kewei granule, Kewei capsule, Yangjiantai capsule products during the Track Record Period. During the Track Record Period, we also generated small amount of revenue from (i) the sales of dry suspension form of oseltamivir phosphate in the amount of nil, RMB6.0 million and RMB3.5 million for 2022, 2023 and 2024, respectively and (ii) the sales of 30 mg and 45 mg unbranded oseltamivir phosphate capsules which in aggregate generated revenue in the amount of nil, RMB763.5 thousands, RMB33.1 thousands for 2022, 2023 and 2024, respectively.

- (i) Kewei granules. For our Kewei granules, as the provincial VBP schemes had been implemented on Kewei granules since 2023, we sell Kewei granule through provincial VBP schemes or to hospitals, pharmacies and other medical institutions outside of VBP schemes.

*(a) Sales of Kewei granules through provincial VBP schemes*

During the Track Record Period, the implementation of the provincial VBP schemes which started in 2023 impacted the average selling price of Kewei granules as a result of the reduction of sales opportunities to hospitals outside of the VBP scheme at a higher average selling price. Six provinces implemented the provincial VBP schemes for Kewei granules in 2023, and 20 provinces implemented the provincial VBP schemes for Kewei granules in 2024. According to the provincial VBP scheme for 2024, the price for a package of 15mg\*10 sachets of Kewei granules was RMB40.95, while the list price displayed on government platform pursuant to the provincial VBP schemes for the same pack of Kewei granules which is the sales price for outside the provincial VBP scheme is RMB45.68. The price under the provincial VBP is stable for our Kewei granules in 2023 and 2024. Please see “— Our Oseltamivir Phosphate Products and the Reasons for the Fluctuation of the Sales of Our Oseltamivir Phosphate Products during the Track Record Period — Key factors affecting the sales of our oseltamivir phosphate products during the Track Record Period” for details.

*2023 as compared with 2022*

The sales of Kewei granules through the provincial VBP schemes increased from nil in 2022 to RMB424.3 million in 2023, as Kewei granules commenced the sales through provincial VBP scheme in six provinces in 2023. The sales volume of Kewei granules through the provincial VBP schemes increased from nil in 2022 to 127.8 million sachets in 2023.

*2024 as compared with 2023*

The sales of Kewei granules through the provincial VBP schemes increased by 111.4% from RMB424.3 million in 2023 to RMB896.8 million in 2024 which was primarily driven by the increase in sales volume from 127.8 million sachets to 260.4 million sachets. Such increase was primarily driven by the increase in the number of provinces which had implemented provincial VBP schemes for Kewei granules from six in 2023 to 20 in 2024. The average selling price of Kewei granules sold through the provincial VBP schemes increased slightly from RMB3.3 in 2023 to RMB3.4 in 2024.

***(b) Sales of Kewei granules (15 mg) outside the provincial VBP schemes***

*2023 as compared with 2022*

The sales of Kewei granules outside the provincial VBP schemes increased by 72.2% from RMB2,441.0 million in 2022 to RMB4,204.3 million in 2023. Such increase was primarily driven by an increase in the sales volume from 818.1 million sachets in 2022 to 1,311.8 million sachets in 2023, as the flu incidence in China increased significantly in 2023, which resulted in a significant increase in the demand for our Kewei granules by hospitals located in the provinces which had not implemented VBP schemes, pharmacies and other medical institutions. In addition, the average selling price of our Kewei granules sold to hospitals outside the provincial VBP schemes, pharmacies and medical institutions remained relatively stable at RMB3.0 in 2022 and RMB3.20 in 2023.

*2024 as compared with 2023*

The sales of Kewei granules outside the provincial VBP schemes decreased by 69.44% from RMB4,204.3 million in 2023 to RMB1,284.7 million in 2024. Such decrease was primarily driven by the decrease in the sales volume from 1,311.8 million sachets in 2023 to 475.1 million sachets in 2024. The decrease in sales volume in 2024 was primarily due to the drop of flu incidence in 2024 which resulted in the decreasing demand for Kewei granules from hospitals outside the provincial VBP schemes, pharmacies and medical institutions. In addition, the scope of the provincial VBP scheme for Kewei granules expanded from six provinces in 2023 to 20 provinces in 2024, which also reduced on the sales volume of Kewei granules classified as non-VBP sales.

The average selling price for Kewei granules outside of the provincial VBP schemes decreased from RMB3.2 to RMB2.7 as the proportion of Kewei granules sold to pharmacies as a percentage to all Kewei granules sold outside of the provincial VBP schemes increased in 2024. Such increase in the proportion of Kewei granules sold to pharmacies was caused by the greater decrease in sales of Kewei granules to hospitals as compared with the sales of Kewei granules to pharmacies. The average selling price for Kewei granules sold to Kewei pharmacy distributors in general is lower than the average selling price for Kewei granules sold to general distributors which distribute it to hospitals, as we give bigger sales rebates to our Kewei pharmacy distributors to compensate for their marketing and promotion activities as compared with that for the general distributors which distribute the drug to hospitals, either in or outside of the VBP scheme.

*(c) Sales of Kewei granules (25 mg)*

During the Track Record Period, we also sold a relatively small amount of Kewei granules (25 mg) outside the provincial VBP schemes in 2022 and 2023. The revenue from such sales increased from RMB144.1 million in 2022 to RMB196.0 million in 2023 which was primarily driven by the increase in sales volume from 43.7 million sachets in 2022 to 48.9 million sachets in 2023, as a result of the increased market demand. The average selling price also increased from RMB3.3 to RMB4.0 which was mainly due to the fact that we offered a special promotion to our distributors in 2022 to promote our Kewei capsules due to COVID-19 and we did not offer such promotion in 2023. We stopped selling Kewei granules (25 mg) in 2024 due to the lack of market demand for the product.

- (ii) Kewei capsules. For our oseltamivir phosphate capsules (Kewei) product (“**Kewei capsules**”), as there has not been any VBP schemes implemented on Kewei capsules, we sell Kewei capsules outside of the VBP schemes. However, in cases where there is a sudden outbreak of flu season and oseltamivir phosphate capsules procured by the public hospitals through VBP schemes is not sufficient to meet the patients’ demand, the public hospitals will purchase extra oseltamivir phosphate capsules, including our Kewei capsules, outside the VBP schemes.

*2023 as compared with 2022*

The sales of Kewei capsules increased significantly from RMB507.6 million in 2022 to RMB684.9 million in 2023, as the sales volume of our Kewei capsules increased from 66.4 million capsules in 2022 to 84.2 million capsules in 2023. The increase in sales volume was due to the fact that the flu incidence in China spiked in 2023, which resulted in a significant increase in the demand from public hospitals, pharmacies and other medical institutions. We believe that our competitive advantage in production capacity of oseltamivir phosphate allows us to benefit from such sudden demand from public hospitals. In addition, the average selling price of our Kewei capsules also increased from RMB7.64 in 2022 to RMB8.13 due to the fact that we offered a special promotion discount to our distributors in 2022 to promote our Kewei capsules due to COVID-19 which we did not offer in 2023.

*2024 as compared with 2023*

According to Frost & Sullivan, the PRC public hospitals generally determine the annual amounts of drugs they procure for each year under the VBP scheme according to their estimates of the clinical demand for such drugs every year and the public hospitals generally make purchases every month according to the annual order subject to any additional purchases. The public hospitals usually make such estimates by referencing the historical purchase amount of the drug and the relevant disease incidence in the previous year. The PRC public hospitals increased the



procurement amount for oseltamivir phosphate capsules through the VBP scheme in 2024, as there was a significant outbreak of influenza in China which resulted in a spike in patients' demand for oseltamivir phosphate capsules in 2023. However, the demand for oseltamivir phosphate capsules was not as high as originally expected due to the lack of significant influenza outbreaks in 2024. As a result, there was less demand to purchase Kewei capsules from the market as the amount of oseltamivir phosphate capsules the public hospitals purchased through the VBP scheme was sufficient to meet patients' demand. In particular, we faced increasingly intense competition from manufacturers of other types of anti-influenza drugs and other oseltamivir phosphate products and such competition had caused (i) the market share of oseltamivir phosphate as a percentage of total anti-influenza drug market decreased from 78.0% in 2023 to 70.3% in 2024 and (ii) the market share of our oseltamivir phosphate products as a percentage of total PRC oseltamivir phosphate market decreased from 64.8% in 2023 to 54.8% in 2024. As a result, such competition negatively affected our revenue generated from Kewei capsules in 2024 as compared to 2023. The sales of Kewei capsules decreased significantly from RMB684.9 million in 2023 to RMB307.0 million in 2024, as the sales volume of our Kewei capsules decreased from 84.2 million capsules in 2023 to 47.6 million capsules in 2024. In addition, the average selling price for our Kewei capsules also decreased from RMB8.1 in 2023 to RMB6.4 in 2024 due to the downward adjusted prices of Kewei capsules displayed on the government platform.

- (iii) For our oseltamivir phosphate capsules (Yangjiantai) product (“**Yangjiantai capsules**”), as the national VBP scheme had been implemented on Yangjiantai capsules since 2022, we sell Yangjiantai capsules to public hospitals pursuant to the national VBP scheme and to pharmacies and medical institutions outside of the VBP scheme.

*(a) Sales through the national VBP scheme*

Our sales of Yangjiantai capsules through public hospitals via the national VBP scheme recorded a significant increase from RMB4.7 million in 2022 to RMB15.9 million in 2023 and further to RMB45.5 million in 2024. The increase was mainly due to the fact that the PRC public hospitals increased their procurement volume for oseltamivir phosphate capsules (Yangjiantai) during the period, especially in 2024 as there was a significant outbreak of influenza in China in 2023. The average selling price of our Yangjiantai capsules remained stable at RMB0.9 throughout the Track Record Period.

*(b) Sales outside the VBP scheme*

We started to sell Yangjiantai to pharmacies and medical institutions in 2023. Our sales of Yangjiantai capsules outside the VBP scheme recorded a significant increase from RMB13.3 million in 2023 to RMB42.2 million in 2024. The increase was mainly due to the increase in sales volume, which in



turn was driven by demand from customers who are price conscious. The selling price for our Yangjiantai capsules outside the VBP schemes is competitive as compared with other oseltamivir phosphate capsules. For example, our average selling price for Yangjiantai capsules outside the VBP schemes was RMB1.6 in 2024 as compared with RMB6.4 for our Kewei capsules in 2024.

### **Our Marketing Strategies for Kewei and Yangjiantai**

Our sales volume of Yangjiantai sold through public hospitals via VBP schemes recorded a significant increase in 2024 as compared with 2023, which was mainly due to the fact that the PRC public hospitals increased their procurement of oseltamivir phosphate capsules including Yangjiantai in 2024, as there was a significant outbreak of influenza in China in 2023. Our sales volume of oseltamivir phosphate capsules under the brand of Kewei decreased due to the lower flu incidence in 2024 as well as the reduced purchase from public hospitals as they increased the purchase of oseltamivir phosphate capsules through the VBP scheme in 2024. Therefore, we believe the increase in the sales volume of Yangjiantai and the decrease in the sales volume of Kewei was not directly prompted by the shifting of demand from oseltamivir phosphate capsules under the brand of Kewei to oseltamivir phosphate capsules under the brand of Yangjiantai.

We leverage our established advantages in the influenza field, utilizing marketing and promotional strategies to continuously enhance patient awareness of the Kewei brand. Specifically, we aim to establish and maintain a strong connection between influenza treatment and the Kewei brand, through targeted market education, academic promotion and patient communication. We believe this will strengthen the market competitiveness of Kewei products and solidify its leadership position in the influenza field.

The launch of the Yangjiantai brand of oseltamivir phosphate capsules is primarily focused on addressing market competition of national VBP and meeting the user demand for low-price capsule markets. We do not plan to conduct large-scale market promotion but will instead drive sales through market demand. Yangjiantai will serve as a supplement to the Company's influenza treatment product line with a focus on price-sensitive markets. We believe those two oseltamivir phosphate capsule brands help us meet the demand of different types of customers, with Yangjiantai focusing on meeting the demand of public hospitals through VBP schemes, as well as users who are more price conscious, and Kewei focusing on meeting the demand of customers who are willing to pay a price premium for high-end brand drugs.

According to Frost & Sullivan, the PRC public hospitals generally determine the annual amounts of drugs they procure under the VBP scheme according to their estimates of the clinical demand for such drugs every year and the public hospitals generally make purchases every month according to the annual order subject to any additional purchases. The public hospitals usually make such estimates by referencing the historical purchase amount of the drug and relevant disease incidence in the previous year. Please see “— Our oseltamivir

phosphate products and the reasons for the fluctuation of the sales of our oseltamivir phosphate products during the Track Record Period — Key factors affecting the sales of our oseltamivir phosphate products during the Track Record Period” for details. Given that future purchase amounts made by the public hospitals will fluctuate with the flu incidence in the previous year, we believe that the significant increase in sales of oseltamivir phosphate capsules pursuant to the VBP scheme in 2024 is not likely to be sustainable in future.

Based on the above, to compete with other oseltamivir phosphate capsules drugs which are in the low-price capsule market or have been included in the VBP scheme, we started to produce oseltamivir phosphate capsules under the brand Yangjiantai since the commencement of the VBP scheme with respect to oseltamivir phosphate capsules in 2022. As a result, our Yangjiantai capsules are directly competing with other oseltamivir phosphate capsules which are already in the VBP scheme or in the low-price capsule market. Therefore, our two brands are complementing, rather than competing with each other, with each focusing on a different type of users.

Yangjiantai has been included in the national VBP scheme since 2022, and it will cease to be included in the national VBP scheme after 2025. We plan to participate in the centralized tender process and submit bids for Yangjiantai to be included in the provincial VBP scheme after 2025. Given the relatively small revenue contribution from Yangjiantai and the fact that we do not plan to conduct large-scale marketing to promote the brand, we do not expect our overall financial and business performance will be significantly impacted by whether Yangjiantai is included in the national VBP scheme or not.

In addition, we have established a comprehensive oseltamivir phosphate production line in China with a supply chain system from starting materials to finished formulations. We believe our manufacturing capabilities enable us to quickly respond to sudden spikes in market demand for oseltamivir phosphate during flu season, which is a crucial competitive strength for us. In addition, as the leading domestic pharmaceutical company in terms of anti-viral drug sales in the PRC, our brands in relation to anti-viral products have been widely recognized in the industry and among the patients.

### **Commercialization Plan for Our Products and Product Candidates**

We believe the drop of our revenue in 2024 as compared with that of 2023 is short-term due to the following reasons:

- (1) the main reason for the drop of our revenue in 2024 was the low incidence of influenza due to the delay of outbreak of flu season in 2024. We believe such factor is short-term in nature as the incidence of influenza varies from year to year depending on whether there is a significant outbreak of influenza during that year;
- (2) even though we face increasing competition from other producers of anti-influenza drugs, our market position, brand recognition and advanced production capability give us an advantage over our competitors. According to the Frost & Sullivan, we

ranked first in the PRC in terms of cumulative oseltamivir phosphate shipments and production volume over a period of five years from 2019 to 2023. With over a decade of development and continued efforts, we have established a comprehensive oseltamivir phosphate production line in China with a supply chain system from starting materials to finished formulations. We believe our manufacture capabilities enable us to quickly respond to sudden spiking market demand for oseltamivir phosphate during flu season which is a crucial competitive strength for us. In addition, as the established domestic pharmaceutical company in terms of anti-viral drug sales in the PRC, our brands in relation to anti-viral products have been widely recognized in the industry and among the patients. We believe those competitive advantages take years to develop and cannot be easily replicated by a new competitor; and

- (3) furthermore, we have taken the following measures to boost the sales of our drugs:
  - (i) develop new growth drivers through commercializing new drugs with market potentials
  - (A) the combination treatment regimen of Dong’antai (Netanasvir Phosphate Capsules) and Dong’anqiang (Encofosbuvir Tablets)

According to the Frost & Sullivan Report, the total number of patients diagnosed with chronic hepatitis C in China was 2.6 million in 2023 and is expected to increase to 2.8 million and 3.1 million in 2026 and 2030, respectively. In 2023, the market size of anti-hepatitis C virus drugs in China reached RMB3.7 billion. The combination treatment regimen of Netanasvir Phosphate and Encofosbuvir is a domestic in-house R&D combination treatment regimen for pan-genotypic chronic hepatitis C, which has shown very promising clinical resulting including achieving an SVR12 of 95.0% against pan-genotypic chronic hepatitis C patients.

Netanasvir Phosphate and Encofosbuvir were approved by the NMPA for launching in China in February 2025 and March 2025, respectively. We are currently scaling up production and finalizing our market launch preparations, with sales expected to begin in July 2025. In parallel, we are preparing to initiate negotiations with national medical insurance authorities in December 2025, and we anticipate that our products will be included in the NRDL starting in January 2026. We plan to leverage our well-established sales channels for anti-infective drugs to expand its coverage for our anti-hepatitis C drugs. We plan to collaborate with health authorities, such as the National Health Commission, to promote educational activities on hepatitis C to locate and target more HCV patients. Furthermore, introducing the combination treatment regimen of Netanasvir Phosphate and Encofosbuvir for the treatment of

pan-genotypic chronic hepatitis C will enable our treatment regimen to cover more HCV genotypes, meeting the diverse needs of patients and broadening the treatment population.

(B) Guangjianyou (Insulin Glargine Injection)

According to Frost & Sullivan, from 2018 to 2023, the market size of diabetes drugs in the U.S. increased from USD33.2 billion to USD40.4 billion, with a CAGR of 4.0%. The market size of diabetes drugs in the U.S. will continue to grow steadily and is expected to reach USD46.0 billion in 2026 and USD52.0 billion in 2030, representing a CAGR of 4.4% from 2023 to 2026 and 3.1% from 2026 to 2030, respectively. In 2023, sales of insulin and its analogs accounted for approximately 20% of the diabetes drugs market in the U.S.

We have been collaborating with Lannett to develop Insulin Glargine Injection for the U.S. market. We submitted the BLA for our Insulin Glargine Injection to the U.S. FDA in December 2023. Since then, we have been actively responding to the U.S. FDA's requests for additional information to facilitate the approval process. Based on the current review progress and our understanding of the U.S. FDA's general review timeframe for BLA applications, we expect to receive BLA approval for our Insulin Glargine Injection in the first half of 2026. We are one of the only two PRC pharmaceutical companies that are developing Insulin Glargine Injection for the U.S. market. Following BLA approval, in order to ensure successful market entry, we plan to establish partnerships with insurance companies, long-term care facilities, rehabilitation centers and chain pharmacies to enhance market penetration and strengthen our brand presence among the end-users.

(C) Dongjiandi (Yinfeinidone Hydrochloride Tablets)

According to the Frost & Sullivan, the total number of idiopathic pulmonary fibrosis (IPF) patients in China was 164.3 thousand in 2023 and such number is expected to increase to 231.1 thousand and 339.2 thousand in 2026 and 2030, respectively. The market size of pulmonary fibrosis drugs in China reached RMB1.5 billion in 2023 and is expected to increase to RMB2.7 billion and RMB3.2 billion in 2026 and 2030, respectively. As of the Latest Practicable Date, there were only two drugs for the treatment of IPF (namely Pirfenidone and Nintedanib) available in the world, which had also been approved for sale in China.

We are currently conducting Phase III clinical trial on Yinfeinidone Hydrochloride which is a drug candidate for the treatment of idiopathic pulmonary fibrosis.

As sales channels of the approved pulmonary fibrosis drugs in China extensively overlap with those of our existing anti-infective drug, Oseltamivir Phosphate Capsules. Following NMPA approval, we plan to leverage our existing sales network and integrate it with sales channels used for Oseltamivir Phosphate Capsules to achieve rapid market penetration for Yinfenidone Hydrochloride. We also plan to explore its sales channels such as Direct-to-Patient (DTP) pharmacies and online hospitals to expand its reach and enhance its brand recognition.

(D) Dongjiantang (Olorigliflozin Capsules)

According to the Frost & Sullivan, the total number of type 2 diabetes patients in China was 137.0 million in 2023 and is expected to increase to 144.3 million and 150.5 million in 2026 and 2030, respectively. SGLT-2 inhibitor is a type of innovative antidiabetic medication that can lower the renal glucose threshold and promote urinary glucose excretion, thus reducing blood glucose levels. In addition, SGLT-2 inhibitors can also effectively reduce the risk of cardiovascular diseases and have a protective effect on the kidneys. According to the Frost & Sullivan Report, the market size of SGLT-2 inhibitors in China reached RMB10.5 billion in 2023 and is expected to increase to RMB20.0 billion and RMB27.5 billion in 2026 and 2030, respectively.

We submitted the NDA to the NMPA for Olorigliflozin in December 2023 and expect to receive approval in 2025. Following NMPA approval, we will conduct targeted medical promotion conferences and expert seminars to demonstrate Olorigliflozin's clinical advantages, supported by clinical trial results. We will also consider its combination sales with our other products for the treatment of diabetes, such as insulin products, to provide comprehensive treatment solutions that will meet diverse patient needs. In addition, we will explore new indications for Olorigliflozin, such as specific types of metabolic syndrome, to broaden its application scope. In terms of pricing strategy, we will balance research and development as well as manufacturing costs with therapeutic value to set a market-competitive price to ensure its accessibility. Furthermore, we will actively pursue its inclusion in the NRDL through negotiations with health insurance departments.

(E) Amlodipine Besylate Granules

Amlodipine Besylate Granules is a modified new drug for the treatment of hypertension and coronary heart disease for which we submitted its NDA to the NMPA in November 2024. Following NMPA approval, we plan to prioritize its inclusion in the NRDL and implement combination sales strategies with our existing commercialized drugs for the treatment of hypertension.

(ii) Continue to generate revenue from our commercialized drugs

(A) Our anti-infective product portfolio excluding Oseltamivir Phosphate

Our anti-infective product portfolio excluding Oseltamivir Phosphate has also established itself as a stable cash flow generator with consistent revenue growth. In 2022, 2023 and 2024, our revenue from sales of our major anti-infective drugs (Oseltamivir Phosphate, Clarithromycin, Moxifloxacin Hydrochloride Tablets, Emitasvir Phosphate Capsules and Levofloxacin Tablets) excluding Oseltamivir Phosphate was RMB122.3 million, RMB159.8 million and RMB208.4 million, respectively, representing a CAGR of 30.5% from 2022 to 2024. Key drugs including Emitasvir Phosphate, Clarithromycin, Levofloxacin and Moxifloxacin Hydrochloride have been included in the NRDL, with the latter three further succeeding in VBP schemes at national and provincial levels, demonstrating strong market acceptance. To increase the sales of Emitasvir Phosphate, we plan to cooperate with health authorities such as the National Health Commission of the People's Republic of China to conduct education campaigns on hepatitis C to identify and target more hepatitis C patients. To ramp up the sales of Clarithromycin, Levofloxacin and Moxifloxacin Hydrochloride, we plan to further expand their provincial VBP schemes to cover more provinces. We also plan to strengthen hospital-to-retail integration via partnerships with leading pharmacy chains, converting in-hospital prescriptions into sustainable retail channel growth. This dual approach enhances patient accessibility to affordable treatment while maintaining operational efficiency across distribution networks.

(B) Our chronic disease treatment drug portfolio

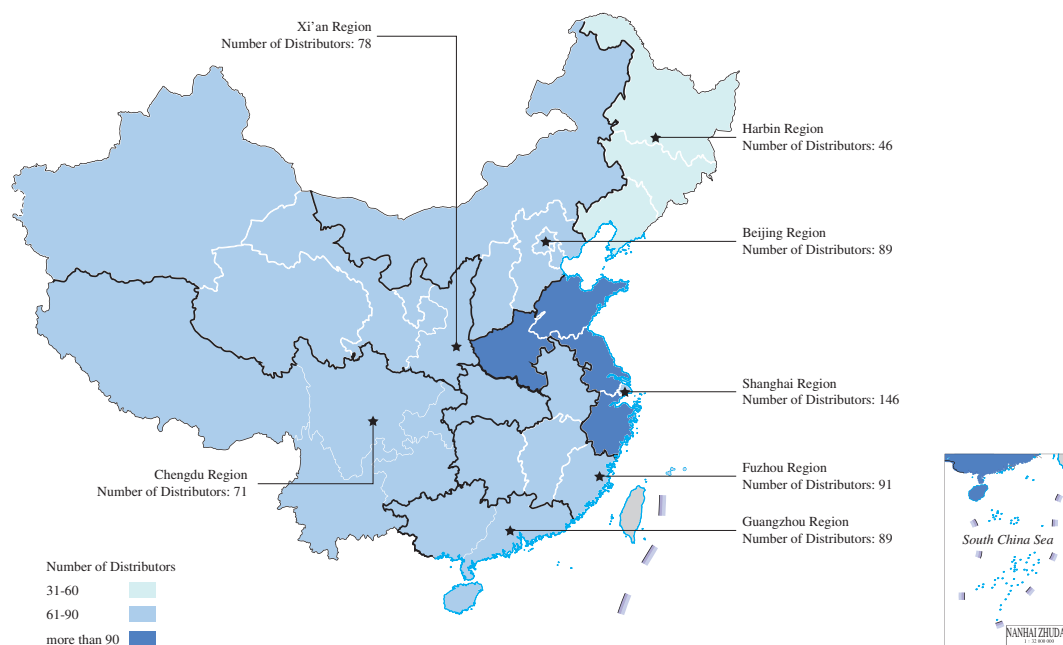
Our chronic disease treatment drug portfolio has also witnessed consistent revenue growth during the Track Record Period. In 2022, 2023 and 2024, our revenue from sales of chronic disease treatment drugs was RMB517.3 million, RMB580.7 million and RMB1,067.7 million, respectively, representing a CAGR of 26.8% from 2022 to 2024. All our major chronic disease treatment drugs have been included in the NRDL and VBP schemes at either national or provincial levels. With all of our five insulin products being included in the VBP scheme at the national level, we expect their sales growth will continue, which will further drive revenue growth of our chronic disease treatment drugs. To ramp up the sales of our major chronic disease treatment drugs, we plan to leverage on the advantage that our insulin products have already entered value-based procurement at the national level to expand their coverage across regions. We also plan to strengthen hospital-to-retail integration by collaborating with leading pharmacy chains to ensure our drugs can be easily accessed outside of hospital. Furthermore, we plan to enhance medical education

through national and regional workshops, including our Discover HEC (“走進東陽光”) program, to promote our brand image. For details of our Discover HEC program, see “— Sales, Marketing and Distribution.”

### Our Distributor Network

We primarily sell our products to third-party offline distributors in the PRC that are GSP certified. For the years ended December 31, 2022, 2023 and 2024, revenue derived from third-party distributors in the PRC amounted to RMB3,722.7 million, RMB6,286.4 million, and RMB3,843.3 million, respectively, representing 99.2%, 99.2% and 95.6% of our revenue generated in the PRC for the respective years. For the years ended December 31, 2022, 2023, and 2024, we also sold RMB9.9 million, RMB6.6 million and RMB5.2 million of our products respectively, directly to pharmacies and other medical institutions representing 0.3%, 0.1% and 0.1%, of our revenue generated in the PRC for the respective years. In general, our third-party distributors are commercial companies who would on-sell our products to hospitals, other medical institutions and pharmacies. All of our third-party distributors are required under PRC laws to obtain pharmaceutical supply permits and GSP certificates. As of December 31, 2024, we had relationships with 610 third-party distributors across the PRC.

The diagram below sets out the number of third-party distributors by regions as of December 31, 2024:





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The table below sets forth the number of the Company's distributors by region during the Track Record Period:

	As of December 31,		
	2022	2023	2024
Shanghai Region . . . . .	127	144	146
Guangzhou Region . . . . .	86	94	89
Fuzhou Region . . . . .	91	95	91
Beijing Region . . . . .	63	77	89
Xi'an Region . . . . .	63	80	78
Chengdu Region . . . . .	81	75	71
Harbin Region . . . . .	36	39	46
Total . . . . .	<u>547</u>	<u>604</u>	<u>610</u>

We group our third-party distributors into seven greater sales regions, with staff dedicated to developing relationships with the third-party distributors in each of those regions. Having dedicated staff assigned to specific regions allows us to develop closer relationships with the relevant third-party distributors in that region and also allows us to respond to any changes in the demand for our products in the relevant area.

In addition, we have a distribution network where we sell our products through third-party distributors including general distributors and our Kewei pharmacy distributors. Through the adoption of such distribution network, we believe that we can (i) diversify our sources of income without over-reliance on markets in any region or a particular type of distribution channel, (ii) customize our sales and marketing strategies with respect to different customer types in different regions and distribution channels and (iii) strengthen our presence in markets which allows our products to penetrate markets more quickly and effectively.

We sell our products to distributors who on-sell our products within a specified territory as stipulated in the distributorship agreements. We benefit from our distributors' established distribution channels and local resources to save costs that would otherwise be required to establish and maintain a nationwide logistics network across the PRC on our own, and to increase the effectiveness of launching and selling our products in our target markets within a short period of time.

We select our distributors based on their proven distribution abilities, familiarity with their own target markets, financial strength, credit records and scale of operations. We require all our distributors to possess all licenses and permits necessary for the sales and distribution of pharmaceutical products. We focus on increasing the scale of cooperation and market share of large-scale distributors which allows us to reduce our costs associated with maintaining a larger distribution network, and benefit from better terms of service with such distributors. Such large-scale distributors are typically SOEs and/or listed companies.

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We have two types of distributors, namely (i) general distributors which are mainly responsible for distributing our products to hospitals and other medical institutions and, to a lesser extent, distributing our products other than Kewei to pharmacies in the geographic areas stipulated in the relevant distributorship agreements and (ii) our Kewei pharmacy distributors, which are mainly responsible for marketing and distributing our top-selling product, Kewei, to pharmacies in the PRC.

The table below sets forth a breakdown of our distribution revenue by each type of distributor during the Track Record Period:

	Year ended December 31,					
	2022		2023		2024	
	<i>RMB'000</i>	<i>% of total</i>	<i>RMB'000</i>	<i>% of total</i>	<i>RMB'000</i>	<i>% of total</i>
General Distributors . . . .	3,114,039	83.6	4,939,412	78.6	3,278,198	85.3
Kewei Pharmacy Distributors . . . . .	608,668	16.4	1,347,025	21.4	565,054	14.7
<b>Total</b> . . . . .	<u>3,722,707</u>	<u>100.0</u>	<u>6,286,437</u>	<u>100.0</u>	<u>3,843,252</u>	<u>100.0</u>

The table below sets forth a breakdown of the number of our distributors by each distributor type during the Track Record Period:

	Year ended December 31,		
	2022	2023	2024
General Distributors <sup>(1)</sup> . . . . .	546	600	606
Kewei Pharmacy Distributors <sup>(1)(2)</sup> . . . . .	2	5	6
<b>Total</b> . . . . .	<u>548</u>	<u>605</u>	<u>612</u>

*Notes:*

- (1) One distributor, one distributor and two distributors are both general distributor and Kewei pharmacy distributor for the years ended December 31, 2022, 2023 and 2024, respectively.
- (2) One Kewei pharmacy distributor coordinated the distribution, marketing and promotion of Kewei with the other Kewei pharmacy distributors. Each of the other Kewei pharmacy distributor is either such distributor's subsidiary, associate or business partner.

***General Distributors***

We generally enter into standard distribution agreements with our general distributors, which set out the rights and obligations of both parties. We primarily govern the conduct of our general distributors through distributorship agreements and we have no ownership or management control over any of our general distributors, and they operate independently from our Group. We consider our general distributors to be our direct customers, primarily because (i) these distributors generally purchase our products on a purchase order basis, and we have established a simple “buyer-seller” relationship with them and (ii) the title and risks of damage of such products are generally passed to the general distributors upon the delivery of our products to their designated locations and their acceptance of such products, upon which we also recognize income generated from such sales as revenue. For further details about our revenue recognition policies, see “Financial Information — Critical Accounting Policies and Estimates — Revenue and Other Income” and Note 2(w) to the Accountants’ Report as set out in Appendix I to this Listing Document.

We did not enter into tripartite agreements among us, our general distributors and end customers for the sale of our products, nor did we transact directly with any sub-distributors during the Track Record Period.

***Kewei Pharmacy Distributors***

We enter into distribution arrangements with pharmacy distributors that market, promote and distribute our top-selling product, Kewei, to pharmacies in the PRC. By contracting with our Kewei pharmacy distributors, we are able to leverage market demand, create greater accessibility to anti-infective drugs for individual customers and deepen our penetration of the markets in which we operate. This in turn further enhances our brand awareness and contributes to our sales of Kewei. Similar to our general distributors, we have a “seller-buyer” relationship with our Kewei pharmacy distributors.

Our distributors are not allowed to deviate from the fixed selling price or offer discounts or promotions without our prior approval. Our general distributors are granted the distributorship of specified certain types of products in their designated distribution areas generally on a non-exclusive basis while our Kewei pharmacy distributors are granted the distributorship on an exclusive basis.

We typically set quarterly and annual sales targets for our Kewei pharmacy distributors and offer discounts to Kewei pharmacy distributors should they achieve the sales targets. The purpose is to incentivize Kewei pharmacy distributors to increase the sales of Kewei through pharmacy sales channel to improve market penetration of our Kewei products. We typically do not impose minimum purchase amounts or sales targets on our general distributors as the general distributors are mainly responsible for distributing our products to hospitals and other medical institutions and they generally do not provide marketing and promotion service for our drugs.

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According to the Kewei pharmacy distribution agreement, in the case where Kewei granule is not included in the national VBP scheme, the sales target for Kewei pharmacy distributor is 25%, 28% and 30% of the aggregate sales amount of Kewei in 2023, 2024 and 2025, respectively. In the case where Kewei granule is included in the national VBP scheme, the sales target for Kewei pharmacy distributor will be increase to 30%, 36% and 38% of the aggregate sales amount of Kewei in 2023, 2024 and 2025, respectively. We impose sales target on our Kewei pharmacy distributors, which is the result of negotiation between us and our Kewei pharmacy distributors. Such sales target is not mandatory in nature, and failure to meet the target does not constitute a ground for automatic termination of distributorship. However, if a Kewei pharmacy distributor repeatedly fails to hit its target, we reserve the right to terminate our cooperation with such distributor, and we would take such underperformance into consideration when it comes to distributorship renewal.

According to the Kewei pharmacy distribution agreement, if Kewei pharmacy distributors meet their quarterly and annual sales target, we will offer a sales rebate of 2% and 3%, respectively. In addition to the rebate provided in connection with the quarterly and annual sales target, we also provide sales rebate to our distributors which provide marketing and promotion service for our products. The distributors may subsequently offset such rebate amount against their trade payables to us. During the Track Record Period, the amount of total sales rebate offered was RMB913.8 million, RMB885.4 million and RMB541.2 million, representing a rebate of 19.7%, 12.3% and 12.3% of our gross sales amount for 2022, 2023 and 2024, respectively. During the Track Record Period, the amount of sales rebate offered in connection with our distributors' marketing and promotion services was RMB879.2 million, RMB816.5 million and RMB536.7 million, representing a rebate of 19.0%, 11.4% and 12.2% of our gross sales amount received from Kewei pharmacy distributors, for 2022, 2023 and 2024, respectively. According to Frost & Sullivan, such sales rebate terms are in general consistent with industry norm. We recognize revenue from the sales to distributors after taking into account the adjustment to transaction price arising from the above-mentioned sales rebates. Please see "Financial Information — Critical Accounting Policies and Estimates — Revenue and Other Income" for details.

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### *Key Arrangements with our General Distributors and Kewei Pharmacy Distributors*

Set forth below is a summary of key arrangements with our general distributors and Kewei pharmacy distributors during the Track Record Period.

	<u>General Distributors</u>	<u>Kewei Pharmacy Distributors</u>
<b>Duration . . . . .</b>	One year	One to three years
<b>Geographic location or other exclusivity . . . .</b>	General distributors are generally prohibited from marketing and selling our products and services outside their designated geographic area.	Our Kewei pharmacy distributors are only allowed to sell our Kewei products within the PRC to pharmacies and not to hospitals or medical institutions.
<b>Drugs . . . . .</b>	All drugs to hospitals, medical institutions and pharmacies except distribution of Kewei to pharmacies in the PRC.	Mainly Kewei to pharmacies in the PRC.
<b>Sub-distributors . . . . .</b>	Distributor is permitted to fulfill its distributorship obligations through its affiliates and may engage sub-distributors subject to the terms in the distribution agreement. We do not have any direct contractual relationships with sub-distributors, and we do not enter into tripartite distribution agreements among us, our distributors and any sub-distributors. Accordingly, we have no direct control over any sub-distributors.	
<b>Pricing policies. . . . .</b>	Our selling prices to our general distributors are fixed during the term of the distribution agreements. We generally require our general distributors to sell our products at (i) the successful bid prices with respect to products included in the VBP schemes, and (ii) prices approved by local government authorities and displayed on their websites with respect to other products.	Our selling prices to our Kewei pharmacy distributors are fixed during the term of the distribution agreement. In the event of a retail price change as a result of market, regulatory or policy changes, we and our Kewei pharmacy distributors may negotiate price adjustments accordingly.

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	General Distributors	Kewei Pharmacy Distributors
<b>Product return and exchange . . . . .</b>	We generally do not accept product returns or exchanges upon delivery of our products, except for quality defects where we may arrange for product returns or exchanges upon receipt of our distributors' requests, and this is in line with industry practice.	
<b>Minimum purchase amounts or sales target . . . . .</b>	We typically do not impose minimum purchase amounts or sales targets on our general distributors.	We typically impose minimum purchase amounts on our Kewei pharmacy distributors. We typically set quarterly and annual sales targets for our Kewei pharmacy distributors and offer sales rebates to our Kewei pharmacy distributors should they achieve the sales targets. If a Kewei pharmacy distributor failed to achieve minimum purchase amounts or sales targets, we will not offer them such sales rebates.
<b>Payment and credit term . . . . .</b>	We generally provide our general distributors a fixed credit term of up to 90 days and accept payment through wire transfer.	We generally provide our Kewei pharmacy distributors a credit term of 30 to 90 days. We generally allow our Kewei pharmacy distributors to make payment through wire transfer.
<b>Confidentiality . . . . .</b>	Our general distributors are generally required to keep confidential any confidential information relating to our business, products and customers.	Our Kewei pharmacy distributors are required to keep confidential any confidential information relating to our product sales, pricing policies and market strategies.
<b>Termination . . . . .</b>	We have the right to terminate the agreement if our general distributors breach the terms and conditions contained therein.	We have the right to terminate the agreement if our Kewei pharmacy distributors breach the terms and conditions contained therein.

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With respect to our majority of distribution agreements, we have the right to terminate our relationship with distributors for various reasons, including: (i) if a third-party distributor fails to generate sufficient business, (ii) if we believe that the relevant third-party distributor does not have a sufficiently close or sustained relationship with the hospitals, doctors, or other healthcare institutions we intend to target, (iii) if we determine that other distributors more effectively cover the target hospitals, doctors, and other healthcare institutions, (iv) if the relevant third-party distributor fails to maintain its universal certification, (v) if the relevant third-party distributor has been acquired or merged with another existing third-party distributor or (vi) if we believe that the relevant third-party distributor does not have sufficient financial capacity to fulfill the obligations under relevant sales orders.

As of the Latest Practicable Date, our Directors confirm that we (i) had not been deemed to have violated any national and/or local regulations, rules or policies in relation to the two-invoice system, (ii) had not been subject to any administrative fines or penalties by the competent authorities in relation to the two-invoice system, and (iii) had not received any warning or notice from any competent authorities in relation to the compliance with the two-invoice system.

The two-invoice system in China generally requires a manufacturer to issue only one invoice to its distributor followed by the distributor issuing a second invoice directly to the end customer public hospital. Only one distributor is permitted to distribute drug products between the manufacturer and the public hospital. Public hospitals are required to adopt the two-invoice system. Private medical institutions or pharmacies are not required to adopt the two-invoice system.

To ensure our distributors comply with the two-invoice system, we (i) specifically require our distributors to comply with relevant laws and regulations relating to the two-invoice system in the distribution agreements; (ii) communicates closely with our distributors to ensure that there are no unauthorized sales to any third party in such provinces; (iii) conducts regular review on our distributor's performance of their contractual obligations and their business operations; (iv) for our general distributors, we reviews their inventory data for material drugs at least twice a week and their sales data at least once every month which enables us to (a) grasp the general distributors' inventory level in a timely manner and (b) identify where our general distributors sell the our products and identify any sales which violates two-invoice system. For our Kewei pharmacy distributors, we engage them to distribute, market and promote our Kewei products to pharmacies which is not subject to the requirement of the two-invoice system. During the Track Record Period and up to the Latest Practicable Date, we did not identify any failure by our distributors to comply with the two-invoice system during the process of distributing our drugs which may have a material impact on our business.

As advised by our PRC Legal Advisor, according to the Notice of Publishing Opinions on Implementing Two-invoice System in Drug Procurement Among Public Medical Institutions (For Trial Implementation) (the "Two-invoice System Notice", 《印發<關於在公立醫療機構藥品採購中推行“兩票制”的實施意見(試行)>的通知》) which was issued on December 26, 2016, the pharmaceutical manufacturers and pharmaceutical distributors who fail to comply with the



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requirements of the “two-invoice system”, may lose their qualification to participate in the bidding and procurement process of public hospitals as well as to win bids and distribute drugs to public hospitals. In addition, the relevant pharmaceutical manufacturers and pharmaceutical distributors will also have a bad record on its activities relating to drug sales. We have not terminated the cooperation with any of our distributors as a result of any non-compliance with the laws and regulations relating to the two-invoice system during the Track Record Period.

### *Number of Distributors*

The table below sets forth the number of third-party distributors in our network in 2022, 2023 and 2024.

	2022	2023	2024
Number of third-party distributors at the beginning of the period . . . . .	517	547	604
New third-party distributors during the period <sup>(1)</sup> . . . . .	165	180	103
Termination of existing third-party distributors during the period <sup>(2)</sup> . . . . .	135	123	97
Net increase (decrease) . . . . .	<u>30</u>	<u>57</u>	<u>6</u>
Number of third-party distributors at the end of the period . . . . .	<u>547</u>	<u>604</u>	<u>610</u>

#### *Notes:*

- (1) New third-party distributors refer to third-party distributors who (i) had at least one transaction with us in the relevant period and (ii) did not have any transactions with us in the immediately preceding financial year.
- (2) Terminated third-party distributors refer to third-party distributors who (i) did not have any transaction with us in the relevant period and (ii) had at least one transaction with us in the immediately preceding financial year.

We focus on increasing the scale of cooperation and market share with large-scale distributors which allows us to reduce our costs associated with maintaining a larger distribution network, and benefit from better terms of service with such distributors. Such strategy allows us to reallocate our sales and marketing resources for other sales and marketing activities, such as further developing our educational promotion activities.

During the Track Record Period, in order to increase our coverage and penetration of hospitals, pharmacies and other medical institutions, we added new distributors to our distribution network. Conversely, we also terminated distributors for reasons such as subpar performance or small amounts purchased from us on an infrequent basis, which is in line with an industry consolidation trend among distributors. We can terminate our third-party distributors should we deem necessary because we generally do not enter into long term distribution agreements with our third-party general distributors. We believe that in the long

term, we should focus on maintaining distribution relationships with those distributors that have a proven track record in the PRC pharmaceutical industry and are considered to be leaders within their respective regions in the PRC.

We consider our distributors to be our direct customers. We have a simple “buyer-seller” relationship with them and the title and risks of damage of such products are generally passed to the distributors upon the delivery of our products to their designated locations and their acceptance of such products. There is no obligation for us to buy back unsold inventories.

To the best knowledge of the Directors, none of our third-party distributors are owned or controlled by the former or current employees of our Group, and all of our third-party distributors are Independent Third Parties. We believe that the use of third-party distribution model for the sale of our products is a customary model for pharmaceutical manufacturers in the PRC and it also allows us to maintain a sufficient coverage of hospitals, pharmacies and other medical institutions for the sale of our products across the PRC. We do not have any arrangements with our distributors that allow our distributors to use the “*HEC*” brand name or otherwise trade in the name of the Company. None of our third-party distributors has received any material advance or financial assistance from us during the Track Record Period.

### *Measures to Manage Cannibalization and Channel Stuffing*

As mentioned above, we have in place a strategy of optimizing the number of our third-party distributors in order to strengthen our distribution network. By optimizing the number of third-party general distributors in our network, we minimize the risk of cannibalization. In addition, we will continue to monitor the performance of our third-party distributors on an annual basis, and since we generally do not enter into long term distribution agreements with our third-party general distributors, we can terminate our relationship with any third-party general distributors based on our assessment results of our third-party general distributors and our business needs. In this way, we have the ability to manage and minimize the risk of cannibalization by removing distributors from our distribution network. Furthermore, pursuant to the distribution agreements entered into with our third-party distributors, we generally require our third-party distributors to sell only in their designated areas, which will help reduce cannibalization. As part of our strategy of strengthening and optimizing our distribution network, when we consider whether to terminate a relationship with a distributor, one of the factors that we consider is whether the relevant hospitals and other medical institutions are more effectively covered by another third-party distributor.

As far as we are aware, there were no incidents of distributors selling products outside the designated regions which had materially impacted on our business during the Track Record Period.

We have implemented the following policies and measures to help ensure that our sales to distributors reflect genuine market demand and mitigate the risk of channel stuffing in the distribution channels. We generally grant our distributors credit terms of less than 90 days. We believe that the short credit term requires our distributors to effectively manage their

commercial inventory and ensure that procurements are made based on actual demand. In addition, we require our distributors to provide us access to their sales data for our products. In general, we review sales and inventory data of our distributors on a regular basis to enable us to make periodic assessments of actual market demand for our products and analyze the inventory levels of our distributors. We actively adjust our sales strategy and product coverage of each distributor based on market demand and each distributor's capacity.

Our average trade and bills receivables turnover days in 2024 increased to 164.8 days from 77.6 days in 2023 primarily due to a reduction in seasonal flu outbreaks in 2024, which led to a decline in sales of our major distributors and consequently slowed our payment collection from these distributors. In 2024, our major distributors increased the purchases of Kewei (oseltamivir phosphate) based on metrics such as regional population data and projected pandemic scale to ensure sufficient drug supply amid uncertainties around the timing and severity of potential outbreaks. Such increased purchases were prompted by such distributors' estimates on how much Kewei (oseltamivir phosphate) they need in order to meet their customers' demand. However, the actual severity and duration of the flu season were lower than anticipated, resulting in inventory levels exceeding actual market demand. This led to slower inventory turnover for our distributors, which in turn extended our receivables collection period. We continued to communicate with our distributors to monitor their sales data for our products and to make periodic assessments of actual market demand for our products. We believe our measures to control channel stuffing is effective, as we believe the slower inventory turnover for our distributors in 2024 was caused by the unexpected lower flu incidence in 2024 and the increased purchase of Kewei by our distributors in 2024 reflected their genuine business judgment made in 2024 that similar to the flu incidence in 2023, the flu incidence in 2024 should continue to be high. In view of the challenging market conditions in 2024, we strategically opted to temporarily extend the credit terms for some of our distributors after good-faith negotiations, with the aim of supporting their liquidity needs. With more incidence of seasonal flu and accelerated sales of Kewei in early 2025, we expect the distributors to speed up their payment to us. We believe the trade and bills receivables turnover days will stabilize when the impact caused by the delay of outbreak of flu season wanes. In addition, as we usually grant our distributors a relatively short credit term of 90 days and we usually do not accept any return of goods from our distributors, we believe the channel staffing risk is relatively low. As of April 30, 2025, 53.8% of our trade and bills receivables have been settled as of December 31, 2024.

#### ***Anti-corruption and Anti-bribery Measures***

Our distributors are generally subject to anti-corruption and anti-bribery obligations pursuant to the terms of the distribution agreements, under which our distributors (i) are required to comply with PRC laws and regulations, including anti-corruption and anti-bribery laws and regulations; (ii) are required to notify us immediately if any of our employee asks such distributors to grant him any form of improper benefit; (iii) are prohibited from granting any loans to our employees without our written authorization; and (iv) are prohibited from

granting any forms of interests to our employee in exchange for any commercial interest. If any distributors fail to comply with the terms of the distribution agreements, we will terminate cooperation and take legal actions against such distributors.

### **Sales Outside the PRC**

During the years ended December 31, 2022, 2023 and 2024, our total sales to customers outside the PRC conducted mainly through pharmaceutical companies and to a lesser extent, through our own overseas branches, amounted to RMB60.4 million, RMB49.7 million, and RMB138.4 million, respectively, representing 1.6%, 0.8%, and 3.4% of our revenue for the respective years. During the Track Record Period, our overseas sales were conducted through both direct sales and distributors.

During the Track Record Period, we sold our products in the United States, Germany, and the United Kingdom and the majority of our overseas revenue was generated through the sales of (i) Azithromycin and Clarithromycin Tablets in the United States, (ii) Azithromycin, Entacapone and Moxifloxacin Tablets in Germany, (iii) revenue from overseas R&D collaboration projects, and (iv) Clarithromycin Tablets in the United Kingdom. In addition, with respect to certain of our products including Clarithromycin, Entacapone and Azithromycin Tablets, we conduct our sales outside the PRC through our own overseas branches. As of December 31, 2024, we have a total of eight overseas branches in the United States, Germany, Japan, South Korea, Australia, Indonesia, the United Kingdom and Singapore.

In European market, we use our own sales channel to sell our products by using the strategy of promoting our own in-house brand, “HEC.” Through such marketing approach, we seek to enhance our market presence and brand recognition, thereby supporting our long-term product recognition and revenue growth. In other international markets, we primarily adopt a partnership-driven strategy by leveraging the local market expertise of our partners. By cooperating with reputable and experienced regional partners, we aim to accelerate market entry and optimize the commercial potential of our products.

### **Our Major Customers**

In each year during the Track Record Period, our five largest customers in each of such year mainly included pharmaceutical companies who are our third-party distributors. Revenue from our five largest customers in each of the years ended December 31, 2022, 2023 and 2024 amounted to RMB2,504.0 million, RMB4,176.6 million and RMB2,514.4 million, respectively, which accounted for 65.7%, 65.4% and 62.6% of our total revenue for the respective years, respectively. None of our five largest customers in each year during the Track Record Period are also our suppliers and vice versa. Revenue generated from sales to our largest customer in each year during the Track Record Period were RMB993.9 million, RMB1,469.3 million and RMB1,010.0 million, respectively, representing 26.1%, 23.0% and 25.1% of our revenue for the respective years.

## BUSINESS

To the best knowledge of the Directors, all of our five largest customers in each year during the Track Record Period were Independent Third Parties and none of our directors, their close associates or any Shareholder (which to the knowledge of the Directors that owns more than 5% of our Shares) are interested in our five largest customers in each year during the Track Record Period.

The tables below set out the details of our five largest customers in each year during the Track Record Period.

For the year ended December 31, 2022:

Ranking	Customer	Major products supplied by us	Credit terms granted and settlement information	Revenue amount (RMB'000)	% of total revenue (%)	Length of business relationship	Background and principal business
1	Sinopharm Group Co., Ltd. (國藥控股股份有限公司)	Pharmaceuticals	Within 90 days, by wire transfer	993,903	26.1	More than five years	A public pharmaceutical company based in the PRC and listed on the Hong Kong Stock Exchange principally engaged in the distribution of pharmaceutical products and medical devices, with approximately 113,100 employees.
2	Jointown Pharmaceutical Group Co., Ltd. (九州通醫藥集團股份有限公司)	Pharmaceuticals	Within 30 days, by wire transfer	781,121	20.5	More than five years	A public pharmaceutical company based in the PRC and listed on the Shanghai Stock Exchange principally engaged in the wholesale, logistics and distribution through retail and e-commerce, of western and traditional Chinese medicine and medical devices, with approximately 32,000 employees.

## BUSINESS

Ranking	Customer	Major products supplied by us	Credit terms granted and settlement information	Revenue amount (RMB'000)	% of total revenue (%)	Length of business relationship	Background and principal business
3	Customer A	Pharmaceuticals	Within 60 days, by wire transfer	444,849	11.7	More than five years	A pharmaceutical company, part of a listed group, in the PRC and listed on the Hong Kong Stock Exchange principally engaged in the R&D, manufacturing, distribution and retail of medicine and nutraceutical products, with approximately 28,000 employees.
4	Customer C	Pharmaceuticals	Within 60 days, by wire transfer	161,307	4.2	More than five years	A public pharmaceutical company based in the PRC and listed on the Shanghai Stock Exchange and the Hong Kong Stock Exchange principally engaged in the R&D, manufacturing, distribution and retail of western and traditional Chinese medicine, with approximately 26,000 employees.
5	Luyan Pharma Co., Ltd. (鸞燕醫藥股份有限公司)	Pharmaceuticals	Prepayment/ payment upon delivery	122,866	3.2	More than five years	A public pharmaceutical company based in the PRC and listed on the Shenzhen Stock Exchange principally engaged in the distribution and retail of western and traditional Chinese medicine, medical devices and vaccines, with approximately 5,200 employees.
Total				2,504,046	65.7		

## BUSINESS

For the year ended December 31, 2023:

Ranking	Customer	Major products supplied by us	Credit terms granted and settlement information	Revenue amount (RMB'000)	% of total revenue (%)	Length of business relationship	Background and principal business
1	Jointown Pharmaceutical Group Co., Ltd. (九州通醫藥集團股份有限公司)	Pharmaceuticals	Within 30 days, by wire transfer	1,469,312	23.0	More than five years	A public pharmaceutical company based in the PRC and listed on the Shanghai Stock Exchange principally engaged in the wholesale, logistics and distribution through retail and e-commerce, of western and traditional Chinese medicine and medical devices, with approximately 32,000 employees.
2	Sinopharm Group Co., Ltd. (國藥控股股份有限公司)	Pharmaceuticals	Within 90 days, by wire transfer	1,438,911	22.5	More than five years	A public pharmaceutical company based in the PRC and listed on the Hong Kong Stock Exchange principally engaged in the distribution of pharmaceutical products and medical devices, with approximately 113,100 employees.
3	Customer A	Pharmaceuticals	Within 60 days, by wire transfer	840,316	13.2	More than five years	A pharmaceutical company, as part of a listed group, in the PRC and listed on the Hong Kong Stock Exchange principally engaged in the R&D, manufacturing, distribution and retail of medicine and nutraceutical products, with approximately 28,000 employees.



## BUSINESS

Ranking	Customer	Major products supplied by us	Credit terms granted and settlement information	Revenue amount (RMB'000)	% of total revenue (%)	Length of business relationship	Background and principal business
4	Customer C	Pharmaceuticals	Within 60 days, by wire transfer	236,906	3.7	More than five years	A public pharmaceutical company based in the PRC and listed on the Shanghai Stock Exchange and the Hong Kong Stock Exchange principally engaged in the R&D, manufacturing, distribution and retail of western and traditional Chinese medicine, with approximately 26,000 employees.
5	C.Q. Pharmaceutical Holding Co Ltd (重藥控股股份有限公司)	Pharmaceuticals	Within 90 days, by wire transfer	191,159	3.0	More than five years	A public pharmaceutical company based in the PRC and listed on the Shenzhen Stock Exchange principally engaged in the wholesale and retail of biopharmaceuticals, traditional Chinese medicine, medical devices, health products and cosmetics, with approximately 14,000 employees.
<b>Total</b>				4,176,604	65.4		

## BUSINESS

For the year ended December 31, 2024:

Ranking	Customer	Major products supplied by us	Credit terms granted and settlement information	Revenue amount <i>(RMB'000)</i>	% of total revenue <i>(%)</i>	Length of business relationship	Background and principal business
1	Sinopharm Group Co., Ltd. (國藥控股股份有限公司)	Pharmaceuticals	Within 90 days, by wire transfer	1,010,048	25.1	More than five years	A public pharmaceutical company based in the PRC and listed on the Hong Kong Stock Exchange principally engaged in the distribution of pharmaceutical products and medical devices, with approximately 113,100 employees.
2	Jointown Pharmaceutical Group Co., Ltd. (九州通醫藥集團股份有限公司)	Pharmaceuticals	Within 30 days, by wire transfer	532,239,727	13.2	More than five years	A public pharmaceutical company based in the PRC and listed on the Shanghai Stock Exchange principally engaged in the wholesale, logistics and distribution through retail and e-commerce, of western and traditional Chinese medicine and medical devices, with approximately 32,000 employees.

## BUSINESS

Ranking	Customer	Major products supplied by us	Credit terms granted and settlement information	Revenue amount	% of total revenue	Length of business relationship	Background and principal business
				(RMB'000)	(%)		
3	Customer A	Pharmaceuticals	Within 60 days, by wire transfer	437,469	10.9	More than five years	A pharmaceutical company, part of a listed group, in the PRC and listed on the Hong Kong Stock Exchange principally engaged in the R&D, manufacturing, distribution and retail of medicine and nutraceutical products, with approximately 28,000 employees.
4	Jiangxi Yingjiang Pharmaceutical Co., Ltd. (江西鷹江醫藥有 限公司)	Pharmaceuticals	Within 90 days, by wire transfer	392,328	9.8	Three years	A pharmaceutical company in the PRC principally engaged in drug wholesale, drug import and export, third-class medical device operations, medical device internet information services, and drug internet information services, with approximately 200 employees.
5	Customer C	Pharmaceuticals	Within 60 days, by wire transfer	142,333	3.5	More than five years	A public pharmaceutical company based in the PRC and listed on the Shanghai Stock Exchange and the Hong Kong Stock Exchange principally engaged in the R&D, manufacturing, distribution and retail of western and traditional Chinese medicine, with approximately 26,000 employees.
Total				2,514,417	62.6		

**Product Pricing**

The PRC government regulates the prices at which pharmaceutical manufacturers sell drugs to public hospitals mainly through VBP schemes. All drugs used by public hospitals must be procured via the centralized drug procurement platforms or the public procurement platforms established by provincial-level healthcare security administrations (collectively, the “government’s platforms”). A pharmaceutical manufacturer is required to declare its products on the government’s platforms before such products are allowed to be sold to public hospitals. For the drugs that win the bids during the centralized tender process and are included in the VBP schemes, their bidding prices are displayed on the government’s platforms. As for the other non-centralized procured drugs or drugs which are not included in the VBP schemes, the drug prices on the government’s platforms are those declared by the relevant pharmaceutical manufacturers and officially vetted by the relevant authority, with such prices being subject to routine monitoring by the provincial healthcare security administration. Please see “Regulatory Environment — Principal Regulatory Provisions — Laws and Regulations on Drug Supply” for more details on the VBP schemes and drug price regulation in the PRC.

Our Kewei granules are included in the provincial VBP schemes, and our Yangjiantai capsules are included in the national VBP schemes. Kewei granules and Yangjiantai capsules are required to declare their bidding prices on the government’s platforms, and they are sold to public hospitals at such prices. Our Kewei capsules (10 capsules per pack) has not been included in any national or provincial VBP schemes. Like many other drugs, Kewei capsules must comply with the government’s platforms pricing policies in order for public hospitals to purchase it through such government’s platforms.

Pursuant to our product pricing policy, we monitor the relevant product market and set our prices by reference to the latest market price for such products. This includes monitoring whether prices have increased or decreased at the retail level and whether there are any substantial increase or decrease to the demand for products in the therapeutic areas that we operate in. During the Track Record Period, we determined our selling price based on a number of factors, including: (i) the successful bid prices for products included in the VBP schemes, (ii) the retail price of similar pharmaceutical products available in the market, (iii) our costs of production, (iv) our gross margins, and (v) our estimate of the margins of our third-party distributors.

**Returned Products Policy**

If we receive any requests for product return, in accordance with our policy on returned products, we would first communicate with the relevant customer to determine the reason for returning the product (for example, to determine whether it related to the quality or quantity of our product). We would then review the relevant products to verify the validity of the relevant customer’s claim. Pursuant to our policy, all returned products cannot be repackaged unless we have verified that the relevant product has not been damaged or is not otherwise defective. Any damaged or defective products will be destroyed.

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## BUSINESS

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If, following review of the returned product, we do not consider the relevant customer's claim to be valid, we will liaise with the relevant customer accordingly. If there is a risk of dispute or legal proceedings with a customer, the issue will be elevated to senior management. During the Track Record Period, we did not experience any returned products of a material nature, did not instigate any general recalls of our products and were not involved in any material disputes or legal proceedings with our customers.

As mentioned above, we have a “buyer-seller” relationship with our distributors. Therefore, we generally do not accept returned products from our distributors due to the distributor not being able to on-sell our products to its customers, except in exceptional circumstances based on our discretion.

For the three years ended December 31, 2022, 2023 and 2024, goods returned to us from our customers with the revenue amounted to RMB0.8 million, RMB3,326.6 and RMB0.3 million, respectively.

### **Customer Complaint Policy**

We have implemented a standardized complaint management system to ensure accountability, regulatory compliance and the protection of stakeholder interests. The quality department holds overall responsibility for overseeing all customer complaints, reflecting our commitment to operational integrity and consumer welfare. A designated complaint officer ensures the systematic receipt, documentation, and escalation of complaints in accordance with established protocols. Complaints received by the sales department are promptly forwarded to the complaint officer for formal registration and categorization.

Investigations into complaints are conducted under the supervision of the complaint officer, with investigative plans subject to review by the quality department director or deputy quality department manager to confirm alignment with regulatory and procedural requirements. Product disposition measures arising from complaints are determined by the quality department director or deputy quality department manager, followed by stringent approval from the quality authorized person. The complaint officer monitors the execution of such measures to ensure timely resolution and compliance.

## **MANUFACTURING**

We have obtained GMP certification from China, the United States and Europe for the production of our current drugs. Our Songshan Lake base has obtained GMP certifications from the United States, the European Union and China, including recently passing EU GMP audit conducted by National Office for Health and Social Affairs of Germany in November 2023, GMP inspection by the U.S. FDA in March 2024, and a GMP compliance check by the Guangdong Provincial Drug Administration in January 2025. Our Yidu production base obtained PRC GMP certification, and recently passed the inspection conducted by the U.S. FDA in May 2024. A summary of our certifications are set out in “— Permits, Licenses and Certifications”. During the Track Record Period and up to the Latest Practicable Date, we obtained production licenses for all of our production facilities, GMP certifications for all of our workshops and production lines used for the production of our existing drugs, and production permits for each of our drugs and APIs manufactured in-house.

## **Manufacturing Team**

We have separate manufacturing teams for each of Songshan Lake Factory and Yidu Factory, which are led by our Deputy General Manager, Mr. Zhang Zhiyong (張志勇), who has 21 years of experience in the biopharmaceutical industry and Mr. Wang Danjin (王丹津), who has 32 years of experience in the biopharmaceutical industry, respectively. As of the Latest Practicable Date, we had a total of approximately 2,371 manufacturing personnel, with 373 manufacturing personnel and 1,998 manufacturing personnel at the Songshan Lake Factory and Yidu Factory, respectively. We will provide training to our manufacturing personnel to ensure that they possess the skill sets and techniques required in the relevant production process, and comply with our quality control requirements, as well as applicable laws and regulations.

## **Production Facilities**

Our production base are located in Dongguan, Guangdong province, and Yidu, Hubei province, China. We currently have four production facilities for the manufacturing of our drugs, including one in Dongguan base and three in Yidu base (which also has API workshops). As of the Latest Practicable Date, our production facilities had a total GFA of approximately 301,160 square meters across 16 main production workshops, certain of which were still under construction. As of the Latest Practicable Date, we did not outsource any manufacture process to external parties and we intended to further develop and rely on our own manufacturing capabilities.

We own all of our production facilities and production lines in our production workshops. We have obtained all necessary governmental approvals, permits and licences, including GMP certifications for all of our production workshops and production lines in respect of the products that we currently produce. We also conduct regular inspection, repairs and maintenance to ensure that we comply with the GMP and relevant regulations.

Please see “— Land and Properties” for further information regarding our properties.

The table below sets out a summary of our production facilities.

<b>Production Facility</b>	<b>Production Line</b>
Songshan Lake Factory (GFA: 21,298 square meters) . . . . .	Oral solid dosage form (tablets and capsules)
Yidu Factory No. 1 (GFA: 29,621 square meters) . . . . .	Oral solid dosage form (tablets, capsules and granules) Freeze-drying powder for injection
Yidu Factory No. 2 (GFA: 18,299 square meters) . . . . .	APIs
Yidu Factory No. 3 (GFA: 231,942 square meters) . . . . .	Oral solid dosage form (tablets, capsules and granules) Injections APIs
Total GFA: 301,160 square meters . . . . .	

## BUSINESS

### Songshan Lake Factory

Our Songshan Lake Factory is located at No. 1 Gongye North Road, Songshan Lake Park, Dongguan City, Guangdong, China (中國廣東省東莞市松山湖園區工業北路1號). Our Songshan Factory mainly produces (i) commercialized drugs such as Esomeprazole Magnesium Enteric-Coated Capsules, Olmesartan Medoxomil Tablets, Rivaroxaban Tablets and Moxifloxacin Hydrochloride Tablets and (ii) drugs for our pre-clinical studies and clinical trials such as Yinfenidone Hydrochloride Tablets.

The following table is a summary of Songshan Lake facility's production capacity, production volume and utilization rates by production line during the Track Record Period.

Product	Unit	2022			2023			2024		
		Designed production capacity <sup>(1)</sup>	Actual production volume	Utilization rate <sup>(2)</sup>	Designed production capacity <sup>(1)</sup>	Actual production volume	Utilization rate <sup>(2)</sup>	Designed production capacity <sup>(1)</sup>	Actual production volume	Utilization rate <sup>(2)</sup>
				(%)			(%)			(%)
Tablets . . . .	100,000	15,000	4,400	29.3	15,000	6,700	44.7	15,000	10,000	66.7
	pills									
Capsules . . .	100,000	3,500	1,200	34.3	3,500	1,100	31.4	3,500	2,400	68.6
	pieces									

*Notes:*

- (1) Designed production capacity for a production line is calculated based on 16 working hours per day and 280 effective production days per year with no material breakdown of facilities.
- (2) Utilization rate is calculated by dividing the actual production volume by the designed production capacity. The fluctuations in our utilization rates generally reflect the fluctuations in our production volumes in line with the level of market demand for the corresponding products. We recorded relatively lower utilization rates in 2021 owing to adverse market conditions as a result of the pandemic. The increased production utilization rate was primarily attributable to our successful bids for multiple products in the VBP schemes from 2022 to 2024, which led to increased demand for our products. Our increased production was further supported by the gradual growth of our new retail channels, which resulted in further demand for our products.

As of the Latest Practicable Date, we had a biologics production facility within our Songshan Lake Factory that was still under construction. We expect construction to be completed in 2026 and in compliance with international GMP standards, upon which the facility will have two biologics production lines and manufacture primarily Insulin Degludec and GLP-1 biologics including liraglutide and dulaglutide. We expect the facility to have an annual production capacity of 400kg of freeze-dried powder, 50kg of raw solution and 40 million vials of injection pens.



## BUSINESS

### *Yidu Factory No. 1*

Our Yidu Factory No. 1 is located at No. 38 Binjiang Road, Yidu, Hubei province, the PRC (中國湖北宜都市濱江路38號). and is our primary production facility and currently produces parts of our oral dosage form (tablets, capsules and granules) and freeze-dried powder for injections, which primarily includes Kewei (Oseltamivir Phosphate Capsules and Granules), Benzbromarone Tablets, Telmisartan Tablets, Azithromycin Capsules and Emitasvir Phosphate Capsules.

The table below is a summary of Yidu Factory No. 1's production capacity, production volume and utilization rates by production line during the Track Record Period.

Product	Unit	2022			2023			2024		
		Designed production capacity <sup>(1)</sup>	Actual production volume	Utilization rate <sup>(2)</sup>	Designed production capacity <sup>(1)</sup>	Actual production volume	Utilization rate <sup>(2)</sup>	Designed production capacity <sup>(1)</sup>	Actual production volume	Utilization rate <sup>(2)</sup>
				(%)			(%)			(%)
Tablets <sup>(4)</sup> . . .	100,000 tablets	10,000	3,133	31.3	10,000	2,036	20.4	10,000	2,726	27.3
Granules <sup>(4)</sup> . .	100,000 packets	5,000	1,269	25.4	6,000	5,866	97.8	6,000	3,239	54.0
Capsules <sup>(4)</sup> . .	100,000 pieces	10,000	293	2.9	10,000	442	4.4	10,000	429	4.3
Freeze-dried powder for injection <sup>(5)</sup> .	100,000 vials	45	3.0	6.7	45	N/A	N/A	45	1.3	2.9

*Notes:*

- (1) Designed production capacity for a production line is calculated based on 16 working hours per day and 280 effective production days per year with no material breakdown of facilities.
- (2) Utilization rate is calculated by dividing the actual production volume by the designed production capacity. The fluctuations in our utilization rates generally reflect the fluctuations in our production volumes in line with the level of market demand for the corresponding products. The decreased utilization rate for tablets production in 2023 primarily reflects the production adjustment in 2023 where some of the tablets production was moved to Yidu Factory No. 3. The granules production utilization rate reflected the changing market conditions. Its lower utilization rate in 2022 was attributed to decreased production and sales during the pandemic. The utilization rate for our granules production significantly increased in 2023 with the easing of restrictions and an influenza outbreak. Consequently, production has been increased to meet the market demand for top-selling product Kewei (oseltamivir phosphate). However, in 2024, as the influenza epidemic subsided, the rate decreased due to lower production and sales volumes.
- (3) We have two production lines which can be modified to produce tablets, granules or capsules. For the purposes of determining designed production capacity, we have assumed that: (a) production line 1 is used entirely for the production of tablets (280 effective production days per year at 16 working hours per day); and (b) production line 2 is split as to 160 effective production days per year for the production of granules and 120 effective production days per year for the production of capsules (with each effective production day at 16 working hours per day).
- (4) In 2023, we terminated production of freeze-dried powder for injection in Yidu Factory No. 1.

## BUSINESS

### ***Yidu Factory No. 2***

Our Yidu Factory No. 2 is located at No. 62 Binjiang Road, Yidu, Hubei province, the PRC (中國湖北宜都市濱江路62號) and is our primary production facility for APIs. Yidu Factory No. 2 mainly produces APIs including oseltamivir phosphate, benzbromarone, fudosteine, olmesartan medoxomil, emitasvir phosphate, esomeprazole magnesium, salt duloxetine acid, etc.

The table below is a summary of Yidu Factory No. 2's production capacity, production volume and utilization rates by production line during the Track Record Period.

Product	Unit	2022			2023			2024		
		Designed production capacity <sup>(1)</sup>	Actual production volume	Utilization rate <sup>(2)</sup>	Designed production capacity <sup>(1)</sup>	Actual production volume	Utilization rate <sup>(2)</sup>	Designed production capacity <sup>(1)</sup>	Actual production volume	Utilization rate <sup>(2)</sup>
				(%)			(%)			(%)
APIs . . . . .	Tonnes	60.3	34.4	57.2	60.3	59.1	98.0	60.3	52.4	87.0

***Notes:***

- (1) Designed production capacity for a production line is calculated based on 24 working hours per day and 330 effective production days per year with no material breakdown of facilities.
- (2) Utilization rate is calculated by dividing the actual production volume by the designed production capacity. The fluctuations in our utilization rates generally reflect the fluctuations in our production volumes in line with the level of market demand for the corresponding products. The increase in our utilization rates from 2022 to 2023 reflected a ramping up of our production of the oseltamivir phosphate APIs to meet an increase in demand for our top-selling product Kewei (oseltamivir phosphate). The decreased utilization rate in 2024 was mainly due to a drop of the sales of Kewei.

### ***Yidu Factory No. 3***

Our Yidu Factory No. 3 is located at Lot 3, Industrial Park, Yidu, Hubei province, the PRC (中國湖北宜都市東陽光3號地工業園區). Within Yidu Factory No. 3, we have our primary production facility for our insulin product series, including Yibilin R (Human Insulin Injection), Yibilin 30 (Mixed Protamine Human Insulin Injection), Yibigan (Insulin Glargine Injection), Yibirui (Insulin Aspart Injection) and Yibirui 30 (Insulin Aspart 30 Injection). We also have a formulation production facility that produces Kewei (oseltamivir phosphate) in granule and capsule form, Oumeining (Telmisartan Tablets), Fudosteine Tablets, Olanzapine Tablets, Febuxostat Tablets, Ticagrelor Tablets, etc.

## BUSINESS

The table below is a summary of Yidu Factory No. 3's production capacity, production volume and utilization rates by product type during the Track Record Period.

Product	Unit	2022			2023			2024		
		Designed production capacity <sup>(1)</sup>	Actual production volume	Utilization rate <sup>(2)</sup>	Designed production capacity <sup>(1)</sup>	Actual production volume	Utilization rate <sup>(2)</sup>	Designed production capacity <sup>(1)</sup>	Actual production volume	Utilization rate <sup>(2)</sup>
				(%)			(%)			(%)
Insulin (API) . .	Kg	1,000	96.5	9.7	1,000	95.6	9.6	1,000	134.6	13.5
Insulin (injection) . .	vials	15 million	0.6 million	4.0	15 million	1.7 million	11.4	15 million	6.2 million	41.1
Tablets . . . .	100,000 tablets	10,000	11,161	1.1	10,000	1,349	13.5	10,000	2,034	20.3
Granules . . . .	100,000 packets	10,000	7,163	71.6	10,000	10,812	108.1	10,000	5,486	54.9
Capsules . . . .	100,000 pieces	5,000	335	6.7	5,000	610	12.2	5,000	368	7.4

*Notes:*

- (1) Designed production capacity for a production line is calculated based on 24 working hours per day and 280 effective production days per year with no material breakdown of facilities.
- (2) Utilization rate is calculated by dividing the actual production volume by the designed production capacity. The fluctuations in our utilization rates generally reflect the fluctuations in our production volumes in line with the level of market demand for the corresponding products. On average, our utilization rates increased during the Track Record Period, due to the successful bidding of all of our five insulin products in the Centralized Procurement Process, which led to a significant increase in market demand for insulin products. Consequently, production has been increased to meet the market demand for these products. The decreased utilization rates for granules and capsules production in 2024 primarily reflected a decline in production due to a decrease in demand for our top-selling product Kewei (oseltamivir phosphate).

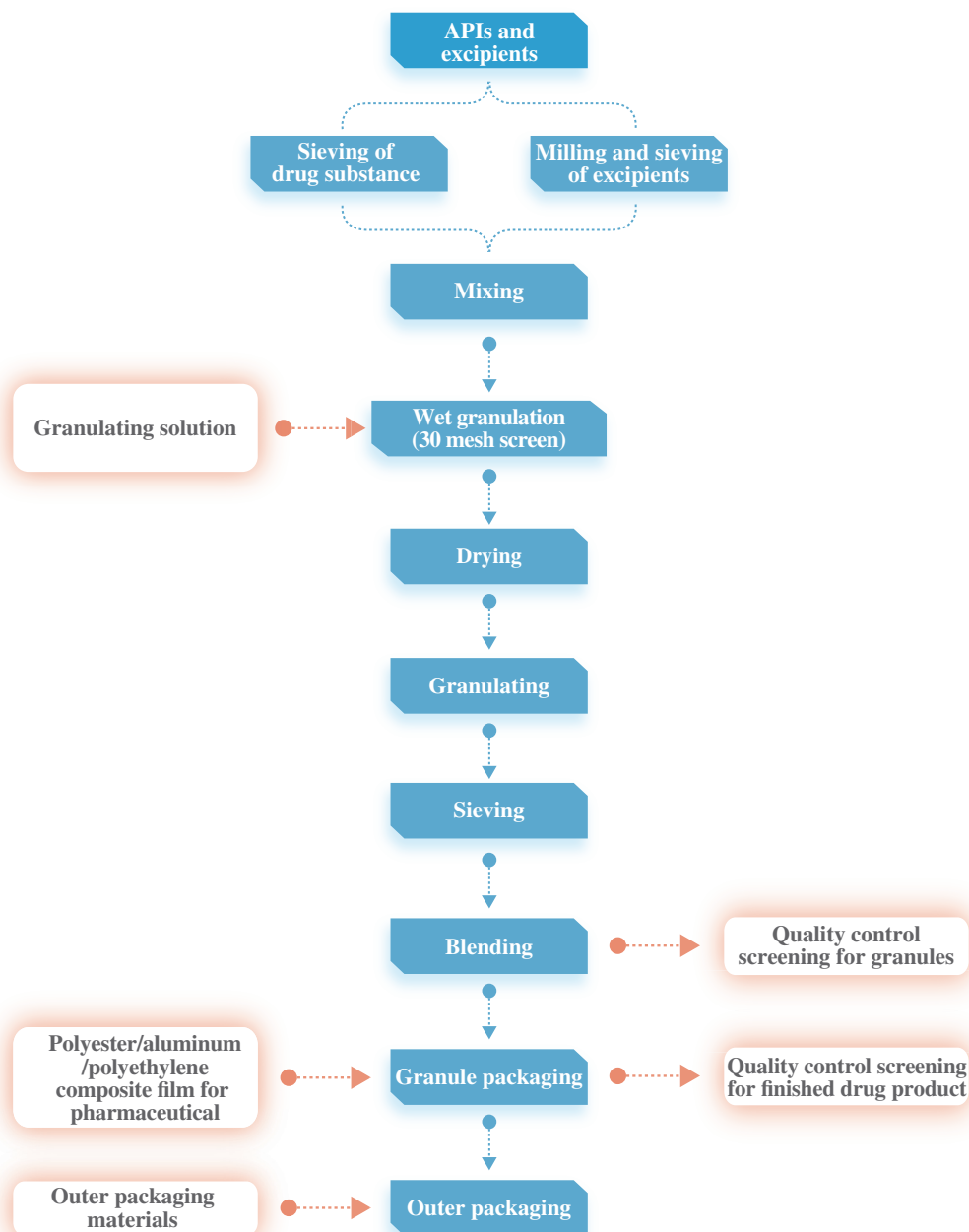
As of the Latest Practicable Date, we had an ancillary facility within Yidu Factory No. 3, HEC API Yichang Co., Ltd., which we plan to use for the production of APIs for use in our clinical trials, such as moxifloxacin hydrochloride.

### Manufacturing Process

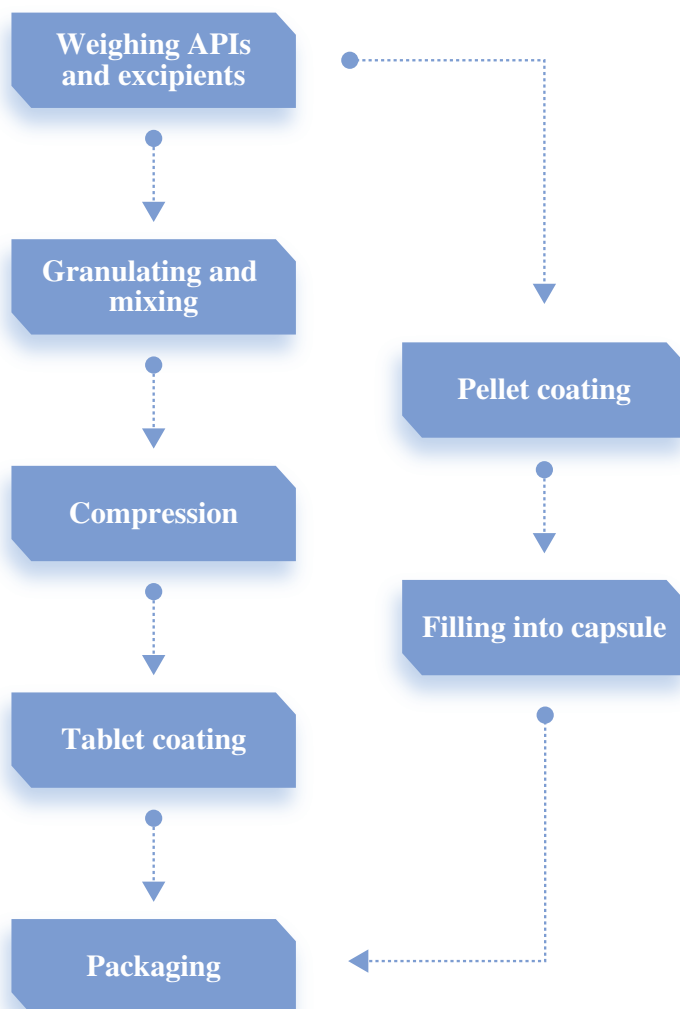
Our ability to manufacture different commercialized drugs in large scale is demonstrated by the unique production process and techniques for our various drugs used in our facilities. The diagrams below are simplified flow charts of our key production processes at our production facilities, and there may be variations to the processes depending on the nature of the drugs. However, the flow charts generally describe the production processes of our top five products (being Kewei (oseltamivir phosphate), Esomeprazole Magnesium Enteric-Coated Capsules, Ertongshu (Benzbromarone Tablets), Oumeining (Telmisartan Tablets) and Yibigan (Insulin Glargine Injection).

## BUSINESS

The simplified flow chart setting out the key production processes for our granules (Kewei) is as follows:



The simplified flow chart setting out the key production processes for our tablets and capsules is as follows:

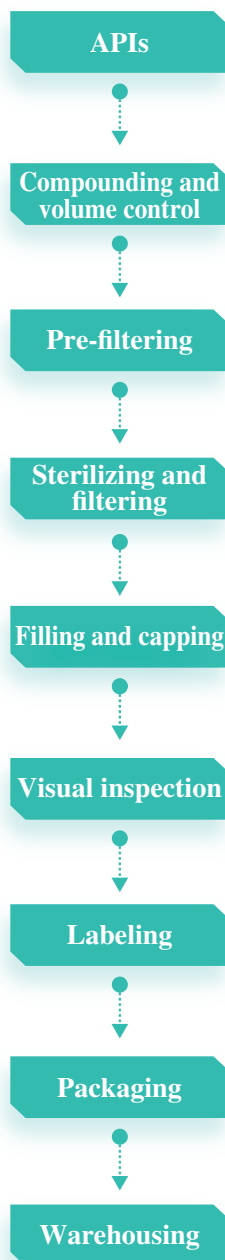


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## BUSINESS

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The simplified flow chart setting out the key production processes for our Insulin Glargine Injection (Yibigan) is as follows:



**PROCUREMENT**

Our suppliers mainly include (i) equipment and construction service providers, (ii) suppliers of raw materials for the manufacturing of our drugs (such as APIs) and packaging material, (iii) suppliers of raw materials and consumables for our research and development, (iv) CROs, which provide third-party contracting services for research and development, (v) suppliers of production and research and development equipment and (vi) marketing and advertising service providers. Majority of our purchases are acquired within the PRC. We made 97.5%, 96.8% and 94.5% of our purchases in the PRC for the years ended December 31, 2022, 2023 and 2024, respectively. Other countries from which we made purchases are mainly India, Switzerland and the United Kingdom. In each of the years ended December 31, 2022, 2023 and 2024, 4.4%, 7.6% and 5.5% of our raw materials were acquired outside the PRC, respectively. In each of the years ended December 31, 2022, 2023 and 2024, our purchases from our five largest suppliers in each of such year were RMB430.0 million, RMB431.1 million and RMB572.4 million, respectively, representing 27.0%, 22.0% and 27.1% of our total purchases for the respective years, respectively. Purchases attributable to our largest supplier in each of the years ended December 31, 2022, 2023 and 2024, amounted to RMB245.6 million, RMB248.8 million and RMB305.0 million, respectively, representing 15.4%, 12.7% and 14.5% of our total purchases for the respective years, respectively. Our suppliers are evaluated and selected based on a comprehensive set of objective criteria, including their ability to demonstrate technical and quality compliance with project specifications, the provision of competitive pricing that meets all stipulated standards, and the submission of valid documentation evidencing legal operation and adherence to applicable laws and regulations in their home jurisdictions and in China generally. Additionally, suppliers must ensure that all materials or products supplied conform to our established quality standards without compromising end-user safety. The evaluation process may also consider supplementary factors such as the supplier's industry reputation, reliability in delivery, financial stability, and responsiveness to the requirements of the company.

Below is a summary of the material terms of typical procurement agreements that we entered into with our suppliers of raw materials during the Track Record Period:

<b>Specification</b> . . . . .	The agreement sets out product specifications, including quality, quantity, and standards. Products must comply with national, local, and industry standards. Seller must provide a national standard-compliant quality inspection report upon delivery.
<b>Term</b> . . . . .	The agreement is effective upon signing and remains in force until terminated according to the terms of the agreement.



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<b>Price . . . . .</b>	The price is determined based on the agreed unit price, inclusive of tax, transportation, insurance, and all related fees. The price is fixed and not subject to fluctuations in labor costs, market conditions, or policy changes. No additional costs beyond the agreed terms may be charged by the seller.
<b>Minimum supply commitment . . . . .</b>	Seller must supply within 90%-110% of the ordered quantity, calculated by the smallest packaging unit. Final settlement is based on the actual received quantity.
<b>Delivery . . . . .</b>	Delivery must occur by a specified date and to a specified address. Seller bears the risk of loss or damage during transit. Packaging must meet safety and environmental standards, with costs borne by the seller.
<b>Payment and Credit Term . . . . .</b>	Payment is due upon receipt and acceptance of the goods, accompanied by a valid VAT invoice. Payments are made monthly, with invoices received by the 25th of each month being settled by the 25th of the following month, via bank electronic draft.
<b>Warranty, Safety and Metering . . . . .</b>	The warranty period begins upon delivery and acceptance. Seller is responsible for free replacement of defective products during the warranty period. Products must meet safety and technical standards, with seller liable for any damages caused by defects.
<b>Termination . . . . .</b>	We have the right to terminate the agreement without liability before the seller delivers the products. In all other cases, termination requires mutual agreement and written confirmation from both parties.

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The tables below set out the details of our five largest suppliers in each year during the Track Record Period.

For the year ended December 31, 2022:

Ranking	Supplier	Major products/ services purchased	Credit terms granted and settlement information	Purchase amount	% of total purchase	Length of business relationship	Background and principal business
<i>(RMB'000)</i>							
1	Shenzhen HEC Industrial Development Co., Ltd. (深圳市東陽光實業發展有限公司)	APIs, pharmaceutical products, packaging, energy, leases and others	Within 90 days, by wire transfer	245,576	15.4	More than five years	A private manufacturing company based in the PRC principally engaged in the manufacturing of pharmaceuticals and electronic materials, with approximately 24,000 employees.
2	Syntegon Technology GmbH	Equipment	30% prepayment, by wire transfer and 70% after acceptance, by letter of credit	71,872	4.5	More than five years	A private manufacturing company with global operation engaged in the provision of processing and packaging within the pharmaceuticals, food and medical devices industries, with approximately 6,300 employees.
3	Beijing Chieftain Control Engineering Technology Co., Ltd. (北京誠益通控制工程股份有限公司)	Equipment	Within 30 days, by wire transfer	58,513	3.7	More than five years	A public manufacturing company based in the PRC and listed on the Shenzhen Stock Exchange principally engaged in the provision of process automation systems within the biological and pharmaceutical industries, with approximately 1,500 employees.

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Ranking	Supplier	Major products/ services purchased	Credit terms granted and settlement information	Purchase amount	% of total purchase	Length of business relationship	Background and principal business
				(RMB'000)			
4	Shanghai Shengrui Mechanical and Electrical Engineering Co., Ltd. (上海聖銳機電工程 有限公司)	Equipment	30 days, by wire transfer	31,943	2.0	More than five years	A private construction company based in the PRC principally engaged in the provision of mechanical and electrical engineering, ventilation and construction within the pharmaceutical, electronics, machinery, food processing and healthcare industries, with approximately 120 employees.
5	Supplier B	R&D services	40 days, by wire transfer	22,078	1.4	More than five years	A hospital and public research institution of medical sciences based in the PRC, with approximately 19,000 employees.
Total				<u>429,983</u>	<u>27.0</u>		

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For the year ended December 31, 2023:

Ranking	Supplier	Major products/ services purchased	Credit terms granted and settlement information	Purchase amount	% of total purchase	Length of business relationship	Background and principal business
(RMB'000)							
1	Shenzhen HEC Industrial Development Co., Ltd. (深圳市東陽光實業發展有限公司)	APIs, pharmaceutical products, packaging, energy, leases and others	Within 90 days, by wire transfer	248,792	12.7	More than five years	A private manufacturing company based in the PRC principally engaged in the manufacturing of pharmaceuticals and electronic materials, with approximately 24,000 employees.
2	Rieckermann GmbH	Equipment	30% prepayment, by wire transfer and 70% after acceptance, by letter of credit	70,609	3.6	More than five years	A private industrial services company with global operations and based primarily in Asia and Europe, principally engaged in engineering, construction management, equipment supply and installation and related technical services within the pharmaceutical, food processing, packaging, chemical and energy and construction industries, with approximately 750 employees.
3	Supplier C	Advertising services	Within 30 days, by wire transfer	55,812	2.9	Less than one year	A public internet services company based in the PRC and listed on the Shenzhen Stock Exchange, with approximately 1,500 employees.

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Ranking	Supplier	Major products/ services purchased	Credit terms granted and settlement information	Purchase amount	% of total purchase	Length of business relationship	Background and principal business
				<i>(RMB'000)</i>			
4	Supplier D	Equipment	30 days, by wire transfer	33,072	1.7	More than three years	A private manufacturing company based in the USA, Ireland and the PRC, principally engaged in providing process solutions and services for the development and manufacturing of biopharmaceutical products.
5	Supplier E	APIs	Within 30 days, by wire transfer	22,830	1.2	More than five years	A private integrated manufacturing company based in the PRC principally engaged in R&D and production of functional chemicals such as polymer materials and APIs, with approximately 15,000 employees.
Total				<u>431,115</u>	<u>22.0</u>		

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For the year ended December 31, 2024:

Ranking	Supplier	Major products/ services purchased	Credit terms granted and settlement information	Purchase amount	% of total purchase	Length of business relationship	Background and principal business
				(RMB'000)			
1	Shenzhen HEC Industrial Development Co., Ltd. (深圳市東陽光實業發展有限公司)	APIs, pharmaceutical products, packaging, energy, leases and others	Within 90 days, by wire transfer	304,988	14.5	More than five years	A private manufacturing company based in the PRC principally engaged in the manufacturing of pharmaceuticals and electronic materials, with approximately 24,000 employees.
2	Supplier C	Advertising services	Within 30 days, by wire transfer	80,444	3.8	Less than two years	A public internet services company based in the PRC and listed on the Shenzhen Stock Exchange, with approximately 1,500 employees.
3	Austar Equipment Limited (奧星設備有限公司)	Equipment	Within 30 days, by wire transfer	71,481	3.4	More than five years	A manufacturing company based in Hong Kong principally engaged in the manufacturing of container and spare parts as well as the installing of electromechanical equipment.
4	MSN Pharmachem Private Limited	APIs	30 days, by wire transfer	63,023	3.0	More than five years	A pharmaceutical company based in India principally engaged in R&D.
5	Supplier F	Renovation services	Within 10 days, by wire transfer	52,500	2.5	Less than one year	A construction and interior and exterior decoration services company with a total of 120 employees.
Total				<u>572,436</u>	<u>27.1</u>		

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During the Track Record Period, only one of our five largest suppliers in each year during the Track Record Period was a related party, being Shenzhen HEC Industrial (深圳市東陽光實業發展有限公司) (who supplies us with primarily APIs, pharmaceutical products, packaging, energy and leases). Our aggregate purchase of goods from Shenzhen HEC Industrial was RMB245.6 million, RMB248.8 million and RMB305.0 million in each of the years ended December 31, 2022, 2023 and 2024, respectively. Shenzhen HEC Industrial is one of our Controlling Shareholders and a related party of the Company.

Our purchases from Shenzhen HEC Industrial are on arm's length terms. Our Directors believe that we are not reliant on the supply of raw materials from Shenzhen HEC Industrial as the Company has established relationships with other third party suppliers that also supply the raw materials Shenzhen HEC Industrial supplies to us.

We have entered into various framework agreements in relation to the supply of raw materials from our related parties going forward. Please see “Connected Transactions — Partially Exempted Continuing Connected Transactions” for further details. To the knowledge of our directors, except for Shenzhen HEC Industrial, none of our other five largest suppliers in each year during the Track Record Period are related parties and none of our Directors, their close associates or any Shareholder which, to the knowledge of our Directors that owns more than 5% of our Shares, are interested in our five largest suppliers in each year during the Track Record Period. None of our suppliers are our competitors or our customers.

We track production status and production plans in real time, maintain close communication with suppliers, and require suppliers to prepare appropriate quantities of goods to minimize any disruptions to our supply chain to the extent possible. We pay close attention to the market in real time, particularly with respect to bulk materials. Any big price fluctuations in our raw materials are reported to the management, which will then evaluate and discuss any measures to be taken, including preparing stocks in advance, locking prices, and requesting price reductions. During the Track Record Period, there was no significant disruption to our raw material supply caused by shortages or delays and the prices of our raw materials remained relatively stable.

In addition, we believe that adequate alternative sources for such supplies exist, and we have developed alternative sourcing strategies for these supplies. We will establish necessary relationships with alternative sources based on supply continuity risk assessment. We generally do not enter into long-term supply contracts with our suppliers, and majority of our raw materials and other supplies are provided on an individual basis on an “per order” basis. In general, we have been granted a credit term of around 15 to 60 days by our raw material suppliers.



### QUALITY CONTROL AND ASSURANCE

We have our own independent quality control system and devote significant attention to quality control for the designing, manufacturing and testing of our products and drugs under development. We have established a strict quality control system in accordance with the relevant regulations. Our laboratories are staffed with highly educated and skilled technicians to ensure the quality of all batches of products released. We monitor our operations in real time throughout the entire production process, from inspection of raw materials and excipients, to the manufacture and delivery of finished products to clinical testing at hospitals. Our quality assurance team is also responsible for ensuring that we are in compliance with all applicable regulations, standards and internal policies. Our senior management team is actively involved in setting quality policies and managing the internal and external quality performance of our Company.

In order to ensure the quality of our products and drugs under development, we have established and implemented an effective quality assurance system into our production processes. Our quality assurance system is divided into four main elements: (i) responsibility management; (ii) resources management; (iii) product management; and (iv) testing, analysis and improvement. Responsibility management refers to reviewing the archived documentary aspects of the production processes to ensure that the correct procedures in relation to production are strictly adhered to. It also involves designing a system to ensure that quality control reviews and testing are conducted during the production processes. Resources management refers to reviewing the sources and raw materials used in our production processes. This would include reviewing and assessing the raw materials that we receive from our suppliers and assessing the performance of our suppliers against that of their competitors. Product management involves the quality control aspects during the actual production of our products.

Testing, analysis and improvement refers to the internal testing and analysis of our products and drugs under development. In connection with this, we have set up a team dedicated to testing, analyzing and improving our production processes to ensure that our production processes consistently produce high-quality products. This department has different teams that review various aspects of our production processes, including: (i) reviewing and checking whether micro-organisms are produced in our production processes; and (ii) reviewing the quality consistency of our final products through sample testing. To the extent that we discover any issue in our production processes, this would be reported and the relevant production process would be reviewed.

To ensure the highest standards of production quality control, we have implemented rigorous procedures for managing raw material suppliers and finished products. Our supplier management program categorizes materials based on quality risk, batch usage, and their impact on product quality and process operations. Suppliers are evaluated and approved through a comprehensive process that includes questionnaires, sample quality confirmation, trial evaluations, and on-site audits. Approved suppliers are included in a qualified supplier list and

are subject to ongoing performance assessments based on supply history to ensure compliance with our stringent quality requirements. Only materials procured from qualified suppliers and verified through acceptance testing are used in production.

For finished products, we maintain strict controls throughout the manufacturing process. Each batch undergoes thorough monitoring to ensure compliance with approved manufacturing procedures and quality standards. Intermediate products are tested during production to confirm adherence to specifications, while finished products are subjected to comprehensive inspections before release. This includes reviewing production and testing records to verify that the manufacturing process was strictly controlled and that the final product meets all regulatory and registration requirements. These measures collectively ensure that our products consistently achieve the highest levels of quality and safety. The objective of our quality assurance system is to continuously improve our production processes. We believe that our stringent quality assurance system ensures that our production processes produce pharmaceutical products of a high quality on a consistent basis.

We have received all necessary GMP certifications for all our production facilities for our current products. We have also received certification from certain overseas regulatory authorities. For example, we have received Certificates of Suitability from the European Directorate for the Quality of Medicine & Healthcare for the production of some of our products.

### **INVENTORY MANAGEMENT**

Our inventory primarily consists of finished products and certain production materials such as raw materials, excipients, packaging materials, finished products, consumables for reagents and consumables for workshops. We have personnel responsible for reviewing and managing our inventory of finished products and inventory of production materials. In general, we formulate purchase plans for production materials on an order-by-order basis or based on our monthly plans of production, purchase non-production supplies based on the needs of various departments on a monthly basis and perform strict inventory control from the time we have them in stock. Our production targets for each product are determined after discussions with our sales and marketing department to determine the number of products that are required to meet the corresponding demand on a monthly or quarterly basis. In this way, we are able to manage our inventory levels to ensure that we do not over-stock finished products or production materials. Our overall objective with the inventory management processes is to minimize the amount of inventory stored by us. In addition, to ensure that our drugs are sold before their expiry dates, our warehouse managing staff will (i) timely alert us when the remaining shelf lives of our drugs are less than three months; and (ii) move drugs to a separate storage area and label them as pending disposal when their remaining shelf lives are less than one week. We conduct monthly audit to ensure the accuracy of the shelf lives of the drugs in our inventory and the expired products will be disposed of promptly.

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We write down our inventories on a case-by-case basis in accordance with IFRS. For the years ended December 31, 2022, 2023 and 2024, we recorded write-down of inventories of RMB59.7 million, RMB24.4 million and RMB44.7 million, respectively. The write-down in 2022 was primarily due to our lower than usual sales of Kewei (oseltamivir phosphate) due to travel restrictions, social-distancing measures and business closures which significantly reduced the movement of people, resulting in a decline in the incidence of influenza. The write-downs in 2023 and 2024 were primarily due to low utilization rates of our insulin production lines, which led to increased unit costs; as a result, the net realizable value of our insulin products fell below their book value.

### INTELLECTUAL PROPERTY

Intellectual property rights are central to the success of our business. Our commercial future will depend, in part, on our ability to acquire and protect our intellectual property rights for commercially significant and proprietary technologies and inventions. This includes the acquisition of new patents, defense of existing patents, and protection of our trade secrets. We will also have to operate without infringing, misappropriating, or otherwise violating third parties' valid and enforceable intellectual property rights.

As of December 31, 2024, we and our subsidiaries made a total of 2,446 invention patent applications, including 382 PCT patent applications, 1,131 PRC domestic invention patent applications and 933 overseas invention patent applications, among which, a total of 1,401 invention patents have been granted by the relevant patent authorities, including 746 in the PRC and 655 overseas.

We have also established a confidentiality system to protect our core technologies, which adopts a number of measures to ensure our data and information from research and development experiments and test reports are kept confidential, and requires confidentiality agreements to be entered into with our employees. We have also implemented measures to control intellectual property risk, and established different types of intellectual property searches and prepared analysis reports at various stages including research and development, production and sales. This includes but is not limited to the Project Establishment Analysis Report, the Existing Technology Report, the Freedom of Operation Risk Report and Ineffectiveness Analysis or Stability Analysis Report.

We continue to safeguard our intellectual properties and products through patent-related measures. For chemical drugs, we focus our patent applications on compounds and also cover crystal forms, combinations, formulations, manufacturing processes, uses, and combination therapies, so as to form comprehensive patent protection in relation to our intellectual property regarding chemical drugs. Similarly, for biologics, we focus our patent applications on molecular sequence structures, and also cover recombinant plasmids and cells, compositions, formulations, manufacturing processes, uses, and combination therapies in order to create overall patent protection for the relevant intellectual property. By ensuring comprehensive protection for our intellectual properties and products, we have established robust patent

barriers, which prevent third parties from circumventing the protection of a single patent and effectively extend the duration of patent protection. This approach eventually contributes to our products' long-term competitive advantage in the market.

The term of an individual patent may vary based on the jurisdictions in which it is granted. The actual protection afforded by a patent varies on a claim-by-claim and jurisdiction-by-jurisdiction basis and depends upon many factors, including the type of patent, the scope of its coverage, the availability of any patent term extension or adjustment, the availability of legal remedies in a particular jurisdiction and the validity and enforceability of the patent. We cannot provide any assurance that patents will be issued with respect to any of our pending patent applications or any such patent applications that may be filed in the future, nor can we provide any assurance that any of our owned, in-licensed issued patents or any such patents that may be issued in the future will be commercially useful in protecting our products, drugs under development and the methods of manufacturing the same.

We may rely, in some circumstances, on trade secret and/or confidential information to protect aspects of our products and drugs under development. We seek to protect our proprietary products, drugs under development and processes, in part, by entering into confidentiality agreements with consultants, scientific advisors and contractors, and entering into invention assignment agreements with our employees. We have entered into confidentiality agreements with our senior management and key members of our research and development team and other employees who have access to trade secrets or confidential information about our business. Our standard employment contract, which we use to employ each of our employees, contains an assignment clause, under which we own all the rights to all inventions, technology, know-how and trade secrets derived during the course of such employee's work.

These agreements may not provide sufficient protection of our trade secret and/or confidential information. These agreements may also be breached, resulting in the misappropriation of our trade secret and/or confidential information, and we may not have an adequate remedy for any such breach. In addition, our trade secret and/or confidential information may become known or be independently developed by a third party, or misused by any collaborator to whom we disclose such information. Despite any measures taken to protect our intellectual property, unauthorized parties may attempt to or successfully copy aspects of our products or obtain or use information that we regard as proprietary without our consent. As a result, we may be unable to sufficiently protect our trade secrets and proprietary information.

We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining the physical security of our premises and physical and electronic security of our information technology systems. Despite any measures taken to protect our data and intellectual property, unauthorized parties may attempt to or successfully gain access to and use information that we regard as proprietary. Please see the paragraphs headed "Risk Factors — Risks Relating to Our Intellectual Property Rights" for a description of risks related to our intellectual property.

We conduct our business under the brand name of “HEC”, “東陽光” or “東陽光藥”. As of December 31, 2024, we held 599 trademarks and trademark applications in China, Europe, the United States and several other jurisdictions. In addition, we are the owner of seven software copyrights and seven domain names. Please see “Appendix VI — Statutory and General Information — B. Further Information about Our Business — 2. Our Intellectual Property Rights” for further information in relation to our material intellectual property rights.

We enter into collaboration agreements and other relationships with pharmaceutical companies and other industry participants to leverage our intellectual property or gain access to the intellectual property of others. For details, please see the paragraphs headed “— Collaboration and Licensing Agreements” in this section. As of the Latest Practicable Date, we were not involved in any proceedings in respect of, and we had not received notice of any claims of infringement of, any intellectual property rights that may be threatened or pending, in which we may be a claimant or a respondent that will have a material adverse financial impact on our business.

### **LAND AND PROPERTIES**

Our headquarters is located at Dongguan city, Guangdong province, China.

We occupy certain properties in connection with our business operation. As of December 31, 2024, we did not have any single property with a book value accounting for 15% or more of our total assets. Our Directors are of the view that we are not required to set out all of our interests in land and buildings in the valuation report described in paragraph 34(2) of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance according to Chapter 5 of the Listing Rules and section 342(1)(b) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance.

#### **Owned Properties**

As of December 31, 2024, we have obtained land use right certificates for 13 parcels of land with an aggregate site area of approximately 826,505.6 square meters, which are primarily used for our production facilities, warehouse and administrative offices. In addition, as of December 31, 2024, we owned building ownership certificates in respect of 107 properties with a total gross floor area of approximately 203,982.37 square meters. As of December 31, 2024, 13 parcels of land over which we held land use rights with an aggregate site area of approximately 826,505.61 square meters and nine of our owned properties with building ownership certificates with a gross floor area of approximately 78,365.78 square meters were pledged to secure certain bank loans.

#### ***Properties pending building ownership certificates***

As of December 31, 2024, we had not yet obtained building ownership certificates for five properties with an aggregate gross floor area of approximately 113,164.17 square meters. Four of those properties are located on four parcels of land owned by us. We purchased the

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remaining property with a gross floor area of approximately 704.6 square meters, which is currently occupied by us as office premises (“**Acquired Property**”). The table below sets out the details about each of the five properties whose building ownership certificates are pending.

No.	Location	Building Area (m <sup>2</sup> )	Property use <sup>1</sup>	Timeline for building ownership certificate	Status as of December 31, 2024
1.	Louzihecun, Zhicheng, Yidu, Hebei Province	84,040.88	Technical Center, Quality Inspection Building, Class A Warehouse, Class C Warehouse, Recycling Workshop, Hazardous Waste Room, Central Control Room, Synthesis Workshop, Hydrogenation Workshop, Power Workshop, Temperature and Pressure Reduction Station, Tank Area, Sewage Treatment Station, Frame Room, Regional Control Room, IPC Building, Guard Room, Cafeteria, etc.	By end of 2026	Acceptance inspection completed with building ownership certificate pending
2.	Zone A, Songshan Lake North Industrial City, Dongguan, Guangdong Province	32.00	Security Room	By end of 2026	No building ownership certificates due to incomplete construction procedures
3.	Longwocun, Baotawancun, Lucheng Subdistrict, Yidu, Hebei Province	28,187.00	Staff Apartment, Cafeteria, Training Center	By end of 2026	Acceptance inspection completed with building ownership certificate pending
4.	No. 38 Binjiang Avenue, Lucheng Subdistrict, Yidu, Hebei Province	199.73	Power Distribution Room, Back Gate Room, Air Compressor Room	By end of 2026	No building ownership certificates due to incomplete construction procedures
5.	Unit 19CD, Building 2, Wanhua Financial Center, Xiamen, Fujian Province	704.56	Office	By end of 2026	Acquired Property

<sup>1</sup> During the Track Record Period, only Property No. 1 in the table was used as production facility with a production capacity of 300 tons of raw materials and APIs per year. The rest of the properties were not directly involved in any revenue-generating activities and were only used for supporting function such as staff apartment, office and cafeteria.

The procedure of obtaining building ownerships certificates is to (i) obtain the requisite approvals relating to planning, construction and other procedures, (ii) apply for the acceptance inspection and (iii) issue of building ownership certificates upon satisfactory inspections. As advised by our PRC Legal Advisor, after completing the relevant legal procedures, there is no substantial legal impediment to obtaining the building ownership certificates for Properties No. 1 and No. 3 in the table above. As of December 31, 2024, we did not obtain building ownership certificates for Properties No. 2 and No. 4 in the table above due to incomplete construction procedures, and there is a risk that administrative penalties, such as orders of rectification or demolition of the property within a specified period, may be imposed on us. According to applicable PRC laws and regulations, we estimate that these properties would expose us to administrative measures or penalties, including rectification, orders, a maximum amount of fines which is up to RMB16.3 million. However, as advised by our PRC Legal Advisor, the defects of these two properties would not have a material adverse effect on our business operations considering that: (i) these two properties that have not obtained building ownership certificates are not used for revenue-generating purposes and are not part of our core production and operation properties; (ii) the total area of these properties that have not obtained building ownership certificates accounts for a very small proportion of the total area of the properties we utilize; and (iii) during the Track Record Period, we were able to utilize these two properties and did not receive any administrative penalties such as orders for rectification and demolition within a specified period from the competent authorities in respect of these properties.

In respect of the Acquired Property, we entered into the relevant sales contract with the relevant property developer for the development in November 2020. Whilst we are waiting for the building ownership certificate from the property developer, we started using the Acquired Property as office premises from November 2022. As advised by our PRC Legal Advisor, upon completing the relevant legal procedures, there is no substantial legal impediment to obtaining the building ownership certificate for the Acquired Property. In addition, based on the terms of the sales contract, the property developer is required to deliver the relevant building ownership certificate to us.

We have obtained certification documents issued by the competent authorities confirming that, in respect of the five aforementioned properties, we had not been and would not be subject to investigation, handling or administrative punishment by such competent authorities for violating relevant laws and regulations during the Track Record Period. We continue to communicate with the competent authorities on the processes of obtaining relevant building ownership certificates, and had not received any notice of investigation, handling or administrative punishment made by the competent authorities as of the Latest Practicable Date. Based on the above, we are unlikely to be prosecuted or be subject to fines or penalty of confiscation of revenue for the non-compliance of the aforementioned properties. Our Directors confirm that, in respect of each of the Acquired Properties: (i) none of these properties are material to the business, operation or financial condition of our Group, and our Group can lease other premises in the same city to establish replacement sales offices if our Group is no longer permitted to use the Acquired Properties; and (ii) our Company will continue to discuss and work with the relevant property developers to obtain the building



ownership certificates for the Acquired Properties. We have been actively discussing with the relevant property developers and regulators and have been actively preparing for the required materials for obtaining such building ownership certificates. Based on our discussions with the relevant property developers as of the Latest Practicable Date, we expect that the building ownership certificates for the Acquired Properties should be issued by the relevant governmental authorities by December 31, 2025.

### **Leased Properties**

As of December 31, 2024, we leased 10 properties, each exceeding 1,000 square meters, with an aggregate gross floor area of approximately 114,949.92 square meters in mainland China, which are used as production facilities, warehousing facilities, dormitories and office premises. In addition, we leased certain properties in the United States and Germany as office premises, which are leased under legal, valid, subsisting and enforceable lease agreements that are duly registered.

As of December 31, 2024, for certain of our leased properties in the PRC with an aggregate gross floor area of approximately 38,895.9 square meters, the lessors failed to provide the corresponding building ownership certificates or credentials entitling them to lease such properties. Such lease contracts are subject to the risk of being deemed invalid by the relevant government authorities under PRC laws. The leased properties constructed without approval or permit by relevant competent authorities are subject to risk of demolition as ordered by the relevant government authorities. During the Track Record Period and up to the Latest Practicable Date, we have not been subject to any penalties from the competent authorities due to the lessors' failure to provide building ownership certificates for such leased properties.

In addition, as of December 31, 2024, ten properties leased by us or our subsidiaries in China had not registered with the relevant housing authorities. Pursuant to the Measures on the Administration of the Registration of Urban House Title (《城市房地產管理法》) and the provisions of the Administrative Measures for Commodity House Leasing (《商品房屋租賃管理辦法》), for lease agreements that are not registered with the relevant housing authorities, we may be subject to a maximum fine of RMB10,000 per unregistered lease agreement. Our PRC Legal Advisor advised us that our failure to register the lease agreements does not affect the validity of the lease agreements. During the Track Record Period and up to the Latest Practicable Date, we have not received any notice from the relevant housing authorities to rectify or any penalty in relation to our failure to register these leases.

Our Directors believe that such defects in our leased properties described above will not have a material adverse impact on our business or results of our operations, mainly because:

- i. we received confirmation letters with respect to the properties for which the lessors failed to provide the corresponding building ownership certificates from the relevant competent government authorities (as advised by our PRC Legal Advisor), confirming that during the Track Record Period and up to the date of issuance of

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such letters (i) our leasing of the above-mentioned leased properties does not constitute a material breach of laws and regulations, and our land use does not result in administrative penalties for breaching the relevant laws and regulations on land management; (ii) relevant competent government authorities will not take back or forcibly dismantle such buildings, and we may continue to utilize such buildings for the current uses within the scope of our business; and (iii) we had no record of administrative penalties from the relevant competent government authorities, and such government authorities have no plans to investigate or penalize us for our leasing and the use of the relevant leased properties; and

- ii. our leased properties are mainly used as warehousing facilities, dormitories and office premises, and if we have to terminate the occupation of any leased property, we believe we can find a suitable alternative in a timely manner, and without significant disruption to our business. Such relocation is estimated to take 30 days to complete and may cost us RMB1.5 million.

## COMPETITION

The pharmaceutical industry is highly competitive and subject to rapid changes. While we believe that our pipeline of innovative products, clinical and pre-clinical drugs under development, as well as our research and development capabilities, technology platforms, and leadership team provide us with competitive advantages, we face potential competition from many other sources working to develop therapies that target the same indications against which we are developing our products and drugs under development. These include major pharmaceutical companies as well as specialty pharmaceutical and biotechnology companies of various sizes, research institutions, academic institutions and government agencies. Any products or drugs under development that we successfully develop and commercialize will compete with both existing drugs and any new drugs that may become available in the future.

Furthermore, we face competition from other pharmaceutical companies engaged in the research, production, marketing or sales of pharmaceutical products similar to our products. In relation to our business, our products compete with other products that treat similar conditions or illnesses on the basis of effectiveness in treating of the relevant condition or illness, price, brand recognition and the preference of medical professionals and hospitals. For detailed discussions regarding our competitors in relation to our major products, see “Business — Our Products”.

Given the competitive nature of the PRC pharmaceutical market and the impact of the historical price control regime over some of our products, we believe that we primarily compete on the basis of brand recognition, sales network, educational promotional activities, quality assurance and the extent to which we are able to reduce our production costs. In our view, we need to maintain our competitiveness in the PRC pharmaceutical manufacturing industry by continuing to develop our manufacturing capabilities, diversifying our product portfolio, maintaining and improving the quality standards of our products, maintaining and

obtaining all necessary regulatory approvals in respect of every part of our business and developing our educational promotional activities to raise awareness of our products among medical professionals and hospitals.

With the PRC pharmaceutical market being so highly regulated, we believe there are significant barriers for new pharmaceutical companies that wish to enter into it. For example, significant capital expenditure is required in order to construct and maintain production and manufacturing facilities that satisfy the necessary GMP requirements and the relevant environmental, health and safety regulations. In addition, the development of new drugs takes significant time and resources (including obtaining the necessary manufacturing approvals), which means it is unlikely to lead to a significant and sudden increase in the number of pharmaceutical manufacturers in the PRC.

### ENVIRONMENTAL, SOCIAL, AND GOVERNANCE

We believe our long-term success rests on our ability to make a positive impact on society.

#### Governance on ESG Matters

We are committed to social responsibilities and consider environmental, social and governance (“ESG”) essential to our continuous development. Our Board is responsible for overseeing and guiding our ESG initiatives and setting our ESG strategies and policies.

In order to ensure the achievement of our strategic objectives, we have established a comprehensive ESG management structure with clear division of responsibilities among different levels, providing a strong foundation for further improvement and implementation of our ESG strategies:

- **ESG leading group.** We have established an ESG leading group, comprising the relevant directors and senior management, which is responsible for the overall control of our ESG management, including setting ESG management objectives, strategic deployment of ESG medium and long-term planning, top-level design and regulations signing of ESG management system and ESG report approval.
- **ESG coordination group.** The ESG coordination group, led by the secretary of the Board, is mainly responsible for overall planning of ESG work arrangements and promoting and implementing publicity of our ESG strategy, conveying the Board’s major resolutions regarding ESG-related work, planning our annual ESG work plan, drafting ESG-related policies, improving our ESG indicator system, facilitating ESG-related training and communication, and preparing our annual ESG report. In addition, it provides regular feedback to the ESG leading group on work progress and results, and proposes recommendations on ways to improve ESG work.

- **ESG execution group.** The ESG execution group comprises the heads of the ESG-related functional departments of our Company. Each department has designated personnel who will be responsible for that particular department's ESG management, its collection and submission of ESG information and data, as well as reporting on the results of its ESG practices.

Our Board has formulated internal policies, such as the Environmental Protection Management System and the Responsibility System for the Prevention and Control of Environmental Pollution by Hazardous Wastes, to clarify the division of responsibilities for environmental protection, and set up a target, control, evaluation and assessment mechanism to prevent and reduce any adverse impact that our production and operational activities may have on the environment.

### **Environmental Protection**

We strive to operate our facilities in a manner that protects the environment. During the Track Record Period and up to the Latest Practicable Date, we had been in compliance with the relevant environmental laws and regulations applicable to our operations in all material respects and there had been no material claim or penalty imposed on us as a result of a violation of environmental laws and regulations that would materially and adversely affect our business, financial condition or results of operations. For the three years ended December 31, 2022, 2023 and 2024, our expenses in relation to environmental compliance matters were RMB12.5 million, RMB6.6 million and RMB15.1 million, respectively, which primarily include investment in environmental governance, investment in environmental protection equipment and sewage treatment.

### ***Climate-related risks***

The environmental and climate-related risks we are exposed to can be divided into two broad categories: physical and transition risks. We define physical risks as risks relating to the physical impacts of climate change, consisting of (i) acute physical risks, such as increased severity of extreme weather events which affect production stability; and (ii) chronic physical risks, such as risks of climate change which have accumulated over time and can negatively impact our production. We define transition risks as the transition from a dependence on fossil fuels to one on a low-carbon economy, which may alter our production technology, costs and other aspects of our business. Potential risks to product quality, research and development, operations, production control, supply chains, transportation needs, and employee safety also impact our finances.

Our ESG leading group closely monitors climate change policies to reduce the possible impacts of physical and transition risks. We incorporate environmental risk analysis into our risk assessment process and risk preference setting. If risks and opportunities are deemed material, we incorporate them into our strategic and financial planning processes and take appropriate mitigation measures.

Our business, financial condition and results of operations had not been materially affected by any climate-related events during the Track Record Period and up to the Latest Practicable Date.

### *Energy Conservation*

We actively explore strategies to reduce energy consumption, primarily on water and electricity consumption. We have established a top-down environmental management system and have set up a relevant leading group as well as departments to formulate annual environmental targets for water, electricity and gas consumption, and strive to achieve standardization, formalization and refinement of environmental protection management.

### *Water Resources Consumption*

We focus on issues surrounding water resources and actively shoulder the social responsibility of protecting water resources. Municipal water supply networks are the main incoming source of our Company's water, and we did not encounter major difficulties in seeking suitable water sources during the Track Record Period. In the manufacturing process, we have implemented measures to improve water-consuming processes. The measures implemented include:

- reducing the demand for water from industrial production by shortening the hot water pipes, minimizing water pressure, reasonably making industrial or production layout;
- changing the way of production water consumption (e.g., turning direct current water to recycled water), promoting water-saving technologies such as the reuse of condensed steam, recycling of indirect condensed water, reuse of treated sewage, and improvement of the water recycling rate and reuse rate; and
- conducting water balance tests to calculate the amount of water required by each production unit and set up inspection measures.

Our major production bases are located in cities such as Yichang and Dongguan, or regions along the rivers or coastal regions, which are areas with relatively low pressure from demand for water, indicating that the use of water resources has a relatively low impact on our operations. The total water consumption intensity of our Group for the three years ended December 31, 2022, 2023 and 2024 showed a downward trend, which was mainly attributable to our lean production and process improvement.

For the three years ended December 31, 2022, 2023 and 2024, our water consumption costs (including sewage charges) amounted to RMB9.427 million, RMB9.927 million and RMB9.898 million, respectively, accounting for 0.25%, 0.16% and 0.25% of our operating income, respectively, which means that the overall financial impact of water consumption costs on us is relatively low.

Nevertheless, we are well aware that freshwater resources are precious and that water conservation is beneficial to our long-term efficiency. Therefore, we will continue to adopt lean production management to reduce the need for water consumption and increase and improve water recycling facilities to enhance the proportion of recycling water. In the next three years, our target for water consumption is to reduce the water consumption for the output per unit of APIs by 2%. Investment of certain funds may be required for among others, the rainwater collection and reuse system and water resources recycling projects in the short term. However, these will help saving the water consumption cost in the long run.

### *Electricity Consumption*

We actively promote energy conservation and consumption reduction in our daily operations. We encourage the purchase and use of energy-efficient electronic equipment in our office premises, including the replacement of LED light tubes in workshops and other energy-saving appliances. Our employees are reminded to make sure that all air conditioning and other power-consuming equipment at our office premises are switched off when not in use.

### *Packaging Material Consumption*

We have procedures in place to reduce the usage of single-use plastic packaging materials and recycle metal packaging materials. We continuously optimize product packaging design, advocate the use of green and environmental-friendly materials, and reduce the use of packaging materials while meeting market and production needs. For the procurement of product packaging materials, we have formulated a group-level procurement management plan. At the same time, we have also established a supplier evaluation control procedure, which is applicable to regulating and controlling the supplier evaluation process and the implementation of procurement. The green procurement principle has been implemented in our daily operations.

### *Emission Management*

We have internal policies and procedures in place to ensure compliance relating to air and greenhouse emissions, discharges into water and land, and generation of hazardous and non-hazardous waste.

### *Wastewaters*

We have formulated targeted treatment measures for various types of wastewaters such as industrial, living and rainwater. Industrial wastewater, steam condensate water, equipment and ground cleaning wastewater are collected on site before entering the sewage pipe network. The fire-fighting water in the event of an accident is discharged into the emergency water basin and pumped into the sewage treatment system, and can only be discharged after treatment which makes it up to standard. For rainwater, we have implemented the separation of rainwater and sewage. In order to ensure that the rainwater pipe network is used separately from the sewage pipe network, we strictly prohibit the discharge of other wastewater of non-rainwater into the

rainwater pipe network, and ensure that the rainwater can be discharged directly without chemical pollution, oil pollution and solid waste. At the end of our Company's sewage pipe network is a sewage regulating basin. All sewage is collected in the regulating basin, and part of the sewage is treated in the sewage treatment station while the other part enters our sewage treatment plant. All the sewage is treated up to the required standards before discharge. We have further added tests on the content of sewage antibiotics for some of our factories to strictly control the chemical oxygen demand (COD) discharge standards, and to continuously improve the in-depth treatment effect of wastewater.

#### *Greenhouse gas emission*

Greenhouse gas (GHG) emissions include Scope 1 (i.e. direct emissions), Scope 2 (i.e. energy indirect emissions) and Scope 3 (i.e. other indirect emissions). Among them, Scope 1 emissions and Scope 2 emissions are all from the controllable energy use of our Group. In order to address the global challenge of climate change and meet the national goal of “peak carbon and carbon neutrality”, we actively promote energy conservation and emission reduction to reduce GHG emissions in our operations, and have achieved certain results.

For the three years ended December 31, 2022, 2023 and 2024, our energy consumption costs amounted to RMB43.171 million, RMB51.656 million and RMB59.733 million, accounting for 1.13%, 0.81% and 1.49% of our revenue, respectively, and we are not categorized as energy-intensive industry. Therefore, the GHG emissions (energy use) have no direct and material effect on financial condition and operation of our Group as a whole.

In terms of Scope 1 and Scope 2 GHG emissions, our target is to reduce GHG emissions intensity by 10% from the level in 2023 by 2028. We will realize the target by reducing energy demand through lean production, retrofitting existing equipment to save energy, using renewable energy and purchasing carbon offsets tools.

For Scope 3 GHG emissions, we are currently conducting a survey on the applicability of 15 categories of Scope 3 GHG emissions, with the departments involved and the relevant external stakeholders, to determine and review the feasibility of the projects and prioritize the categories of Scope 3 GHG emissions. Due to the complexity of supply chain data, the task is still in progress currently. In the future we will make disclosures in accordance with the requirements under the Stock Exchange's Environmental, Social and Governance Reporting Code.

Following an assessment of applicability and feasibility, we will measure the relevant Scope 3 GHG emissions in accordance with the GHG Protocol. This work is expected to be completed by June 2025. Subsequently, based on data from Scope 3 GHG emissions in 2025 and 2026, we will establish reduction targets for Scope 3 emissions and collaborate with upstream and downstream partners to contribute to the reduction of GHG emissions.



Due to the special requirements for raw materials in our products, there is limited room for reduction in Category 1 (purchased goods and services). However, in Categories 4 and 9, we will implement more scientific and reasonable procurement plans and more efficient and centralized transportation plans to reduce corresponding Scope 3 GHG emissions. In Category 6 and 7, we encourage employees to adopt green commuting and reduce business travel to further reduce Scope 3 GHG emissions.

### *Solid Waste*

The solid waste we produce is divided into hazardous waste (such as chemical waste and liquid) and non-hazardous waste (such as domestic waste from general office operations). We are committed to achieving an innocuous and efficient management of waste disposal that strictly controls the use of chemicals in the pharmaceutical process.

We have formulated internal systems to separate the disposal of solid wastes, so as to ensure that our Company can effectively control and properly dispose of all kinds of waste generated during the production, activities and service process, and prevent and reduce environmental pollution and workplace injuries.

Waste includes hazardous waste and non-hazardous waste. Hazardous wastes include pharmaceutical wastes and other hazardous wastes.

Among them, pharmaceutical waste includes the disposal of expired drugs, such as the disposal of 320.46 tons of expired drugs in previous years by our Group in 2023. Expired drugs not only cause wastage of production resources, but also affect the financial performance of our Group. Therefore, we devoted greater efforts to enhance timeliness and accuracy in forecasting market demand, carry out on-demand production and strengthen management on drugs that are near their expiration dates, and reduce expired drugs through promotion campaigns. For the three years ended December 31, 2022, 2023 and 2024, our hazardous waste disposal costs amounted to RMB0.311 million, RMB0.678 million, and RMB0.276 million respectively, accounting for 0.01%, 0.01% and 0.01% of our Group's operating income. Except for the factor of expired drugs, the generation of hazardous waste is stable and unavoidable, while it has no direct and material effects on financial condition and operation of our Group as a whole. There was no significant fluctuation in our hazardous waste intensity during the Track Record Period. In the next three years, our target for hazardous waste generation is to ensure that intensity of hazardous wastes shall not exceed 0.002 ton/kg of API production.

Non-hazardous wastes include general industrial wastes and household wastes, while these wastes are inevitably generated during normal production and office work. For the three years ended December 31, 2022, 2023 and 2024, our non-hazardous waste disposal costs amounted to RMB0.236 million, RMB0.234 million and RMB0.303 million, respectively, accounting for 0.006%, 0.004% and 0.008% of our Group's operating income, respectively, indicating that non-hazardous waste has no direct and material effect on financial condition and operation of our Group.

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For general industrial waste, we set up a management ledger to record the amount, type, destination and other information for statistical analysis and supervision to provide data support for waste reduction and continuously improve overall utilization rate. For domestic waste, we implement a paperless office through the OA system to reduce office waste, and reduce food waste by collecting statistics on the number of diners, small dishes and self-service rice. We regularly promote the above policies and measures to our staff members so that they can understand various aspects of waste reduction, including classification standards of wastes, and methods and importance of waste reduction, while rewarding staff members whose reasonable suggestions on waste reduction are adopted. In the next three years, our Group's target for the amount of non-hazardous wastes generated is to ensure that the intensity of non-hazardous wastes shall not exceed 0.02 ton/kg of API production.

Hazardous waste includes expired drugs, which are influenced by multiple factors such as market demand, production forecasts, and product shelf life. There is no fixed pattern for the generation and disposal of expired drugs, and with improved market demand forecasting and production scheduling experience, the generation and disposal of expired drugs generally show a decreasing trend. For other hazardous wastes (excluding expired drugs), the amount generated in 2024 was slightly higher than that in 2023, as the production volume of APIs in 2024 was also higher than that in 2023.

For non-hazardous waste, which includes general industrial waste and household waste, all such waste is handled by third parties. In 2024, under the circumstance of ensuring product quality and meeting production needs, we continuously improved our production processes and optimized production workflows. Meanwhile, we enlarged batch sizes, reduced testing frequencies for equivalent materials, and improved raw material utilization rates. These efforts contributed to a reduction in the generation of non-hazardous waste.

We rely on various metrics to measure the impact of environmental risks, which are broadly aligned with industry standards. Such metrics include the number of resource consumption, amount of wastewater generated and the amount of hazardous waste generated. We have also set various goals to reduce our environmental impacts, and we continue to take significant steps towards these targets. The following table sets forth our resource use and emission-related indicators during the Track Record Period.

Unit	For the years ended December 31,		
	2022	2023	2024
<b>Energy consumption</b>			
Externally purchased electricity . . . . . kWh	73,698,122.0	79,046,487.0	87,173,297.0
Externally purchased steam . . . . . Tons	81,037.2	93,011.6	104,996.1
Diesel <sup>2</sup> . . . . . Liters	420.0	720.0	1,800.0
Total energy consumption . . . . . Tons of standard coal	16,657.8	18,488.9	20,702.7

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		For the years ended December 31,		
	Unit	2022	2023	2024
Total energy consumption intensity . .	Tons of standard coal/output per kilogram of APIs <sup>1</sup>	0.5	0.2	0.2
<b>Water consumption</b>				
Freshwater consumption . . . . .	Tons	1,856,424.6	1,816,590.3	1,985,883.0
Total water consumption intensity . . .	Tons/output per kilogram of APIs <sup>1</sup>	54.0	18.1	15.0
<b>Packaging materials used for finished goods</b>				
Packaging materials used . . . . .	Tons	3,035.3	4,606.0	3,154.6
Packaging material intensity . . . . .	Tons/output per kilogram of APIs <sup>1</sup>	0.09	0.05	0.02
<b>Emissions</b>				
Industrial wastewater . . . . .	Tons	387,286.5	529,596.0	469,257.9
Chemical oxygen demand COD <sub>Cr</sub> . . .	Tons	11.7	15.1	18.9
Ammonia nitrogen . . . . .	Tons	0.1	0.3	0.4
<b>Greenhouse gas emissions</b>				
Greenhouse gas emissions . . . . .	Tons of CO <sub>2</sub> e	67,025.2	73,683.5	83,237.4
Scope 1 total greenhouse gas emissions. . . . .	Tons of CO <sub>2</sub> e	816.9	828.5	842.9
Scope 2 total greenhouse gas emissions. . . . .	Tons of CO <sub>2</sub> e	66,208.3	72,855.0	82,394.5
Intensity of greenhouse emissions . . .	Tons of CO <sub>2</sub> e/output per kilogram of APIs <sup>1</sup>	1.9	0.7	0.6
<b>Hazardous waste generated</b>				
Pharmaceutical waste . . . . .	Tons	178.5	400.8	86.0
Other hazardous wastes . . . . .	Tons	55.4	79.8	84.8
Total hazardous waste . . . . .	Tons	233.9	480.6	170.8
Intensity of hazardous waste. . . . .	Tons/output per kilogram of APIs <sup>1</sup>	0.007	0.005	0.001

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		For the years ended December 31,		
	Unit	2022	2023	2024
<b>Non-hazardous waste generated</b>				
General industrial waste and domestic waste . . . . .	Tons	2,886.9	3,346.4	1,979.8
Intensity of non-hazardous wastes . . .	Tons/output per kilogram of APIs <sup>1</sup>	0.08	0.03	0.01

1. Given the businesses of various subsidiaries of our Group, we believe that it is better to include output (but not revenue) in the measurement of intensity. Of which, the output of APIs is an appropriate denominator for this purpose as the unit of measurement has been applied consistently and all of the APIs have been supplied to other subsidiaries of our Group.
2. The increase in diesel of our Group in 2024 was mainly due to the purchase of a new diesel truck for transporting bacteria residue.

With the expansion of our business and anticipated commercialization of our drugs under development, we expect our resource consumption and emissions to increase. However, we will continue to adopt a wide range of measures, including strengthening source control, implementing cleaner production, rationing the use of resources, treating laboratory waste and water discharge conscientiously and responsibly, and reducing pollution in the whole process. At the same time, we strive to cultivate a corporate culture of environmental protection and work closely with our business partners to build an environmentally friendly ecosystem. We are committed to improving the environmental performance of our entire value chain, including office operations, supplier selection, raw material inflow, laboratory experiments, manufacturing process and waste management. We aim to reduce its overall energy intensity by 10% by 2028 compared to the level in 2023.

### Supplier Management

We have established a comprehensive and effective procurement system. We have also signed the Anti-commercial Bribery Agreement between the Supplier and the Purchaser of Materials 《物資供需雙方反商業賄賂協議》 and the Letter of Commitment to Integrity 《廉潔承諾書》 to strictly control the occurrence of corruption. We attach great importance to and continue to identify the environmental and social risks in our supply chain, and believe that supply chain management can help reduce environmental and social risks. As such, we have established rigorous and standardized processes for supply chain management and supplier selection.

Our Group has always attached great importance to the environmental protection philosophy and social responsibility of its suppliers. In selecting and managing suppliers, we make the judgments by taking account of their quality and qualifications, while conducting assessment by taking account of the concept of environmental protection and social responsibilities, so as to ensure that all suppliers comply with our environmental protection

standards and social responsibilities. We continue to optimize the design of product packaging and advocate the use of green materials, so as to reduce the use of packaging materials while meeting the market demand and production requirements. When choosing equipment, we should strive to choose those equipment that can achieve maximum output with minimum input, or efficient equipment. In terms of craftsmanship, which means the ability of equipment to meet the requirements of production process. In addition to meeting the technical requirements of the product craftsmanship, the equipment must also comply with the requirements of GMP in relation to energy conservation and reduction in raw material consumption and energy consumption.

With regard to animal welfare, as described in the Business Section (page 377), all of our animal experiments are conducted through CROs that are qualified in animal experimentation and comply with regulations on the keeping and use of laboratory animals. We set strict standards for the protection of animal experiments. For outsourced service institutions that for the entrusted animal experiments to be conducted, we rigorously review and assess their testing capabilities and qualifications, such as those research institutions with AAALAC (Association for Assessment and Accreditation of Laboratory Animal Care 國際實驗動物評估和認可委員會) accreditation and/or GLP qualifications and with sufficient practical experience. We have clarified the ethical requirements for animal experiments, and stipulated the “3Rs” (Reduction, Replacement, Refinement) principle in the outsourcing contract we signed.

### Corporate Social Responsibility

We are committed to corporate social responsibility and meeting society’s changing needs. We support and participate in socially responsible projects that align with our core values and mission. In particular, we have taken initiatives in the following areas:

- ***Launching health promotional activities.*** The “Medicine and Health Entering Thousands of Homes — Sunshine Science Popularization Tour in Guangdong Province Kick-off Conference” (藥健康進萬家—陽光科普紀行廣東省啟動會) was held in Guangzhou in May 2024. We place great importance on corporate social responsibility and have participated in and supported the “Medicine and Health Entering Thousands of Homes” initiative for many years, witnessing the project’s development and progress. We hope to continue collaborating with the Chinese Pharmacists Association and experts at all levels across the country to further advance this project nationwide and contributing to health promotional activities.
- ***“Blood Donation for National Day” Voluntary Blood Donation in 2023.*** In celebration of the 74th anniversary of the founding of the PRC, in response to the call of the Voluntary Blood Donation Committee Office of Yidu\* (宜都市無償獻血工作委員會辦公室), we organized the “Blood Donation for National Day” voluntary blood donation in September 2023. A total of 130 persons donated blood and a total of 45,600 milliliters of blood were collected.

- **Charity.** On December 18, 2023, a 6.2-magnitude earthquake struck Jishishan County in Linxia Hui Autonomous Prefecture, Gansu Province. We quickly responded by initiating an emergency relief plan, pursuant to which we donated RMB1 million in cash to the disaster-stricken area in Gansu Province to alleviate the urgent needs of those affected and support their post-disaster rebuilding efforts as much as possible.
- **Launching a series of popularization activities on influenza prevention and treatment.** We attach great importance to disease prevention and education, dedicating efforts to promote and develop the concept of standardized diagnosis and treatment of influenza, organize public welfare activities to enhance public health awareness, serve the health and well-being of the public, and contribute to the construction of a healthy China. During the peak season for influenza, we, in collaboration with CCTV.com and Baidu Health, launched a series of popularization activities on influenza prevention and treatment. On December 20, 2023, our brand operation director made a guest appearance in the CCTV live broadcast room, where he provided scientific explanations on influenza prevention and treatment issues that concern the public, helping the public acquire accurate knowledge about influenza and establish correct medication concept. In the future, we will continue to collaborate with experts and platforms in various health fields to promote the popularization of proper methods of influenza prevention and treatment and the concept of rational drug use, disseminate scientific knowledge, jointly build a health line of defense against influenza, and contribute to the establishment of the national influenza prevention and control system.

### Work Safety and Health

The PRC government imposes a number of regulatory requirements on pharmaceutical companies in relation to health and occupational safety. Please see “Regulatory Environment — Principal Regulatory Provisions — Laws and Regulations on Labor and Employee Incentives — Labor, Social Insurance and Housing Provident Funds” for a discussion of these requirements. We are committed to complying with PRC regulatory requirements, preventing and reducing hazards and risks associated with our operation and ensuring the health and safety of our employees and surrounding communities.

We have established a Safety Department to conduct annual inspections of our operating facilities and processes, and to set out an annual action plan each year to ensure that our pharmaceutical manufacturing operations are in compliance with the applicable laws and regulations. We conduct regular training sessions for employees on accident prevention and management. We also provide annual medical checks for our employees, and we require our production staff to attend training sessions on the required safety standards.

We are committed to regularly identifying, inspecting and rectifying workplace safety hazards and risks relating to employees’ health and safety to ensure that our employees have both a healthy and safe working and living environment, as we believe a safe and healthy

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workplace is not only crucial for the well-being of our employees, but also essential to the sustainability of our business. We have implemented rigorous company-wide work safety guidelines and host regular production and operation training programs to ensure that all of our employees are constantly refreshed and equipped with the necessary awareness and technical know-how to perform their work in a safe and effective manner in accordance with our internal Employee Safety Behavior Manual. We conduct regular safety inspections for our laboratories and manufacturing facilities and have formulated targeted rectification action plans to assist responsible employees in identifying and rectifying potential health and safety hazards, in order to continuously improve our safety risk protection level. As an integral part of work safety and quality assurance, we also perform routine maintenance to ensure that all equipment in the laboratories and manufacturing facilities are safe for use, including by identifying and repairing faulty equipment and equipment parts. Since our operations involve the use of hazardous materials, we carry out regular special cleaning and disinfection work, and have implemented safety protocols that set out guidelines on potential safety hazards and procedures for working in the laboratory and manufacturing facilities, including but not limited to the handling, use, storage, treatment and disposal of hazardous materials, as well as emergency planning and response. During the Track Record Period and up to the Latest Practicable Date, we did not have any major workplace accidents.

		For the years ended December 31,		
Unit		2022	2023	2024
<b>Number and rate of employee turnover . . . .</b>				
Total staff turnover	Number of staff members	1,192	1,177	1,306
Employee turnover rate	Percentage	21%	19%	20%

Our employee turnover rate remained at around 20% without significant fluctuation during the Track Record Period.

Our employee turnover rate during the Track Record Period was between 19% and 21%. Employee turnover is influenced by industry, region, and corporate ownership characteristics. To benchmark against industry standards, we referenced data from Wind Database for all Hong Kong-listed companies headquartered in Guangdong Province in the private biopharmaceutical-western medicine industry (a total of 4 companies). The most recent disclosed employee turnover rate for these companies ranged from 13% to 28%. Therefore, we believe that our Group's employee turnover rate is consistent with industry norms.

We are fully aware of the importance of a stable workforce, especially the stability of our core talents, for the long-term stable development of our Group. Therefore, we strive to enhance staff's recognition and sense of belonging to our Group. We optimized the recruitment



process to clarify the responsibilities, skill requirements and career development paths of each position, and used scientific talent assessment tools to ensure that the recruited personnel were highly matched with the positions and reduce turnover due to a mismatch as a result of different abilities or interests. We formulate individualized career development plans for staff members based on their interests, abilities and corporate needs, and provide clear promotion paths and development directions. Mechanisms such as regular staff communication meetings and symposiums have been established to provide staff with opportunities to express their ideas and opinions. Suggestion boxes and online feedback platform have been set up to encourage staff to provide feedback and suggestions at any time.

### **Workplace Diversity**

Within our organization, we are committed to creating an open and inclusive workplace that promotes equality. We hire employees based on their merits and it is our corporate policy to offer equal opportunities to them regardless of gender, age, race, religion or any other social or personal characteristics. As of December 31, 2024, approximately 50% of our total employees were female. We adhere to a fair and transparent employee management system and strive to enhance gender and age diversity of our workforce.

Going forward, we intend to actively identify and monitor the actual and potential impact of ESG-related risks on our business, strategy and financial performance and incorporate considerations of ESG issues into our business, strategic and financial planning, in compliance with the recommendation of the Environmental, Social and Governance Reporting Code in Appendix C2 to the Listing Rules.

### **INSURANCE**

In line with what we consider to be customary for PRC pharmaceutical manufacturing companies, we maintain clinical trial insurance relating to adverse events in clinical trials, property insurance covering our production facilities and equipment, insurance relating to public liability, insurance relating to transport of goods as well as insurance covering our construction projects (including accidents), all of which, combined, we believe to be sufficient. We also maintain social security insurance in accordance with the relevant laws and regulations in the PRC. We do not carry any product liability insurance or business interruption insurance as these are not mandatory under PRC law as confirmed by our PRC Legal Advisor. Please see “Risk Factors — Risks Relating to Our Business and Industries — We have limited insurance coverage, and any claims beyond our insurance coverage may result in us incurring substantial costs and a diversion of resources.”

Our Directors are of the view that our current insurance coverage is in line with industry practice and norm and is adequate for our operations.

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### EMPLOYEES

As of December 31, 2024, we had 6,550 full-time employees. The table below sets out a breakdown of our employees by function as of December 31, 2024:

	<u>Number of employees</u>
Research and development personnel . . . . .	1,135
Manufacturing personnel . . . . .	2,391
Quality control personnel . . . . .	731
Administrative personnel . . . . .	409
Sales and marketing personnel . . . . .	<u>1,884</u>
<b>Total:</b> . . . . .	<u><u>6,550</u></u>

Most of our employees are located in Dongguan and Yidu. Some of our sales and marketing personnel are located in various sales offices within the PRC.

We provide orientation training for all new employees to ensure that they are able to understand our internal policies, employee manual and corporate culture in an efficient manner. The orientation training also provides them with the necessary skills and knowledge to perform their required duties. We also have a continuing education program to provide training for all of our employees. The aim of such continuing education program is to improve our employees' knowledge and skills in a number of important areas of our operations, including key requirements under the GMP certification system, laws and regulations applicable to our operation, quality control and workplace safety. The training is delivered by our employees, as well as by external speakers. We evaluate our training results every year and adjust training programs accordingly for the next training term. Moreover, all departments in our Company are required to keep their own training records and prepare their annual training plan each year.

We have entered into confidentiality agreements with some of our employees, which provide that all relevant intellectual properties developed by our staff during their employment with us become our intellectual properties and are treated as trade secrets, and that our employees are refrained from disclosing any trade secrets to third parties. We also enter into non-competition agreements with selected employees.

To remain competitive in the labor market, we provide various incentives and benefits to our employees. Our employees' remuneration consists of wages, bonuses, allowances, employees' provident fund, as well as social security contributions and other welfare payments pursuant to applicable laws and regulations. We have also adopted an employee incentive plan to incentivize and recognize the contribution of certain of our employees, advisor and officers. Please see "Appendix VI — Statutory and General information — D. Employee Incentive Plan" for further details of the employee incentive plan.

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We have complied with the statutory social security insurance fund and housing fund obligations applicable to us under the laws and regulations in China in all material aspects during the Track Record Period and as of the Latest Practicable Date. Please see “Risk Factors — Risks Relating to Our Business and Industries — We may be subject to additional payments or penalties relating to contributions to social security insurance and housing provident funds” for further details.

During the Track Record Period, we had not made full contributions to the social insurance premium and housing provident fund based on the actual salary level of some of our employees as prescribed by relevant laws and regulations, with a contribution shortfall of approx. RMB40.7 million, RMB39.7 million and RMB41.5 million for the years ended on December 31, 2022, 2023 and 2024. As advised by our PRC Legal Advisor, pursuant to relevant PRC laws and regulations, if we fail to pay the full amount of social insurance contributions as required, we may be ordered to pay the outstanding social insurance contributions within a prescribed period and may be subject to an overdue fine of 0.05% of the delayed payment per day from the date on which the payment is payable. If such payment is not made within the prescribed period, the competent authorities may further impose a fine from one to three times the amount of any overdue payment. In respect of the housing provident fund contributions, if any competent authority is of the view that the housing provident fund contributions we made do not satisfy the requirements under the relevant PRC laws and regulations, it can order us to make the outstanding balance to the relevant local authorities within a given period. As advised by our PRC Legal Advisor, pursuant to the Social Insurance Law of PRC (《中華人民共和國社會保險法》), we may be required by relevant authorities to pay the outstanding social insurance within a prescribed period, and pay an overdue fee equivalent to 0.05% of the outstanding amount for each late payment day. If we fail to pay the outstanding social insurance within the prescribed period, we may be subject to a fine equivalent to one to three times of the outstanding social insurance amount.

Our Directors believe that such non-compliance would not have a material adverse effect on our business and results of operations, considering that: (i) as advised by our PRC Legal Advisor, to the extent that there are no significant changes in the current policies and regulations related to social insurance and housing provident fund, as well as the implementation and supervision requirements of local governments, and there are no collective complaints or reports made or related litigation and arbitration initiated by employees, the risk of us being ordered to make a one-off payment and subject to significant administrative penalties by the social insurance and housing provident fund regulatory authorities due to issues such as social insurance and housing provident fund payment bases being lower than actual wages during the Track Record Period is relatively low. This view is supported by the confirmation letters that we obtained from the relevant competent authorities confirming that we were not subject to any material penalties in relation to the social insurance premium and housing provident fund; (ii) we had not been subject to any administrative penalties during the Track Record Period and up to the Latest Practicable Date; (iii) we were neither aware of any employee complaints filed against us nor involved in any labor disputes with our employees with respect to social insurance and housing provident funds during the Track Record Period and up to the Latest Practicable Date; and (iv) as of the Latest Practicable Date, we had not

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received any notification from the relevant PRC authorities requiring us to pay for the shortfalls or any overdue charges with respect to social insurance and housing provident funds. Other than the matters as described in this sub-section, we made all other contributions during the Track Record Period in compliance with the applicable laws and regulations.

To ensure on-going compliance with PRC laws and regulations in relation to social security insurance and housing provident funds contributions, we have designated our human resources department to be responsible for matters relating to the social security insurance and housing provident funds contributions of our Group, which will continue to monitor our on-going compliance, investigate any issues detected in a timely manner and communicate with the relevant local governmental authority to ensure we fulfill our obligations under the applicable PRC laws and regulations. We will also continue to consult our PRC legal counsel on a regular basis for advice on relevant PRC laws and regulations to enhance our awareness and to keep us abreast of relevant regulatory developments.

Our Directors confirmed that we have complied with applicable employment laws and regulations in all material respects and there have been no outstanding material labor related legal proceedings or disputes against us as of the Latest Practicable Date.

### PERMITS, LICENSES AND CERTIFICATIONS

We are subject to regular inspections, examinations and audits and are required to maintain or renew the necessary permits, licenses and approvals for our business. Our Directors, as advised by our PRC Legal Advisor, confirm that, during the Track Record Period and up to the Latest Practicable Date, our Group had complied with relevant PRC laws and regulations in all material respects and had obtained all material permits, licenses and certifications from the relevant PRC authorities for its operations in China.

The following table sets forth key permits, licenses and certifications relating to our business and operations (apart from those pertaining to general business requirements), their respective purpose, issuing authority and expiry date as of the Latest Practicable Date:

Permit/License/ Approval	Purpose	Issuing authority	Expiry date
Production Permit (SLP) . . . .	Granules, oral suspension, tablets, hard capsules production	Guangdong Provincial Medical Products Administration	April 22, 2030

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Permit/License/ Approval	Purpose	Issuing authority	Expiry date
Production Permit (Dongguan Yangzhikang) . . . . .	Clarithromycin Sustained-Release Tablets, Moxifloxacin Hydrochloride Tablets, Clarithromycin Tablets, Levofloxacin Tablets, and Olmesartan Medoxomil Tablets production	Guangdong Provincial Medical Products Administration	April 7, 2030
Production Permit (Yichang HEC Pharmaceutical). . . . .	API production	Hubei Provincial Medical Products Administration	May 10, 2026
Production Permit (HEC CJ Pharm) . . . . .	freeze-dried powder injection, tablets, hard capsules, granules, dry suspensions, powders, API, therapeutic biological products production	Hubei Provincial Medical Products Administration	November 4, 2025 <sup>1</sup>
Drug Operation Permit (Yichang HEC Medical). . . . .	Chinese medicines, chemical raw materials, chemical pharmaceutical formulation, antibiotic raw materials, and antibiotic formulations (excluding refrigerated and frozen medicines) operation	Hubei Provincial Medical Products Administration	November 3, 2025 <sup>2</sup>
Certificate of GMP Compliance of a Manufacturer (SLP) <sup>3</sup> . . . . .	Tablets, hard capsules, oral suspension	National Office for Health and Social Affairs of Germany	January 28, 2027

*Note 1:* The renewal application is planned to be submitted in early July, with the renewal expected to be completed by the end of September in 2025.

*Note 2:* The renewal application is planned to be submitted in late August, with the renewal expected to be completed by the end of October in 2025.

*Note 3:* According to the relevant requirements under the Circular on the Relevant Issues Concerning the Implementation of the Drug Administration Law of the PRC (《關於貫徹實施〈中華人民共和國藥品管理法〉有關事項的公告》) (2019 No. 103 announcement), the GMP certification was canceled from December 1, 2019, after which, no application for GMP certification would be accepted and no GMP certificate would be granted. Therefore, the GMP certificates held by the Company and its subsidiaries will not be renewed upon expiration. Regulatory departments will continue to supervise enterprises to ensure compliance with

relevant requirements for drug production through routine supervision. For further information relating to GMP certification, please see “Regulatory Environment — Principal Regulatory Provisions — Laws and Regulations on the Manufacturing of Drugs — Good Manufacturing Practice”.

We monitor the validity status of, and make timely applications for the renewal of, relevant licenses, permits, approvals, and certificates prior to the expiration date. During the Track Record Period and up to the Latest Practicable Date, we had not experienced any material difficulty in obtaining or renewing the required licenses, permits, approvals, and certificates for our business operations. We do not expect there to be any material legal impediment in renewing these licenses, permits, approvals and certificates as they expire in future as long as we are in compliance with applicable laws, regulations, and rules.

### INTERNAL CONTROL AND RISK MANAGEMENT

#### Risk Management

We recognize that risk management is critical to the success of our business operation. Key operational risks faced by us include changes in the general market condition and the regulatory environment of the Chinese and global pharmaceuticals markets, our ability to develop, manufacture and commercialize our drugs under development, and our ability to compete with other biopharmaceutical companies. Please see “Risk Factors” for a discussion of various risks and uncertainties we face.

We have adopted a comprehensive set of risk management policies which set out a risk management framework to identify, assess, evaluate and monitor key risks associated with our strategic objectives on an on-going basis. We categorize the risks into strategic risks, market risks, operational risks, financial risks and legal risks based on the impacts that these risks pose to our development strategy and operational targets. Risks identified by our management team will be analyzed on the basis of likelihood and impact, and will be properly followed up with mitigated and rectified by our Group and reported to our Directors. Our Directors are responsible for supervising the implementation of our risk management policies.

To monitor the ongoing implementation of risk management policies and corporate governance measures after the listing, we have adopted or will continue to adopt, among other things, the following risk management measures:

- Our Directors will oversee and manage the overall risks associated with our business operations, including (i) reviewing and approving our risk management policy to ensure that it is consistent with our corporate objectives; (ii) reviewing and approving the annual working plan and annual report of our corporate risk management; (iii) monitoring the most significant risks associated with our business operation and our management’s handling of such risks; (iv) reviewing our corporate risk in the light of our corporate risk tolerance; (v) monitoring and ensuring the appropriate application of our risk management framework across our Group; and (vi) establishing the risk management committee to report on the effectiveness of the comprehensive risk management to the Board.

- Our audit department will be responsible for (i) formulating our risk management policy and reviewing major risk management issues of our Company; (ii) formulating the annual working plan and annual report of risk management; (iii) providing guidance on our risk management approach to the relevant departments in our Company and supervising the implementation of our risk management policy by the relevant departments; (iv) reviewing the relevant departments' reports on key risks and providing feedback; (v) education and training in relation to risk management; and (vi) daily coordination of risk management.
- The relevant departments in our Company, including but not limited to the finance department, the legal department and the human resources department, are responsible for implementing our risk management policy and carrying out our day-to-day risk management practice. In order to formalize risk management across our Group and set a universal level of transparency and risk management performance, the relevant departments will (i) gather information about the risks relating to their operation or function; (ii) conduct risk assessments, which include the identification, prioritization, measurement and categorization of all key risks that could potentially affect their objectives; (iii) continuously monitor the key risks relating to their operation or function; (iv) implement appropriate risk responses where necessary; (v) develop and maintain an appropriate mechanism to facilitate the application of our risk management framework; and (vi) timely report to our audit department upon the discovery of material risks.

### **Internal Control**

In order to achieve control objectives, the board of directors, board of supervisors, managers and all employees of our Company continue to establish and improve our Company's internal control system. Our Board is responsible for establishing our internal control system and reviewing its effectiveness. During the process of preparing for the Listing, we have engaged an internal control consultant to perform a review based on an agreed-upon scope in connection with the internal control of our Company and our major operating subsidiaries on our Group's entity-level controls and internal controls of various processes, including financial reporting and disclosure controls, human resources and payroll management, general controls of IT system, taxation management, contract management and other procedures of our operations in accordance with AATB 1 issued by the Hong Kong Institute of Certified Public Accountants, and no further recommendation has been provided by the internal control consultant during the follow-up review.

During the Track Record Period, we regularly reviewed and enhanced our internal control system. Below is a summary of the internal control policies, measures and procedures we have implemented or plan to implement:

- **Internal Audit.** We put in place the internal audit charter that clearly states the objectives, organization, roles and responsibilities, working scope and procedures of our internal audit function. We established an internal audit department that is



responsible for internal auditing and execution of anti-bribery measures in accordance with the internal audit charter. The internal audit department reports to our senior management and the audit committee.

- **Audit Committee.** We have established an audit committee which (i) makes recommendations to our Directors on the appointment and removal of external auditors; (ii) reviews our financial statements and gives advice in respect of financial reporting and (iii) oversees internal control procedures of our Group.
- **Internal Control Management Handbook.** In order to continuously improve risk management capabilities, promote our Company's sustainable development, implement the "Basic Standards for Corporate Internal Control" and supporting guidelines, and establish and improve our internal control system, we have compiled the "Internal Control Management Manual" as a guide for (i) establishing, implementing and evaluating internal controls, (ii) specifying the departments responsible for implementing the internal controls and the departments accountable and (iii) refining the control requirements and key points.
- **Listing Rules Compliance.** We have adopted various policies to ensure compliance with the Listing Rules, including but not limited to aspects relating to corporate governance, connected transactions, notifiable transactions, inside information and securities transactions by our Directors. We have designated staff to monitor our compliance with the Listing Rules and other applicable laws and regulations, who have the power to investigate relevant incidents (if any) and communicate with the related authorities or advisers.
- **Code of Conduct.** Our code of conduct explicitly communicates to each employee our values, acceptable criteria for decision-making and our ground rules for behavior. Our code of conduct also includes whistle-blowing policies to encourage all employees to speak up against any sub-standard behavior. We also established an anti-money laundering management group and a related working group that are responsible for monitoring and supervising the implementation of our code of conduct and our anti-money laundering policies.
- **Legal compliance.** We have engaged a law firm to advise us on and keep us abreast with PRC and Hong Kong laws and regulations. We will continue to arrange various trainings to be provided by external legal advisers from time to time when necessary and/or any appropriate accredited institution to update our Directors, senior management, and relevant employees on the latest PRC and Hong Kong laws and regulations.

To ensure the effective management of our intellectual property and to mitigate the risk of litigation related to intellectual property infringement, we have implemented comprehensive internal policies and established a robust intellectual property management system. These measures include:

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- ***Prevention of Third-Party Intellectual Property Infringement.*** Our intellectual property department, which oversees intellectual property management, conducts rigorous searches and analyses of research and development outcomes upon the completion of research projects and technological developments. This process involves identifying potential infringements on third-party intellectual property rights, preparing detailed inspection reports, and ensuring compliance with applicable laws to prevent any unauthorized use of protected intellectual property.
- ***Employee Confidentiality and Compliance Measures.*** Employees are required to strictly adhere to confidentiality obligations concerning technical trade secrets. To this end, they must sign confidentiality agreements and non-compete covenants, as well as comply with an internal confidentiality framework that defines their specific responsibilities. In addition, R&D staff is required to conduct a search for their R&D outcome to confirm it does not involve patented technology that may impose infringement risks.
- ***Training and Knowledge Development.*** We provide regular training programs to ensure employees have a thorough understanding of our intellectual property policies and their obligations under them. These programs include periodic assessments to evaluate employee knowledge and compliance, as well as access to updated resources reflecting changes in intellectual property laws and regulations. A feedback mechanism has also been established to refine training initiatives based on employee input and evolving industry standards.
- ***Lifecycle Management of Intellectual Property.*** An internal intellectual property management system has been implemented to oversee the full lifecycle management of our proprietary IP assets. This system supports various functions, including patent applications, and maintenance, ensuring effective administration and protection of our intellectual property portfolio.

We will conduct periodic review of relevant laws and regulations and amend our internal policies to ensure compliance with the latest applicable laws and regulations.

## LEGAL AND COMPLIANCE

### Legal Proceedings

During the Track Record Period and as of the Latest Practicable Date, no member of our Group or any of our Directors was engaged in any litigation, arbitration or claim of material importance, and no litigation, arbitration or claim of material importance was known to the Directors to be pending or threatened by or against our Group or any of our Directors, that would have a material adverse effect on its business, financial condition or results of operations. We may, from time to time, become a party to various legal, arbitration or administrative proceedings arising in the ordinary course of our business. Please see “Risk Factors — Risks Relating to Our Business and Industries — We are and may be involved in

litigation, legal disputes, claims or administrative proceedings which could be costly and time-consuming to resolve” and “Risk Factors — Risks Relating to Our Business and Industries — If we are sued for infringing, misappropriating, or otherwise violating intellectual property rights of third parties or engaging in unfair competition, such litigation could be costly and time-consuming and could prevent or delay us from developing or commercializing our drug candidates” for further details.

### **Recent Intellectual Property Infringement Claim**

In November 2021, Boehringer Ingelheim Pharma GmbH & Co. KG (“勃林格殷格翰製藥兩合公司”) (“**Boehringer**”) alleged that parties including HEC CJ Pharm, Ruyuan HEC Pharma, and we infringed its patent rights under Patent No. ZL03819760.X by engaging in the manufacturing, sale, and offering for sale of Linagliptin tablets and filed a lawsuit with the Shanghai Intellectual Property Court in July 2021 seeking an injunction to stop the alleged infringement and demanding compensation for economic losses and reasonable expenses incurred in enforcing its rights, initially amounting to RMB50 million (“**Linagliptin Case**”). Boehringer alleged that the patent-in-dispute protects the compound, compositions, and methods of use related to the active pharmaceutical ingredient known by the International Nonproprietary Name (INN) Linagliptin. Boehringer contended that our Linagliptin falls within the patent’s scope under applicable pharmaceutical nomenclature regulations and approved labeling, satisfying claim limitations for infringement. On June 3, 2024, Boehringer submitted an application to amend its claims, requesting punitive damages totaling RMB100 million, such amount being our maximum monetary exposure at the moment based on the current claims submitted by Boehringer. On July 2, 2024, the Shanghai Intellectual Property Court issued a ruling transferring the case to the Shanghai High People’s Court for further proceedings. In January and February 2025, the Shanghai High People’s Court organized two evidence examinations (質證). The case is currently awaiting trial by the Shanghai High People’s Court. The percentage of revenue contribution from Linagliptin tablets during the Track Record Period is 2.67%, 0.90% and 4.69% for the years ended December 31, 2022, 2023 and 2024, respectively. As of Latest Practicable Date, no judgment has been rendered by the court regarding this case. Besides the disputes regarding Linagliptin, we do not have any other relationship with the plaintiff.

On July 4, 2018, we applied to the NMPA for marketing approval of a generic drug, Linagliptin tablets, and received approval on July 8, 2020 (Approval Number: H20203294). In February 2019, HEC CJ Pharm entered into a purchase agreement with us to acquire the technology, marketing approval, and sales rights associated with the approved Linagliptin tablets (“**Linagliptin Purchase Agreement**”). In March 2021, HEC CJ Pharm and we executed a manufacture framework agreement under which we were commissioned to manufacture Linagliptin tablets (“**Linagliptin Framework Agreement**”). Starting from February 2021, we listed the relevant products on the drug procurement platform under our own name for sale following HEC CJ Pharm’s instruction. HEC CJ Pharm retains all rights and interests for Linagliptin within China.

In November 2021, Boehringer filed an administrative adjudication request with the China National Intellectual Property Administration against HEC CJ Pharm and us (“**Respondents**”) in connection with Linagliptin tablets. In July 2022, the CNIPA issued an administrative decision ordering the Respondents to cease the alleged infringement and sales of Linagliptin tablets in various provinces in China. After receiving the notices from each local government to enforce CNIPA’s decision, we delisted or suspended the listings of the products involved from various sales platforms in that local government area. The CNIPA’s administrative decision ceased to be effective in August 2023 upon the expiration of Boehringer’s patent in respect of the Linagliptin tablets, after which we resumed sales of the products. The administrative decision by the CNIPA is an independent legal proceeding and is procedurally separate from the Linagliptin Case, as it involves a different patent. Accordingly, the administrative decision does not affect the progress of the Linagliptin Case.

Since the administrative decision was made by CNIPA in July 2022, CNIPA has not initiated any further administrative procedures, nor has it made any other administrative decisions or taken any administrative measures regarding this case.

Having considered the legal advice from our PRC Legal Advisor and the facts of the Linagliptin Case, our Directors are of the view that the Linagliptin Case does not have any material adverse impact on our business operations and financial performance, and thus do not consider it as material litigation of our Group because:

- The patent in dispute (Patent No. ZL03819760.X) held by Boehringer expired in August 2023. As advised by our PRC Legal Advisor, the expiration of a patent means its associated rights are no longer protected, and our manufacturing or sales activities related to linagliptin tablets after the expiry date do not constitute infringement of the patent in dispute.
- We acquired the Linagliptin tablets related rights from one of our Controlling Shareholders in 2019, who developed the Linagliptin tablets and indemnifies us of any legal liabilities and obligations and any losses, damages and claims associated with the Linagliptin tablets under the Linagliptin Purchase Agreement and Linagliptin Framework Agreement. As advised by our PRC Legal Advisor, based on the Linagliptin Purchase Agreement the amount claimed in the Linagliptin Case, if any, shall be covered by the Controlling Shareholder’s indemnity. As a result, we have not made any provisions in relation to the Linagliptin Case during the Track Record Period.

### **Legal Compliance**

During the Track Record Period and up to the Latest Practicable Date, we had not been and were not involved in any material non-compliance incidents that led to fines, enforcement actions or other penalties that could, individually or in aggregate, have a material adverse

effect on our business, financial condition or results of operations, and there were no material intellectual property disputes and we had complied with the relevant laws and regulations in all material respects and obtained all material permits, licences and certifications for our overseas operations.

## **DATA PRIVACY AND PROTECTION**

We receive, collect, generate, store, process, transmit and maintain medical data treatment records, clinical trial data and other medical or clinical details of the subjects enrolled in our clinical trials. Such medical or clinical data does not include any personal data and we do not receive, collect, generate, store, process, transmit and maintain the personal data of our subjects who enrolled in our clinical trials. The “medical data treatment records” refer to clinical trial-related data collected, stored, and processed by us. These data are crucial to the success of clinical trials and includes information such as subject identifiers (e.g., coded identifiers, screening numbers, randomization codes), demographic data, medical history, drug intervention details, efficacy endpoints, and safety information. We do not store personal data, such as subject names and ID numbers. Such information is retained exclusively by the research centers or hospitals conducting the trials. We submit medical or clinical data as required by US FDA review of our drug applications, but such medical or clinical data required by the US FDA does not include any personal data. We did not conduct any cross-border personal data transmission during the Track Record Period and up to the Latest Practicable Date.

As of the Latest Practicable Date, we had designed strict data protection policies to ensure that the collection, use, storage, transmission, dissemination and destruction of data are in compliance with applicable laws, regulations and prevalent industry practice. As advised by our PRC Legal Advisor, during the Track Record Period and up to the Latest Practicable Date, we have not been subject to any administrative penalties imposed by the relevant authorities for violation of any applicable laws and regulations relating to data privacy and protection.

### **Data Protection Policy**

We have implemented a comprehensive data privacy and protection policy that includes the following key principles: (i) We will collect personal information and data from users only with their prior informed consent. We make reasonable efforts to use, disclose, and request only the minimum amount of information necessary for the intended purposes related to our products and services. (ii) Users must acknowledge the terms and conditions of the user agreement and the privacy policy before accessing our products and services. If personal data processing is required, users need to consent to our collection, use, and disclosure of their data in compliance with applicable laws and regulations. We will only utilize user data with their prior informed consent. (iii) When transmitting and storing sensitive personal information, we employ security measures such as encryption to ensure its protection. (iv) We do not sell, share, or otherwise provide any personal information to third parties, except as required by law. (v) We will implement relevant and appropriate internal procedures and controls to protect user data and prevent leakage or loss.

We have established a robust internal governance framework focused on data privacy and protection. This framework includes a variety of management regimes, such as: Data Security Management Measures, Personal Information Lifecycle Management Measures, Personal Information Breach Incident Management Measures, Data Destruction Management Measures. In addition to these measures, we have implemented a range of internal safeguards designed to ensure the privacy and security of user data.

- (i) Data is categorized, hierarchically classified, encrypted, and securely backed up throughout the storage phase to maintain integrity and security.
- (ii) User data collected during daily business operations within the PRC is stored within the PRC.
- (iii) We have established an Information Security Management Committee and a dedicated Information Security Management Team. These groups manage and supervise network and data security, personal information protection, and ensure the enforcement of internal policies and measures.
- (iv) Access controls are strictly enforced, ensuring personnel access personal information only on a need-to-know basis, adhering to the principle of least privilege. Employees can only access the minimum data required to perform their specific tasks.
- (v) We are dedicated to the continuous education and training of our employees to cultivate a strong culture of information security protection throughout the organization.

During the Track Record Period and up to the Latest Practicable Date, we have not experienced any material data leakage.

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### AWARDS AND RECOGNITIONS

As a result of the quality and strong reputation of our products, creditworthiness and contribution to the community, we have been given the following awards, authentication and recognition:

No.	Award	Awardee/Awarded product	Year	Awarding unit
1.	The 25th China Patent Gold Award — Oseltamivir phosphate granules and its preparation method (第二十五屆中國專利金獎 — 磷酸奧司他韋顆粒劑及其制備方法)	SLP	2025	China National Intellectual Property Administration
2.	First Class Sci-Tech Advancement Award of Guangdong Province for 2023 (“2023年度廣東省科技進步獎一等獎”)	SLP	2024	People’s Government of Guangdong Province
3.	The First Tier of the “Top 100 in Research and Development of Chinese Pharmaceutical Industry for 2024” List (“2024中國醫藥工業研發百強”榜單第一梯級)	SLP	2024	Sinohealth
4.	National Key Laboratory for Research and Development of New Anti-infective Drugs (抗感染新藥研發全國重點實驗室)	SLP	2023	Ministry of Science and Technology of the PRC
5.	The First Tier of the “Top 100 Chinese Pharmaceutical Innovators for 2022 and 2023” List (“2022、2023中國醫藥創新企業100強”榜單第一梯級)	SLP	2022, 2023	Healthcare Executive Magazine
6.	Top 100 Invention Patents in the Global Biomedical Industry in 2022 (No. 4 in China) (2022年全球生物醫藥產業發明專利排行榜TOP 100(中國第4位))	SLP	2023	incoPat (Global Patent Database) Innovation Index Research Center



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No.	Award	Awardee/Awarded product	Year	Awarding unit
7.	2023 Pharmaceutical Industry Competitiveness Top 100 List (2023醫藥工業競爭力百強榜)	HEC CJ Pharm	2023	Sinohealth
8.	National High-Tech Enterprise (國家高新技術企業)	SLP	2023	Provincial Department of Science and Technology and other departments
9.	2017~2023 China Pharmaceutical R&D Comprehensive Strength Ranking TOP 20 List (2017~2023中國藥品研發綜合 實力排行榜TOP 20榜單)	SLP	2023	Yaozh.com (藥智網)
10.	The Second Prize of the Beijing Science and Technology Progress Award (北京市科學 技術進步獎二等獎)	SLP/HEC CJ Pharm	2023	People's Government of Beijing Municipality
11.	The “Most Innovative Enterprise with R&D Strength “in the 4th China Biopharmaceutical Industry Chain Innovation List for 2023 (2023年第四屆中國 生物醫藥產業鏈創新風雲榜“年 度最具研發實力創新型企業”稱 號)	SLP	2023	China Biopharmaceutical Industry Chain Innovation and Transformation Consortium
12.	The “Principal” Enterprise of the Biopharmaceutical and High-end Medical Device Industry Chain (生物藥醫藥及 高端醫療器材產業鏈 “鏈主” 企業)	SLP	2023	Dongguan Municipal Bureau of Industry and Information Technology Bureau, Dongguan Municipal Bureau of Science and Technology

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No.	Award	Awardee/Awarded product	Year	Awarding unit
13.	2023 Influenza Medicine Brand List (2023年流行性感冒藥品牌榜)	Kewei	2023	CPEO (西普會)
14.	2023 Most Valuable Collaboration Item in Chinese Chain Pharmacies (2023中國連鎖藥店最具合作價值單品)	Kewei Granules	2023	Menet.com (米內網)
15.	Most Popular Star Product in Pharmacies (最受藥店歡迎的明星單品)	Kewei Granules	2023	West Lake Forum (西湖論壇)
16.	Golden Horse Award for the Most Innovative Enterprise with the Best R&D Strength (最具研發實力創新BigPharma企業金馬獎)	SLP	2022	China Biomedical Industry Chain Innovation and Transformation Alliance
17.	China Pharmaceuticals – Top Brand of Anti-infective Drugs in Hospital Terminal of China’s Pharmaceutical Brands (中國醫藥•品牌榜醫院終端抗感染用藥榜首品牌)	Kewei	2022	Menet.com (米內網)
18.	2022 Top Brand of Anti-infective Drugs in Hospital Terminal of China’s Pharmaceutical Brands (2022中國醫藥品牌榜醫院終端抗感染用藥榜首品牌)	HEC CJ Pharm/ Kewei	2022	Menet.com (米內網)
19.	Enterprise Technology Center of Guangdong Province (廣東省省級企業技術中心)	SLP	2021	Department of Industry and Information Technology of Guangdong Province and other departments

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No.	Award	Awardee/Awarded product	Year	Awarding unit
20.	Breakthrough New Drug of the Year at the 13th Health China Forum (第十三屆健康中國論壇年度突破新藥)	Emitasvir phosphate capsules (Dongweien)	2021	People's Daily Health APP
21.	Technological Giant, the Invisible Champion of the Subdivision of Pillar Industries in Hubei Province (湖北省支柱產業細分領域隱形冠軍科技小巨人)	HEC CJ Pharm	2021	Department of Economy and Information Technology of Hubei Province
22.	Best ESG Award of the 5th Golden Hong Kong Stocks Awards (第五屆金港股年度頒獎盛典最佳ESG獎)	HEC CJ Pharm	2021	RoyalFlush Finance
23.	“Enterprise Management Award” of the Pharmaceutical Industry in the “13th Five-Year Plan” (醫藥行業“十三五”“企業管理獎”)	HEC CJ Pharm	2021	R&D-based Pharmaceutical Industry Association Committee under the China Association of Enterprises with Foreign Investment (中國外商投資企業協會藥品研製和開發行業委員會)
24.	Top 100 List of China's Pharmaceutical Industry (中國醫藥工業百強榜)	HEC CJ Pharm	2020	Menet.com (米內網)
25.	National Intellectual Property Demonstration Enterprise (國家知識產權示範企業)	SLP	2017	China National Intellectual Property Administration