

*The Stock Exchange of Hong Kong Limited and the Securities and Futures Commission take no responsibility for the contents of this Post Hearing Information Pack, make no representation as to its accuracy or completeness and expressly disclaim any liability whatsoever for any loss howsoever arising from or in reliance upon the whole or any part of the contents of this Post Hearing Information Pack.*

**Post Hearing Information Pack of**



**绿竹生物**

**LUZHU BIOTECH**

**Beijing Luzhu Biotechnology Co., Ltd.**

**北京綠竹生物技術股份有限公司**

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

**WARNING**

The publication of this Post Hearing Information Pack is required by The Stock Exchange of Hong Kong Limited (the “**Stock Exchange**”) and the Securities and Futures Commission (the “**Commission**”) solely for the purpose of providing information to the public in Hong Kong.

This Post Hearing Information Pack is in draft form. The information contained in it is incomplete and is subject to change which can be material. By viewing this document, you acknowledge, accept and agree with Beijing Luzhu Biotechnology Co., Ltd. (the “**Company**”), its sponsor, overall coordinator, advisors or members of the underwriting syndicate that:

- (a) this document is only for the purpose of providing information about the Company to the public in Hong Kong and not for any other purposes. No investment decision should be based on the information contained in this document;
- (b) the publication of this document or any supplemental, revised or replacement pages on the Stock Exchange’s website does not give rise to any obligation of the Company, its sponsor, overall coordinator, advisors or members of the underwriting syndicate to proceed with an offering in Hong Kong or any other jurisdiction. There is no assurance that the Company will proceed with the offering;
- (c) the contents of this document or any supplemental, revised or replacement pages may or may not be replicated in full or in part in the actual final listing document;
- (d) this document is not the final listing document and may be updated or revised by the Company from time to time in accordance with the Rules Governing the Listing of Securities on the Stock Exchange;
- (e) this document does not constitute a prospectus, offering circular, notice, circular, brochure or advertisement offering to sell any securities to the public in any jurisdiction, nor is it an invitation to the public to make offers to subscribe for or purchase any securities, nor is it calculated to invite offers by the public to subscribe for or purchase any securities;
- (f) this document must not be regarded as an inducement to subscribe for or purchase any securities, and no such inducement is intended;
- (g) neither the Company nor any of its affiliates, advisors or underwriters is offering, or is soliciting offers to buy, any securities in any jurisdiction through the publication of this document;
- (h) no application for the securities mentioned in this document should be made by any person nor would such application be accepted;
- (i) the Company has not and will not register the securities referred to in this document under the United States Securities Act of 1933, as amended, or any state securities laws of the United States;
- (j) as there may be legal restrictions on the distribution of this document or dissemination of any information contained in this document, you agree to inform yourself about and observe any such restrictions applicable to you; and
- (k) the application to which this document relates has not been approved for listing and the Stock Exchange and the Commission may accept, return or reject the application for the subject public offering and/or listing. No offer or invitation will be made to the public in Hong Kong until after a prospectus of the Company has been registered with the Registrar of Companies in Hong Kong in accordance with the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Chapter 32 of the Laws of Hong Kong).

If an offer or an invitation is made to the public in Hong Kong in due course, prospective investors are reminded to make their investment decisions solely based on a prospectus of the Company registered with the Registrar of Companies in Hong Kong, copies of which will be made available to the public during the offer period.

## IMPORTANT

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



绿竹生物  
LUZHU BIOTECH

# Beijing Luzhu Biotechnology Co., Ltd. 北京綠竹生物技術股份有限公司

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

### [REDACTED]

Total number of [REDACTED] under the [REDACTED] : [REDACTED] H Shares (subject to the [REDACTED])  
Number of [REDACTED] : [REDACTED] H Shares (subject to adjustment)  
Number of [REDACTED] : [REDACTED] H Shares (subject to adjustment and the [REDACTED])  
Maximum [REDACTED] : HK\$[REDACTED] per H Share, plus brokerage of 1%, SFC transaction levy of 0.0027%, Stock Exchange trading fee of 0.00565% and the Accounting and Financial Reporting Council transaction levy of 0.00015% (payable in full on [REDACTED] in Hong Kong dollars and subject to refund)  
Nominal value : RMB1.00 per H Share  
Stock code : [●]

Sole Sponsor [and [REDACTED]]



[REDACTED], [REDACTED] and [REDACTED]

[●]

Financial Advisor



Hong Kong Exchanges and Clearing Limited, The Stock Exchange of Hong Kong Limited and Hong Kong Securities Clearing Company Limited take no responsibility for the contents of this document, make no representation as to its accuracy or completeness and expressly disclaim any liability whatsoever for any loss howsoever arising from or in reliance upon the whole or any part of the contents of this document.

A copy of this document, having attached thereto the documents specified in “Appendix VIII — Documents Delivered to the Registrar of Companies and Available on Display”, has been registered by the Registrar of Companies in Hong Kong as required by section 342C of the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Chapter 32 of the Laws of Hong Kong). The Securities and Futures Commission of Hong Kong and the Registrar of Companies in Hong Kong take no responsibility for the contents of this document or any other document referred to above.

The [REDACTED] is expected to be fixed by agreement between the [REDACTED] and the [REDACTED], on behalf of the [REDACTED], and our Company on or before [REDACTED] or such later time as may be agreed between the parties, but in any event, no later than [REDACTED]. If, for any reason, the [REDACTED] and the [REDACTED], on behalf of the [REDACTED], and our Company are unable to reach an agreement on the [REDACTED] by [REDACTED], the [REDACTED] will not become unconditional and will lapse immediately. The [REDACTED] will be not more than [REDACTED] per [REDACTED] and is expected to be not less than HK\$[REDACTED] per [REDACTED] although the [REDACTED] and the [REDACTED], on behalf of the [REDACTED], and our Company may agree to a lower [REDACTED]. Applicants for [REDACTED] are required to pay, on application, the maximum [REDACTED] of [REDACTED] for each [REDACTED] together with a brokerage fee of 1.0%, a SFC transaction levy of 0.0027%, a Hong Kong Stock Exchange trading fee of 0.00565% and an Accounting and Financial Reporting Council transaction levy of 0.00015%, subject to refund if the [REDACTED] as finally determined is less than [REDACTED].

The [REDACTED] and the [REDACTED], on behalf of the [REDACTED], may, with the consent of our Company, reduce the number of [REDACTED] and/or the indicative [REDACTED] range below that stated in this document (being [REDACTED] per [REDACTED] to [REDACTED] per [REDACTED]) at any time on or prior to the morning of the last date for lodging [REDACTED] under the [REDACTED]. In such a case, notices of the reduction in the number of [REDACTED] and/or the indicative [REDACTED] range will be published on the websites of the Stock Exchange at [www.hkexnews.hk](http://www.hkexnews.hk) and our Company at [www.luzhubiotech.com](http://www.luzhubiotech.com) as soon as practicable following the decision to make such reduction, but in any event not later than the morning of the day which is the last day for lodging [REDACTED] under the [REDACTED]. For further information, see “Structure of the [REDACTED]” and “How to Apply for [REDACTED]” in this document.

We are incorporated and a substantial majority of our business and assets are located in the PRC. Potential [REDACTED] should be aware of the differences in the legal, economic and financial systems between the PRC and Hong Kong, and the fact that there are different risk factors relating to [REDACTED] in PRC-incorporated companies. Potential [REDACTED] should also be aware that the regulatory framework in the PRC is different from the regulatory framework in Hong Kong, and should take into consideration the different [REDACTED] nature of the H Shares. Such differences and risk factors are set out in the sections headed “Risk Factors” and “Regulatory Overview” in this document and in Appendix IV, Appendix V and Appendix VI to this document.

Pursuant to the termination provisions contained in the [REDACTED] in respect of the [REDACTED], the Sole Sponsor, the [REDACTED] and the [REDACTED], on behalf of the [REDACTED], have the right in certain circumstances, in their absolute discretion, to terminate the obligation of the [REDACTED] pursuant to the [REDACTED] at any time prior to 8:00 a.m. on the [REDACTED]. Further details of the terms of the termination provisions are set out in the paragraph headed “[REDACTED] — [REDACTED] Arrangements and Expenses — [REDACTED] — Grounds for Termination” in this document. It is important that you refer to that section for further details.

The [REDACTED] have not been and will not be registered under the [REDACTED] or any state securities laws in the United States, and may not be offered, sold, pledged or transferred within the United States, except pursuant to an exemption from, or in a transaction not subject to, the registration requirements of the [REDACTED] and in accordance with any applicable U.S. state securities laws. The [REDACTED] may only be offered, sold or delivered outside of the United States in offshore transactions in reliance on [REDACTED] under the [REDACTED].

[REDACTED]

[REDACTED]

**IMPORTANT**

---

[REDACTED]

**IMPORTANT**

---

[REDACTED]

## EXPECTED TIMETABLE<sup>(1)</sup>

---

[REDACTED]

**EXPECTED TIMETABLE<sup>(1)</sup>**

---

[REDACTED]

**EXPECTED TIMETABLE<sup>(1)</sup>**

---

[REDACTED]

## TABLE OF CONTENTS

*This document is issued by our Company solely in connection with the [REDACTED] and the [REDACTED] and does not constitute an offer to sell or a solicitation of an offer to subscribe for or buy any security other than the [REDACTED]. This 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 or invitation in any other jurisdiction or in any other circumstances. No action has been taken to permit a public [REDACTED] of the [REDACTED] or the distribution of this document in any jurisdiction other than Hong Kong. The distribution of this document and the [REDACTED] and sale of the [REDACTED] in other jurisdictions are subject to restrictions and may not be made except as permitted under the applicable securities laws of such jurisdiction pursuant to registration with or authorization by the relevant securities regulatory authorities or an exemption therefrom.*

*You should rely only on the information contained in this document to make your [REDACTED] decision. We have not authorized anyone to provide you with information that is different from what is contained in this document. Any information or representation not included in this document must not be relied on by you as having been authorized by us, the [REDACTED], the [REDACTED], the [REDACTED], the [REDACTED], the Sole Sponsor, the [REDACTED], [REDACTED], any of our or their respective directors, officers, employees, partners, agents or representatives, or any other party involved in the [REDACTED]. Information contained on our website [www.luzhubiotech.com](http://www.luzhubiotech.com) does not form part of this document.*

	<i>Page</i>
<b>EXPECTED TIMETABLE</b> .....	i
<b>TABLE OF CONTENTS</b> .....	iv
<b>SUMMARY</b> .....	1
<b>DEFINITIONS</b> .....	31
<b>GLOSSARY OF TECHNICAL TERMS</b> .....	44
<b>FORWARD-LOOKING STATEMENTS</b> .....	53
<b>RISK FACTORS</b> .....	55
<b>WAIVERS FROM STRICT COMPLIANCE WITH THE LISTING RULES AND EXEMPTION FROM STRICT COMPLIANCE WITH THE COMPANIES (WINDING UP AND MISCELLANEOUS PROVISIONS) ORDINANCE</b> .....	107
<b>INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]</b> .....	113
<b>DIRECTORS, SUPERVISORS AND PARTIES INVOLVED IN THE [REDACTED]</b> .....	118
<b>CORPORATE INFORMATION</b> .....	123



---

**TABLE OF CONTENTS**

---

	<i>Page</i>
<b>INDUSTRY OVERVIEW</b> .....	125
<b>REGULATORY OVERVIEW</b> .....	167
<b>HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE</b> .....	186
<b>BUSINESS</b> .....	209
<b>RELATIONSHIP WITH CONTROLLING SHAREHOLDERS</b> .....	328
<b>SHARE CAPITAL</b> .....	333
<b>SUBSTANTIAL SHAREHOLDERS</b> .....	338
<b>DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT</b> .....	341
<b>FINANCIAL INFORMATION</b> .....	364
<b>FUTURE PLANS AND USE OF [REDACTED]</b> .....	401
<b>[REDACTED]</b> .....	405
<b>STRUCTURE OF THE [REDACTED]</b> .....	416
<b>HOW TO APPLY FOR [REDACTED]</b> .....	426
<b>APPENDIX I — ACCOUNTANTS’ REPORT</b> .....	I-1
<b>APPENDIX II — UNAUDITED [REDACTED] FINANCIAL INFORMATION</b> .....	II-1
<b>APPENDIX III — PROPERTY VALUATION REPORT</b> .....	III-1
<b>APPENDIX IV — TAXATION AND FOREIGN EXCHANGE</b> .....	IV-1
<b>APPENDIX V — SUMMARY OF PRINCIPAL LEGAL AND REGULATORY PROVISIONS</b> .....	V-1
<b>APPENDIX VI — SUMMARY OF ARTICLES OF ASSOCIATION</b> .....	VI-1
<b>APPENDIX VII — STATUTORY AND GENERAL INFORMATION</b> .....	VII-1
<b>APPENDIX VIII — DOCUMENTS DELIVERED TO THE REGISTRAR OF COMPANIES AND AVAILABLE ON DISPLAY</b> .....	VIII-1

## SUMMARY

*This summary aims to give you an overview of the information contained in this document and is qualified in its entirety by, and should be read in conjunction with, the more detailed information and financial information appearing elsewhere in this document. As this is a summary, it does not contain all the information that may be important to you and we urge you to read the entire document carefully before making your [REDACTED] decision. There are risks associated with any investment. In particular, we are a biotechnology company seeking a [REDACTED] on the Main Board of the Stock Exchange under Chapter 18A of the Listing Rules on the basis that we are unable to meet the requirements under Rule 8.05 (1), (2) or (3) of the Listing Rules. Some of the particular risks in investing in the [REDACTED] are set out in the section headed “Risk Factors” in this document. You should read that section carefully before you decide to [REDACTED] in the [REDACTED].*

## OVERVIEW

We are a biotechnology company committed to developing innovative human vaccines and therapeutic biologics to prevent and control infectious diseases and treat cancer and autoimmune diseases. Since our inception in 2001, we have focused on human medicine and have established technology platforms with our understanding of immunology and protein engineering, which empowers us to develop our recombinant vaccine and antibody product candidates with favorable efficiency, high purity and improved stability. As of the Latest Practicable Date, our product pipeline consisted of three clinical-stage product candidates, including our Core Product LZ901, and four pre-clinical-stage product candidates. As of the same date, we had two invention patents and seven pending applications relating to our Core Product. All of the registered patents and patent applications for our Core Product are related to the same set of patent claims filed to nine different jurisdictions to protect our intellectual property, given that in addition to China and the U.S., the other jurisdictions are also the target markets or potential markets in the future for LZ901.

## WE MAY NOT BE ABLE TO SUCCESSFULLY DEVELOP AND/OR MARKET OUR CORE PRODUCT, OR ANY OF OUR PIPELINE PRODUCTS.

Since our inception, we have strategically focused on internally developing innovative human vaccines, including bacterial-based vaccines and recombinant vaccines, and therapeutic biologics, such as monoclonal antibodies and bispecific antibodies, targeting a broad spectrum of infectious diseases, cancer, and autoimmune diseases. Leveraging our technology platforms and strong research and development capabilities, we established a diversified and advanced product pipeline. During the Track Record Period and up to the Latest Practicable Date, we did not generate any revenue as we had out-licensed most of our historically developed candidates before the Track Record Period, and by the Latest Practicable Date we had not commercialized any of our product candidates. The following diagram summarizes the status of our product pipeline as of the Latest Practicable Date:

PRODUCT TYPE	PRODUCT PIPELINE	MECHANISM/TARGET	INDICATIONS	PRE-CLINICAL	CLINICAL TRIALS			Expected Timetable
					Phase I	Phase II	Phase III	
Recombinant Vaccine	LZ901 <sup>(1)</sup>	VZV gE	Herpes zoster			China		Complete Phase II in Q2 2023 and expected to initiate Phase III in Q2 2023
			Herpes zoster	US				Complete Phase I in Q1 2024 and expected to initiate Phase II in Q1 2024
Monoclonal Antibody	K3 <sup>(2)</sup>	TNF-α	Rheumatoid arthritis, ankylosing spondylitis, plaque psoriasis			China		Initiate Phase III in Q2 2023 and expected to submit a BLA in Q4 2024
Bispecific Antibody	K193	CD3/CD19	Relapsed/Refractory B-cell lymphoma/leukemia			China		Complete Phase I in Q2 2023 and expected to initiate Phase II in Q1 2024
Recombinant Vaccine	Recombinant Varicella Vaccine	VZV gE	Varicella		China			Initiate Phase I in Q3 2023 and expected to initiate Phase II in Q3 2024
Recombinant Vaccine	Recombinant Rabies Vaccine	RABV-G	Rabies		China			Request pre-IND meeting with the NMPA in Q4 2023
Bispecific Antibody	K333	CD33/CD3	Myeloid leukemia		China			Request pre-IND meeting with the NMPA in the second half of 2024
Bispecific Antibody	K1932	CD19/CD3	Relapsed/Refractory B-cell lymphoma		China			Request pre-IND meeting with the NMPA in the second half of 2024

### Notes:

- (1) Core Product.
- (2) K3 is a biosimilar of adalimumab and therefore, is not required to conduct a Phase II clinical trial. For more details, please see “Business — Our Products and Product Candidates — Our Core Product and Clinical-Stage Product Candidates — 2. K3” in this document.

## SUMMARY

---

### OUR BUSINESS MODEL

We operate a business model focused on in-house discovery, research and development and commercialization, and out-licensing of high-quality and affordable human vaccines and therapeutic biologics. We are led by an experienced management team that manages our research and development, manufacturing and commercialization. Our co-founder, executive Director, general manager and chief scientist, Mr. KONG Jian, has over 33 years of biopharmaceutical experience leading scientific research of biological products and has developed five bacteria vaccines (the “**Bacteria Vaccines**”). For details, please see “— Our Products and Product Candidates — Our Other Historically Developed Products” and “Business — Our Products and Product Candidates — Our Commercialized Vaccine Products” in this document. Led by our management team and supported by our research and development team with strong execution capabilities, we have adopted an efficient approach to identify proven targets, such as antigens, that have produced effects during treatment to optimize, transform and develop into product candidates that enhance our portfolio for the treatment of cancer and autoimmune diseases. We have built a diversified and advanced product pipeline. We expect to continue to advance our pipeline of clinical-stage and pre-clinical stage product candidates and discover new product candidates over time.

Since our inception in 2001 and prior to the Series A Financing in 2019, we primarily relied on (i) capital injections from our shareholders, primarily due to which our registered capital increased from RMB0.5 million in 2001 to RMB78.6 million in 2019, (ii) one-off or milestone payments of RMB34.8 million in total received from our historically developed products that had been transferred or out-licensed to third-parties prior to the Track Record Period, and (iii) revenue generated from the sales of the Immunoreagent Testing Kits to support our business operations, which amounted to RMB9.1 million from 2004 to 2018. For details of the our registered capital and subsequent capital injections by our shareholders since our inception and prior to the Series A Financing, please see the section headed “History, Development and Corporate Structure” in this document. For details of the revenue generated from the sales of the Immunoreagent Testing Kits, please see “— Our Products and Product Candidates — Our Other Historically Developed Products” in this section.

In the future, we plan to prioritize the development of innovative recombinant protein vaccines, followed by innovative biological products to meet the unmet needs of disease prevention and treatment. Other than K3, a biosimilar of adalimumab, we do not plan to develop or commercialize any other biosimilars as biosimilars have low profit margins due to fierce competition from originator drugs and other competing biosimilars and the development and commercialization of K3 requires strict cost controls to maintain profit margin. As a result, we plan to focus on innovative recombinant protein vaccines and innovative biological products that have higher profit margins. K3 is the only biosimilar we plan to develop and commercialize as adalimumab holds the largest market share of anti-TNF- $\alpha$  biologics globally and has large market opportunity.

Going forward, we will actively explore collaboration opportunities in the development, manufacturing and sales of our products, including out-licensing of our product candidates. We currently do not have any plan to out-license LZ901 and our other product candidates in China. We plan to collaborate with multinational pharmaceutical companies who have a robust sales and marketing network to rapidly commercialize LZ901 globally in overseas markets, including in the U.S. and Southeast Asian countries. As of the Latest Practicable Date, we had only initiated preliminary discussions with third parties to explore opportunities to out-license LZ901 in markets outside of China, and had not identified any collaboration partners. For details, please see “Business — Commercialization” in this document. Before deciding whether to out-license a product candidate, we identify collaboration partners who may be better positioned to accelerate or further research and development or successful commercialization of

## SUMMARY

the product candidate. We communicate with our collaboration partners, approximately once a quarter and on an irregular basis for related technologies for Beijing Science Sun and from time to time for Zhifei Biopharma, to monitor the progress of product development or achievement of commercialization performance targets.

### OUR PRODUCTS AND PRODUCT CANDIDATES

Our clinical-stage product candidates comprise one vaccine candidate, LZ901 and two antibody injection product candidates, including K3 and K193. LZ901 is our Core Product. Our Core Product and other product candidates are internally developed. Many of our product candidates are in early-stage of clinical trials and thus face higher risks of clinical trial failure. Furthermore, the recession or eradication of the infectious diseases that our vaccine candidates target and the availability of alternative vaccines or treatment technologies may adversely affect our sales. For more details, please see “Risk Factors — Risks Relating to Our Business and Industry — Risks Relating to the Research and Development of Our Product Candidates” and “Risk Factors — Risks Relating to Our Business and Industry — Risks Relating to Sales and Distribution of Our Product Candidates” in this document.

#### Our Core Product and Clinical-Stage Product Candidates

##### *LZ901*

LZ901, our Core Product and independently developed recombinant herpes zoster vaccine candidate, has a tetrameric molecular structure to prevent shingles caused by varicella-zoster virus (“VZV”) for adults aged 50 years and older. LZ901 prevents the occurrence of herpes zoster and related complications caused by herpes zoster, including PHN. LZ901 is designed on the basis of making full use of the mechanism of the human immune system for processing foreign antigens. Employing our mammalian expression technology platform, we developed LZ901 based on the VZV glycoprotein E (“gE”)-fragment crystallizable (“Fc”) region. VZV gE is an antigen that is abundantly expressed on the surface of VZV, and the Fc region is the tail region of immunoglobulin G (“IgG”), a human antibody, that interacts with cell surface receptors. LZ901 is a recombinant tetramer fusion protein consisting of VZV gEs expressed on CHO cells bound to two Fc fragment of IgG.

We commenced the development of LZ901 in March 2018. LZ901 has demonstrated high immunogenicity, efficacy and safety profile in pre-clinical studies, while inducing specific humoral and cellular immunity. In the Phase I clinical trial for LZ901 in China, the overall number and incidence rate of Grade I AEs and Grade II AEs of subjects dosed with LZ901 were lower compared to subjects dosed with Shingrix<sup>®</sup>, and no Grade III AEs were observed in subjects dosed with LZ901 while one Grade III AE was observed in subjects dosed with Shingrix<sup>®</sup>, demonstrating the mild side effects of LZ901. In addition, based on immunogenicity data collected from the Phase I clinical trial for LZ901 in China, it has been demonstrated that there is no significant difference in the levels of anti-VZV antibodies after the full course of vaccination of LZ901 compared to Shingrix<sup>®</sup>, indicating that the immunogenicity of LZ901 is not inferior to that of Shingrix<sup>®</sup>.

We have initiated a Phase I clinical trial in January 2022 and completed the Phase I clinical trial and initiated a Phase II clinical trial for LZ901 in China in April 2022. We expect to complete the Phase II clinical trial for LZ901 in China in the second quarter of 2023, initiate a multi-center, randomized, double-blind, placebo-controlled Phase III clinical trial comparing LZ901 against Shingrix<sup>®</sup> in the second quarter of 2023, and file the BLA in the third quarter of 2024 for LZ901 to the NMPA. In addition, we have received IND approval from the FDA in July 2022 for LZ901 and initiated a Phase I clinical trial in the U.S. in February 2023. We plan to complete the Phase I clinical trial and initiate a Phase II clinical

## SUMMARY

trial in the first quarter of 2024. Furthermore, we expect to complete the Phase II clinical trial in the second quarter of 2025, initiate a Phase III clinical trial in the fourth quarter of 2025, and complete the Phase III clinical trial in the second quarter of 2027.

### *Market Opportunities and Competition*

Shingles is becoming more prevalent in China due to a growing aging population that is more susceptible to shingles. According to Frost & Sullivan, the number of new cases of herpes zoster in people aged 50 years old and above in China increased from 2.5 million in 2015 to 3.9 million in 2021 at a CAGR of 7.8%. It is expected to increase to 4.9 million in 2025 at a CAGR of 6.0% from 2021 to 2025, and further increase to 6.0 million in 2030 at a CAGR of 4.2% from 2025 to 2030. As the public awareness of herpes zoster continues to grow and the number of available herpes zoster vaccine products increases, the herpes zoster vaccine market in China is expected to grow significantly.

In 2021, the vaccination rate of herpes zoster, among those aged 50 years and older, was 0.1% in China, 5.2% in the EU and 26.8% in the U.S., according to Frost & Sullivan. According to 2022 China Herpes Zoster Vaccine Expert Consensus (帶狀皰疹疫苗預防接種專家共識)\*, herpes zoster vaccine is recommended in order to prevent herpes zoster, and individuals aged 50 years and older (regardless of whether the individual has a history of varicella infection or varicella vaccination) are recommended to receive herpes zoster vaccine. The U.S. CDC recommends that adults aged 50 years and older receive herpes zoster vaccine as a prevention regimen for shingles. The U.S. CDC recommends Shingrix<sup>®</sup> as the primary vaccine for shingles, and immunocompetent adults aged 50 years and older should obtain two doses of Shingrix<sup>®</sup> two to six months apart. For details regarding the incidence and prevalence of shingles, please see “Industry Overview” in the document. According to Frost & Sullivan, in terms of sales revenue, the herpes zoster vaccine market in China increased from nil in 2015 to RMB0.6 billion in 2021, and is expected to grow to RMB10.8 billion in 2025 at a CAGR of 103.8% from 2021 to 2025, and further grow to RMB28.1 billion in 2030 at a CAGR of 21.1% from 2025 to 2030.

As of the Latest Practicable Date, there were two herpes zoster vaccines approved in China, namely GlaxoSmithKline plc’s Shingrix<sup>®</sup>, which captured almost 100% of the global market share in terms of sales revenue in 2021, and BCHO Biotechnology’s Gan Wei (感維), which was recently approved in January 2023 and will commence to be sold in June 2023. As of the Latest Practicable Date, there was only one marketed herpes zoster vaccine, namely Shingrix<sup>®</sup>, and four herpes zoster vaccines under development in the U.S. In November 2020, Zostavax<sup>®</sup> was no longer available for use in the U.S., as it has discontinued production in the U.S. due to its low effectiveness as a herpes zoster prophylaxis and its weakened market competitiveness.

As of the Latest Practicable Date, there were four herpes zoster vaccine candidates, including LZ901, at the clinical stage in China and there were six other herpes zoster vaccine candidates at the clinical stage in Australia, the Philippines and the U.S., according to Frost & Sullivan. For details, please see “Industry Overview — Herpes Zoster Vaccine Market — Competitive Landscape” in this document.

### *Note:*

\* “2022 China Herpes Zoster Vaccine Expert Consensus”: Dermatology Branch of China Medical Care International Exchange Promotion Association, Senile Dermatology Research Center of Chinese Medical Association Dermatology Branch. Herpes Zoster Vaccine Expert Consensus. Medical Journal, 2022, 102(8): 538-543. DOI: 10.3760/cma.j.cn112137-20210828-01958.

## SUMMARY

We believe there is significant market potential for our LZ901, considering the following factors.

- ***Favorable government policies for domestic vaccine manufacturers in China.*** In 2017, Opinions of the General Office of the State Council on Further Strengthening the Management of Vaccine Circulation and Vaccination (國務院辦公廳關於進一步加強疫苗流通和預防接種管理工作的意見) set out principles to promote domestic vaccine manufacturers to scale up production of vaccines, independent R&D and to improve the quality of vaccines to support R&D and industrialization of new vaccines. Therefore, we believe we will benefit from such favorable government policies and LZ901 will capture a large market share in the future.
- ***Government support and new initiatives to encourage developments for vaccination.*** According to China’s 14th Five-Year Plan, it proposes improving the health of the elderly as a key task during this period. In addition, the NHC recommends people aged 50 years and older to obtain herpes zoster vaccination to prevent shingles. According to 2022 China Herpes Zoster Vaccine Expert Consensus (帶狀皰疹疫苗預防接種專家共識), herpes zoster vaccine is recommended in order to prevent herpes zoster, and individuals aged 50 years and older (regardless of whether the individual has a history of varicella infection or varicella vaccination) are recommended to receive herpes zoster vaccine.
- ***Cost effectiveness of vaccination.*** Shingles is a viral infection that causes a painful rash that can negatively impact quality of life. Shingles can also reoccur, with the recurrence rate of shingles increasing with age. The recurrence rate of shingles for unvaccinated patients is approximately 4% to 6%. After receiving herpes zoster vaccination, the risk of recurrence of shingles is reduced by approximately 50% in vaccinated patients. Based on a research study, the average cost of treatment for shingles (including both patients that develop and do not develop complications) is approximately RMB840 per patient and the average cost of treatment for shingles for patients that develop complications is approximately RMB1,221 per patient in people aged 50 years old and above in China according to Disease Burden Due to Herpes Zoster among Population Aged ≥50 Years Old in China: A Community Based Retrospective Survey\*, while LZ901 is expected to be priced at a retail price of approximately RMB500 to RMB800 an injection, with a total of two injections per treatment and does not require a third booster shot.<sup>(1)</sup> The treatment for shingles mainly includes outpatient service, hospitalization and medical treatment, and the average cost of treatment for shingles was calculated based on (i) outpatient expenses, (ii) hospitalization expenses, and (iii) other expenses which include the cost of over-the-counter medication, transportation costs from seeking medical service, productivity loss for caring for the patient, and other costs considered to be associated with shingles. According to Frost & Sullivan, taking into consideration the pain and negative impact to quality life caused by shingles, higher recurrence rate of shingles for unvaccinated patients which could lead to increasing costs to treat shingles and its complications, and the cost of LZ901 is fixed at two injections of RMB500 to RMB800 an injection, it is the most advisable choice to receive LZ901 vaccination for shingles.

*Note:*

\* Li Y, An Z, Yin D, Liu Y, Huang Z, Xu J, Ma Y, Tu Q, Li Q, Wang H. Disease Burden Due to Herpes Zoster among Population Aged ≥50 Years Old in China: A Community Based Retrospective Survey. PLoS One. 2016 Apr 7; 11(4):e0152660.

## SUMMARY

- ***Non-inferior safety and indicative efficacy of LZ901 compared to Shingrix®.*** As demonstrated in the Phase I clinical trial for LZ901 in China, the overall number and incidence rate of Grade I AEs and Grade II AEs of subjects dosed with LZ901 were lower compared to subjects dosed with Shingrix®, and no Grade III AEs were observed in subjects dosed with LZ901 while one Grade III AE was observed in subjects dosed with Shingrix®, demonstrating the mild side effects and favorable safety profile of LZ901. In addition, both the low-dosed and high-dosed LZ901 groups reported an incidence rate of AEs of 55%, which is lower compared to the Shingrix® positive control group that reported an incidence rate of AEs of 100% and similar to the placebo group that reported an incidence rate of AEs of 50%.

LZ901 induces a cellular immune response that confers strong protection against shingles. Compared to Shingrix® in BALB/c mice, LZ901 induces a stronger cellular immune response with higher expression of multiple types of immune cell activating biomarkers. In addition, based on immunogenicity data collected from the Phase I clinical trial for LZ901 in China, it has been demonstrated that there is no significant difference in the levels of anti-VZV antibodies after the full course of vaccination compared of LZ901 to Shingrix®, indicating that the immunogenicity of LZ901 is not inferior to that of Shingrix®.

### *Competitive Advantages*

We believe LZ901 has the following advantages when compared to the currently marketed herpes zoster vaccine in China:

- ***Low price.*** LZ901 is expected to be priced at a retail price of approximately RMB500 to RMB800 an injection, with a total of two injections per treatment and does not require a third booster shot, which is more affordable compared to the retail price of the other commercially available herpes zoster vaccines in China, with Shingrix® priced at RMB1,600 an injection with a total of two injections per treatment. As LZ901 is indicated for middle-aged and elderly adults aged 50 years and older, who are price sensitive and will likely choose a lower priced herpes zoster vaccine, we priced LZ901 at approximately RMB500 to RMB800 an injection. We believe that we are able to maintain a healthy profit margin and to increase acceptance of herpes zoster vaccines in the target population while gaining market share for LZ901 taking into consideration (i) the current competitive landscape of herpes zoster vaccines; (ii) the expected pricing of LZ901 and the pricing of other herpes zoster vaccines with Shingrix® priced at approximately RMB1,600/dose with a total of two doses per treatment and Gan Wei (感維) to be priced at approximately RMB1,369/dose with a total of one dose per treatment once it commences sales in June 2023; and (iii) our manufacturing capacity, which will enable us to lower production cost and improve the profitability for LZ901.
- ***Mild side effects and favorable safety profile.*** The side effects from the administration of LZ901 are minimal as its liquid formulation only contains an aluminum hydroxide adjuvant and is free of immune stimulants, which reduces the likelihood of serious adverse reactions at the injection site. As demonstrated in the Phase I clinical trial for LZ901 in China, the overall number and incidence rate of Grade I AEs and Grade II AEs of subjects dosed with LZ901 were lower compared to subjects dosed with Shingrix®, and no Grade III AEs were observed in subjects dosed with LZ901 while one Grade III AE was observed in subjects dosed with Shingrix®, demonstrating the mild side effects and favorable safety profile of LZ901. In addition, both the low-dosed and high-dosed LZ901 groups reported an incidence rate of AEs of 55%, which is lower compared to the Shingrix® positive control group that reported an incidence rate of AEs of 100% and similar to the placebo group that reported an incidence rate of AEs of 50%.

## SUMMARY

---

- ***Molecular structure advantages.*** LZ901 has a tetrameric molecular structure containing two Fc regions that actively present VZV gE to cell membrane surface Fc receptors of APCs to trigger an immune response. In pre-clinical studies, compared to the naturally occurring VZV gE, LZ901 exhibits improved immunogenicity and induces a higher level of neutralizing antibody titers.
- ***Highly stable, easy to store and transport, and convenient to use.*** LZ901 adopts a liquid formulation with high stability, which allows for easy storage and transportation. It is stable for two weeks at 37°C, 12 weeks at 25°C and 24 months at 2-8°C.
- ***Strong protection.*** LZ901 induces a cellular immune response that confers strong protection against shingles. Compared to Shingrix<sup>®</sup> in BALB/c mice, our LZ901 induces a stronger cellular immune response with higher expression of multiple types of immune cell activating biomarkers. In addition, based on immunogenicity data collected from the Phase I clinical trial for LZ901 in China, it has been demonstrated that there is no significant difference in the levels of anti-VZV antibodies after the full course of vaccination of LZ901 compared to Shingrix<sup>®</sup>, indicating that the immunogenicity of LZ901 is not inferior to that of Shingrix<sup>®</sup>.

For more details, see “Business — Our Products and Product Candidates — Our Core Product and Clinical-Stage Product Candidates — 1. LZ901” in this document.

### *Limitations and Imminent Risks on the Market Potential*

We are subject to the following limitations and imminent risk on the market potential of LZ901:

- The lack of disease awareness in shingles and its complications, the low awareness of herpes zoster vaccination for disease prevention and the current low vaccination rate and number of people who get vaccinated in China, and the low mortality rate caused by shingles may hinder the market growth for herpes zoster vaccines. For more details, please see “Risk Factors — Risks Relating to Our Business and Industry — Risks Relating to Sales and Distribution of Our Product Candidates — The actual market size of our product candidates may be smaller than we anticipate, which could render some product candidates ultimately unprofitable even if commercialized” and “Industry Overview — Herpes Zoster Vaccine Market” in this document.
- We face strong competition from Shingrix<sup>®</sup> and existing treatment methods for herpes zoster and its complications, including antiviral drugs, glucocorticoid therapy and analgesic treatment, and may fail to achieve market penetration and acceptance for LZ901. For more details, please see “Risk Factors — Risks Relating to Our Business and Industry — Risks Relating to Sales and Distribution of Our Product Candidates — We operate in a competitive environment, and we may not be able to compete effectively against current and future competitors” and “Industry Overview — Herpes Zoster Vaccine Market” in this document.
- LZ901 is currently under Phase II clinical trial, and the current clinical trial stage and patient size from Phase I clinical trial do not necessarily support the advantages of the Core Product compared to other peer products in terms of quality, safety and efficacy. For more details, please see “Risk Factors — Risks Relating to Our Business and Industry — Risks Relating to the Research and Development of Our Product Candidates” in this document.



## SUMMARY

In order to increase the market share of LZ901, we plan to set up our commercialization team in China after the filing of the BLA of LZ901. We expect to build a commercialization team with about 300 people, consisting of four departments, including sales department, marketing department, medical department, storage and transportation department. Our sales department will be responsible for the nationwide sales of LZ901. We will also cooperate with CSOs to jointly promote and market LZ901. For details, please see “Business — Commercialization” in this document.

### **WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET LZ901 SUCCESSFULLY.**

#### **K3**

K3, our independently developed recombinant human anti-TNF- $\alpha$  monoclonal antibody injection product candidate, is a biosimilar of adalimumab and mainly used for the treatment of various autoimmune diseases, such as rheumatoid arthritis, ankylosing spondylitis and plaque psoriasis. We developed K3 based on the antibody structure of adalimumab.

The molecular design of K3 maximizes the safety of the antibody when used in the human body. We expect K3 to expand the market in China for adalimumab biosimilars.

We initiated our Phase I clinical trial in September 2018, and have completed a Phase I clinical trial for K3 in China in December 2019 for the treatment of various autoimmune diseases. Based on the interview with the CDE of the NMPA in June 2022, it confirmed that our Phase I clinical trial in China was completed in December 2019 and it has no objection for us to proceed to Phase III clinical trial in China directly. Our PRC Legal Adviser is of the view that the CDE is the competent authority to give the above confirmations. We plan to initiate a Phase III clinical trial for K3 in China in the second quarter of 2023, complete the Phase III clinical trial in the second quarter of 2024 and submit a BLA to the NMPA in the fourth quarter of 2024. We expect K3 to receive BLA approval from the NMPA in 2025.

#### *Market Opportunities and Competition*

Adalimumab is a blockbuster TNF- $\alpha$  inhibitor marketed by AbbVie Inc. under the brand name Humira<sup>®</sup>. Humira<sup>®</sup> was approved by the NMPA in 2010 and included in the National Reimbursement Drug List (“NRDL”). Its average selling price was originally RMB7,729 per unit in 2015, and decreased from RMB5,572 in 2019 to RMB1,258 in 2020. The patent of Humira<sup>®</sup> expired in Europe in October 2018, and is expected to expire in the U.S. in 2023. The launch of biosimilars of Humira<sup>®</sup> led to the declined sales of Humira<sup>®</sup> in Europe since 2019. Humira<sup>®</sup> was launched in China in 2010 and was included in the NRDL in 2019, which resulted in the significant decrease of its retail price. Meanwhile, Humira<sup>®</sup> is now facing competition from its biosimilars, which will also result in the decline of its retail prices. The decrease of its retail prices in 2020 contributed to a 440% increase in sales in 2020 compared to 2019 according to Frost & Sullivan.

Due to the wide range of indications for adalimumab, large market demand and continuous availability of new biosimilar products, the adalimumab market size is growing rapidly in China. In terms of sales revenue, the adalimumab market in China increased from RMB0.2 billion in 2015 to RMB1.6 billion in 2021 at a CAGR of 41.3%, and is expected to grow to RMB6.8 billion in 2025 at a CAGR of 42.7% from 2021 to 2025, and further grow to RMB11.7 billion in 2030 at a CAGR of 11.3% from 2025 to 2030.

## SUMMARY

---

In China, K3 is expected to primarily compete with biosimilars of adalimumab that have been launched or currently under development. As of the Latest Practicable Date, there were six biosimilars of adalimumab approved in China, namely Qletli<sup>®</sup> (格樂立), Sulinno<sup>®</sup> (蘇立信), Anjianning (安建寧), Handayuan (漢達遠), Taibowei (泰博維) and Junmaikang (君邁康), and 10 biosimilars of adalimumab in development in China, according to Frost & Sullivan. Due to the high cost of adalimumab and its biosimilars, we plan to price K3 at a retail price of approximately RMB400 to RMB500 a dose, which will significantly reduce the out-of-pocket expense of patients and provide a competitive pricing advantage for K3 as K3 faces fierce competition from adalimumab and its biosimilars.

### *Competitive Advantages*

The molecular design of K3 maximizes the safety of the antibody when used in the human body. The pharmacokinetic, safety and immunogenicity evaluations of K3 have shown that it is highly similar to adalimumab, with no clinically meaningful difference between K3 and adalimumab, indicating K3’s potential to treat autoimmune diseases, such as rheumatoid arthritis, ankylosing spondylitis and plaque psoriasis. K3 is expected to be priced at a retail price of approximately RMB400 to RMB500 a dose. We expect K3 to expand the market in China for adalimumab biosimilars.

### *Licenses, Rights and Obligations*

In July 2019, we entered into a technology transfer agreement with Beijing Science Sun, a Shenzhen Stock Exchange-listed biopharmaceutical company focused on research, manufacture and sales of injectable products, (the “**Beijing Science Sun License Agreement**”), with respect to the assets and intellectual property rights in and to K3 and K11 in China. Pursuant to the Beijing Science Sun License Agreement, we originally agreed to assign Beijing Science Sun the intellectual property rights in and to our K3 and K11 product candidates and transfer all test results and research data in relation to pre-clinical studies of K3 and K11, testing and proprietary technology related to K3 and K11, as well as pilot-scale manufacturing and testing, related testing technologies, clinical research approval documents and Phase I clinical research results and materials of K3 to Beijing Science Sun.

After signing the Beijing Science Sun License Agreement, we completed the Phase I clinical trial for K3 in December 2019 and continued to monitor and improve the product stabilities, and Beijing Science Sun did not perform substantive research and development for K3. As Beijing Science Sun did not establish necessary facilities to manufacture K3 antibodies or identify a suitable CDMO in China with high-quality mass-production capacity, we did not transfer any K3 products to Beijing Science Sun and the Beijing Science Sun License Agreement was not consummated as a result.

In January 2021, however, Beijing Science Sun and us had begun to discuss to rescind the Beijing Science Sun Licensing Agreement, shortly after we won the bid for purchasing manufacturing land in Zhuhai on December 29, 2020 and obtained a construction permit to build our Zhuhai manufacturing facilities on January 18, 2021. In April 2021, we obtained the state-owned land use right certificate to build the Zhuhai manufacturing facilities. Furthermore, in November 2021, we reached a consensus with Beijing Science that we would be better positioned to accelerate the development and commercialization of K3 and lower the cost of manufacturing K3 to strengthen market competitiveness because of our increased R&D efficiency and expanded production capacity due to the construction of our first- and second-phase Zhuhai manufacturing facilities, and accordingly we and Beijing Science Sun entered into a supplemental technology transfer agreement (the “**Supplemental Beijing Science Sun License Agreement**”), which rescinded the previous technology transfer in respect to K3. The Supplemental

## SUMMARY

Beijing Science Sun License Agreement did not involve the re-assignment to us of any intellectual property rights related to our K3 product candidate. Under the Beijing Science Sun License Agreement in July 2019, we transferred our test results and research data in relation to pre-clinical studies of K3, and other materials that did not involve intellectual property rights (including patents, trade secrets and know-hows) of K3, such as operating procedures and inspection standards relating to the production of K3. After the signing of the Supplemental Beijing Science Sun License Agreement in November 2021, Beijing Science Sun returned the above-mentioned materials back to us. As we had not filed any patent applications relating to K3 when we entered Beijing Science Sun License Agreement, we did not transfer any patent of K3 to Beijing Science Sun, and we maintained and owned the intellectual property rights (including patents, trade secrets and know-hows) and other materials of K3.

As advised by Hiways Law Firm, our legal adviser as to intellectual property law (the “**IP Legal Adviser**”), the intellectual property rights of K3 are well protected through the combination of patent, trade secret and know-how and there is no material risk that future development and commercialization of K3 will be interfered or challenged by any relevant third parties known to the Company. Based on the view of our IP Legal Adviser, our Directors are of the view that all the intellectual property rights (including patents, trade secrets and know-hows) in relation to K3 are well protected against infringement by Beijing Science Sun and/or other relevant third parties, and there is no material risk that future development and commercialization of K3 will be interfered or challenged by any relevant third parties. We have primarily engaged in and are responsible for the R&D of K3, including the Phase I clinical trial, and we have the global rights to develop and commercialize K3.

For more details, see “Business — Our Products and Product Candidates — Our Core Product and Clinical-Stage Product Candidates — 2. K3” in this document.

### **WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET K3 SUCCESSFULLY.**

#### ***K193***

K193, our independently developed bispecific antibody injection (CD19-CD3) product candidate for the treatment of B cell leukemia and lymphoma, is a bispecific antibody against CD19/CD3 with an asymmetric structure. K193 binds to CD19 on the surface of human B cells and CD3 on the surface of T cells, which activates the T cells to kill B cells and tumor cells derived from B cells associated with leukemia and lymphoma. K193 has a short half-life and is expected to be a lastline treatment option for patients with rapidly progressing relapsed or refractory B cell leukemia and lymphoma. K193 is recommended for patients with relapsed or refractory B cell leukemia and lymphoma, who have received at least two failed chemotherapy and/or at least one failed combination therapy with CD20 monoclonal antibody, or for patients who are ready to receive CAR-T treatment, which may significantly limit the market potential of K193.

K193 displayed high *in vivo* and *in vitro* anti-tumor activity in pre-clinical studies. K193’s ability to activate T cells to kill B cells and tumor cells derived from B cells associated with leukemia and lymphoma is 10,000 times higher than OKT3 monoclonal antibody commonly used in CAR-T therapy.

We initiated a Phase I clinical trial for K193 in China in December 2019 and we expect to complete the Phase I clinical trial in the second quarter of 2023. The outbreak of COVID-19 reduced the number and availability of patients with relapsed/refractory B cell non-Hodgkin lymphoma who could commit to the 28 consecutive days of hospitalization and treatment of K193 for the Phase I clinical trial, which caused a temporary delay in subject enrollment. In addition, subject enrollment was further delayed due to difficulty finding suitable subjects, as K193 is a later-line therapy which requires enrolling patients

## SUMMARY

who have failed other therapies. We plan to initiate a Phase II clinical trial for K193 in the first quarter of 2024 and complete the Phase II clinical trial of K193 in China in the fourth quarter of 2027. We plan to apply for a conditional BLA approval from the NMPA in 2027 prior to conducting a Phase III clinical trial for K193 as K193 is used for serious life-threatening diseases for which there are no effective treatment and therefore, may obtain conditional approval and then conduct the Phase III clinical trial afterwards in accordance with Drug Registration Regulation. For details, please see “Regulatory Overview — Regulatory Provisions — Laws and Regulations Related to Drugs — New Drug Application and Approval” in this document.

### *Market Opportunities and Competition*

As of the Latest Practicable Date, there was only one bispecific antibody injection (CD19-CD3) approved in China, namely Amgen Inc.’s Blincyto<sup>®</sup>. Besides our K193, there were three other bispecific antibody injections (CD19-CD3), namely Generon Biomed’s A-319, Curon Biopharma’s CN201 and Shandong Xinshidai Pharmaceutical Co., Ltd’s LNF1904, and one trispecific antibody injection (CD19-CD20-CD3), namely CMG1A46 of BioRay Pharmaceutical and Chimagen Biosciences, under clinical development registered with the Center for Drug Evaluation of the NMPA (“CDE”) in China, according to Frost & Sullivan. Although the patient number is not large, the treatment cost is relatively high, and there remain great unmet medical needs from patients.

### *Competitive Advantages*

We believe K193 has the following advantages when compared to currently marketed antibody injections for the treatment of B cell leukemia and lymphoma globally: (i) low price. K193 is expected to be priced at a retail price of approximately RMB200,000 for the first two treatments, RMB200,000 for the third treatment, and no cost for unlimited treatments after the third treatment, for a maximum total cost of RMB400,000 per patient, which is more affordable compared to the retail price for a treatment of Blincyto<sup>®</sup>; (ii) liquid formulation is convenient and easy to administer. K193 has an optimized liquid formulation which remains stable for more than 36 months when stored in 2-8°C conditions; (iii) strong affinity to B cells and ability to kill B cells. K193 has strong binding affinity to CD19 on the surface of B cells, with a KD value of 2.6x10<sup>-9</sup> mole/L. It adopts a humanized Fab antibody, which has a stronger affinity to CD19 than murine ScFv antibody. The effect of K193’s order of binding is strongly amplified by the participation of B7 molecules present on the surface of B cells, which interacts with cluster of differentiation 28 (“CD28”) co-stimulatory molecules on the surface of T cells to release perforin and Granzyme B to efficiently and accurately kill B cells and tumor cells derived from B cells associated with leukemia and lymphoma; (iv) easy to control side effects. The side effects of K193 are controllable with a low incidence.

For more details, see “Business — Our Products and Product Candidates — Our Core Product and Clinical-Stage Product Candidates — 3. K193” in this document.

## **WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET K193 SUCCESSFULLY.**

### **Our Pre-clinical-Stage Product Candidates**

Our pre-clinical-stage product candidates comprise two vaccine candidates, including Recombinant Varicella Vaccine and Recombinant Rabies Vaccine, and two antibody injection product candidates, including K333 and K1932.

## SUMMARY

---

### *Recombinant Varicella Vaccine*

Recombinant Varicella Vaccine, our independently developed recombinant varicella vaccine candidate, is an adjusted dosage of LZ901 for the prevention of chickenpox caused by VZV. We developed Recombinant Varicella Vaccine based on LZ901. Recombinant Varicella Vaccine is expected to partially replace live attenuated vaccines of the OKA strain of VZV as an alternative vaccination method, reduce the chance of children suffering from VZV infection, and reduce the risk of developing shingles in adults. Unlike other marketed live-attenuated vaccines that contain weakened forms of VZV which may lay dormant in the patient and reactivate causing shingles, Recombinant Varicella Vaccine does not contain VZV and does not carry the risk of developing into shingles. We submitted the IND application for Recombinant Varicella Vaccine to the NMPA in June 2022. We expect to initiate a Phase I clinical trial in the third quarter of 2023, and complete the Phase I clinical trial for Recombinant Varicella Vaccine in the second quarter of 2024. We plan to initiate a Phase II clinical trial in the third quarter of 2024, complete the Phase II clinical trial in the third quarter of 2025, initiate a Phase III clinical trial in the fourth quarter of 2025 in China, and complete the Phase III clinical trial in the second quarter of 2027.

For more details, see “Business — Our Products and Product Candidates — Our Pre-clinical-Stage Product Candidates — 1. Recombinant Varicella Vaccine” in this document.

**WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET RECOMBINANT VARICELLA VACCINE SUCCESSFULLY.**

### *Recombinant Rabies Vaccine*

We are currently developing Recombinant Rabies Vaccine, our recombinant RVG subunit vaccine candidate, for the prevention of rabies in humans. We developed Recombinant Rabies Vaccine based on the genetically engineered expression of rabies virus glycoprotein G in CHO cells.

Recombinant Rabies Vaccine is currently undergoing pre-clinical studies. We anticipate requesting pre-IND meeting for Recombinant Rabies Vaccine with the NMPA as early as the fourth quarter of 2023. We initiated pre-clinical studies for Recombinant Rabies Vaccine in the second quarter of 2020, and we expect to complete the pre-clinical studies in the fourth quarter of 2023. We expect to initiate a Phase I clinical trial for Recombinant Rabies Vaccine in the second quarter of 2024 and complete the Phase I clinical trial in the third quarter of 2024 in China. We expect to initiate a Phase II clinical trial for Recombinant Rabies Vaccine in the third quarter of 2024, and complete the Phase II clinical trial in the first quarter of 2025. Furthermore, we expect to initiate the Phase III clinical trial in the first quarter of 2025 and complete the Phase III clinical trial in the second quarter of 2026 in China.

For more details, see “Business — Our Products and Product Candidates — Our Pre-clinical-Stage Product Candidates — 2. Recombinant Rabies Vaccine” in this document.

**WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET RECOMBINANT RABIES VACCINE SUCCESSFULLY.**

## SUMMARY

---

### ***K333***

We are currently developing K333, our bispecific antibody injection (CD33-CD3) product candidate, for the treatment of myeloid leukemia. K333 is a bispecific antibody that binds to human CD33 and CD3. K333 is currently undergoing pre-clinical studies. K333 exhibited statistically significant antitumor activity *in vivo* in established disseminated and subcutaneous mouse models of human acute myeloid leukemia (“AML”). We anticipate requesting a pre-IND meeting for K333 with the NMPA in the second half of 2024.

For more details, see “Business — Our Products and Product Candidates — Our Pre-clinical-Stage Product Candidates — 3. K333” in this document.

**WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET K333 SUCCESSFULLY.**

### ***K1932***

We are currently developing K1932, our bispecific antibody injection (CD19-CD3) product candidate, for the treatment of B cell lymphoma. K1932 is a bispecific antibody that binds to human CD19 and CD3. K1932 is recommended for patients with relapsed or refractory B cell leukemia and lymphoma, who have received at least two failed chemotherapy and/or at least one failed combination therapy with CD20 monoclonal antibody, or for patients who are ready to receive CAR-T treatment, which may significantly limit the market potential of K1932. We developed K1932 based on the molecular structure of K193, with the same binding sites for CD19 and CD3ε to K193. Compared with K193, K1932 has a much longer half-life in the human body. K1932 is expected to be administered in combination with K193 for the treatment of relapsed or refractory B cell lymphoma, and is not expected to compete with K193 for the treatment of B cell leukemia. Patients administered K1932 following the first stage administration of K193 have lower risk of experiencing a cytokine storm, which allows for dose escalation. After the induction period of K193 for seven days to 10 days, K1932 can be administered on a weekly basis. K1932 is currently undergoing pre-clinical studies. We anticipate requesting a pre-IND meeting for K1932 with the NMPA in the second half of 2024.

For more details, see “Business — Our Products and Product Candidates — Our Pre-clinical-Stage Product Candidates — 4. K1932” in this document.

**WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET K1932 SUCCESSFULLY.**

## SUMMARY

### Our Other Historically Developed Products

We self-developed all our other historically developed products. The following table sets forth the key and material information on our other historically developed and commercialized products which were transferred or out-licensed before the Track Record Period. For more details, please see “Business — Our Products and Product Candidates — Our Other Historically Developed Products” in this document.

Product	Development Stage Upon Out-Licensing	Latest Development Status	Licenses	Residual Rights and Obligations	Income Contribution			Market of Focus	Exclusivity Rights <sup>(2)</sup>
					Before Track Record Period	During Track Record Period <sup>(1)</sup>	After Track Record Period (Expected)		
Inactivated Enterovirus 71 (“EV71”) Vaccine	Pre-IND	In October 2021, Zhifei Biopharma initiated a single-center, randomized, blinded, different-dosed and positive-controlled Phase II clinical trial for Inactivated EV71 Vaccine in China, which is currently ongoing.	We transferred all assets of Inactivated EV71 Vaccine to Beijing Zhifei Luzhu Biopharmaceutical Co., Ltd. (“Zhifei Biopharma”), and co-own all intellectual property rights in and to Inactivated EV71 Vaccine with Zhifei Biopharma.	Milestone payments and royalty payments of low single-digit percentage of sales of Inactivated EV71 Vaccine	RMB15.0 million under the 2011 Zhifei License Agreement <sup>(3)</sup>	NA	Milestone payment of RMB4.0 million after receiving approval to commercialize Inactivated EV71 Vaccine and royalty payments of 3% of sales for a period of five years after the commercialization of Inactivated EV71 Vaccine	China	Global
K11	initiated Phase I clinical trial	Beijing Science Sun obtained approval for the clinical trial protocol from the ethics committee of a clinical trial institution in April 2020. In September 2021, Beijing Science Sun engaged a CDMO to produce K11. Beijing Science Sun plans to initiate and sponsor a Phase I clinical trial of K11 in China. Beijing Science Sun plans to initiate and sponsor a Phase III clinical trial of K11 in China, to complete the Phase III clinical trial in the fourth quarter of 2024 and file the BLA to the NMPA in the first quarter of 2026.	We transferred all assets and intellectual property rights in and to K11 to Beijing Science Sun.	Royalty payments of mid-single digit percentage of net sales or net profits of K11	NA <sup>(4)</sup>	NA	Royalty payments of 8% of net sales or 50% of net profits when the net profit margin is lower than 15% for a period of ten years after the commercial launch of K11	China	Global
Bacteria Vaccines	Haemophilus Influenzae Type b Conjugate Vaccine: initiated Phase I clinical trial; Group A and C Meningococcal Polysaccharide Vaccine: completed Phase III clinical trial; Meningococcal Groups A and C and Haemophilus Influenzae Type b Conjugate Vaccine: completed Phase II clinical trial; Group ACYW135 Meningococcal Polysaccharide Vaccine and Meningococcal Group A and C Polysaccharide Conjugate Vaccine: commercialized	Commercialized	We transferred the intellectual property rights in and to the Bacteria Vaccines and technical data and materials to produce the Bacteria Vaccines to Zhifei Biopharm.	NA	RMB19.8 million under the 2008 Zhifei License Agreement	NA	NA	China	Global

*Note:*

- As we out-licensed Inactivated EV71 Vaccine, K11, and the Bacteria Vaccines before the Track Record Period, we had no income arising from these historically developed products during the Track Record Period. For Inactivated EV71 Vaccine, we will receive milestone payment of RMB4.0 million after receiving approval to commercialize Inactivated EV71 Vaccine and royalty payments of low single-digit percentage of sales for a period of five years after receiving approval to commercialize Inactivated EV71 Vaccine. For K11, we will receive royalty payments of mid-single digit percentage of net sales or net profits for a period of ten years after the commercial launch of K11. As of the Latest Practicable Date, Inactivated EV71 Vaccine and K11 had not been commercialized yet. As for Bacteria Vaccines, we will not receive royalty payments in the future.
- We currently have no global commercialization plan for Inactivated EV71 Vaccine, K11 and the Bacteria Vaccines because we do not own any patents in other countries in relation to these licensed-out assets. Furthermore, the global market for the Bacteria Vaccines is highly saturated with many similar products, and therefore, we have no plan to pursue global commercialization.
- As of the Latest Practicable Date, Zhifei Biopharma had paid us a total of RMB15.0 million under the 2011 Zhifei License Agreement and will pay us RMB4.0 million within 30 days after receiving approval to commercialize Inactivated EV71 Vaccine.
- As we did not have any payment arrangement with third parties in relation to the development of K11, there was nil upfront payment for K11.

## SUMMARY

The following table sets forth the key and material information on our Immunoreagent Testing Kits, which are historically developed and commercialized by us. For more details, please see “Business — Our Products and Product Candidates — Our Other Historically Developed Products” in this document.

Product	Development Stage Upon Out-Licensing	Latest Development Status	Licenses	Residual Rights and Obligations	Income Contribution before Track Record Period	Income Contribution during Track Record Period	Market of Focus	Exclusivity Rights
Immunoreagent Testing Kits	NA	Commercialized	We own all assets and intellectual property rights in and to Immunoreagent Testing Kits.	NA	RMB12.7 million from 2004 to 2020	RMB2.6 million in 2021; RMB2.1 million in 2022	China	Global

## OUR COMPETITIVE STRENGTHS

We believe the following strengths have contributed to our success and differentiate us from our competitors:

- Innovative precision protein engineering platform, which empowers us to develop our recombinant vaccine and antibody product candidates with favorable efficiency, high purity and improved stability.
- LZ901, our Core Product, is a herpes zoster vaccine in China seeking global filing with improved immunogenicity, and high safety and stability due to its specific structure
- Strong pipeline of vaccine, autoimmune disease and hematological malignancy product candidates
- Vaccine and antibody production facilities with commercial-scale manufacturing capacity and professional quality management system
- Experienced scientific and management team backed by strong investor support

For more details, see “Business — Our Competitive Strengths” in this document.

## OUR STRATEGIES

Our goal is to utilize state-of-the-art technologies to develop and produce various biological products that meet clinical needs, and focus on the research and development of vaccines and therapeutic bispecific antibodies for human disease prevention, control and treatment. We plan to implement the following strategies to achieve this goal:

- Actively promote the clinical development of our pipeline candidates
- Rapidly advance the development of our other pipeline candidates
- Expand production capacity to meet growing market demand
- Lay out strategic plans to promote commercialization at home and abroad
- Expand our product pipeline with global collaboration

For more details, see “Business — Our Strategies” in this document.



## SUMMARY

---

### RESEARCH AND DEVELOPMENT

Research and development activities are crucial to our business. Our in-house R&D team is involved in all stages of novel vaccine and biologic therapeutic candidates development, from pre-clinical studies, laboratory research, to clinical trials, regulatory filings and manufacturing process development. Nearly a third of our researchers have more than ten years of industry experience, and almost half of our researchers have at least five years of industry experience. We have established a full range of in-house product discovery capabilities, including recombinant protein design and optimization, amplification, cultivation and harvesting. Please see “Business — Research and Development — Our Research and Development Platforms” in this document for more information.

As of the Latest Practicable Date, our research and development team in China consisted of 71 personnel, most of whom hold bachelor's or higher degrees, mainly majoring in bioengineering, biology, organic chemistry, pharmaceutical engineering and pharmaceutical sciences. The team is led by Mr. KONG Jian, our co-founder, executive Director, general manager and chief scientist, who has over 33 years of biopharmaceutical experience. For details of the background of Mr. KONG, please see “Directors, Supervisors and Senior Management” in this document. We plan to expand our research and development team to approximately 80 to 120 personnel in the next one to two years based on development and launch plans of our product candidates. As of the Latest Practicable Date, we do not have research and development personnel in the U.S., but we currently have one administrative personnel in the U.S., who is mainly responsible for our business development overseas, and will supervise the Phase I clinical trial of LZ901 in the U.S. In addition, we have engaged a CRO to support the research and development of LZ901 in the U.S. since November 2022.

Our research and development expenses primarily consisted of staff costs, including salaries, welfare and share-based payment to our research and development staff, third-party contracting costs, costs of raw materials and depreciation and amortization. Our research and development expenses increased from RMB43.0 million in 2021 to RMB91.4 million in 2022, largely due to (i) an increase of share-based payments of RMB15.7 million primarily arising from the share options and awards we granted to our research and development personnel and (ii) an increase of sub-contracting costs of RMB12.5 million mainly arising from our Phase I clinical trial and Phase II clinical trial for LZ901. The research and development expenses incurred for our Core Product, excluding share-based payments, amounted to RMB6.2 million and RMB38.2 million in 2021 and 2022, respectively. As our research and development expenses incurred for our Core Product (excluding share-based payments) increased by RMB32.0 million from 2021 to 2022, primarily relating to our initiations of the Phase I clinical trial and the Phase II clinical trial for LZ901 in China in 2022, the proportion of the research and development expenses incurred for our Core Product (excluding share-based payments) in our total research and development expenses (excluding share-based payments) increased from 38.3% in 2021 to 78.1% in 2022, and the proportion of our total research and development expenses in our total operating expenses\* increased from 41.7% in 2021 to 51.6% in 2022. The proportion of our total research and development costs (excluding share-based payments) in our total cash operating costs increased from 80.0% in 2021 to 82.6% in 2022.

For more details, see “Business — Research and Development” in this document.

*Note:*

\* Operating expenses consist of research and development expenses and administrative expenses.

## SUMMARY

---

### INTELLECTUAL PROPERTY RIGHTS

Our continued success depends on our ability to obtain and maintain proprietary or intellectual property protection for our vaccine products, vaccine and therapeutic biologics candidates and our core technologies and other know-how. We also have internal protocols in place to ensure that we operate without infringing, misappropriating or otherwise violating the proprietary rights of others, and to prevent others from infringing, misappropriating or otherwise violating our proprietary or intellectual property rights. We protect our proprietary and intellectual property position by, among other methods, licensing or filing patent applications related to our proprietary technology, inventions and improvements. We also rely on trade secrets, know-how and continuing technological innovation to develop and maintain our proprietary and intellectual property position, which we generally seek to protect through contractual obligations with third parties.

As of the Latest Practicable Date, we had three invention patents granted and eight registered trademarks in the PRC, one invention patent granted in Russia and one registered trademark in Hong Kong. As of the same date, we had filed eight patent applications worldwide. Among our patent portfolio, two invention patents and seven pending patent applications are relating to our Core Product. All of the registered patents and patent applications for our Core Product are related to the same set of patent claims filed to nine different jurisdictions to protect our intellectual property, given that in addition to China and the U.S., the other jurisdictions are also the target markets or potential markets in the future for LZ901. All of our material patents and pending patent applications are self-owned. As of the Latest Practicable Date, we were not involved in any proceedings in respect of, and we had not received written notice of any material claims of infringement of any intellectual property rights, in which we may be a claimant or a respondent.

For more details, see “Business — Intellectual Property Rights” in this document.

### MANUFACTURING

Our manufacturing team is led by our deputy general manager and head of manufacturing and engineering, Mr. HAN Chaowei, who has 21 years of experience in the biopharmaceutical industry. As of the Latest Practicable Date, we had 29 manufacturing personnel. 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.

We have an R&D and pilot manufacturing facility located in Beijing, China to supply materials for our pre-clinical studies and early-stage clinical trials for all of our product candidates, which occupies approximately 27 acres of land with a total GFA of approximately 3,757 sq.m. in the R&D and production area. During the Track Record Period, we did not outsource any manufacturing activities of our product candidates to CDMOs.

We plan to commence construction of a new R&D and manufacturing facility in Beijing in the second quarter of 2023 and expect to complete construction of the new Beijing R&D and manufacturing facility in the first quarter of 2025. The new Beijing R&D and manufacturing facility is expected to have a total production capacity of eight million doses of Recombinant Varicella Vaccine a year and four million doses of Recombinant Rabies Vaccine a year.

## SUMMARY

---

We commenced operations at our first-phase Zhuhai manufacturing facility and are constructing our second-phase Zhuhai manufacturing facility to expand our production in preparation for commercialization of our pipeline candidates. Currently, our existing Zhuhai manufacturing facility occupies a total GFA of approximately 8,000 sq.m. and is equipped with several 500L stainless steel bioreactors, purification equipment and a high-speed vial filling linkage line.

We commenced construction of our second-phase Zhuhai manufacturing facility, which is expected to commence operations by the second quarter of 2023. Our second-phase Zhuhai manufacturing facilities, as planned and approved by the local government agency, occupy approximately 69,366 sq.m. of land with a total GFA of approximately 120,000 sq.m. in the production area. The second-phase Zhuhai manufacturing facility will be equipped with multiple 2.5-ton stainless steel bioreactors and two antibody biopharmaceutical production workshops. In total, the first-phase Zhuhai manufacturing facility and the second-phase Zhuhai facility will have an annual capacity to manufacture 20 million doses of LZ901, three million doses of K193 and two million doses of K3.

The construction standards of the above-mentioned manufacturing facilities in Zhuhai are designed according to international standards and are expected to meet the GMP requirements of the NMPA, the EMA, the FDA and related ICH guidelines. We will equip our workshops with appropriate facilities, equipment and instruments to enhance the quality management systems in chemistry, manufacturing and controls of large-scale production.

For more details, see “Business — Manufacturing” in this document.

## QUALITY CONTROL AND ASSURANCE

The quality and safety of our vaccine and therapeutic biologics products are crucial to our continued success. We endeavor to ensure the quality of our operations through a comprehensive quality management system. Our quality management system was designed to adhere to applicable national standards, including the GMP standards, covering substantially every aspect of our operations including product design, raw materials and manufacturing, among others.

We had an experienced quality management team consisting of 27 personnel as of the Latest Practicable Date. All of our Zhuhai quality management team members have received professional training in regulations, GMP standards and quality control analysis methods. After the commercialization of K3, we plans to employ 10 more personnel to enlarge the quality management team and further enhance the quality management systems. We have implemented quality management systems that conform to national regulations and industry guidelines and adopted standard operating procedures. All of our manufacturing facilities are designed and maintained, and we implement quality standards, in conformity with GMP standards adopted by NMPA, the EMA, the FDA and related ICH guidelines. GMP is the basic principle of pharmaceutical manufacturing and quality management for ensuring that products are consistently produced while achieving the required quality.

For more details, see “Business — Quality Control and Assurance” in this document.

## SUMMARY

---

### COMMERCIALIZATION

According to Frost & Sullivan, our vaccine candidates, once approved, are not likely to be included in the National Immunization Program, which primarily aims to protect children in China. When determining the types of vaccines to be included in the National Immunization Program, the government would consider various factors, such as the prevalence of infectious diseases, disease burden, effectiveness and safety of the vaccine, the supply capacity of vaccine manufacturers, adequate government funds and social benefits.

LZ901, Recombinant Varicella Vaccine and Recombinant Rabies Vaccine are prophylactic vaccines, which are not included in the NRDL and unlikely to be included in the NRDL in the foreseeable future with expenses for these vaccines expected to be paid by individuals. In addition, K193, K333 and K1932 are Class A innovative biological products, which are unlikely to be included in the NRDL as no innovative biological products are currently covered by the NRDL. Therefore, we plan to seek opportunities to collaborate with insurance companies to include such product candidates into their coverage.

As of the Latest Practicable Date, we did not have a commercialization team. Our director of overseas business development has over 17 years of experience in the biopharmaceutical. We are in the process of executing our launch readiness plan and formulating our sales and marketing plans in anticipation of multiple potential product launches within the next few years. The focus will be on product readiness, market readiness, and organizational readiness. We plan to begin building our commercialization team ahead of the launch of our product candidates. We intend to build our commercialization capabilities through a combination of efficient and specialized internal sales and marketing teams and external marketing and distribution partnerships with CSOs, with the goal of achieving broad product access across the globe to benefit patients worldwide. We plan to set up our commercialization team in China after the filing of the BLA of LZ901. We expect to build a commercialization team with about 300 people, consisting of four departments, including sales department, marketing department, medical department, storage and transportation department.

In China, we plan to adopt a two-pronged approach for sales and marketing activities. Our commercialization team will cover Beijing, Chengdu, Guangzhou, Shanghai, Tianjin, Wuhan, Xi'an, Zhengzhou and other provincial capitals in China. We plan to engage CSOs to cover major provinces and municipalities in China, including the same cities as our commercialization team and neighboring second- and third-tier cities. Such CSOs will be responsible for sales of our products in the regions that they are selected to cover. Our commercialization team will be responsible for national promotion of our products, including educating the market of the advantages of our products and promoting our products through national media advertisements, and will collaborate with our CSOs to promote and increase market awareness of our products in their respective regions, including holding academic conferences and events. Our commercialization team will formulate the criteria for screening CSOs, determine the cooperation conditions, select CSOs, assess the performance of CSOs, participate in the discussion of CSO sales strategies, and carry out national promotion of our product candidates, while do not participate in terminal sales. CSOs will mainly be responsible for regional promotion of our product candidates, establishment of sales channels and provision of logistics services, and will regularly report market demands and other feedbacks to our commercialization team. We do not have any plan to out-license our Core Product and product candidates in China.

## SUMMARY

---

We intend to formulate targeted commercialization strategies for each of our product candidates in China.

- *LZ901*. To support our sales and marketing efforts for LZ901, we plan to build our commercialization team for LZ901 in or around the third quarter of 2024 upon submitting the BLA for LZ901 to the NMPA. We plan to continuously educate and guide the market by conducting academic promotion and publishing scientific papers to introduce the advantages of LZ901, especially its mild side effects, favorable safety profile and strong protection. Our marketing department will cooperate with not-for-profit organizations and local CDCs to organize seminars and participate in industry conferences to introduce the importance of vaccination of the herpes zoster vaccine and the competitiveness of LZ901 both to relevant doctors and the public. We will customize the forms of doctor education, including but not limited to academic lectures and seminars, to deepen doctors’ understanding of the various advantages of LZ901. We plan to adopt favorable and competitive pricing for our LZ901. LZ901 is expected to be priced at a retail price of approximately RMB500 to RMB800 an injection, with a total of two injections per treatment and does not require a third booster shot, which is more affordable compared to the retail price of the other commercially available herpes zoster vaccines in China, with Shingrix<sup>®</sup> priced at RMB1,600 an injection with a total of two injections per treatment. According to public data, there is no booster shot requirement for other peer products of herpes zoster vaccine.
- *K3*. To support our sales and marketing efforts for K3, we plan to build our commercialization team for K3 in or around the fourth quarter of 2024 upon submitting the BLA for K3 to the NMPA. We plan to adopt favorable and competitive pricing for our K3. K3 is expected to be priced at a retail price of approximately RMB400 to RMB500 a dose, which is more affordable compared to the retail price of the other commercially available biosimilars of adalimumab in China, which are priced at approximately RMB700 to RMB1,200 a dose.
- *K193*. To support our sales and marketing efforts for K193, we plan to build our commercialization team for K193 in 2027 after completing the Phase II clinical trial for K193.

For overseas markets, we plan to formulate international commercialization strategies according to market conditions to promote our products. In particular, we plan to seek collaboration opportunities with global partners to leverage their established sales expertise. For LZ901, we plan to collaborate with multinational pharmaceutical companies who have a robust sales and marketing network to rapidly commercialize LZ901 globally outside of China, and we may develop corresponding out-licensing or collaboration strategies. For other products, we do not have plans or intention for out-licensing. We may build overseas production workshops and establish our own overseas sales team. In addition, we will focus on our layout strategy of the countries under China’s Belt and Road Initiative, with a focus on Southeast Asian countries, and accelerate our products’ entry into relevant countries through seeking collaborations with local partners, which should have in-depth market expertise and are familiar with regulatory requirements of the relevant jurisdiction, after the successful commercialization of LZ901 in China and realize commercial opportunities with the support of government policies. We currently do not have concrete overseas commercialization plans for our other product candidates, and may develop commercialization strategies for them in the future. For more details, see “Business — Commercialization” in this document.

## SUMMARY

### SUPPLIERS

During the Track Record Period, our major suppliers primarily consisted of (i) suppliers of raw materials and consumables for our vaccine and therapeutic biologics development, (ii) construction service providers, (iii) property leasing providers and (iv) CROs, who provide third-party contracting services for research and development. Our purchases from our five largest suppliers in each year during the Track Record Period amounted to RMB86.7 million and RMB152.2 million, respectively, representing 66.3% and 80.3% of our total purchases for the same periods, respectively. Our purchases from our largest supplier in each year during the Track Record Period amounted to RMB26.4 million and RMB127.1 million, respectively, representing 20.2% and 67.1% of our total purchases for the same periods, respectively. During the Track Record Period, all of our five largest suppliers were Independent Third Parties. None of our Directors, Supervisors, their respective associates nor any shareholder who, to the knowledge of our Directors, owned more than 5% of our issued share capital as at the Latest Practicable Date, had any interest in any of our five largest suppliers during the Track Record Period.

For more details, see “Business — Suppliers” in this document.

### SUMMARY OF HISTORICAL FINANCIAL INFORMATION

This summary of key financial information set forth below has been derived from, and should be read in conjunction with, our consolidated audited financial statements, including the accompanying notes, set forth in the Accountants’ Report set out in Appendix I to this document, as well as the information set forth in the section headed “Financial Information.”

#### Description of Selected Components of Consolidated Statements of Profit or Loss and Other Comprehensive Income

The following table sets forth our consolidated statements of profit or loss and other comprehensive income for the periods indicated:

	<b>Year ended December 31,</b>	
	<b>2021</b>	<b>2022</b>
	<i>RMB’000</i>	<i>RMB’000</i>
Other income	6,896	13,923
Other gains and losses, net	10,794	15,100
Fair value loss of financial liabilities at FVTPL	(441,077)	(551,546)
Administrative expenses	(60,217)	(85,830)
Research and development expenses	(42,983)	(91,426)
Finance costs	(603)	(722)
[REDACTED] expenses	[REDACTED]	[REDACTED]
Other expenses	(9,041)	(3,137)
<b>Loss before tax</b>	<b>(539,357)</b>	<b>(725,180)</b>
<b>Loss and total comprehensive expense for the year</b>	<b>(539,357)</b>	<b>(725,180)</b>

## SUMMARY

We currently have no products approved for commercial sale, and we have not generated any revenue from product sales. During the Track Record Period, substantially all of our losses resulted from administrative expenses, research and development expenses, and fair value losses on financial liabilities at FVTPL.

### Discussion of Certain Selected Items from the Consolidated Statements of Financial Position

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

	As of December 31,	
	2021	2022
	<i>RMB'000</i>	<i>RMB'000</i>
<b>Total non-current assets</b>	<b>151,602</b>	<b>469,166</b>
<b>Total current assets</b>	<b>574,293</b>	<b>601,004</b>
<b>Total assets</b>	<b>725,895</b>	<b>1,070,170</b>
<b>Total non-current liabilities</b>	<b>1,286,998</b>	<b>38,590</b>
<b>Total current liabilities</b>	<b>23,422</b>	<b>94,114</b>
<b>Net current assets</b>	<b>550,871</b>	<b>506,890</b>
<b>Total liabilities</b>	<b>1,310,420</b>	<b>132,704</b>
<b>Net (liabilities) assets</b>	<b>(584,525)</b>	<b>937,466</b>

We recorded net current assets of RMB550.9 million and RMB506.9 million as of December 31, 2021 and 2022, respectively. The increased net current assets during the Track Record Period were primarily attributable to the increased financial assets at FVTPL, primarily representing the wealth management products we purchased using proceeds from our Series B Financing, Series B+ Financing and Series C Financing.

Our financial position changed from net liabilities of RMB584.5 million as of December 31, 2021 to net assets of RMB937.5 million as of December 31, 2022, primarily reflecting changes in equity comprising (i) an increase of share capital of RMB92.5 million and an increase of share premium of RMB2,034.6 million, as all preference shares held by our [REDACTED] Investors were reclassified from financial liabilities to equity at their fair value after the termination of special rights granted to the [REDACTED] Investors in June 2022, (ii) loss and total comprehensive expense of RMB725.2 million in 2022, and (iii) equity-settled share-based payments of RMB111.4 million recognized for the same period. For further details on the equity movement of our Group, see “Consolidated Statements of Changes in Equity” of the Accountants’ Report set out in Appendix I to this document. We do not have any outstanding convertible redeemable preference shares that will be re-designated from financial liabilities to equity upon [REDACTED].

## SUMMARY

### Selected Consolidated Cash Flow Statements Data

The following table sets forth our cash flows for the years indicated:

	Year ended December 31,	
	2021	2022
	<i>RMB'000</i>	<i>RMB'000</i>
Net cash flows used in operating activities	(19,165)	(77,265)
Net cash flows used in investing activities	(403,997)	(223,262)
Net cash flows from financing activities	454,991	336,978
Net increase in cash and cash equivalents	31,829	36,451
Cash and cash equivalents at beginning of the year	201	32,030
Effect of foreign exchange rate changes	–	495
<b>Cash and cash equivalents at end of the year</b>	<b>32,030</b>	<b>68,976</b>

We had negative cash flows used in operating activities of RMB19.2 million and RMB77.3 million in 2021 and 2022, respectively. Our negative cash flows from operating activities were primarily attributable to our loss before tax, positively adjusted by non-cash items such as fair value loss of financial liabilities at FVTPL and equity-settled share-based payments, partially offset by non-cash items such as fair value gains on financial assets at FVTPL. For details, please see “Financial Information — Liquidity and Capital Resources — Net Cash Flows Used in Operating Activities” in this document. Going forward, we believe our liquidity requirements will be satisfied by using funds from a combination of our cash and cash equivalents and net proceeds from the [REDACTED]. As of December 31, 2022, we had cash and cash equivalents of RMB69.0 million. In addition, RMB512.7 million was recorded as financial assets at FVTPL as of December 31, 2022.

Taking into account the financial resources available to our Group, including cash and cash equivalents, future operating cash flows in respective periods, and the estimated net proceeds from the [REDACTED], our Directors are of the view that we have sufficient working capital to cover at least 125% of our costs and expenses, including research and development expenses, administrative expenses, finance costs and other expenses (including any production costs), for at least the next 12 months from the date of this document.

Our cash burn rate refers to our average monthly (i) net cash used in operating activities and (ii) capital expenditures (including purchase of property, plant and equipment and purchase of right-of-use assets). Taking into consideration the higher-than-before research and development expenses after LZ901 proceeded to its Phase III clinical trial in China and its Phase I clinical trials in the U.S., and assuming an average cash burn rate going forward of approximately 1.4 times the level for the 12 months ended December 31, 2022, we estimate that our cash and cash equivalents and financial assets at FVTPL, which were redeemable on demand as of December 31, 2022, or had been redeemed as of the date of this document, will be able to maintain our financial viability for approximately 13.3 months or, if we also take into account the estimated net proceeds (based on the low-end of the indicative [REDACTED]) from the [REDACTED], for approximately 18.6 months. We will continue to monitor our working capital closely and expect to raise our next round of financing, if needed, with a minimum buffer of twelve months.



## SUMMARY

Rule 13.46(2) of the Listing Rules requires an overseas issuer or a PRC issuer to send an annual report or a summary financial report to its shareholders within four months after the end of the financial year to which the report relates. As this document already includes the financial information of our Group for the year ended December 31, 2022 as required under Appendix 16 to the Listing Rules, we will not separately prepare and send an annual report to our Shareholders for the year ended December 31, 2022, which will not be in breach of the Articles of Associations, laws and regulations of the PRC or other regulatory requirements. In addition, we will issue an announcement by April 30, 2023 stating that we will not separately prepare and send an annual report to our Shareholders for the year ended December 31, 2022 as the relevant financial information has been included in this document. We have complied with applicable code provisions of the Corporate Governance Code as set out in Appendix 14 to the Listing Rules, other than as disclosed in “Directors, Supervisors and Senior Management — Corporate Governance — Deviation From the Corporate Governance Code” in this document.

### Key Financial Ratios

The table below sets forth our key financial ratio as of the dates indicated:

	As of December 31,	
	2021	2022
Current ratio <sup>(1)</sup>	24.5	6.4
Quick ratio <sup>(2)</sup>	24.5	6.4

*Notes:*

- (1) Current ratio represents current assets divided by current liabilities as of the same date.
- (2) Quick ratio represents current assets less inventories and divided by current liabilities as at the same date.

For more details, see “Financial Information” in this document.

### RISK FACTORS

We are a biopharmaceutical company seeking to [REDACTED] on the Main Board of the Stock Exchange under Chapter 18A of the Listing Rules. There are unique challenges, risks and uncertainties associated with [REDACTED] in companies such as ours, including the following:

- Our business and financial prospects depend substantially on the success of our clinical stage and pre-clinical stage product candidates, and we may not successfully complete clinical trials or procedures relating to our product candidates or demonstrate the safety and efficacy of our product candidates to the satisfaction of regulatory authorities, and many of our product candidates are in early-stage of clinical trials and thus face higher risks of clinical trial failure. Furthermore, results of earlier clinical trials may not be predictive of results of later-stage clinical trials.
- Results of earlier clinical trials may not be predictive of results of later-stage clinical trials.

## SUMMARY

---

- We rely on third-party testing agencies to obtain testing results of clinical trials of our product candidates, and we may experience delay or obtain inaccurate data due to factors beyond our control.
- Our product candidates may cause AEs or undesirable side effects, which could interrupt, delay or halt clinical trials, delay or prevent regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following any regulatory approval.
- The recession or eradication of the infectious diseases that our vaccine candidates target in China or globally and the availability of alternative vaccines or treatment technologies may adversely affect our sales.
- We operate in a competitive environment, and we may not be able to compete effectively against current and future competitors, and our Core Product may fail to achieve high market acceptance as Shingrix<sup>®</sup> has first-mover advantages and captured almost 100% of the global and Chinese market share in terms of sales revenue in 2021 as the only commercialized product in China at that time.
- We incurred net losses and net operating cash outflows during the Track Record Period, and we may continue to incur net losses and net operating cash outflows.
- We incurred net liabilities during the Track Record Period, and may continue to have net liabilities going forward, which can expose us to liquidity risk.
- If we are unable to obtain and maintain adequate patent and other intellectual property protection for our product candidates throughout the world, or if the scope of such intellectual property rights obtained is not sufficiently broad, third parties could compete directly against us and our ability to successfully develop and commercialize any of our product candidates would be materially and adversely affected.
- Seven of our patent applications relating to our Core Product were pending approval as of the Latest Practicable Date.

Given the high risks involved in our business and our industry in general, you may lose substantially all your [REDACTED] in us. You should read the entire section headed “ Risk Factors” in this document before you decide to [REDACTED] in the [REDACTED].

## DIVIDEND

No dividends have been declared or paid by our Group during the Track Record Period. We currently expect to retain all future earnings for use in operation and expansion of our business, and currently do not have any dividend policy to declare or pay any dividends in the foreseeable future. The declaration and payment of any dividends in the future will be determined by our board of directors and subject to our Articles of Association and the PRC Company Law, and will depend on a number of factors, including the successful commercialization of our products as well as our earnings, capital requirements, overall financial condition and contractual restrictions. No dividend shall be declared or payable except

## SUMMARY

out of our profits and reserves lawfully available for distribution. As confirmed by our PRC Legal Adviser, according to the PRC law, any future net profit that we make will have to be first applied to make up for our historically accumulated losses, after which we will be obliged to allocate 10% of our net profit to our statutory common reserve fund until such fund has reached more than 50% of our registered capital. We will therefore only be able to declare dividends after (i) all our historically accumulated losses have been made up for; and (ii) we have allocated sufficient net profit to our statutory common reserve fund as described above.

### [REDACTED] STATISTICS

All statistics in the following table are based on the assumptions that (i) the [REDACTED] has been completed and [REDACTED] new Shares are issued pursuant to the [REDACTED] and (ii) the [REDACTED] is not exercised.

	Based on an [REDACTED] per [REDACTED] of HK\$[REDACTED]	Based on an [REDACTED] per [REDACTED] of HK\$[REDACTED]
Our market [REDACTED] <sup>(1)</sup>	HK\$[REDACTED]	HK\$[REDACTED]
Unaudited [REDACTED] adjusted consolidated net tangible assets per Share <sup>(2)</sup>	HK\$[REDACTED]	HK\$[REDACTED]

*Notes:*

- (1) The calculation of market [REDACTED] is based on [REDACTED] Shares in issue immediately following the completion of the [REDACTED] based on assumptions described above and an [REDACTED] of HK\$[REDACTED] per Share and HK\$[REDACTED] per share, respectively.
- (2) The unaudited [REDACTED] adjusted net tangible asset per Share as of December 31, 2022 is calculated after making the adjustments referred to in “Appendix II — Unaudited [REDACTED] Financial Information.”

### OUR CONTROLLING SHAREHOLDERS

As of the Latest Practicable Date, Mr. KONG, Ms. ZHANG and Hengqin Luzhu LP held 58,294,513, 20,200,000 and 12,307,500 Shares, respectively, representing approximately 30.35%, 10.52% and 6.41% of our total issued Shares, respectively. As (i) Ms. ZHANG is the spouse of Mr. KONG, and (ii) Mr. KONG is the sole general partner of Hengqin Luzhu LP and can exercise the voting rights attached to the Shares held by Hengqin Luzhu LP in accordance with the partnership agreement entered into among the general and limited partners of Hengqin Luzhu LP, Mr. KONG, Ms. ZHANG and Hengqin Luzhu LP are considered to be a group of Controlling Shareholders, who collectively held approximately 47.28% of our total issued Shares as of the Latest Practicable Date.

Immediately following the completion of the [REDACTED] (assuming the [REDACTED] is not exercised), Mr. KONG, Ms. ZHANG, and Hengqin Luzhu LP will collectively hold approximately [REDACTED]% of our total issued Shares. Accordingly, Mr. KONG, Ms. ZHANG and Hengqin Luzhu LP will remain as our Controlling Shareholders immediately after [REDACTED].

Both Mr. KONG and Ms. ZHANG are our executive Directors. For further information, see “Relationship with Controlling Shareholders” in this document.

## SUMMARY

### [REDACTED] INVESTMENTS

The [REDACTED] Investments included (i) Series A Financing from which we raised approximately RMB250.0 million; (ii) Series B Financing from which we raised approximately RMB350.0 million; (iii) Series B+ Financing from which we raised approximately RMB120.0 million; and (iv) Series C Financing from which we raised approximately RMB218.0 million. Our [REDACTED] Investors include major pharmaceutical companies and experienced investors such as seasoned healthcare funds and established funds with a focus on investments in the biopharmaceutical sector. In this connection, CCB International Capital Management (Tianjin) Ltd. (建銀國際資本管理(天津)有限公司) (“CCB Capital”), being one of our [REDACTED] Investors, is a Sophisticated Investor having made meaningful investment in our Company during the Series B Financing. As of the Latest Practicable Date, our [REDACTED] Investors held approximately 48.15% of the issued share capital of our Company, among which CCB Capital held approximately 6.07% of the issued share capital of our Company. Immediately after completion of the [REDACTED] assuming the [REDACTED] is not exercised, our [REDACTED] Investors will hold approximately [REDACTED]% of the issued share capital of the Company, among which CCB Capital will hold approximately [REDACTED]% of the issued share capital of our Company. Our [REDACTED] Investors are subject to a lock-up period of 12 months following the [REDACTED] pursuant to the PRC Company Law. For more details, see “History, Development and Corporate Structure — [REDACTED] Investments” in this document.

As of the Latest Practicable Date, (i) approximately 12.7% of proceeds of the Series A Financing, amounting to approximately RMB31.8 million, remained unutilized; and (ii) approximately 52.6% of proceeds of Series B Financing, amounting to approximately RMB184.2 million, remained unutilized. On the other hand, the proceeds of the Series B+ Financing and the Series C Financing had yet been utilized as of the Latest Practicable Date. All the unutilized proceeds will be used as our working capital to support our development and production of pharmaceutical products, clinical trials and other operations.

### USE OF [REDACTED]

We estimate that the aggregate net proceeds to our Company from the [REDACTED] (after deducting [REDACTED] and other estimated expenses in connection with the [REDACTED] paid and payable by us taking into account any additional discretionary incentive fee and assuming that the [REDACTED] is not exercised and an [REDACTED] of HK\$[REDACTED] per Share, being the mid-point of the indicative [REDACTED] range of HK\$[REDACTED] to HK\$[REDACTED] per Share) will be approximately HK\$[REDACTED]. We currently intend to apply such net proceeds we will receive from this [REDACTED] for the following purposes:

- Approximately [59.9]%, or HK\$[REDACTED], will be used primarily for clinical development, manufacturing and commercialization of our Core Product, LZ901.
- Approximately [22.7]%, or HK\$[REDACTED], will be used primarily for clinical development and manufacturing of K3.
- Approximately [16.5]%, or HK\$[REDACTED], will be used primarily for construction of our second-phase commercial manufacturing facility in Zhuhai.
- Approximately [0.9]%, or HK\$[REDACTED], will be used primarily for working capital and other general corporate purposes.

For details, please see “Future Plans and Use of [REDACTED]” in this document.

## SUMMARY

### [REDACTED] EXPENSES

[REDACTED] expenses to be borne by us are estimated to be approximately RMB[REDACTED] (HK\$ [REDACTED]), or [REDACTED]% of the gross proceeds estimated to be received by us from the [REDACTED] (at the [REDACTED] of HK\$[REDACTED] per Share, being the mid-point of the indicative [REDACTED] range, and assuming the [REDACTED] is not exercised). [REDACTED] expenses to be borne by us include (i) [REDACTED]-related expenses, including [REDACTED], of RMB[REDACTED] (HK\$ [REDACTED]); (ii) fees and expenses of legal advisors and Reporting Accountants of RMB[REDACTED] (HK\$[REDACTED]); and (iii) other fees and expenses, including sponsor fees, of RMB[REDACTED] (HK\$[REDACTED]). As of December 31, 2022, we incurred a total of RMB[REDACTED] (HK\$[REDACTED]) in [REDACTED] expenses, among which RMB[REDACTED] was recognized in our consolidated statement of profit or loss and other comprehensive income, and RMB[REDACTED] was directly attributable to the issue of our [REDACTED] to the [REDACTED] and will be deducted from equity upon the [REDACTED].

We estimate that additional [REDACTED] expenses of approximately RMB[REDACTED] (HK\$ [REDACTED]) (including [REDACTED] of approximately RMB[REDACTED] (HK\$[REDACTED]), assuming the [REDACTED] is not exercised and based on the [REDACTED] of HK\$[REDACTED] per [REDACTED], being the mid-point of the indicative [REDACTED] range) will be incurred by our Company, approximately RMB[REDACTED] (HK\$[REDACTED]) of which is expected to be charged to our consolidated statements of profit or loss, and approximately RMB[REDACTED] (HK\$[REDACTED]) of which is directly attributable to the issue of our [REDACTED] to the [REDACTED] and will be deducted from equity upon the [REDACTED]. The [REDACTED] expenses above are the latest practicable estimate for reference only, and the actual amount may differ from this estimate. The exchange rate used in translations between Hong Kong dollars and Renminbi above, including such [REDACTED] expenses incurred as of December 31, 2022, is set forth in “Information about This Document and the [REDACTED] — Exchange Rate Conversion”.

### RECENT DEVELOPMENTS AND NO MATERIAL ADVERSE CHANGE

We expect that we will record net loss in 2023, primarily because we expect to continue to incur research and development expenses as we advance the development of our pipeline. In particular, we expect to complete the Phase II clinical trial for LZ901 in China in the second quarter of 2023, and initiate a Phase III clinical trial in the second quarter of 2023, which would expect to result in a significant increase in research and development expenses in 2023.

#### Research and Development Progress

For LZ901, we have enrolled 450 subjects for the Phase II clinical trial of LZ901. They were divided into placebo group, low-dose group and high-dose group, with 150 subjects in each group. As of the Latest Practicable Date, we had completed six-month follow-ups with trial subjects following the administration of the second dose and collected blood samples from trial subjects to evaluate the long-term immune persistence of LZ901.

For K193, we are currently conducting the Phase I clinical trial in China. As of the Latest Practicable Date, we had enrolled 17 subjects and were in the dose escalation stage for this trial. We expect to complete the Phase I clinical trial for K193 in the second quarter of 2023. In addition, we are also advancing our other pre-clinical product candidates.

For more details, see “Business — Our Products and Product Candidates — Our Core Product and Clinical-Stage Product Candidates” in this document.

## SUMMARY

---

### Impact of COVID-19

Since December 2019, the outbreak of a novel strain of coronavirus causing coronavirus disease 2019 (COVID-19) has materially and adversely affected the global economy. As of the Latest Practicable Date, the development timeline of our product candidates has not been materially impacted or delayed by the outbreak of COVID-19, and our operation has not been materially affected by the outbreak of COVID-19.

The outbreak of COVID-19 since the end of 2019 has limited impact on us, causing temporary delays in subject enrollment for our clinical trials, testing of serum samples to obtain data for the exploratory endpoint for the Phase I clinical trial for LZ901 and construction of our manufacturing facilities in Zhuhai. It has made it less convenient for the participants of the Phase I clinical trial for K193 to travel to Beijing, and our Phase I clinical trial for K193 experienced a temporary delay in subject enrollment due to the outbreak of COVID-19, which reduced the number and availability of patients with relapsed/refractory B cell non-Hodkin’s lymphoma who could commit to the 28 consecutive days of hospitalization and treatment of K193. In addition, subject enrollment was further delayed due to difficulty finding suitable subjects, as K193 is a later-line therapy which requires enrolling patients who have failed other therapies. We are headquartered in Tongzhou, Beijing, and the recent outbreak of the Omicron virus variant had limited impact on us and did not cause us to temporarily suspend our operations or materially disrupt our normal operations.

Our operations for our clinical trial and patient engagement activities have not been materially affected by the COVID-19 as we have employed various measures to mitigate any impact the COVID-19 outbreak may have on our ongoing clinical trials in China, including providing alternative methods for safety and efficacy assessment, continuing patient visit through remote access, and engaging necessary communications with our investigators to identify and address any issues that may arise. Due to the enhanced containment policies implemented by the PRC government, the COVID-19 outbreak has been largely controlled in China and the travel restrictions have been gradually relaxed. In December 2022, the PRC government at all levels began to lift some of the restrictive measures aimed at controlling the spread of the COVID-19 virus. Most of our employees were infected with the COVID-19, and then recovered after being infected. Our operations for clinical trials have experienced disruptions and delays due to the outbreak of COVID-19 at that time. However, since January 2023, we have resumed the normal patient enrollment and data entry for our clinical trials in China.

Based on our management account and as measure by purchase price, in 2021 and 2022, the raw materials from overseas suppliers accounted for approximately 50.6% and 42.1% of our total raw materials, respectively. The price of raw material sourced from overseas and their delivery time increased due to the outbreak of COVID-19. However, we have not experienced any shortage of raw materials from our suppliers and the increasing price of raw materials sourced from overseas has little impact on our costs. We currently do not expect our supply chain to be materially and negatively impacted by the COVID-19. Our major domestic suppliers maintained normal operations during the Track Record Period and up to the Latest Practicable Date. We expect the situation to continue to be improved with the sustained implementation of containment policies in response to the COVID-19 outbreak, and we may adjust our current clinical development plan covering multiple jurisdictions to the extent necessary depending on the status of the COVID-19 outbreak worldwide.

The above analyses are made by our management based on currently available information concerning COVID-19. It is uncertain whether the continuance or recurrence of the COVID-19 outbreak in China or the rest of the world will have an adverse effect on our results of operations, financial position or prospects. For more details, please see the paragraphs headed “Risk Factors — Risks Relating to Our Business and Industry — Risks Relating to Our General Operations — Our business, results of operations and financial position could be adversely affected by the ongoing COVID-19 pandemic” in this document.

## SUMMARY

---

### Regulatory Update

On February 17, 2023, the CSRC released the Trial Administrative Measures of Overseas Securities Offering and Listing by Domestic Companies (《境內企業境外發行證券和上市管理試行辦法》) (the “**Overseas Listing Trial Measures**”), which will become effective on March 31, 2023 and stipulates that domestic companies that seek to offer or list securities overseas, both directly and indirectly, shall complete the filing procedures and report relevant information to the CSRC. On the same date, the CSRC also released the Circular on the Arrangements for the Filing-based Administration of Overseas Securities Offering and Listing by Domestic Companies (《關於境內企業境外發行上市備案管理安排的通知》), which stipulates that domestic enterprises that have obtained the approval documents issued by the CSRC for overseas offering and listing (including new issuance) by joint-stock companies may continue their overseas offering and listing during the valid term of the approval documents. If the domestic companies fail to complete overseas offering and listing upon expiry of the term of the approval documents issued by the CSRC for overseas offering and listing, they shall go through filing as per relevant regulations. Please see “Regulatory Overview — Regulatory Provisions — Laws and Regulations Related to Overseas Securities Offering and Listing” in this document.

We obtained the approval issued by the CSRC for the [REDACTED] and the [REDACTED] on November 11, 2022, and such approval is valid for twelve months. According to Overseas Listing Trial Measures and the Circular on the Arrangements for the Filing-based Administration of Overseas Securities Offering and Listing by Domestic Companies, if the [REDACTED] is not completed within the validity period of the approval of CSRC, we will be required to complete the necessary filing procedures for the [REDACTED] and the [REDACTED]. Please see “Risk Factors — Risks Relating to Doing Business in China — The approval of, or filing with, CSRC or other regulatory authorities may be required in connection with the [REDACTED] and future [REDACTED], and we cannot predict whether we will be able to obtain all necessary approval or complete such filing” in this document.

### Impact of the collapse of Silicon Valley Bank (“SVB”)

On March 10, 2023, SVB, a commercial bank founded in 1983 and headquartered in Santa Clara, California, failed after a bank run. The collapse of SVB has had a significant impact on startups from the U.S. and abroad, with many companies unable to withdraw money from the bank for a limited period of time. The SVB downfall will not have any direct or developing impact on our operations, cash flows, or research and development progress in China and overseas as we are not a customer or shareholder of SVB. However, given the SVB downfall continues to be an evolving development and going forward, it is uncertain whether the SVB downfall will have any adverse impact on Chinese financial market, which in turn may adversely affect our results of operations, financial position or prospects in the future. For more details, please see the paragraphs headed “Risk Factors — Risks Relating to Our Business and Industry — Risks Relating to Our General Operations — Our business, results of operations and financial position could be adversely affected by the SVB collapse” in this document.

### No Material Adverse Change

Our Directors confirm that, there has been no material adverse change in our business, financial condition and results of operations since December 31, 2022, being the latest balance sheet date of our consolidated financial statements as set out in the Accountants’ Report included in Appendix I to this document, and up to the date of this document.

## DEFINITIONS

*In this document, the following expressions shall have the meanings set out below unless the context otherwise requires.*

“Actual Controller”	the individual or entity that can control the behavior of a company by way of investment, contract or other arrangements according to the Listing Rules of the Shenzhen Stock Exchange (《深圳證券交易所股票上市規則》) published and as amended from time to time by the Shenzhen Stock Exchange, where Beijing Science Sun is listed
“AFRC” or “Accounting and Financial Reporting Council”	the Accounting and Financial Reporting Council of Hong Kong
	[REDACTED]
“Articles” or “Articles of Association”	our articles of association, as adopted by Shareholders on April 10, 2023 and will come into effect upon [REDACTED] (as amended, supplemented or otherwise modified from time to time), a summary of which is set out in Appendix VI to this document
“associate(s)”	has the meaning ascribed to it under the Listing Rules
“Beijing Luzhu”	Luzhu Biologics (Beijing) Co., Limited (綠竹生物製品(北京)有限公司), a company established in the PRC with limited liability on March 31, 2022, and a direct wholly-owned subsidiary of our Company
“Beijing Science Sun”	Beijing Science Sun Pharmaceutical Co., Ltd. (北京賽升藥業股份有限公司), a joint stock company established in the PRC on May 20, 1999 and listed on the ChiNext board of the Shenzhen Stock Exchange (stock code: 300485)
“Beijing Yizhuang”	Beijing Yizhuang Biological Medicine Investment Center (Limited Partnership) (北京亦莊生物醫藥併購投資中心(有限合夥)), one of our [REDACTED] Investors, the details of which are set out in “History, Development and Corporate Structure” in this document
“Beijing Yizhuang II”	Beijing Yizhuang II Biological Medical Industry Investment Fund (Limited Partnership) (北京亦莊二期生物醫藥產業投資基金(有限合夥)), one of our [REDACTED] Investors, the details of which are set out in “History, Development and Corporate Structure” in this document



## DEFINITIONS

---

“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 that is not a Saturday, Sunday or public holiday in Hong Kong
“CAGR”	compound annual growth rate

[REDACTED]

## DEFINITIONS

[REDACTED]

“CFDA”	China Food and Drug Administration (國家食品藥品監督管理總局), the PRC governmental authority responsible for regulating food and drugs before the Institutional Reform Plan in 2018
“China”, “mainland China”, “the PRC”, or “State”	the People’s Republic of China excluding, for the purposes of this document and for geographical reference only and except where the context requires otherwise, Hong Kong, the Macau Special Administrative Region of the People’s Republic of China and Taiwan
“close associate(s)”	has the meaning ascribed thereto under the Listing Rules
“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”, “Luzhu Biotechnology”	Beijing Luzhu Biotechnology Co., Ltd. (北京綠竹生物技術股份有限公司), a joint stock company established in the PRC with limited liability on July 19, 2013, or, where the context requires (as the case may be), its predecessor, Beijing Luzhu Biotechnology Limited Liability Company (北京綠竹生物技術有限責任公司), a company established in the PRC with limited liability on November 9, 2001
“Company Law” or “PRC Company Law”	Company Law of the People’s Republic of China (中華人民共和國公司法) as amended, supplemented or otherwise modified from time to time, which was lately amended on October 26, 2018 to take effective on the same date
“connected person(s)”	has the meaning ascribed thereto under the Listing Rules

## DEFINITIONS

“Controlling Shareholders”	has the meaning ascribed to it under the Listing Rules and in this context, refers to the Mr. KONG, Ms. ZHANG and Hengqin Luzhu LP, for further details of which, please refer to “Relationship with Controlling Shareholders” in this document
“core connected person(s)”	has the meaning ascribed thereto under the Listing Rules
“Core Product”	has the meaning ascribed to it in Chapter 18A of the Listing Rules and in this context, our Core Product refers to LZ901
“CSDCC”	China Securities Depository and Clearing Corporation Limited (中國證券登記結算有限責任公司)
“CSRC”	the China Securities Regulatory Commission (中國證券監督管理委員會)
“Director(s)”	the director(s) of our Company or any one of them
“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 and paid up in Renminbi and are unlisted Shares not currently listed or traded on any stock exchange
“EIT”	enterprise income tax
“EIT Law”	the PRC Enterprise Income Tax Law (中華人民共和國企業所得稅法)
“EMA”	the European Medicines Agency, the EU agency responsible for evaluating and granting centralized approval for market authorization valid in all EU, European Economic Area states, and European Free Trade Association states
“EU”	the European Union
“Extreme Conditions”	extreme conditions caused by a super typhoon as announced by the government of Hong Kong
“E-town Sun”	Beijing E-town Sun Fund Management Co., Ltd. (北京屹唐賽盈基金管理有限公司), a company established in the PRC with limited liability on May 25, 2016, and was owned as to 34.00% by Saiding Fangde, 46.00% by Saide Ruibo and 20.00% by an Independent Third Party as of the Latest Practicable Date

## DEFINITIONS

---

“FDA”	U.S. Food and Drug Administration, the U.S. federal agency responsible for regulating food and drugs
“Frost & Sullivan”	Frost & Sullivan (Beijing) Inc., Shanghai Branch Co., an independent market research and consulting company
“Frost & Sullivan Report”	the industry report commissioned by us and independently prepared by Frost & Sullivan, summary of which is set forth in the section headed “Industry Overview” in this document
	<b>[REDACTED]</b>
“Group”, “our Group”, “our”, “we” or “us”	the Company and all of its subsidiaries, or any one of them as the context may require or, where the context refers to any time prior to its incorporation, the business which its predecessors or the predecessors of its present subsidiaries, or any one of them as the context may require, were or was engaged in and which were subsequently assumed by it
“H Share(s)”	ordinary share(s) in the ordinary share capital of our Company, with a nominal value of RMB1.00 each, which are to be <b>[REDACTED]</b> and <b>[REDACTED]</b> Hong Kong dollars and for which an application has been made for the granting of <b>[REDACTED]</b> and permission to <b>[REDACTED]</b> in on the Stock Exchange
	<b>[REDACTED]</b>
“Hengqin Luzhu LP”	Zhuhai Hengqin Luzhu Enterprise Management Partnership (Limited Partnership) (珠海橫琴綠竹企業管理合夥企業(有限合夥)), a limited partnership established in the PRC on January 14, 2021, and an employee incentive platform of our Group
“HKFRS”, “HKAS”	the Hong Kong Financial Reporting Standards and Hong Kong Accounting Standards (“ <b>HKAS</b> ”), which includes standards, amendments and interpretations promulgated by the Hong Kong Institute of Certified Public Accountants (HKICPA)

## DEFINITIONS

---

[REDACTED]

“Hong Kong” the Hong Kong Special Administrative Region of the PRC

“Hong Kong dollars” or “HK\$” Hong Kong dollars and cents respectively, the lawful currency of Hong Kong

[REDACTED]

“Hong Kong Luzhu” Luzhu Biologics (Hong Kong) Co., Limited (綠竹生物製品(香港)有限公司), a company incorporated in Hong Kong with limited liability on December 20, 2021, and a direct wholly-owned subsidiary of our Company

[REDACTED]

“Hong Kong Stock Exchange” or “Stock Exchange” The Stock Exchange of Hong Kong Limited, a wholly-owned subsidiary of Hong Kong Exchanges and Clearing Limited

[REDACTED]

## DEFINITIONS

---

[REDACTED]

“IFRSs”	International Financial Reporting Standards
“IIT Law”	the Individual Income Tax Law of the PRC (中華人民共和國個人所得稅法)
“Independent Third Party(ies)”	a person or entity who is not a connected person of our Company under the Listing Rules

[REDACTED]

## DEFINITIONS

---

“K3”	our anti-human tumor necrosis factor (“TNF”)- $\alpha$ monoclonal antibody injection product candidate
“Latest Practicable Date”	April 10, 2023, being the latest practicable date for the purpose of ascertaining certain information contained in this document prior to its publication
	[REDACTED]
“Listing Rules”	the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited (as amended, supplemented or otherwise modified from time to time)
“LZ901”	our recombinant herpes zoster vaccine candidate, a herpes zoster vaccine with a tetrameric molecular structure and our Core Product
“Main Board”	the stock market (excluding the option market) operated by the Hong Kong Stock Exchange which is independent from and operated in parallel with GEM of the Stock Exchange
“MOF”	the Ministry of Finance of the PRC (中華人民共和國財政部)
“MOFCOM”	the Ministry of Commerce of the PRC (中華人民共和國商務部)
“Mr. KONG”	Mr. KONG Jian (孔健), our executive Director, general manager, chairman of our Board, one of our promoters and one of our Controlling Shareholders
“Ms. JIANG”	Ms. JIANG Xianmin (蔣先敏), our executive Director, the vice-chairlady of our Board and one of our promoters
“Ms. ZHANG”	Ms. ZHANG Yanping (張琰平), our executive Director, one of our promoters and one of our Controlling Shareholders
“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)

## DEFINITIONS

---

“NIFDC”	the National Institutes for Food and Drug Control (中國食品藥品檢定研究院)
“NIPA”	the National Intellectual Property Administration of the PRC (中華人民共和國國家知識產權局)
“NMPA”	the National Medical Products Administration of the PRC (國家藥品監督管理局), successor to the China Food and Drug Administration or CFDA (國家食品藥品監督管理總局)
“NPC”	the National People’s Congress of the PRC (中華人民共和國全國人民代表大會)

[REDACTED]

“PBOC”	the People’s Bank of China (中國人民銀行), the central bank of the PRC
--------	--



## DEFINITIONS

“PRC Government”	the central government of the PRC and all governmental subdivisions (including provincial, municipal and other regional or local government entities) and instrumentalities thereof or, where the context requires, any of them
“PRC Legal Advisors”	Commerce & Finance Law Offices
[REDACTED] Investment(s)”	the [REDACTED] investment(s) in our Company undertaken by the [REDACTED] Investor(s), details of which are set out in “History, Development and Corporate Structure” in this document
[REDACTED] Investors”	Beijing Yizhuang Biological Medicine Investment Centre (Limited Partnership) (北京亦莊生物醫藥併購投資中心(有限合夥)); Beijing Science Sun Pharmaceutical Co., Ltd. (北京賽升藥業股份有限公司); Beijing Yizhuang II Biological Medical Industry Investment Fund (Limited Partnership) (北京亦莊二期生物醫藥產業投資基金(有限合夥)); CCB International Capital Management (Tianjin) Ltd. (建銀國際資本管理(天津)有限公司); Jinjiang Zhenrui Equity Investment Partnership (Limited Partnership) (晉江禎睿股權投資合夥企業(有限合夥)); Zhuhai Livzon Pharmaceutical Equity Investment Management Co., Ltd. (珠海市麗珠醫藥股權投資管理有限公司); Hangzhou Taikun Equity Investment Fund Partnership (Limited Partnership) (杭州泰鯤股權投資基金合夥企業(有限合夥)); Haikou Hengji Rongyu Investment Center (Limited Partnership) (海口恒基榮域投資中心(有限合夥)); Beijing Xinchuang Technology Phase I Venture Capital Center (Limited Partnership) (北京芯創科技一期創業投資中心(有限合夥)); Hainan Zhaoan Private Equity Fund Management Partnership (Limited Partnership) (海南兆安私募基金管理合夥企業(有限合夥)); Gongqingcheng Zhenrui Equity Investment Partnership (Limited Partnership) (共青城臻銳股權投資合夥企業(有限合夥)); Jinjiang Xuanhong No.1 Equity Investment Partnership (Limited Partnership) (晉江軒弘壹號股權投資合夥企業(有限合夥)); Shaanxi Jinou Investment Fund Partnership (Limited Partnership) (陝西金甌投資基金合夥企業(有限合夥)); Tianjin Huapu Biopharmaceutical Technology Partnership (Limited Partnership) (天津華普生物醫藥科技合夥企業(有限合夥)); Beijing Xinyin Xinghong Equity Investment Partnership (Limited Partnership) (北京信銀興弘股權投資合夥企業(有限合夥)); Zibo Runxin Xinchuang Investment Partnership (Limited Partnership) (淄博潤信芯創投資合夥企業(有限合夥)); and Zibo Runwen Kangju Equity Investment Partnership (Limited Partnership) (淄博潤文康聚股權投資合夥企業(有限合夥))

## DEFINITIONS

[REDACTED]

“RMB” or “Renminbi”	Renminbi, the lawful currency of the PRC
“SAFE”	the State Administration of Foreign Exchange of the PRC (中華人民共和國外匯管理局)
“SAIC”	the State Administration for Industry and Commerce of the PRC (中華人民共和國國家工商行政管理總局)
“Saide Ruibo”	Tianjin Saide Ruibo Asset Management Center (Limited Partnership) (天津賽德瑞博資產管理中心), a limited liability partnership established in the PRC on December 1, 2015, with Mr. MA Jianan (馬嘉楠) (the son of Mr. MA Biao) as its general partner holding approximately 80.00% partnership interest, and Ms. MA Li (馬麗) (the sister of Mr. MA Biao) as its limited partner holding approximately 20.00% partnership interest, and is a connected person of our Company
“Saiding Fangde”	Tianjin Saiding Fangde Asset Management Center (Limited Partnership) (天津賽鼎方德資產管理中心), a limited liability partnership established in the PRC on December 1, 2015, with (i) Mr. MA Biao (馬羸) as its general partner holding approximately 60.00% partnership interest; and (ii) Mr. WANG Xuefeng (王雪峰), Mr. MA Jianan (馬嘉楠) (the son of Mr. MA Biao) and Ms. MA Li (馬麗) (the sister of Mr. MA Biao) as its limited partners, holding approximately 10.00%, 10.00% and 20.00% partnership interest, respectively, and is a connected person of our Company
“SAT”	the State Administration of Taxation of the PRC (中華人民共和國國家稅務總局)
“Securities and Futures Commission” or “SFC”	the Securities and Futures Commission of Hong Kong
“Securities Law”	the Securities Law of the PRC (中華人民共和國證券法), as amended, supplemented or otherwise modified from time to time

## DEFINITIONS

---

“SFO”	the Securities and Futures Ordinance, Chapter 571 of the Laws of Hong Kong (as amended, supplemented or otherwise modified from time to time)
“Share(s)”	ordinary share(s) in the capital of our Company with a nominal value of RMB1.00 each, comprising Domestic Shares and H Shares
“Shareholders(s)”	holder(s) of the Share(s)
[“ <b>[REDACTED]</b> ”], “Sole Sponsor” and “Sole <b>[REDACTED]</b> ”	China International Capital Corporation Hong Kong Securities Limited
“Sophisticated Investor(s)”	has the meaning ascribed to it under Guidance Letter HKEX-GL92-18 issued by the Stock Exchange
“Special Regulations”	the Special Regulations of the State Council on the Overseas Offering and Listing of Shares by Joint Stock Limited Companies (國務院關於股份有限公司境外募集股份及上市的特別規定), promulgated by the State Council on August 4, 1994, as amended from time to time, and to the extent applicable
	<b>[REDACTED]</b>
“State Council”	the State Council of the PRC (中華人民共和國國務院)
“subsidiary”	has the meaning ascribed thereto under the Listing Rules
“substantial shareholder(s)”	has the meaning ascribed thereto under the Listing Rules
“Supervisor(s)”	member(s) of our Board of Supervisors
“Takeovers Code”	the Code on Takeovers and Mergers and Share Buybacks, as published by the SFC (as amended, supplemented or otherwise modified from time to time)
“Track Record Period”	the two years ended December 31, 2021 and 2022

**[REDACTED]**

## DEFINITIONS

---

“United States” or “U.S.”	the United States of America, its territories, its possessions and all areas subject to its jurisdiction
“U.S. dollars”, “US\$” or “USD”	United States dollars, the lawful currency of the United States
	<b>[REDACTED]</b>
“VAT”	Value Added Tax
“WHO”	the World Health Organization, a specialized agency of the United Nations concerned with international public health
“Zhuhai Luzhu”	Luzhu Biopharmaceuticals (Zhuhai) Co., Ltd. (綠竹生物製藥(珠海市)有限公司), a company established in the PRC with limited liability on November 29, 2018, and a direct wholly-owned subsidiary of our Company

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

Certain amounts and percentage figures included in this 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, the names of the PRC established companies or entities, laws or regulations have been included in this document in both the Chinese and English languages; in the event of any inconsistency, the Chinese versions shall prevail.

## GLOSSARY OF TECHNICAL TERMS

*This glossary contains definitions of certain technical terms used in this document in connection with us and our business. These may not correspond to standard industry definitions, and may not be comparable to similarly terms adopted by other companies.*

“Acute lymphoblastic leukemia” or “ALL”	a heterogeneous hematologic malignancy that can develop in people of different ages groups, of which 80% of ALL cases occur in children
“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
“ADA”	anti-drug antibody
“ADC”	antibody drug conjugate
“adjuvant”	a drug or other substance, or a combination of substances, that is used to increase the efficacy or potency of certain drugs
“AE(s)”	adverse events, any untoward medical occurrences in a patient or clinical investigation subject administered a drug or other pharmaceutical product during clinical trials and which do not necessarily have a causal relationship with the treatment
“affinity”	the extent or fraction to which a drug binds to receptors at any given drug concentration or the firmness with which the drug binds to the receptor
“antibody”	also known as an immunoglobulin, a protective Y-shaped protein produced by immune system in response to invading foreign particles (antigens) such as bacteria and viruses
“antibody titer”	a measurement of how much antibody an organism has produced that recognizes a particular epitope, expressed as the inverse of the greatest dilution (in a serial dilution) that still gives a positive result
“antigen”	substance that can stimulate an immune response
“APCs”	antigen presenting cells
“B cell”	a type of white blood cell that makes antibodies

## GLOSSARY OF TECHNICAL TERMS

---

“BALB/c mice”	an albino, laboratory-bred strain of the house mouse from which a number of common substrains are derived
“biosimilar”	a biologic medical product (also known as biologic) highly similar to another already approved biological medicine (the “reference medicine”)
“bispecific antibody”	an artificial protein that recognizes and specifically binds two antigens or epitopes. It simultaneously blocks the biological functions mediated by both antigens/epitopes or draws the cells of both antigens closer together and enhances the interaction
“CAR”	chimeric antigen receptor
“CAR-T therapy”	CAR T-cell therapy uses a delivery vehicle such as a lentivirus (LV) to transfer therapeutic gene sequences to the T-cell genome, enabling the patient’s T-cells to specifically recognize and bind to tumor cells, and subsequently kill them by releasing factors such as perforin
“CD19”	cluster of differentiation 19
“CD28”	cluster of differentiation 28
“CD3”	cluster of differentiation 3
“CD33”	a transmembrane receptor expressed on cells of myeloid lineage
“CD40L”	cluster of differentiation marker 40 ligand
“CDC”	Centre for Disease Control and Prevention (疾病預防控制中心)
“cell membrane”	a biological membrane that separates the interior of all cells from the outside environment (the extracellular space) which protects the cell from its environment
“Chemistry Manufacturing and Controls” or “CMC”	processes used in preclinical and clinical development stages to ensure that pharmaceutical and biopharmaceutical drug products are consistently effective, safe and high quality for consumers

## GLOSSARY OF TECHNICAL TERMS

---

“Chinese hamster ovary cell” or “CHO cell”	an epithelial cell line derived from the ovary of the Chinese hamster, often used in biological and medical research and commercially in the production of recombinant therapeutic proteins
“CI”	confidence interval
“Class I vaccine”	a vaccine that the Chinese government provides to its citizens free of charge and that citizens should be vaccinated in accordance with relevant government regulations, including vaccines determined in the national immunization program, additional vaccines required by provincial government in the implementation of national immunization programs, and vaccines used in emergency vaccination or mass vaccination organized by the government at county-level or above, or their respective healthcare department
“Class II vaccine”	a vaccine that is voluntarily vaccinated by citizens in China, and the cost of which is paid by the recipient or his/her guardian
“clinical trial”	a research study for finding or validating the therapeutic and protective effects and side-effects of test drugs to determine the safety and efficacy of such drugs
“clinical trial application” or “CTA”	clinical trial application, the PRC equivalent of investigational new vaccine application
“conjugate”	chemically link bacterial capsular polysaccharide to a protein to enhance immunogenicity
“COVID-19”	a viral respiratory disease caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)
“CRO”	contract research organization, a company that provides support to pharmaceutical companies by providing a range of professional research services on a contract basis
“CSO”	contract sales organizations
“culture media”	a solid, liquid or semi-solid designed to support the growth of microorganisms or cells

## GLOSSARY OF TECHNICAL TERMS

---

“cytokines”	a large group of proteins, peptides or glycoproteins that are secreted by specific cells of immune system. Cytokines are a category of signaling molecules that mediate and regulate immunity, inflammation and hematopoiesis
“cytotoxic (CD8+) T cell”	a type of important T lymphocytes for immune defense against intracellular pathogens, including viruses and bacteria, and for tumor surveillance
“dendritic cells”	cells that constantly sample their surroundings for pathogens such as viruses and bacteria, detect dangers, and initiate immune responses
“DNA”	deoxyribonucleic acid, a self-replicating material which is present in nearly all living organisms as the main constituent of chromosomes and is the carrier of genetic information
“efficacy”	the beneficial change resulted from a given intervention (vaccination and medicine)
“EHS”	environmental, health and safety
“ELISA”	enzyme-linked immunosorbent assay
“ESG”	Environmental, social, and governance
“EV71”	Enterovirus 71, most EV71 infections commonly result in hand-foot-mouth disease (HFMD)
“Fab”	fragment antigen-binding
“Fc”	fragment crystallizable
“GCP”	Good Clinical Practice for Drug Trials (GCP) (《藥物臨床試驗質量管理規範》) issued by CFDA on August 6, 2003 and implemented since September 1, 2003 as amended from time to time
“gE”	glycoprotein E
“GMT”	geometric mean titer
“GFA”	gross floor area



## GLOSSARY OF TECHNICAL TERMS

---

“GMP”	Good Manufacturing Practice, guidelines and regulations from time to time issued pursuant to the PRC Drug Administration Law (《中華人民共和國藥品管理法》) as part of quality assurance which aims to minimize the risks of contamination, cross contamination, confusion and errors during the manufacture process of pharmaceutical products and to ensure that pharmaceutical products subject to these guidelines and regulations are consistently produced and controlled in conformity to quality and standards appropriate for their intended use
“Haemophilus influenzae type b” or “Hib”	a type of bacteria that is associated to bacteremia, acute bacterial meningitis, pneumonia and epiglottitis
“HDCV”	human diploid cell vaccines
“Hematopoietic stem cell transplantation”	a process whereby hematopoietic stem cells from the donor are removed from the body as a graft and then transfused back to the pre-treated recipient to rebuild the recipient’s hematopoietic and immune systems. Pre-treatment with ultra-lethal doses of chemoradiotherapy has a bone marrow-clearing effect and the graft has anti-leukemic and anti-tumor effects
“Humira <sup>®</sup> (adalimumab)”	a monoclonal antibody used to treat rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn’s disease, ulcerative colitis, plaque psoriasis, hidradenitis suppurativa, uveitis, and juvenile idiopathic arthritis
“IL-2”	interleukin 2
“IL-4”	interleukin 4
“IL-6”	interleukin 6
“IFN- $\gamma$ ”	interferon- $\gamma$
“IMIDs”	immune-mediated inflammatory diseases
“immunogenicity”	the ability of a particular substance, such as an antigen, to provoke an immune response in the body of a human and other animal
“immunoglobulin G” or “IgG”	the most common type of antibody which is found in blood and other body fluids, and protects against bacterial and viral infections

## GLOSSARY OF TECHNICAL TERMS

---

“in vivo”	performed or taking place on (or in) a living organism, such as a laboratory animal
“in vitro”	performed or taking place in a test tube, culture dish, or elsewhere outside a living organism
“IND”	investigational new drug or investigational new drug application, also known as clinical trial application in China
“K11”	our independently developed humanized anti-VEGF monoclonal antibody injection product candidate, a biosimilar of bevacizumab and mainly used for the treatment of colorectal cancer, lung cancer and other cancers
“K193”	our independently developed bispecific antibody injection (CD19-CD3) product candidate, an innovative drug for the treatment of B cell lymphoma and leukemia
“K1932”	a bispecific antibody injection product candidate we are developing for the treatment of B cell lymphoma
“K3”	recombinant human anti-TNF- $\alpha$ monoclonal antibody injection, a biosimilar of adalimumab and mainly used for the treatment of various autoimmune diseases, such as rheumatoid arthritis, ankylosing spondylitis and psoriasis
“K333”	a bispecific antibody injection (CD33-CD3) product candidate we are developing for the treatment of myeloid leukemia
“LZ901”	our Core Product and independently developed recombinant herpes zoster vaccine candidate, has a tetrameric molecular structure to treat shingles caused by varicella-zoster virus for adults aged 50 years and older
“mAb”	monoclonal antibody
“messenger RNA” or “mRNA”	messenger ribonucleic acid or messenger RNA, a single-stranded molecule of RNA that corresponds to the genetic sequence of a gene, and is read by a ribosome in the process of synthesizing a protein

## GLOSSARY OF TECHNICAL TERMS

---

“MHC”	major histocompatibility complex, a large locus on vertebrate DNA containing a set of closely linked polymorphic genes that code for cell surface proteins essential for the adaptive immune system
“NADA”	neutralizing anti-drug antibody
“NHL”	the most common type of lymphoma, accounting for 90% of newly diagnosed cases of lymphoma
“PCEC”	purified chick embryo cell vaccines
“PEP”	post-exposure prophylaxis
“Phase I clinical trial”	Clinical trials testing potential medical products are commonly classified into four phases. The drug development process will normally proceed through all four phases over many years. If the drug successfully passes through Phases I, II, and III, it will usually be approved by the national regulatory authority for use in the general population. Phase IV trials are ‘post-marketing’ or ‘surveillance’ studies conducted to monitor safety over several years. Phase I trials are generally designed to test the safety, side effects
“Phase II clinical trial”	Phase II trials are generally designed to evaluate whether the drug has any biological activity or effect
“Phase III clinical trial”	Phase III trials are generally designed to assess the effectiveness of the new intervention and, thereby, its value in clinical practice
“PHN”	postherpetic neuralgia
“polysaccharide”	a carbohydrate that can be decomposed by hydrolysis into two or more molecules of monosaccharides
“PrEP”	pre-exposure rabies prophylaxis
“psoriasis”	a chronic skin disease characterized by circumscribed red patches covered with white scales
“psoriatic arthritis”	a form of arthritis that affects some people who have psoriasis – a condition that features red patches of skin topped with silvery scales

## GLOSSARY OF TECHNICAL TERMS

---

"PVCV"	purified Vero cell vaccines
"R&D"	research and development
"Rabies"	a disease caused by rabies virus transmitted through animal bites to humans and is almost always fatal following the onset of clinical symptoms
"recombinant"	the formation by the processes of crossing-over and independent assortment of new combinations of genes in progeny that did not occur in the parents
"rheumatoid arthritis"	an autoimmune disorder that occurs when the body's immune system mistakenly attacks its healthy tissues, affect the joints and, in some cases, damage a wide range of human body systems, including the skin, eyes, lungs, heart and blood vessels
"RNA"	ribonucleic acid, a polymeric molecule essential in various biological roles in coding, decoding, regulation and expression of genes
"SAE"	severe adverse event
"scFv"	single-chain variable fragment
"SMO"	site management organization, an organization that provides clinical trial-related services to a contract research organization, a pharmaceutical company, a biotechnology company, a medical device company, or a clinical site
"T cell"	cells that originate in the thymus, mature in the periphery, become activated in the spleen/nodes if their T-cell receptors bind to an antigen presented by an MHC molecule and they receive additional co-stimulation signals driving them to acquire killing (mainly CD8+ T cells) or supporting (mainly CD4+ T cells) functions
"T-ALL"	T-lymphocytic leukemia
"titer"	a measurement of the amount or concentration of a substance in a solution
"TM"	a symbol to indicate that the preceding mark that has not been registered at the U.S. Patent and Trademark Office

## GLOSSARY OF TECHNICAL TERMS

---

"TNF- $\alpha$ "	tumor necrosis factor- $\alpha$
"tumor"	an abnormal mass of tissue that forms when cells grow and divide more than they should or do not die when they should. Tumors may be benign (not cancer) or malignant (cancer)
"vaccine"	a vaccine is a biological preparation that provides active acquired immunity to a particular disease
"varicella"	an acute infectious disease caused by the first infection of varicella zoster virus
"varicella-zoster virus" or "VZV"	one of nine herpesviruses known to infect humans, causes chickenpox (varicella) in children and shingles (herpes zoster) in adults
"VEGF"	vascular endothelial growth factor
"VZV gE" or "VZV glycoprotein E"	an antigen that is abundantly expressed on the surface of VZV.

## FORWARD-LOOKING STATEMENTS

---

This document contains certain forward-looking statements relating to our plans, objectives, beliefs, expectations, predictions and intentions, which are not historical facts and may not represent our overall performance for the periods of time to which such statements relate. Such statements reflect the current views of our management with respect to future events, operations, liquidity and capital resources, some of which may not materialize or may change. These statements are subject to certain risks, uncertainties and assumptions, including the other risk factors as described in this document. You are strongly cautioned that reliance on any forward-looking statements involves known and unknown risks and uncertainties. The risks, uncertainties and other factors facing the Company which could affect the accuracy of forward-looking statements include, but are not limited to, the following:

- our business strategies and plans to achieve these strategies;
- our ability to complete the development and obtain the relevant requisite regulatory approvals of our drug candidates;
- our ability to commercialize our approved drugs in a timely manner;
- our future debt levels and capital needs;
- changes to the political and regulatory environment in the industry and markets in which we operate;
- our expectations with respect to our ability to acquire and maintain regulatory licenses or permits;
- changes in competitive conditions and our ability to compete under these conditions;
- future developments, trends and conditions in the industry and markets in which we operate;
- general economic, political and business conditions in the markets in which we operate;
- effects of the global financial markets and economic crisis;
- our financial conditions and performance;
- our dividend policy; and
- change or volatility in interest rates, foreign exchange rates, equity prices, volumes, operations, margins, risk management and overall market trends.

Additional factors that could cause actual performance or achievement to differ materially including but not limited to those discussed in “Risk Factors” and elsewhere in this document. In some cases, we use the words “aim,” “anticipate,” “believe,” “can,” “continue,” “could,” “estimate,” “expect,” “going forward,” “intend,” “ought to,” “may,” “might,” “plan,” “potential,” “predict,” “project,” “seek,” “should,” “will,” “would” and similar expressions to identify forward-looking statements. In particular, we use these forward-looking statements in the “Business” and “Financial Information” sections of this document in relation to future events, our future financial, business or other performance and development, the future development of our industry and the future development of the general economy of our key markets.

## FORWARD-LOOKING STATEMENTS

---

We caution you not to place undue reliance on these forward-looking statements which are based on current plans and estimates, and speak only as of the date they were made. We undertake no obligation to update or revise any forward-looking statements in light of new information, future events or otherwise. Forward-looking statements involve inherent risks and uncertainties and are subject to assumptions, some of which are beyond our control. We caution you that a number of important factors could cause actual outcomes to differ, or to differ materially, from those expressed in any forward-looking statements.

Our Directors confirm that the forward-looking statements are made after reasonable care and due consideration. Nonetheless, due to the risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this document might not occur in the way we expect, or at all. Statements of or references to our intentions or those of any of our Directors are made as of the date of this document. Any such intentions may change in light of future developments.

Accordingly, you should not place undue reliance on any forward-looking statements in this document. All forward-looking statements contained in this document are qualified by reference to this cautionary statement.

## RISK FACTORS

*An [REDACTED] in our H Shares involves significant risks. In particular, we are a biotechnology company seeking to [REDACTED] on the Main Board of the Stock Exchange under Chapter 18A of the Listing Rules on the basis that we are unable to meet the requirements under Rule 8.05(1), (2) or (3) of the Listing Rules. There are unique challenges, risks and uncertainties associated with [REDACTED] in companies such as ours. Potential investors may lose all of their [REDACTED] in the Company given the nature of biotechnology industry. Your [REDACTED] decision should be made in light of these considerations. You should carefully consider all of the information in this document, including the risks and uncertainties described below, as well as our financial statements and the related notes, and the “Financial Information” section, before deciding to [REDACTED] in our H Shares. These factors are contingencies that may or may not occur, and we are not in a position to express a view on the likelihood of any such contingency occurring.*

We believe there are certain risks and uncertainties involved in our operations, some of which are beyond our control. We have categorized these risks and uncertainties into: (i) risks relating to our business and industry, comprising (a) risks relating to the research and development of our product candidates, (b) risks relating to sales and distribution of our product candidates, (c) risks relating to manufacture and supply of our product candidates, (d) risks relating to our cooperation with third parties, (e) risks relating to extensive government regulations, (f) risks relating to our intellectual property rights; (g) risks relating to our financial position and need for additional capital; and (h) risks relating to our general operations; (ii) risks relating to doing business in China; and (iii) risks relating to the [REDACTED].

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 those discussed in this section.

### RISKS RELATING TO OUR BUSINESS AND INDUSTRY

#### Risks Relating to the Research and Development of Our Product Candidates

*Our business and financial prospects depend substantially on the success of our clinical stage and pre-clinical stage product candidates, and we may be unable to successfully complete their clinical development, obtain relevant regulatory approvals or achieve their commercialization, or may experience significant delays in doing so.*

Our ability to generate revenue and realize profitability depends on the successful completion of the development of our product candidates, obtaining necessary regulatory approvals, and manufacturing and commercializing our product candidates, which is contingent upon various factors. Such factors may include:

- successful enrollment in, and completion of, clinical trials, as well as completion of pre-clinical studies and favorable safety and efficacy data therefrom;
- receipt of regulatory approvals;
- enhancing our commercial manufacturing capabilities;



## RISK FACTORS

---

- the performance by CROs or other third parties of their duties to us in manner that complies with our trial protocols and applicable laws and that protects the integrity of the resulting data;
- obtaining, maintaining, protecting and enforcing patent, trade secret and other intellectual property and proprietary protection and regulatory exclusivity, and ensuring we do not infringe, misappropriate or otherwise violate the patent, trade secret or other intellectual property and proprietary rights of third parties;
- successfully launching commercial sales;
- obtaining and/or maintaining favorable governmental and private medical reimbursement;
- efficiently and cost-effectively establishing and enhancing our marketing and distributing capabilities;
- competition with other products and product candidates; and
- continued acceptable safety profile following regulatory approval.

While we have invested a significant portion of our efforts and financial resources in the development, regulatory approval and commercialization of our existing product candidates, and expect to continue doing the same, we may not be able to achieve one or more of the foregoing factors in a timely manner or at all. As a result, we could experience significant delays or inability in obtaining approval for and/or successful commercialization of our product candidates, which would render us unable to achieve our milestones as planned and materially harm our product development prospects.

***We may not successfully complete clinical trials or procedures relating to our product candidates or demonstrate safety and efficacy of our product candidates to the satisfaction of regulatory authorities, and many of our product candidates are in early-stage of clinical trials and thus face higher risks of clinical trial failure.***

Before obtaining regulatory approval for the sale of our product candidates, we must conduct extensive clinical trials to demonstrate their safety and efficacy, but there can be no assurance that such trials will be completed in a timely or cost-effective manner, due to the inherently unpredictable nature of clinical development, and there is no assurance that the results of our clinical trials, including safety and efficacy data, would be what we expect. Furthermore, many of our product candidates are in early-stage of clinical trials and thus face higher risks of clinical trial failure. Specifically, we may experience numerous unexpected events throughout the clinical trials, including but not limited to:

- regulators, institutional review boards or ethics committees not authorizing us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- our inability to reach agreements on acceptable terms with prospective CROs, SMOs and hospitals as trial centers;
- manufacturing issues relating to our own facilities, including problems with manufacturing, supply quality, compliance with good manufacturing practice, or GMP;

## RISK FACTORS

---

- clinical trials producing negative or inconclusive results, and additional clinical trials or abandoning product development programs being required;
- our third-party contractors' failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- our having to suspend or terminate clinical trials for various reasons, including a finding of lack of clinical response or other unexpected characteristics or a finding that participants are being exposed to unacceptable health risks;
- the number of subjects required for clinical trials of our product candidates may be larger, enrollment may be insufficient or slower and the subjects may drop out at a higher rate than we anticipate;
- the cost of clinical trials being greater than we anticipate; and
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials being insufficient or inadequate.

If we experience delays in the completion of, or the termination of, a clinical trial of any of our product candidates because of any of the foregoing events, the commercial prospects of that product candidate will be harmed. Specifically, we may:

- be delayed in obtaining regulatory approval;
- be required to conduct additional clinical trials or other testing beyond those that we currently contemplate;
- not obtain approval for indications that are not as broad as intended;
- be subject to additional post-marketing testing requirements;
- be subject to restrictions on how the product is distributed or used; or
- be unable to obtain reimbursement for the use of the product.

Consequentially, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process, and jeopardize our ability to commercialize our product candidates after obtaining marketing approval and generate related revenues.

### ***Results of earlier clinical trials may not be predictive of results of later-stage clinical trials.***

The results of pre-clinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Our product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through pre-clinical studies and initial clinical trials. Future clinical trial results may not be favorable for these and other reasons. For example, in the BALB/c mice study, LZ901 has induced a stronger cellular

## RISK FACTORS

---

immune response with higher expression of multiple types of immune cell activating biomarkers as compared Shingrix®. However, there is no assurance that results on animal-based studies will be predicative of the results on the clinical trials.

In some cases, there can be significant variability in safety and/or efficacy results between different trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the subject populations, including genetic and biological differences and other trial protocols. As product candidates are developed through pre-clinical to early-to late-stage clinical trials towards approval and commercialization, it is customary that various aspects of the development program, such as manufacturing and formulation, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives. In the case of any trials we conduct, results may differ from earlier trials due to the larger number of clinical trial sites and additional countries and languages involved in such trials. Any of these changes could make the results of planned clinical trials or other future clinical trials we may initiate less predictable and could cause our product candidates to perform differently, which could delay completion of clinical trials, delay approval of our product candidates and/or jeopardize our ability to commence commercialization of our product candidates.

***We may be unable to identify, discover, or develop new product candidates, or to identify additional therapeutic opportunities for our product candidates, in order to expand or maintain our product pipeline.***

Although we continue to design, evaluate and select optimal candidates and continue to enrich our pipeline, we cannot guarantee that we will be successful in identifying potential product candidates. Research programs to pursue the development of our product candidates for additional indications and to identify new product candidates and product targets require substantial technical, financial and human resources and there is no assurance that we may have the depth and breadth in expertise to deliver each of the pipeline product candidates efficiently. Our research programs may initially show promising results in identifying potential indications and/or product candidates, yet fail to yield results for clinical development for a number of reasons. Accordingly, there can be no assurance that we will be able to identify new product candidates or additional therapeutic opportunities for our product candidates or to develop suitable potential product candidates through internal research programs, which could materially and adversely affect our future growth and prospects.

***The data and information that we gather in our research and development process could be inaccurate or incomplete.***

We collect, aggregate, process, and analyze data and information from our preclinical studies and clinical programs. Because data in the healthcare industry is fragmented in origin, inconsistent in format, and often incomplete, the overall quality of data collected or accessed in the healthcare industry is often subject to challenge, the degree or amount of data which is knowingly or unknowingly absent or omitted can be material, and we may discover data issues and errors when monitoring and auditing the quality of our data. If we make mistakes in the capture, input, or analysis of these data, our ability to advance the development of our product candidates may be materially harmed.

We also engage in the procurement of regulatory approvals necessary for the development and commercialization of our product candidates, for which we manage and submit data to governmental entities. These processes and submissions are governed by complex data processing and validation

## RISK FACTORS

---

policies and regulations. Notwithstanding such policies and regulations, interim, top-line or preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data, in which case we may be exposed to liability to a customer, court or government agency that concludes that our storage, handling, submission, delivery, or display of health information or other data was wrongful or erroneous. Even unsuccessful claims could result in substantial costs and diversion of management time, attention, and resources. A claim brought against us that is uninsured or under-insured could harm our business, financial condition and results of operations.

In addition, we rely on third-party collaborators, such as CROs, to monitor and manage data for some of our ongoing preclinical and clinical programs and control only certain aspects of their activities. If any of our CROs or other third party collaborators does not perform to our standards in terms of data accuracy or completeness, data from those preclinical and clinical trials may be compromised as a result, and our reliance on these parties does not relieve us of our regulatory responsibilities. Please see “— Risks Relating to Our Cooperation with Third Parties — As we work with various third parties to conduct a certain number of our pre-clinical studies and clinical trials, we may not be able to obtain regulatory approval for, or commercialize, our product candidates, or experience delay in doing so if these third parties do not successfully carry out their contracted duties or meet expected deadlines” below for more details.

***If we encounter difficulties or delays in enrolling subjects in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.***

The timely completion of clinical trials in line with their protocols depends additionally and specifically on our ability to enroll a sufficient number of subjects who remain in the trial until its conclusion. However, we may experience difficulties in subject enrollment for a variety of reasons, including our product candidates’ targeting diseases, the size and nature of the patient population for such diseases, the public awareness of the infection rates of targeted infectious diseases and the size of population at risks of infection, the subject eligibility criteria defined in the protocol, our investigators or clinical trial sites’ efforts to screen and recruit eligible subjects, the accessibility of trial sites for the subjects, and the subjects’ perceptions as to the potential advantages and side effects of the product candidates being studied in relation to other available products, product candidates or therapies. Moreover, our clinical trials will likely compete with other clinical trials for product candidates that are in the same therapeutic areas as ours, which will reduce the number and types of patients available to us.

Even if we are able to enroll a sufficient number of subjects, delays in subject enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates.

***We rely on third-party testing agencies to obtain testing results of clinical trials of our product candidates, and we may experience delay or obtain inaccurate data due to factors beyond our control.***

We rely on third-party testing agencies, such as clinical trial institutions, to monitor and manage data for some of our ongoing clinical trials and control only certain aspects of their activities. If any of our testing agencies fails to complete testing on time, we may experience delay in obtaining testing results of clinical trials and disclosing data from such clinical trials. For example, we experienced delay in serum sample testing by the NIFDC of the NMPA to obtain exploratory endpoint data to preliminarily

## RISK FACTORS

---

explore the immunogenicity of LZ901 for the Phase I clinical trial due to the COVID-19 outbreak. We cannot guarantee that we will not experience similar delay in sample testing by the NIFDC of the NMPA to obtain exploratory endpoint data in relation to the Phase II clinical trial of LZ901, or any other clinical trials for our product candidates.

In addition, due to the testing uncertainty of the testing agencies in terms of data accuracy or completeness, exploratory endpoint data from those clinical trials may be compromised, and such data of clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials.

***Our product candidates may cause AEs or undesirable side effects, which could interrupt, delay or halt clinical trials, delay or prevent regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following any regulatory approval.***

AEs caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the regulatory authority. Results of our clinical trials, including the ongoing Phase II clinical trial for LZ901 in China and planned clinical trials for LZ901 and K3, could reveal a high and unacceptable seriousness or prevalence of AEs. In such an event, our clinical trials could be suspended or terminated and the relevant regulatory authority could order us to cease further development of, or deny approval of, our product candidates for any or all targeted diseases. AEs related to our product candidates could affect subject recruitment or the ability of enrolled subjects to complete the trial, and could result in potential product liability claims.

Additionally, if one or more of our product candidates receive regulatory approval, and we or others later identify undesirable adverse events caused by such products, a number of potentially significant negative consequences could result, including the following:

- we may suspend the marketing of the product;
- regulatory authorities may withdraw approvals or revoke licenses of an approved product candidate;
- regulatory authorities may require additional warnings on the label of an approved product candidate or impose other limitations on an approved product candidate;
- we may be required to develop a risk evaluation mitigation strategy for the product candidate, or to incorporate additional requirements under the risk evaluation mitigation strategy;
- we may be required to conduct post-market studies; and
- we could be subject to litigation proceedings and held liable for harm caused to patients.

In any such events, we may suspend, delay or alter development or marketing of our product candidates, and the costs thereof may be substantially higher than anticipated.

## RISK FACTORS

---

*In conducting research and development, we face potential liabilities, in particular, product liability claims or lawsuits that could cause us to incur substantial liabilities.*

We face an inherent risk of product liability as a result of clinical trials, if our product candidates cause, are perceived to cause injury, or are found to be otherwise unsuitable during clinical testing. Regardless of the merits or eventual outcome, such liability claims may, among others, result in:

- decreased demand for our product candidates after commercialization;
- injury 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; and
- substantial monetary awards to trial participants or patients.

To cover such liability claims arising from clinical studies, we have purchased clinical trial insurance for all our trials. However, it is possible that our liabilities could exceed our insurance coverage or that our insurance will not cover all situations in which a claim against us could be made. We may also not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise.

*Our efforts in research and development in order to develop, enhance or adapt to new technologies and methodologies may fail to materialize ultimately.*

The global pharmaceutical market is constantly evolving, and we must keep pace with new technologies and methodologies to maintain our competitive position. We must continue to invest significant amounts of human and capital resources to develop or acquire technologies that will allow us to enhance the scope and quality of our clinical trials. We also intend to continue to strengthen our technical capabilities in vaccine and therapeutic biologics discovery, development, and manufacturing, which are capital and time intensive. However, there can be no assurance that we will be able to develop, improve or adapt to new technologies and methodologies, successfully identify new technological opportunities, develop and bring new or enhanced products to market, obtain sufficient or any patent or other intellectual property protection for such new or enhanced products, or obtain the necessary regulatory approvals in a timely and cost-effective manner, or, if such products are introduced, that those products will achieve market acceptance. Any failure to do so may make our techniques obsolete, which could harm our business and prospects.

## RISK FACTORS

---

*We may allocate our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may later prove to be more profitable or for which there is a greater likelihood of success.*

Due to limited financial and managerial resources, we focus our product pipeline on product candidates that we identify for specific indications, and, as a result, we may forgo or delay pursuit of opportunities with other product candidates or for other indications that may later prove to have greater commercial potential or a greater likelihood of success. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may allocate internal resources to a product candidate in a therapeutic area in which it would have been more advantageous to enter into a partnering arrangement.

### **Risks Relating to Sales and Distribution of Our Product Candidates**

*The recession or eradication of the infectious diseases that our vaccine candidates target and the availability of alternative vaccines or treatment technologies may adversely affect our sales.*

The recession or eradication of the infectious diseases in China or globally which our vaccine candidates target will have a significant negative impact on the prospects of our vaccine products. According to Frost & Sullivan, the eradication of the infectious diseases that our vaccine candidates target are highly unlikely. However, if the diseases that any of our vaccine candidates are indicated recess or are effectively eradicated, market demand for the relevant vaccine products will consequently diminish. Moreover, medical technologies are evolving and new vaccines or treatment technologies for the diseases that our vaccine candidates target may emerge. If these competing new vaccines or technologies are perceived by vaccines to be more effective than our vaccine candidates, market demand for our vaccines candidates may decline.

*Failure to secure cooperation with qualified cold-chain logistics providers may cause great risk of damage to our future vaccine products and damage our reputation and business.*

Vaccines are sensitive biological products. Some vaccines are sensitive to freezing, some to heat and others to light. To maintain quality and potency, vaccines must be stored in good conditions through cold-chain logistics providers. The Vaccine Administration Law of the PRC (《中華人民共和國疫苗管理法》) requires cold-chain transportation and storage in the entire delivery process of vaccines in order to ensure constant monitoring and control of temperature, with a record system implemented to keep proper records of the temperature of vaccines during transportation and storage. In order to maintain a reliable vaccine cold chain at manufacture level before delivery to our customers, we need to secure cooperation with qualified cold-chain logistics service providers to store our future vaccine products and diluents within the approved temperature range at all sites, pack and transport vaccines to and from outreach sites according to recommended procedures, and perform regular oversight and monitor on the delivery process to our customers. If we or third parties we cooperated with fail to do so, our future vaccine products may be exposed to inappropriate temperatures or other improper storage conditions and subject to potency diminishment or even potency loss. In that case, all the vaccine products are subject to quality damage and may need to be destroyed.

## RISK FACTORS

---

***We expect to sell most of our future vaccine products to CDCs in China, which exposes us to uncertainties associated with the government funding and budgeting process.***

We expect to derive a substantial portion of our revenue directly or indirectly from sales of our future vaccine products to CDCs, which are affiliated with the PRC government. We are accordingly exposed to various risks relating to conducting business with the government. As CDCs are generally required to seek approvals from local governments before making any purchase of vaccines, their demand for our products and their ability to make timely payment may be affected by government budgetary cycles, fluctuating availability of public funds and changes in policy. In addition, we have no influence over government procurement decisions, and CDCs may request to reduce or even cancel orders, or demand price adjustments or other changes under certain conditions. Funding reductions, delays in payment or unilateral demands by CDCs could adversely impact our business and make it difficult for us to allocate resources or anticipate demand for our products.

***Our product candidates may be excluded or removed from national, provincial or other government-sponsored medical insurance programs.***

Under medical insurance programs in the PRC, patients are entitled to reimbursement of all or a portion of the cost of pharmaceutical products listed in the National Reimbursement Drug List, the NRDL, the relevant provincial reimbursement drug lists, the PRDLs, or other medical insurance reimbursement lists. However, such inclusion is based on a variety of factors, including clinical needs, use frequency, efficacy, safety and price, which may be outside of our control. Moreover, the relevant PRC government authorities may also, from time to time, review and revise, or change the scope of reimbursement for, the products that are included in the medical insurance reimbursement lists. Currently herpes zoster vaccine, varicella and rabies vaccines are prophylactic vaccines which are not included in the NRDL. K193, K333, K1932 are Class A innovative biological products. There is no similar products in this category covered by NRDL. Therefore, our vaccine product candidates, K193, K333 and K1932 are unlikely to be included in the NRDL. Not being included under the NRDL would not affect the pricing of our product candidates as we would price our product candidates at market price. However, if peer products are included in the NRDL, our peer products will gain market competitive advantage in market penetration, which would cause market pressure on our product candidates.

There can be no assurance that our future approved products will be included in any medical insurance reimbursement list. Similarly, to the extent that our future approved product are not included in any medical insurance reimbursement list or if any such insurance schemes are changed or canceled which result in any removal of products from medical insurance catalog, patients may choose, CDCs and hospitals may recommend alternative treatment methods, which would reduce demand for our products, and our sales may be adversely impacted.

***We may need to lower our product price in order to qualify for medical insurance reimbursement or due to market competition.***

We may need to lower the prices of our future approved products in order to have them included in the medical insurance reimbursement lists, while such price cut and reimbursement may not necessarily lead to increased sales. As a result, even if they were so included, our potential revenue from the sales thereof could still decrease as a result of the significantly lowered prices.



## RISK FACTORS

---

In addition, it is typical that the prices of pharmaceutical products will decline over the life of the product as a result of, among other things, increased competition from substitute products, the tender process by CDCs, hospitals or government authorities, pricing policies of the relevant government authorities, or voluntary price adjustments by pharmaceutical companies. Any downward adjustments or pricing pressure of our existing or future approved products could have a material and adversely effect on our business and results of operations.

***Our future approved products may fail to achieve the degree of market acceptance by CDCs, local vaccination sites and clinics, physicians, KOLs, patients, third-party payers and others in the medical community necessary for commercial success.***

The commercial success of our future approved products depends upon the degree of market acceptance they can achieve, particularly among CDCs, patients, hospitals and physicians, which is contingent upon a number of factors. Such factors may include:

- the clinical indications for which the product are approved;
- the safety and efficacy of the product;
- the potential and perceived advantages and disadvantages of the product, relative to competing products or treatments;
- treatments compared to alternative products and treatments; and
- the effectiveness of our sales and marketing efforts.

If our future approved products fail to achieve or maintain widespread market acceptance, or if new products introduced by our competitors are perceived more favorably by healthcare practitioners and patients, are more cost-effective or otherwise render our products obsolete, the demand for our products may decline.

***Because some of our vaccine candidates are intended to prevent diseases of major public health concerns, we are at risk of governmental actions detrimental to our business, such as price controls or waivers on vaccine patent.***

In response to infectious diseases or the perceived risk of infectious diseases, governments in China and other countries may take actions to protect their citizens, including but not limited to, intellectual property expropriation, compulsory licenses and/or strict price controls. These actions could affect our ability to control the production and our ability to generate revenue from sales of our vaccine products, if approved, or otherwise impose burdensome regulations on our business. Additionally, we may need to, or we may be required by governmental or non-governmental authorities to, set aside our future approved vaccine products, for designated purposes or geographic areas, and subject to requirements on allocation of supply. For example, there may be further price adjustment for K3 in the next round of National Drug Price Negotiation (國家醫藥談判). The price control along with the fierce competition in the market may significantly impact the profitability of K3. We are also likely to face significant public attention and scrutiny over any future business models and pricing decisions with respect to our future vaccine products.

## RISK FACTORS

---

***We may not bid in the public tender process successfully and we may fail to secure subsequent product orders.***

We are required to participate in the public tender process held by different levels of CDCs in order to sell our future vaccine products in the PRC. Public tenders for Class I vaccines are held by national or provincial-level CDCs. Public tenders for Class II vaccines are held by provincial-level CDCs. Once we win a public tender, we will be eligible for selling vaccine products to CDCs. For our future therapeutic biologics products, we have to submit bids in a centralized tender process to supply our products to public hospitals and other medical institutions in the PRC at specified prices. Each public medical institution in China must generally procure drugs through a provincial centralized drug purchase platform, and make substantially all of its purchases of pharmaceutical products through a centralized tender process.

Our bids during the public tender process may not be successful and our future products may not be chosen for the following reasons:

- our prices are not competitive;
- our products are perceived to be less clinically effective than competing products;
- our service quality or any other aspect of our operation is perceived not to meet relevant requirements; or
- our reputation is adversely affected by unforeseeable events.

If we fail to participate or bid successfully during any public tender process, we will not be able to sell our future approved products to the relevant CDCs, public hospitals and other medical institutions.

Even if we bid successfully, we cannot guarantee that we will be able to secure purchase orders from local CDCs. For our existing vaccine candidates, if approved, public tenders serve as an admission for entry to market, typically for one year and in certain situations two or three years, without a specified volume, and the relevant CDCs will negotiate with us on the actual supply volume based on each CDC's demand. Therefore, winning the public tender does not guarantee that we will make sales to local CDCs and we may fail to secure subsequent product orders from local CDCs after we bid successfully at the higher level of CDCs.

***The actual market size of our product candidates may be smaller than we anticipate, which could render some product candidates ultimately unprofitable even if commercialized.***

Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products, since the market opportunities for our product candidates may be smaller than we anticipate. The total addressable market opportunity will depend on, among other things, acceptance of the product by the medical community and patient access, product pricing and reimbursement. Moreover, the number of patients in the addressable markets may turn out to be lower than expected, patients may not be amenable to treatment with our products, or new patients may become increasingly difficult to identify or access. Further, new studies may change the estimated incidence or prevalence of the diseases that our product candidates target. Any of the above unfavorable developments could have a material adverse effect on our business, financial condition and

## RISK FACTORS

---

results of operations. For example, the growth of herpes zoster vaccine market depends on the increased public health awareness, the lack of effective treatment and other uncertain factors, and the number of patients may turn out to be lower than expected, which may have an adverse effect on the prospect of our Core Product, LZ901.

***We may be unable to conduct effective academic marketing.***

Effective marketing and successful sales are crucial for us to increase the market penetration of our future products, expand our coverage of CDCs, hospitals and other medical institutions and promote new products in the future. In particular, we will place a strong emphasis on academic marketing, through which we promote our products to medical professionals, CDCs and hospitals. While we will actively work with medical professionals, CDCs and hospitals and endeavor to convince them as to the distinctive characteristics, advantages, safety and efficacy of our product candidates as compared to our competitors’ products, we may not be able to successfully enhance our product awareness and receive recognition from them.

***We may fail to establish and maintain a qualified sales and marketing force.***

Sales efforts of pharmaceutical products necessitates our sales and marketing force to possess a relatively high level of technical knowledge, up-to-date understanding of industry trends, necessary expertise in the relevant therapeutic areas and products, as well as sufficient promotion and communication skills. However, there is no assurance that there will be a sufficient amount of competent sales professional with the relevant disease knowledge, academic KOLs or doctor networks available in the market. As a result, if we are unable to effectively recruit and train our in-house sales representatives or monitor and evaluate their academic marketing performances, our sales and marketing may be less successful than desired.

When the competition for experienced marketing, promotion and sales personnel becomes intense, we may be unable to attract, motivate and retain a sufficient number of marketing, promotion and sales professionals. Consequentially, sales volume of our products may be adversely affected and we may be unable to expand our hospital coverage or increase our market penetration as contemplated.

***We operate in a competitive environment, and we may not be able to compete effectively against current and future competitors.***

The pharmaceutical industries are characterized by rapid changes in technology, constant enhancement of industrial know-how and frequent emergence of new products, which renders our targeted markets highly competitive. For example, our Core Product, LZ901, if approved, will be primarily competing against existing commercialized vaccine products, such as Shingrix<sup>®</sup> developed by GlaxoSmithKline plc and other herpes zoster vaccine candidates under development by domestic competitors. Specifically, we may fail to achieve market penetration and acceptance for LZ901 considering that (i) Shingrix<sup>®</sup> has first-mover advantages and captured almost 100% of the global and Chinese market share in terms of sales revenue in 2021 as the only commercialized product in China at that time, and there are several domestic herpes zoster vaccines under development. In addition, peer products under development overseas may also seek market approval for commercialization in China; (ii) LZ901 may not be in more advanced clinical stage compared to peer products under similar development stages as the duration of clinical trial for herpes zoster vaccine is relatively short; (iii) BCHT Biotechnology’s Gan Wei (感維) may be more affordable due to potentially lower production cost and only one dose required; and (iv) there is emerging innovative technology, such as mRNA-based shingles vaccine. For more details, please see “Industry Overview — Herpes Zoster Vaccine Market” in this document.

## RISK FACTORS

In addition, K3, as one of our product candidates, is expected to primarily compete with biosimilars of adalimumab that have been launched or currently under development. According to Frost & Sullivan, (i) as of the Latest Practicable Date, there were six biosimilars of adalimumab approved in China and 10 biosimilars of adalimumab in development in China; and (ii) the average selling price of Humira<sup>®</sup> (under which brand name adalimumab is marketed by AbbVie Inc) per unit in China decreased from RMB5,572 in 2019 to RMB1,258 in 2020 and there may be further price adjustment for K3 in the next round of National Drug Price Negotiation (國家醫藥談判). For more details, please see “Industry Overview — Adalimumab Injectable Market” in this document. The fierce competition in the market and the price control may significantly impact the profitability of K3. Therefore, we may fail to achieve market penetration and acceptance for K3 if we do not have sufficient production capacity to lower production cost and improve the profitability and competitive strength of K3.

Many of our competitors, including foreign pharmaceutical companies and large state-owned pharmaceutical companies, may have substantially greater clinical, research, regulatory, manufacturing, marketing, financial and human resources than we have. Certain of our competitors may be actively engaged in research and development in areas where we have products or where we are developing product candidates. Other companies may discover, develop, acquire or commercialize products more quickly or more successfully than we do. Moreover, there may also be significant consolidation in the pharmaceutical industry among our competitors, or alliances developed among competitors that may rapidly acquire significant market share. Furthermore, our competitors may apply for and obtain marketing approvals in China or other countries for products with the same intended use as our product candidates more rapidly than we do. The capacity of the relevant authorities, such as the NMPA, to concurrently review multiple marketing applications for the same type of innovative drug may be limited, therefore such authorities’ schedule to review our product candidates may be delayed when our product candidates are under the authorities’ concurrent review with our competitors’ products, and the registration process of our product may be prolonged.

***Counterfeits of our product candidates could negatively affect our sales, damage our reputation and brand names, and expose us to liability claims.***

Our product candidates are subject to the risk of being imitated by certain products distributed or sold in the pharmaceutical markets that are manufactured without proper licenses or approvals, or fraudulently mislabeled with respect to their content or manufacturer, i.e., counterfeit pharmaceutical products. The counterfeit pharmaceutical product control and enforcement system, particularly in developing markets such as the PRC, may be inadequate to discourage or eliminate the manufacturing and sale of counterfeit pharmaceutical products.

Since counterfeit pharmaceutical products are generally sold at lower prices than authentic pharmaceutical products, and are in some cases very similar in appearance to authentic pharmaceutical products, counterfeit products imitating our product candidates can quickly erode our sales volume of the relevant products or product candidates. Moreover, counterfeit products may or may not have the same chemical composition as our product candidates, which may make them less effective than our product candidates, entirely ineffective or more likely to cause severe adverse side effects. This could expose us to negative publicity, reputational damage, fines and other administrative penalties, and may even result in litigation against us. Moreover, the continuing presence of counterfeit pharmaceutical products may reinforce the negative image of distributors and pharmacies among consumers in general, and may severely harm the reputation and brand names of our product candidates in specific.

## RISK FACTORS

---

*Our vaccine candidates, once approved, may not to be included in the National Immunization Program, which could put our product candidates at a competitive disadvantage.*

According to Frost & Sullivan, our vaccine candidates, once approved, are not likely to be included in the National Immunization Program, which primarily aims to protect children in China. When determining the types of vaccines to be included in the National Immunization Program, the government would consider various factors, such as the prevalence of infectious diseases, disease burden, effectiveness and safety of the vaccine, the supply capacity of vaccine manufacturers, adequate government funds and social benefits. LZ901 is mainly for adults aged 50 years and older, therefore, it is unlikely to be included in the National Immunization Program in China or similar programs in the U.S. in the foreseeable future. Human rabies vaccine aims to help protect people at risk of being exposed to rabies, regardless of their age, and therefore, it is unlikely that recombinant human rabies vaccine will be included in the National Immunization Program in China. For varicella vaccine, although several economically developed cities in China, such as Beijing, Tianjin and Shanghai, have implemented policies to provide free varicella vaccination for children, it is less likely to be included in the National Immunization Program in the next three to five years since the costs will be very high for the nation to provide free varicella vaccination. Not being included under the National Immunization Program or regional equivalent immunization programs would not affect the pricing of our product candidates as we would price our product candidates at market price. However, if peer products are included under the National Immunization Program or regional equivalent immunization programs, our peer products will gain market competitive advantage in market penetration, which would cause market pressure on our product candidates. For details, please see “Business — Our Products And Product Candidates — Our Core Product and Clinical-Stage Product Candidates” in this document.

### **Risks Relating to Manufacture and Supply of Our Product Candidates**

*Manufacturing pharmaceutical products on a large commercial scale is highly exacting and complex, and we may encounter problems during the process.*

The manufacturing of pharmaceutical products is highly exacting and complex, and problems may arise during manufacturing for a variety of reasons, including but not limited to:

- equipment malfunction;
- failure to follow specific protocols and procedures;
- changes in product specification;
- low quality or insufficient supply of raw materials;
- delays in the construction of new facilities and limits to manufacturing capacity due to regulatory requirements;
- changes in the types of products produced;
- advances in manufacturing techniques;
- physical limitations that could inhibit continuous supply;

## RISK FACTORS

---

- man-made or natural damages, other disasters and environmental factors; and
- shortage of qualified personnel or key contractors.

If problems arise during the production of a batch of product, that batch of product may have to be discarded and we may experience product shortages or incur added expenses. This could, among other things, lead to increased costs, lost revenue, damage to customer relationships, time and expense spent investigating the cause and, depending on the cause, similar losses with respect to other batches or products. If problems are not discovered before the product is released to the market, recall and product liability costs may also be incurred.

Furthermore, manufacturing methods and formulation are sometimes altered through the development of product candidates from clinical trials to approval, and further to commercialization, in an effort to optimize manufacturing processes and results. Such changes carry the risk that they will not achieve these intended objectives, and any of these changes could cause the product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. This could delay the commercialization of our product candidates and require bridging studies or the repetition of one or more clinical trials, which may result in increases in clinical trial costs, delays in regulatory approvals and jeopardize our ability to commence product sales and generate revenue.

We may also encounter problems with achieving adequate or clinical-grade products that meet the NMPA, FDA or other comparable regulatory authority standards or specifications, and maintaining consistent and acceptable production costs. We may also experience shortages of qualified personnel, raw materials or key contractors, and experience unexpected damage to our facilities or the equipment in them. In such events, we may be required to delay or suspend our manufacturing activities. We may be unable to secure temporary, alternative manufacturers for our products with the terms, quality and costs acceptable to us, or at all. It could delay our clinical trials and/or the availability of our future approved products for commercial sale. Moreover, we may spend significant time and costs to remedy these deficiencies before we can continue production at our manufacturing facilities.

In addition, the quality of our product candidates manufactured by us for research and development purposes and, in the future, drugs manufactured by us for commercial use, depends significantly on the effectiveness of our quality control and quality assurance, which in turn depends on factors such as the production processes used in our manufacturing facilities, the quality and reliability of equipment used, the quality of our staff and related training programs and our ability to ensure that our employees adhere to our quality control and quality assurance protocol. However, there is no assurance that our quality control and quality assurance procedures will be effective in consistently preventing and resolving deviations from our quality standards. Any significant failure or deterioration of our quality control and quality assurance protocol could render our products unsuitable for use, or not in compliance with the relevant requirements of the GMP and/or harm our market reputation and relationship with business partners. Any such developments may have a material adverse effect on our business, financial condition and results of operations.

## RISK FACTORS

---

***Any failure to perform proper quality control and quality assurance would have a material adverse effect on our business and financial results.***

Our product candidates and manufacturing processes are subject to applicable laws, regulations and GMP requirements. These regulations and laws govern the manufacturing processes and procedures, such as record keeping, operating and implementing the quality management systems to control and assure the quality of products approved for sale and investigational products. We have established a comprehensive and robust quality control system in our production and sales process. Please see “Business — Quality Control and Assurance” in this document for details. Despite our quality control system and procedures, errors, defects or failures may still occur. Quality defects may be attributable to a number of reasons, including:

- quality issues with the raw materials we purchase or produce;
- manufacturing errors;
- technical or mechanical malfunctions in the production process;
- human error or malfeasance by our quality control personnel;
- tampering by third parties; and
- other failure to comply manufacturing procedures and quality control requirements under applicable laws and GMP.

We have an R&D and pilot manufacturing facility located in Beijing, China to supply materials for our pre-clinical studies and early-stage clinical trials. In addition, we are currently building new manufacturing facilities in Zhuhai to expand our production in preparation for commercialization of our pipeline candidates, which are expected to meet the GMP requirements of the NMPA, the FDA, the EMA and related ICH guidelines. Please see “Business — Manufacturing” in this document for more details. We may not be able to ensure consistent quality control in such new facilities after they come into operation. If we acquire manufacturing facilities from other biotechnology or pharmaceutical companies in the future, we may not be able to immediately ensure that their manufacturing facilities and processes will meet our existing quality standards. Failure to detect and cure quality defects in our future products or to prevent such defective products from being released for sale, failure to comply with relevant quality control requirements under applicable laws or GMP, or failure or deterioration of our quality control system and processes, could result in vaccinees or patients’ injury or death, product destroy, recalls or withdrawals, suspension or disruption in product manufacturing, license revocation or regulatory fines, or other problems that could disrupt our business, seriously harm our reputation, expose us to liability, and adversely affect our results of operations.

***Delays in completing and receiving regulatory approvals for our manufacturing facilities could delay our development plans or commercialization efforts.***

Our existing and planned manufacturing facilities as well as our manufacturing process will be subject to ongoing, periodic inspection by the NMPA or other comparable regulatory agencies to ensure compliance with GMP, which is usually the pre-requisite to obtain marketing approval. Moreover, for our manufacturing facilities and other premises, we must obtain various permits, certificates and other approvals from the relevant administrative authorities at various stages of property development,

## RISK FACTORS

---

including, for example, planning permits, construction permits, land use rights certificates, certificates for passing environmental assessments, certificates for passing fire control assessments, certificates for passing construction completion inspections and ownership certificates. Failure to comply with applicable regulations could lead to increased expense and result in sanctions being imposed on us, including fines, injunctions, civil penalties, requirement to suspend or put on hold one or more of our clinical trials, failure of regulatory authorities to grant marketing approval of our product candidates, delays, suspension or withdrawal of approvals, supply disruptions, license revocation, seizures or recalls of products or product candidates, operating restrictions and criminal prosecutions, any of which could harm our business.

***We may encounter substantial disruption to our production sites on problems in manufacturing our product candidates.***

We are dependent on our manufacturing facilities in Beijing and Zhuhai. The continued operation of our manufacturing facilities and our production safety may be substantially interrupted due to a number of factors, many of which are outside of our control. These may include fire, flood, earthquakes, power outages, fuel shortages, mechanical breakdowns, terrorist attacks and wars, or other natural disasters, as well as loss of licenses, certifications and permits. In addition, changes in governmental planning for the land underlying these facilities or their vicinity and regulatory changes, could also disrupt our operations, including relocation of our existing office and manufacturing facilities to a different site. If the operation of any of our manufacturing facilities is substantially disrupted, we may not be able to replace the equipment or inventories at such facilities or use different sites or a third party contractor to continue our production in a legal, timely and cost-effective manner or at all. Although we maintain property insurance for certain properties, machinery and equipment and other assets owned, operated or deemed important for us, in line with industry practice in China, we do not have certain types of insurances, such as business interruption insurance. Thus, the amount and nature of our insurance coverage may not be sufficient to cover any substantial losses in the event of a significant disruption to any of our manufacturing facilities.

***Our future vaccine and therapeutic biologics products, like any other biologic product, may involve risks of contamination.***

Vaccine and therapeutic biologics products manufacturing usually requires cultivation steps, including growth of the appropriate organism and the use of substances of animal origin, which makes it easy to introduce a contaminant and to amplify low levels of contamination. In addition, cross-contamination could result from manufacturing activities at shared equipment and facilities, which are common. Other activities such as diagnosis and research are frequently linked to manufacturing, which may create opportunities for cross-contamination. Furthermore, improper actions during the long-distance transportation, storage and delivery services may also result in contamination.

In the event of contamination or injury resulting from such contamination, we could be subject to liabilities for any resulting damages to vaccinees and patients, product recalls, confiscation and/or destroy. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with laws and regulations. In addition, contamination of our products could cause customers or other third parties with whom we conduct business to lose confidence in our products' quality and the reliability of our manufacturing procedures, which could adversely affect our sales and profits. In addition, contaminated products that are unknowingly distributed could result in harm on patients, threaten the reputation of our products and expose us to product liability claims, criminal charges and administrative sanctions.



## RISK FACTORS

---

***We may not be able to meet the increasing demand for our product candidates by ensuring that we have adequate manufacturing capacity, or to successfully manage our anticipated growth.***

To produce our increasing number of product candidates, if approved, in the quantities that we believe will be required to meet anticipated market demand, we may need to increase, or “scale up,” our production capacity over the initial level of production by constructing new manufacturing facilities and production lines. However, our ability to successfully implement our expansion plan for increasing production capacities is subject to a number of risks and uncertainties, including, but not limited to, the risk of construction delays and delays in equipment procurement, and our ability to timely recruit sufficient qualified staff to support the increase in our production capacity. If we are unable to do so, are delayed, the cost of this scale up is not economically feasible for us, or we cannot find a third-party manufacturer, we may not be able to product our future approved product candidates in sufficient quantities to meet future demand. Moreover, our plans to increase our production capacities require significant capital investment, and the actual costs of our expansion plan may exceed our original estimates, which could adversely affect the return on our expenditure.

Furthermore, given the size of our existing and planned manufacturing facilities, we may not be able to fully utilize them immediately or within a reasonable period of time after we commence operation. During the construction and ramp up period, 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.

***Fluctuations in prices of our raw materials may have a material adverse effect on us.***

In order to manufacture our product candidates, if approved, we must obtain sufficient quantities of high-quality raw materials at commercially acceptable prices and in a timely manner, which exposes us to risks associated with fluctuations in prices of raw materials. The prices of our raw materials may be affected by a number of factors, including market supply and demand, the PRC or international environmental and regulatory requirements, natural disasters such as the outbreak of COVID-19 and the global economic and political conditions. We may have limited capability to transfer the increasing costs of raw materials to our customers in a timely manner, and a significant increase in the costs of raw materials may increase our cost of sales and negatively affect our profit margins.

***If we fail to obtain regulatory approval in any targeted jurisdictions outside of China, we will not be able to market our products in those jurisdictions. If we obtain approval to commercialize our product candidates outside of China, we could face a variety of risks associated with international operations.***

We are subject to the laws and regulations in relation to obtaining regulatory approval in China. In addition, we may decide to market certain of our product candidates, if approved, in jurisdictions outside of China, such as the U.S. Penetration in any overseas market will require separate regulatory approvals in each market and compliance with numerous and varying regulatory requirements. The approval procedures vary among regions and countries which may involve requirements for additional testing, and the time required to obtain approval may differ from that required to obtain NMPA approval. Our limited experience in overseas markets may expose us to risks and uncertainties, including but not limited to the risks associated with the following:

- dealing with regulatory regimes, regulatory bodies and government policies which may differ materially from those in the PRC or with which we may be unfamiliar;

## RISK FACTORS

---

- substantial time which may be required for us to obtain approval for registering and selling our products;
- commercializing our approved product candidates in new markets where we have limited experience with the dynamics and no sales and marketing infrastructure;
- higher costs for product development and reliance on overseas partners for the development, commercialization and marketing of our product candidates;
- products related and professional liability litigation and regulatory scrutiny arising from the marketing and sale of products in overseas markets and the costs incurred dealing with such procedures, as well as our ability to obtain insurance to adequately protect us from any resulting liabilities;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness and inflation;
- difficulty of effective enforcement of contractual provisions in local jurisdictions;
- compliance with tax, employment, immigration and labor laws for employees traveling abroad;
- the effects of applicable foreign tax structures and potentially adverse tax consequences;
- currency fluctuations, which could result in increased operating expenses and reduced revenue;
- workforce uncertainty and labor unrest; and
- business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters, including earthquakes, volcanoes, typhoons, floods, hurricanes and fires.

In addition, in many countries outside China, the prices that we intend to charge for our products may also be subject to approval. Approval by the NMPA does not ensure approval by regulatory authorities in other countries or other jurisdictions. Similarly, approval by one foreign regulatory authority does not imply the approval by regulatory authorities in other foreign countries or by the NMPA. The foreign regulatory approval process may include all of the risks associated with obtaining NMPA approval. We may not obtain foreign regulatory approvals on a timely basis, if at all. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our vaccines in any market.

In addition, if we obtain such regulatory approval and decide to market certain of our product candidates in international markets, we expect that we will be subject to additional risks in commercializing our product candidates outside of China, including:

- different regulatory requirements for vaccines and biologics in foreign countries;

## RISK FACTORS

---

- weakened protection for our intellectual property rights, or more aggressive protection of our competitors’ intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements; economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad; foreign currency fluctuations and remittance limitations; workforce uncertainty in countries where labor unrest is more common than in China;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism or natural disasters including earthquakes, typhoons, floods and fires.

### **Risks Relating to Our Cooperation with Third Parties**

*We may not realize any or all benefits of collaboration, alliances or licensing arrangements, and disputes may arise between us and our current or future collaboration partners.*

We have in the past formed, and may in the future seek and form, strategic alliances, joint ventures or other collaborations, including entering into licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our existing product candidates and any future product candidates that we may develop. Our strategic collaboration with partners involves numerous risks. First, we may not achieve the revenue and cost synergies expected from the transactions, as such synergies are inherently uncertain and subject to significant business, economic and competitive uncertainties and contingencies, many of which are difficult to predict and are beyond our control. Also, the synergies from our collaboration with our partners may be offset by other costs incurred in the collaboration, increases in other expenses, operating losses or problems in the business unrelated to our collaboration.

We out-licensed Inactivated EV71 Vaccine to Zhifei Biopharma and out-licensed K11 to Beijing Science Sun. Please see “Business — Our Products and Product Candidates — Our Other Historically Developed Products” in this document for details. Under relevant licensing arrangements, we will receive royalties or other payments from Zhifei Biopharma and Beijing Science Sun based on how they commercialize the products they develop under the licensing arrangement. In addition, we do not have plans or intention for out-licensing of any product candidate in China. However, for overseas market, we plan to collaborate with multinational pharmaceutical companies who have a robust sales and marketing network to rapidly commercialize LZ901 globally and may develop corresponding out-licensing or collaboration strategies in the global market outside China and Southeast Asia for the commercialization of LZ901. Please see “Business — Commercialization” in this document for details. Although we carefully select business partners that have the financial resource and capability to develop products when seeking out-licensing or transfer, and after the out-licensing or transfer we communicate with our collaboration partners, approximately once a quarter and on an irregular basis for related technologies for

## RISK FACTORS

---

Beijing Science Sun and from time to time for Zhifei Biopharma, to monitor the progress of product development, we may still be subject to the following risks under licensing arrangements:

- our collaboration partners may delay their drug development plan, including clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a drug candidate, repeat or conduct new clinical trials or require a new formulation of a drug candidate for clinical testing;
- our collaboration partners may not pursue development and commercialization of drug candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in their strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- our collaboration partners with marketing and distribution rights to one or more of our drug candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such drug candidates.

Moreover, disputes may arise between us and our current or future collaboration partners. Such disputes or our partners’ failure to fully perform their obligations may cause delay or termination of the research, development or commercialization of our product candidates, or result in costly litigation or arbitration that diverts management attention and resources. In specific, international business relationships subject us to additional risks that may materially and adversely affect our ability to attain or sustain profitable operations, including: (i) difficulty of effective enforcement of contractual provisions in local jurisdictions; and (ii) third-party collaborators may not properly obtain, maintain, protect or enforce our patent, trade secret and other intellectual property rights and regulatory exclusivity for our product candidates or may use our intellectual property in such a way as to invite litigation or other intellectual property-related proceedings that could jeopardize or invalidate our intellectual property or expose us to potential litigation or other intellectual property-related proceedings.

***As we work with various third parties to conduct a certain number of our pre-clinical studies and clinical trials, we may not be able to obtain regulatory approval for, or commercialize, our product candidates, or experience delay in doing so if these third parties do not successfully carry out their contracted duties or meet expected deadlines.***

We rely on third parties, including clinical trial institutions, public hospitals, CROs and SMOs, to assist us in designing, implementing and monitoring our clinical trials. We rely on these parties for execution of our preclinical studies and clinical trials, and control only certain aspects of their activities. If any of these parties terminates its agreements with us, we may not be able to enter into arrangements with alternative third parties on commercially reasonable terms, or at all, and the development of the product candidates covered by those agreements could be substantially delayed. In addition, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocols, legal and regulatory requirements and scientific standards, and our reliance on these third parties does not relieve us of our regulatory responsibilities. However, these third parties may not successfully carry out their contractual obligations, meet expected deadlines or follow regulatory requirements, including clinical and manufacturing guidelines and protocols. Moreover, if any of these parties fail to perform their obligations under our agreements with them in the manner specified in those agreements, the NMPA, the FDA and/or other comparable regulatory authorities may not accept the data

## RISK FACTORS

---

generated by those studies or relevant regulatory authorities may require us to perform additional clinical trials before approving our marketing applications, which would increase the cost of and the development time for the relevant product candidate. If any of the preclinical studies or clinical trials of our product candidates is affected by any of the above-mentioned reasons, we will be unable to meet our anticipated development or commercialization timelines, which would have a material adverse effect on our business and prospects.

***We are exposed to various supply chain risks as we depend on a stable, adequate and quality supply of raw materials, technical services, equipment and infrastructure construction services, and any price increases or interruptions of such supply may have a material adverse effect on our business.***

Our business operations are exposed to various supply chain risks. During the Track Record Period, we relied on third parties to supply raw materials and technical, construction and other services. We expect to continue to rely on third parties to supply such raw materials and services for the research, development, manufacturing and commercialization of our product candidates. See "Business — Suppliers" in this document.

Currently, the raw materials and the services are supplied by multiple source suppliers. In addition, 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. Any disruption in production or the inability of our suppliers to produce adequate quantities to meet our needs could impair our operations and the research and development of our product candidates.

Moreover, we require a stable supply of raw materials for our product candidates in the course of our research and development activities, and such needs are expected to increase significantly once we enter commercial production of products upon receipt of marketing approvals. However, there can be no assurance that current suppliers have the capacity to meet our demand. Any delay in receiving such materials in the quantities and of the quality that we need could delay the completion of our clinical studies, regulatory approvals of our product candidates or our ability to timely meet market demand for our commercialized products, as applicable. Our suppliers may not be able to cater to our growing demands or may reduce or cease their supply of materials to us at any time.

We are also exposed to the possibility of increased costs, which we may not be able to pass on to customers and as a result, lower our profitability. In the event of significant price increases for such materials, there is no assurance that we will be able to raise the prices of our future products sufficiently to cover the increased costs. As a result, any significant price increase for our needed materials may have an adverse effect on our profitability. Additionally, although we have implemented quality inspection on the materials before using them in the manufacturing process, there is no assurance that we will be able to identify all of the quality issues.

In addition, there can be no assurance that these third parties will be able to maintain and renew all licenses, permits and approvals necessary for their operations or comply with all applicable laws and regulations. Failure to do so by them may lead to interruption in their business operations, which, in turn, may result in shortage of the services, materials and equipment supplied to us, and cause delays in clinical trials and regulatory filings, or the recall of our products. The noncompliance of these third parties may also subject us to potential product liability claims, cause us to fail to comply with the continuing regulatory requirements, and incur significant costs to rectify such incidents of noncompliance, which may have a material and adverse effect on our business, financial condition and results of operation.

## RISK FACTORS

---

### Risks Relating to Extensive Governmental Regulations

*All material aspects of the research, development, manufacturing and commercialization of our product candidates are heavily regulated.*

All jurisdictions in which we intend to conduct our research, development, manufacturing and commercialization activities regulate these activities in great depth and detail. Obtaining regulatory approvals and maintaining compliance with applicable laws and regulations is a lengthy, expensive and uncertain process, which requires the expenditure of substantial time and financial resources. Failure to comply with the applicable requirements at any time during the product 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.

*The regulatory approval processes of the NMPA, FDA and other comparable regulatory authorities are lengthy, time-consuming and inherently unpredictable.*

The process to obtain approval by the NMPA, FDA other comparable regulatory authorities typically takes years following the commencement of pre-clinical studies and clinical trials, and is inherently unpredictable. Specifically, we could fail to receive regulatory approval for our product candidates for many reasons, including:

- failure to begin or complete clinical trials due to disagreements with regulatory authorities;
- failure to demonstrate a product candidate's safety and efficacy;
- failure of clinical trial results to meet the level of statistical significance required for approval;
- data integrity issues related to our clinical trials;
- government authority's disagreement with our interpretation of data from pre-clinical studies or clinical trials;
- government authority's requirement of additional information, including pre-clinical and clinical data, to support approval; 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.

All these factors, among others, may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program.

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

## RISK FACTORS

---

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 there is no assurance that we will be able to meet regulatory requirements of different jurisdictions. Also, our failure to obtain regulatory approval in any country may delay or have negative effects on the process for regulatory approval in other countries.

***Approval pathway for biosimilars in China remains fluid, which may adversely affect the regulatory approval of our biosimilar product candidate.***

The Guidelines for the R&D and Evaluation of Biosimilar Drugs (for Trial Implementation) (《生物類似藥研發與評價技術指導原則(試行)》) and 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》) (collectively, the “**Biosimilar Guidelines**”), which are the prevailing PRC guidelines on biosimilar evaluation, outline the technical guidance for biosimilars, aiming to move toward a clear industry structure for the research and development and evaluation of biosimilars. The Biosimilar Guidelines do not offer an alternative pathway for launching biosimilar products in China; rather, under Biosimilar Guidelines, biosimilars are essentially subject to the same approval pathway as novel biologics, only with a different set of data requirements. Applicants must mark in their IND applications and NDAs that submissions are intended to be reviewed as biosimilars. In addition, various uncertainties surrounding the application and interpretation of the Biosimilars Guidelines could adversely affect the regulatory approval of our existing biosimilar product candidate, K3, as well as other biosimilars we may develop in the future. Uncertainties surrounding the approval pathway for biosimilars in China include:

- the Biosimilar Guidelines serve as a technical guidance only and cannot address several fundamental issues for the administration of biosimilars in the absence of a clear legislative authorization, such as interchangeability with reference products, naming rules and labeling requirements for biosimilars;
- although the Biosimilar Guidelines adopt a stepwise comparability approach, they do not contain sufficient details to be regarded as overarching guidelines and it is also not clear whether the NMPA will take further steps to develop product-specific guidelines on our biosimilars candidates and guidelines addressing issues such as immunogenicity assessment;
- while under the Biosimilar Guidelines, biosimilars are subject to the same approval pathway as innovative biologics with a different set of technical review criteria, it remains unclear if the time to market for biosimilars will be reduced compared with the lengthy review process for innovative biologics; and
- since changes in regulatory requirements and guidance may occur, it is unpredictable whether the NMPA and other regulatory authorities will issue updated policies or guidelines on biosimilars to replace or supplement the Biosimilar Guidelines, or whether such updated policies or guidelines will bring additional compliance costs or substantial impediments for our biosimilar candidates to obtain regulatory approvals.

As such, there is no assurance that our biosimilar candidate will be approved under the Biosimilar Guidelines or any further updated policies or guidelines in the future, in a timely manner or at all, and we may not ultimately be able to develop and market any or all of them successfully.

## RISK FACTORS

---

*After we receive regulatory approvals for our product candidates, we will be subject to ongoing or additional regulatory obligations and continued regulatory review.*

If any of our product candidates receives regulatory approval in the future, it will be subject to ongoing regulatory requirements with respect to manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-market studies, submission of safety, efficacy, and other post-market information, and other requirements of regulatory authorities in China and/or other countries in which we commercialize our product candidates. Also, following an approval for commercial sale of any product candidates, certain changes to the product, such as changes in manufacturing processes and additional labeling claims, may be subject to additional review and approval by the NMPA and/or comparable regulatory authorities. Accordingly, we must continue to devote time, money and effort in all areas of regulatory compliance. For details of other potential consequences in the event that we fail to maintain compliance with such ongoing or additional regulatory requirements, see “— Risks Relating to Extensive Governmental Regulations — All material aspects of the research, development, manufacturing and commercialization of our product candidates are heavily regulated” in this section.

*The recently enacted PRC Vaccines Administration Law may impose unprecedented regulatory compliance challenges encompassing our business.*

On June 29, 2019, the Standing Committee of the National People’s Congress of the PRC promulgated the PRC Vaccines Administration Law (《中華人民共和國疫苗管理法》) (the “**Vaccines Administration Law**”). The Vaccines Administration Law, together with the newly revised PRC Drug Administration Law (《中華人民共和國藥品管理法》) promulgated on August 26, 2019 (the “**Revised Drug Administration Law**”), came into effect on December 1, 2019. With this new enactment, vaccines development, production and circulation, vaccination and supervision and management within the territory of the PRC are all subject to this Vaccines Administration Law. Among others, the Vaccines Administration Law imposes us obligations on manufacturing, safekeeping of sales records, setting up electronic traceability system of vaccines, purchasing compulsory vaccines liability insurance, post-market management of vaccines, mandatory disclosure system as well as increasingly severe regulatory punishment in cases of non-compliance. Under the Vaccine Administration Law, the State implements a vaccination-related abnormal reaction compensation system. Relevant compensation shall be paid in the case of any in-vaccination or post-vaccination death, severe disability or damage such as organ tissue injury to a recipient that is identified as or cannot be ruled out as being a vaccination-related abnormal reaction. The compensation scope shall be subject to management by catalog and dynamical adjustment in light of the actuality.

Adhering to strong safety awareness, stringent risk management and control methods, concurrent scientific supervision, as well as a societal co-governance scheme, this Vaccines Administration Law is considered as, arguably, the strictest regulatory framework for vaccine business in China. As we strive to provide the utmost protection to human safety while conducting our business, our compliance cost under the current vaccine regulatory framework may be unprecedentedly high. For example, under the new Vaccines Administration Law, we will be required to establish vaccines electronic traceability system to be linked with the national vaccine electronic traceability collaboration platform, for the purpose of integrating whole process traceability information on vaccine production, circulation and vaccination so as to realize the traceability of vaccines. Setting up and maintaining the smooth running of such a system would cause us additional costs in not only gathering resources and developing the system, but also sourcing data and statistics management experts. As of the Latest Practicable Date, we had not set up



## RISK FACTORS

---

such system as we are not a vaccine marketing authorization holder at the current stage, which, according to our PRC Legal Advisor, does not contravene the Vaccines Administration Law. Our management and in-house experts might need to spend additional time on decoding and integrating the new rules into our day-to-day operations, which could potentially distract their attention on ongoing essential corporate affairs.

***We may be unable to obtain or renew certain approvals, licenses, permits and certificates required for our business.***

Pursuant to the relevant laws, regulations and relevant regulatory practice by governmental authorities, we are required to obtain and maintain various approvals, licenses, permits and certificates from relevant authorities to operate our business and construct our facilities. Some of these approvals, permits, licenses 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. Any failure to obtain or renew any approvals, licenses, permits and certificates necessary for our operations and construction of our facilities, such as construction work commencement permit, environmental protection inspection, and fire safety approvals, may result in enforcement actions thereunder, including orders issued by the relevant regulatory authorities ceasing our operations, and may include corrective measures requiring capital expenditure or remedial actions. 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, licenses or certificates that were previously not required to operate our existing businesses, there is no assurance that we will successfully obtain such approvals, permits, licenses or certificates.

***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 non-compliance, expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.***

If we obtain approval from the NMPA or other comparable regulatory authorities approval for any of our product candidates and begin commercializing those product candidates in China and our other target markets, our operations may be subject to various fraud and abuse laws of various jurisdictions, including but not limited to, 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 Federal Anti-Kickback Statute and the Federal False Claims Act, and the physician payment sunshine laws and regulations. There are ambiguities as to what is required to comply with any of these requirements, and violations of such fraud and abuse laws may be punishable by criminal and/or civil sanctions, including penalties, fines and/or exclusion or suspension from governmental healthcare programs and debarment from contracting with the relevant government. Moreover, as law enforcement authorities have been increasingly focused on enforcing these laws, efforts to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs.

***Changes in government regulations or in practices relating to healthcare industry, including healthcare reform and compliance with new regulations may result in additional costs.***

The policies of the NMPA and other regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product

## RISK FACTORS

---

candidates, restrict or regulate post-approval activities and affect our ability to profitably sell our products. We cannot predict the likelihood, nature or extent of governmental policies or regulations that may arise from future legislation or administrative actions in China or abroad, where the regulatory environment is constantly evolving. For instance, changes in regulatory requirements and guidance that require us to amend clinical trial protocols submitted to the regulatory authorities may also occur, and amendments thereto to reflect such changes may impact the costs, timing or successful completion of a clinical trial. In addition, there could be changes in government regulations specifically on pharmaceutical product registrations and approvals, such as a relaxation in regulatory requirements, or the introduction of simplified approval procedures which will lower the entry barrier for potential competitors, or an increase in regulatory requirements which may increase the difficulty for us to satisfy such requirements.

Also, in recent years, there have been and will likely continue to be efforts to enact administrative or legislative measures which may result in more rigorous coverage criteria and downward pressure on the price that we fix for any approved product. For details of the risks associated with such downward pricing pressure, see “— Risks Relating to Sales and Distribution of Our Product Candidates — We may need to lower our product price in order to qualify for medical insurance reimbursement or due to market competition” in this section.

Finally, it is also possible that the Chinese government or other government authorities in countries where we plan to sell our products could adopt new or different regulations affecting the way in which pharmaceutical products are sold to address bribery, corruption or other concerns. Any such new or different regulations could possibly increase the costs incurred by us, or our employees in selling our products, or impose restrictions on sales and marketing activities, which could in turn increase our costs.

***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 our management of the medical data of subjects enrolled in our clinical trials and other personal or sensitive information.***

We routinely receive, collect, generate, store, process, transmit and maintain medical data treatment records and other personal details of subjects enrolled in our clinical trials, along with other personal or sensitive information. As such, we are subject to the relevant local, state, 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 jurisdictions in which we may operate and conduct our clinical trials, as well as contractual obligations. These data protection and privacy law regimes continue to evolve and may result in ever-increasing public scrutiny and escalating levels of enforcement and sanctions and increased costs of compliance. Failure to comply with any of these laws could result in enforcement action against us, including fines, imprisonment of company officials and public censure, claims for damages by customers and other affected individuals, damage to our reputation and loss of goodwill. While we have taken measures to maintain the confidentiality of the medical records and personal data of subjects enrolled in our clinical trials we collected, including setting internal rules requiring our employees and business partners to maintain the confidentiality of our subjects’ medical records, these measures may not be always effective.

## RISK FACTORS

---

### Risks Relating to Our Intellectual Property Rights

*If we are unable to obtain and maintain adequate patent and other intellectual property protection for our product candidates throughout the world, or if the scope of such intellectual property rights obtained is not sufficiently broad, third parties could compete directly against us and our ability to successfully develop and commercialize any of our product candidates would be materially and adversely affected.*

Our success depends in a large part on our ability to protect our proprietary technology and product candidates from competition by obtaining, maintaining and enforcing our intellectual property rights, including patent rights. We seek to protect the technologies and product candidates that we consider commercially important by, among others, filing patent applications in the PRC, and other countries. As of the Latest Practicable Date, we had four invention patents granted, including two relating to LZ901, nine registered trademarks and we had filed eight patent applications worldwide. For more details, please see “Business — Intellectual Property Rights” in this document. Although there is no substantive legal impediment for each of our pending patent applications of being granted according to our IP Legal Adviser, there is no assurance that our patent applications will be approved eventually. However, applying for patent protection is an expensive and time-consuming process, and we may not be able to successfully file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. In addition, we may however fail to identify patentable aspects of our R&D output before it is too late to obtain patent protection. As a result, we may not be able to prevent competitors from developing and commercializing competitive products in all such fields and territories. As a result, we may not be able to prevent competitors from developing and commercializing competitive products in all such fields and territories.

Specifically, patents may be invalidated and patent applications may not be granted not only because of known or unknown prior deficiencies in the patent applications, but also due to the lack of novelty or inventiveness of the underlying invention or technology. Although we enter into non-disclosure and confidentiality agreements or include such provisions in our relevant agreements with parties who have access to confidential or patentable aspects of our R&D output, any of these parties may breach such agreements and disclose such output before a patent application is filed, jeopardizing our ability to seek patent protection. As of the Latest Practicable Date, seven of our patent applications relating to our Core Product were pending approval, and our patent applications may not be granted for a number of reasons. For instance, publications of discoveries in the scientific literature often lag behind the 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. We cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications partially because of the oftentimes postpone of publications of discoveries in the scientific or patent literature in relation to the actual discoveries and patent applications filings. Furthermore, under the “first-to-file” system adopted by the PRC, and recently, the United States, even after reasonable investigation we may still be unable to determine with certainty whether any of our products, product candidates, processes, technologies, improvement and other related matters has already become unpatentable as any third party might have filed a patent application for the inventions thereunder that are the same or substantially similar to ours early than we do.

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 report to the National Intellectual Property Administration, or NIPA, for confidentiality examination. Otherwise, if

## RISK FACTORS

---

such application is later filed in China, the patent right will not be granted. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

***Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.***

The China National Intellectual Property Administration (the “CNIPA”) and various governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. For instance, 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. Although an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, 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. Such non-compliance events may 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 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 report to the CNIPA for confidentiality examination; otherwise the patent right will not be granted, if an application is later filed in China.

***The scope of our patent protection may be uncertain, and our current or any future patents may be challenged and invalidated even after issuance.***

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned patents may be challenged in the courts or patent offices in the PRC and other jurisdictions. For instance, we may be subject to a third-party submission of prior art to the CNIPA or other related intellectual property offices or become involved in post-grant proceedings such as opposition, derivation, revocation, invalidation, re-examination, or *inter partes* review, or interference proceedings or similar proceedings in foreign jurisdictions challenging the priority of our invention or other features of patentability of our patents and patent applications. Moreover, any claims that we assert against competitors who are perceived to infringe our patent rights or misappropriate or otherwise violate our intellectual property rights could assert against us invalidity or unenforceability of our patents on numerous grounds. Any abovementioned submission, proceeding or litigation may result in substantial costs and require significant time from our scientists, experts and management, even if the eventual outcome is favorable to us. More importantly, an adverse determination therein 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 technologies and products, or limit the duration of the patent protection of our technologies and product candidates.

***Even if we are able to obtain patent protection for our product candidates, the term of such protection, if any, is limited, and third parties could develop and commercialize products and technologies similar or identical to ours and compete directly against us after the expiration of our patent rights.***

Although various adjustments and extensions may be available, the term of a patent, and the protection it affords, is limited. Given the amount of time required for the development, testing and

## RISK FACTORS

---

regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As such, even if we successfully obtain patent protection for a product candidate, such product candidate may face competition from generic or biosimilar medications once the patent has expired. 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.

***The absence of data exclusivity for NMPA-approved pharmaceutical products could increase the risk of early generic competition for our product candidates in China.***

In China, there is no currently effective law or regulation providing data exclusivity. Therefore, a lower-cost generic product can emerge onto the market much more quickly. While Chinese regulators have set forth a framework for integrating data exclusivity into the Chinese regulatory regime, such a framework will require adoption of regulations in order to be implemented. To date, no regulations have been issued, which results in weaker protection for us against generic competition in China than could be available to us in other jurisdictions where data exclusivity is available.

***We may become involved in lawsuits to protect or enforce our intellectual property or being sued for infringing, misappropriating or other violating the intellectual property rights of third parties, which could be expensive, time-consuming and unsuccessful.***

Our commercial success depends in part on our ability to avoid infringing, misappropriating, or otherwise violating intellectual property rights of third parties. However, our efforts to identify and avoid infringing on third parties' intellectual property rights may not always be successful. Defending ourselves against third parties' intellectual right infringement allegations, meritorious or not, would be expensive and time consuming, and would be a substantial diversion of our resources and our management team's attention. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, some of our confidential information could be compromised by disclosure during this type of litigation. In February 2023, our IP Legal Adviser conducted freedom-to-operate (FTO) searches and analyses in target country(s) and/or region(s) in relation to our Core Product (LZ901), K3 and K193, and did not identify any substantial risk of infringement by all of the current key technologies and features of our Core Product, K3 and K193 against active patents in such country(s) and/or region(s). FTO analysis is a patent search commonly used to determine whether there are any existing patents covering a company's product, and whether such product would infringe any existing patents. However, the potential scope of an FTO search can be immense and all patent databases have limitations. Further, patent applications generally remain unpublished within 18 months after its earliest filing, and hence an earlier-filed, unpublished patent application could potentially present an infringement risk. Therefore, we cannot guarantee that our FTO search and analysis have exhaustively reviewed all the existing and future patents that potentially cover our products. 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 industries generally. As the pharmaceutical 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. FTO analysis is technically complicated and involves significant judgement as to the scope, validity and enforceability of patents. There can be no assurance that a court would agree with our analysis or find in our favor on questions of infringement, and the outcome following legal claims of patent infringement is unpredictable.

## RISK FACTORS

---

In the event that third parties assert infringement claims against us, there is no assurance that the outcome would be in our favor, as whether a product infringes on third parties’ intellectual property rights involves an analysis of complex legal and factual issues, the determination of which is often uncertain, and the burden of proof required to successfully challenge a third-party intellectual property right may be high. If we were found by courts or other competent authorities to have infringed on the patent or other intellectual property rights of third parties, we may be subject to injunctive or other equitable relief, which could prevent us from developing and commercializing our product candidates, or at least delay the development or commercialization process. Even if the litigations or other proceedings are resolved in our favor, our involvement in such proceedings may attract publicity, thereby having a substantial adverse effect on our reputation and brand name.

***Our owned patents and other intellectual property may be subject to further priority disputes or to inventorship disputes and similar proceedings, and we or our collaboration partners may be unsuccessful in any of these proceedings, therefore requiring us to obtain licenses from third parties that may not be available on commercially reasonable terms or at all, or to cease the development, manufacture, and commercialization of one or more of the product candidates we may develop.***

We or our collaboration partners may be subject to claims that former employees, collaboration partners or other third parties have an interest in our owned patents or other intellectual property. If we or our collaboration partners are unsuccessful in any interference proceedings or other priority or validity disputes to which we or they are subject, we may lose valuable intellectual property rights, such as loss of one or more patents or exclusive ownership, or our patent claims’ being narrowed, invalidated, or held unenforceable. As a result, we may be required to obtain and maintain licenses from third parties, including parties involved in any such interference proceedings or other priority or inventorship disputes, in order to continue the development, manufacture and commercialization of one or more of our product candidates. However, such licenses may not be available on commercially reasonable terms or at all, or may be non-exclusive. Even if we are successful in an interference proceeding or other similar priority or inventorship disputes, it could result in substantial costs and be a distraction to our management and other employees.

***Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our pipeline products.***

Depending on decisions by the National People’s Congress of the PRC and the CNIPA, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. The United States has enacted and is currently implementing wide-ranging patent reform legislation. In addition, recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. There could be similar changes in the laws of other jurisdictions that may impact the value of our patent rights or our other intellectual property rights. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained, if any. As the laws and regulations governing patents continue to evolve in China, the U.S. and other jurisdictions, we cannot guarantee that any other changes would not have a negative impact on our intellectual property protection.

## RISK FACTORS

---

***We may fail to protect the confidentiality of our trade secrets, as we may be subject to claims that our employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of their former employers, or that 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, including unpatented know-how, technology and other proprietary information, to maintain our competitive position and to protect our product candidates. Specifically, we seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements or including such undertakings in the agreement with parties that have access to them. However, non-disclosure agreements with employees, consultants, contractors and other parties may not adequately prevent disclosures of our trade secrets and other proprietary information. 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 also be difficult, expensive and time-consuming, and the outcome is unpredictable.

Furthermore, some of our employees, including our senior management, might have previously been employed at other pharmaceutical companies, including our competitors or potential competitors. Some of these employees might have executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, 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 employee's former employer. In the event that litigation is necessary to defend against such claims, we may be subject to monetary damages and lose valuable intellectual property rights or personnel.

***We may fail to protect our trademarks and trade names well to build brand recognition in our markets of interest.***

We currently hold issued trademark registrations and have trademark applications pending, which we need to build name recognition among potential partners or customers in our markets of interest but subjects us to risks of trademark invalidity, dilution and infringement, and etc. First, any of our trademark registrations and applications may be the subject of a governmental or third-party objection, so as to be challenged, infringed, circumvented or declared generic, which could prevent the registration or maintenance of the same. Moreover, as our products mature, our reliance on our trademarks to differentiate us from our competitors will increase, but we may be 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. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected.

***We will not seek to protect our intellectual property rights in all jurisdictions throughout the world, and we may not be able to adequately enforce our intellectual property rights even in the jurisdiction where we seek protection.***

Filing, prosecuting, and defending patents on product candidates in all countries throughout the world would be prohibitively expensive. Moreover, the legal systems of certain countries, particularly

## RISK FACTORS

---

certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally. Consequentially, competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and sell or import products made using our inventions in and into our markets of interest. These products may compete with our products, and our existing patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

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

The degree of protection afforded by our intellectual property rights is essentially uncertain because intellectual property rights have limitations, and may not adequately protect our business or permit us to maintain our competitive advantage. The limitations of currently available intellectual property protection regimes include that:

- others may be able to make products that are similar to any of our product or product candidates or utilize similar technology that are not covered by the claims of our owned patents;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing, misappropriating or otherwise violating our intellectual property rights;
- the proprietary technologies on which we rely may not be patentable; and
- we may choose not to file a patent for certain trade secrets or know-how, yet a third party may subsequently file a patent covering such intellectual property.

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

### **Risks Relating to Our Financial Position and Need for Additional Capital**

#### *We incurred net losses and net operating cash outflows during the Track Record Period, and we may continue to incur net losses and net operating cash outflows.*

Investment in human vaccine and therapeutic biologics product development is highly speculative. It entails substantial upfront capital expenditures and significant risks and a product might fail to demonstrate sufficient efficacy or safety to gain regulatory approval or become commercially viable. Our ongoing operations bring significant expenses. As a result, we have incurred losses in each period during the Track Record Period. We experienced a loss of RMB539.4 million and RMB725.2 million in 2021 and 2022, respectively. As of December 31, 2021 and 2022, we had an accumulated loss attributable to owners of RMB795.3 million and RMB1,520.5 million. We also had net cash used in operating activities of RMB19.2 million and RMB77.3 million in 2021 and 2022, respectively. Substantially all of our net losses resulted from costs incurred in connection with our research and development expense, administrative expenses and fair value loss of financial liabilities at FVTPL.



## RISK FACTORS

---

The amount of our future net losses will depend, in part, on the rate of our future expenditures and our ability to obtain funding through equity or debt financings, strategic collaborations or additional grants. Even if we obtain regulatory approval to market a product candidate, our future revenues will depend upon the size of any markets in which our product candidates have received approval, our ability to achieve sufficient market acceptance, secure procurement from CDCs or hospitals in China and other factors.

We may continue to incur net losses for the foreseeable future, and these losses may increase as we continuously expand our development, including:

- conducting clinical trials and advancing pre-clinical studies of our current product candidates;
- recruiting highly skilled and qualified research and development personnel to further expand our research and development team;
- maintaining and expanding our own manufacturing facilities;
- seeking regulatory approvals for our product candidates that successfully complete clinical trials;
- commercializing our product candidates for which we have obtained marketing approval;
- building up our commercialization, distribution, and sales workforce in anticipation of the future roll-out of our product candidates;
- initiating pre-clinical studies, clinical trials or other research and development activities for new product candidates;
- maintaining, protecting and expanding our intellectual property portfolio; and
- creating additional infrastructures to support our operations as a [REDACTED] company, our product development, and planned future commercialization efforts.

Developing biopharmaceutical products, including conducting pre-clinical studies and clinical trials, is a very time consuming, expensive and uncertain process that takes years to complete. During the process, we may encounter unforeseeable expenses, difficulties, complications, delays, and other unknown factors that may adversely affect our business. The size of our future net losses will depend partially on the number and scope of our vaccine and therapeutic biologics development programs and the associated costs, the rate of the future growth of our expenses and the commercialization costs of any approved products. If any of our product candidates fails during clinical trials or does not gain regulatory approval, or, even if approved, fails to achieve market acceptance, our business may not become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods thereafter. Our prior losses and expected future losses have had, and will continue to have, an adverse effect on our working capital and Shareholders’ equity.

## RISK FACTORS

---

***We incurred net liabilities during the Track Record Period, and may continue to have net liabilities going forward, which can expose us to liquidity risk.***

As of December 31, 2021 and 2022, we had net liabilities of RMB584.5 million and net assets of RMB937.5 million, respectively. Our deficit position was largely due to the accounting treatment for our preference shares, which are classified as financial liabilities at FVTPL. Our obligations with respect to special rights granted to [REDACTED] Investors, other than information rights, were terminated in June 2022. Therefore, the preference shares were reclassified from financial liabilities to equity at their fair value. Please see “Financial Information — Financial Liabilities at FVTPL” and Note 27 to the Accountants’ Report in Appendix I to this document for further details of our financial liabilities at FVTPL during the Track Record Period. We cannot guarantee that we will not incur net liabilities in the future. If we are to record net liabilities again, it will affect our liquidity, as well as our ability to raise funds, obtain bank loans and pay debts when they become due and declare and pay dividends.

***We may need to obtain additional financing to fund our expansion of research and development and our operations, and we may not have access to sufficient funding.***

Our business operations and our implementation of our strategies will require significant funding, including:

- promoting the clinical development of certain of our pipeline candidates, including LZ901, K3 and K193;
- advancing the development of other pipeline candidates;
- expanding our production capacity to meet growing market demands;
- laying out plans to strategically promote commercialization at home and abroad; and
- seeking global collaboration to expand our product pipeline.

In addition, many aspects of our general business operations have on-going funding requirements that may increase over time. While we expect that the implementation of our strategies and business plans will require us to rely in part on external financing sources, our ability to obtain additional capital on commercially reasonable terms is subject to a variety of factors, many of which are outside of our control, including our future financial condition, results of operations and cash flows, the global economic conditions, industry and competitive conditions, interest rates, prevailing conditions in the credit markets and government policies on lending. If we cannot do so successfully, our strategies and business plans will not be carried out as currently contemplated.

***We have historically received government grants and we may not receive such grants or subsidies in the future.***

We have historically received government grants and recognized government grants as other income of RMB1.9 million and RMB11.6 million in 2021 and 2022, respectively. We also recorded deferred government grants of RMB47.3 million and RMB36.8 million as of December 31, 2021 and 2022, respectively. However, there is no assurance that you of the continued availability of the government grants currently enjoyed by us, any reduction or elimination of which would have an adverse

## RISK FACTORS

effect on our financial condition. Our eligibility for government grants depends on a variety of factors, including the assessment of our improvement on existing technologies, relevant government policies, the availability of funding at different granting authorities, and the research and development progress made by other peer companies. In addition, 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. Also, some of the government financial incentives may be subject to the satisfaction of certain conditions, including compliance with the applicable financial incentive agreements and completion of the specific projects therein, which we may fail to satisfy, and the governmental authorities may reduce or discontinue such grants, or require us to repay part or all of the government grants we previously received.

***Share-based payment may cause shareholding dilution to our existing Shareholders and have a negative effect on our financial performance.***

We adopted employee incentive plans for the benefit of our employees as remuneration for their services provided to us to incentivize and reward the eligible persons who have contributed to the success of our Company. For more details, please see “History, Development and Corporate Structure — Employee Incentive Scheme” and Note 31 to the Accountants’ Report set out in Appendix I in this document. In 2021 and 2022, we incurred expenses for share-based payments of RMB76.2 million and RMB111.4 million, respectively. To further incentivize our employees to contribute to us, we may grant additional share-based payments in the future. Issuance of additional Shares with respect to such share-based payments may dilute the shareholding percentage of our existing Shareholders. Expenses incurred with respect to such share-based payments may also increase our operating expenses and therefore have a material and adverse effect on our financial performance.

***We are exposed to credit risks associated with our investment in certain wealth management products.***

As part of our treasury management, we invest in certain wealth management products to better utilize excess cash when our cash sufficiently covers our ordinary course of business. As of December 31, 2021 and 2022, our financial assets at FVTPL amounted to RMB532.4 million and RMB512.7 million, respectively, and we recorded fair value gains on financial assets at FVTPL of RMB10.8 million and RMB13.9 million in 2021 and 2022, respectively. Pursuant to the Guidance on Regulating Financial Institution’s Asset Management Business (《關於規範金融機構資產管理業務的指導意見》) promulgated by the People’s Bank of China, the China Banking and Insurance Regulatory Commission, the China Security Regulatory Commission and the State Administration of Foreign Exchange on April 27, 2018, financial institutions selling wealth management products shall not guarantee the principals and/or returns of such products. As a result, the returns of our investments on the wealth management products were not guaranteed. We measured these financial assets at FVTPL, and we are exposed to credit risks in relation to these financial assets, which may adversely affect their fair value. Net changes in their fair value are recorded in profit or loss, and therefore directly affect our results of operations. We have implemented a series of internal control policies and rules setting forth overall principles as well as detailed approval process of our investment activities. We adopt a prudent approach in selecting wealth management products. We may continue to invest in wealth management products in the future when we believe that we have surplus cash on-hand and the potential investment returns are attractive. For more details, please see the paragraphs headed “Financial Information — Discussion of Certain Selected Items from the Consolidated Statements of Financial Position — Financial Assets at FVTPL” in this document. However, there can be no assurance that our internal management and investment strategy will be effective and adequate with respect to our purchased wealth management products.

## RISK FACTORS

---

### Risks Relating to Our General Operations

*We may fail to sufficiently and promptly respond to clinical demand and market changes in the pharmaceutical industry.*

Clinical demand and market conditions for pharmaceutical products may change rapidly and significantly, and our success depends on our ability to anticipate product offering lead-time and demand, identify customer preferences and adapt our products to these preferences. We may need to adjust our research and development plan, production scale and schedule, product portfolio, and future inventory levels based on customer demand, sales trends and other market conditions. However, there can be no assurance that we will be able to sufficiently and promptly respond to changes in clinical demand and purchasing patterns in the future.

*Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.*

Our operations, and those of our suppliers, research institution collaborators and other business partners, could be subject to natural or man-made disasters, health epidemic, or business interruptions, for which we are predominantly self-insured. Damage or extended periods of interruption to our and our partners' administration, development, research, manufacturing or storage facilities due to fire, natural disaster, health epidemic, power loss, communications failure, unauthorized entry or other events could cause us to cease or delay development or commercialization of some or all of our product candidates, seriously harm our and our partners' operations and financial condition, and increase our and their costs and expenses.

*Our success depends on our key senior management members and our ability to attract, train, motivate and retain highly skilled scientists and other technical personnel.*

Our success depends heavily upon the continued services of the Board members and senior management to manage our business and operations, and on our key research and development personnel to develop new products, technologies and applications and to enhance our existing products. Our ability to attract, hire, retain and motivate qualified scientific, technical, clinical, manufacturing, and sales and marketing personnel, as well as other consultants and advisers, is also crucial for us. Although we have entered into employment agreements and consulting agreements with each of our executives, employees, consultants and advisers, they may terminate their agreements with us at any time. As such, we will have to compete for qualified personnel with other pharmaceutical and biotechnology companies, universities and research institutions. The pool of suitable candidates is limited, and we may not be able to hire and retain enough skilled and experienced scientists or other technical personnel at the current level of wages, and need to offer higher compensation and other benefits, which could materially and adversely affect our financial condition and results of operations.

*We may encounter difficulties in managing our growth and expanding our operations successfully.*

Our success will depend upon our ability to expand our development, regulatory, manufacturing, marketing and sales capabilities or contract with third parties to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with various strategic partners, suppliers and other third parties. Future growth will impose additional responsibilities on members of management. Our ability to commercialize our product candidates and our future financial

## RISK FACTORS

---

performance will depend heavy on whether we are able to manage the future growth effectively. Therefore, hiring, training and integrating additional management, administrative and sale and marketing personnel is crucial in further ensuring the effective clinical trials developments in future. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing our company.

***Our business, results of operations and financial position could be adversely affected by the ongoing COVID-19 pandemic.***

COVID-19, an outbreak of a novel strain of coronavirus since December 2019 that was declared by the World Health Organization to be a pandemic in March 2020, has already resulted in a high number of fatalities and is likely to continue having an adverse impact on the livelihood of the people both in China and globally, which in turn will have a negative impact on the global economy. Our business operation has also been, and may continue to be, negatively affected by the outbreak. For instance, any temporary suspension of productions, shortage of labor and raw materials or disruption of local and international travel and economic may affect imports and exports as related to our business. Also, the development progress of product candidates could be slightly delayed due to the prolonged process of subject enrollment for our ongoing clinical trials, delay of construction of our facilities in Zhuhai, and the slow-down of the responses from the relevant governmental authorities reviewing our clinical trial applications, among other reasons.

There is great uncertainty around the future of the COVID-19 outbreak and how it will impact our operations. In particular, we cannot accurately forecast the potential impact of additional outbreaks as to government restrictions including further shelter-in-place or other government restrictions implemented in response to such outbreaks, or the impact on the ability of our suppliers and other business partners to remain in business as a result of the ongoing pandemic or such additional outbreaks. With the uncertainties surrounding the COVID-19 outbreak until a cure or vaccine has been discovered, the threat to our business and the related financial impact remains.

***We may become a party or are subject to litigation, legal disputes, claims, administrative proceedings or other administrative measures, which may divert our management’s attention and results in costs and liabilities, and there is no assurance that the results of such legal proceedings would favor us.***

We may from time to time become subject to various litigation, legal or contractual disputes, investigations or administrative proceedings arising in the ordinary course of our business, including but not limited to various disputes with or claims from our suppliers, customers, contractors, licensors, business partners, employees and other third parties that we engage for our business operations. Ongoing or threatened litigation, legal disputes, claims, investigations or administrative proceedings may divert our management’s attention and consume their time and our other resources. Furthermore, any such matters which are initially not of material importance may escalate and become important to us, due to a variety of factors, such as the facts and circumstances of the cases, the likelihood of loss, the monetary amount at stake and the parties involved. If any verdict or award is rendered against us or if we settle with any third parties, we could be required to pay significant monetary damages, assume other liabilities and even to suspend or terminate the related business projects. During the Track Record Period, we did not register and/or fully contribute to certain social insurance and housing provident funds for two of our employees. As of the Latest Practicable Date, we had rectified such incidents. Our Directors, having consulted our PRC Legal Adviser, are of the view that such isolated incidents will not have material impact on our business. In any event, negative publicity arising from litigation, legal disputes, investigations or administrative proceedings may damage our reputation and adversely affect the image of our brands and products.

## RISK FACTORS

---

***If we, our employees, agents, suppliers or affiliates engage, or are perceived to engage, in misconduct or breaches, including corrupt practices or leakage of confidential information, we could be exposed to regulatory investigations, costs and liabilities.***

We are subject to risks in relation to actions taken by us, our employees, agents, suppliers or affiliates that constitute violations of anti-corruption and other related laws in jurisdictions where we conduct business. Any allegations of corrupt practices against us, our employees, agents or affiliates or the pharmaceutical industry in general could generate negative publicity and materially and adversely affect our reputation and business prospects. Despite our procedures and controls to monitor compliance with applicable anti-corruption laws, we may still be held liable for actions taken by us, or our employees, in which case the government authorities may seize the products involved in any illegal or improper conduct engaged in by us, or our employees. We may also be subject to claims, fines or suspension of our operations.

Furthermore, if we are involved in criminal, investigational or administrative procedure for commercial bribery, we will be included on the negative list of commercial bribes by provincial health and family planning administrative department, as a result of which our products cannot be purchased by public medical institutions as well as medical and health institutions receiving financial subsidies of specific territorial scope in two years, pursuant to the Provisions on the Establishment of Adverse Records of Commercial Briberies in the Medicine Purchase and Sales Industry (《關於建立醫藥購銷領域商業賄賂不良記錄的規定》).

***Negative publicity and allegations involving us, our Shareholders, Directors, management personnel, employees and business partners may affect our reputation, business and growth prospects.***

We, our Shareholders, Directors, management personnel, employees and business partners may be subject to negative media coverage and publicity from time to time. Such negative coverage in the media and publicity could threaten the perception of our reputation. In addition, to the extent our employees and business partners were not compliant with any laws or regulations, we may also suffer negative publicity or harm to our reputation. As a result, we may be required to spend significant time and incur substantial costs in response to allegations and negative publicity, and may not be able to diffuse them to the satisfaction of our investors and customers.

***Negative publicity on the overall vaccine industry may impact the public confidence in our future vaccine products or vaccine products in general, lead to lower demand of vaccination, and result in more stringent regulations.***

We and the vaccine industry were, and may be in the future, subject to the implications of negative publicity regarding vaccine products or the vaccine industry in general. For example, in March 2016, media reported on improperly stored vaccines illegally sold by distributors in the Shandong province and all across China. The illegal distribution resulted in sales to CDCs of a large amount of vaccine products, including rabies vaccines, that might be ineffective or less effective due to improper storage in distributions. Although this scandal was a result of illegal distributions and had no indication of any quality issues of vaccine manufacturers, this caused panic and public concerns over the safety of vaccines in general. Such incidents led to an overall downturn in the vaccine market in China, and promoted the PRC government to introduce more stringent legislations and regulations for the vaccine industry.

## RISK FACTORS

---

Any such negative publicity may shake the public confidence in vaccine products or industry in general, including our future vaccine products, and lead to lower demand for vaccines in the PRC, which in turn could affect our business and performance adversely. Investigations or more stringent governmental regulations after such negative publicity, if any, may require time and attention of our management team that would otherwise be devoted to operation of our business, or may cause more compliance expenses. In the event that any negative publicity is regarding our own products or our own business, the adverse impact on our financial condition or results of operation will be more significant. The [REDACTED] of our H Shares could also suffer dramatically as a result of such negativity.

*We may be subject to product liability claims that could expose us to costs and liabilities.*

We are exposed to product liability risks as a result of developing, producing, marketing, promoting and selling pharmaceutical products in the PRC and other jurisdictions in which our pharmaceutical products may be marketed and sold. Such claims may arise if any of our products are deemed or proven to be unsafe, ineffective, defective or contaminated or if we are alleged to have engaged in practices such as insufficient or improper labeling of products or providing inadequate warnings or insufficient or misleading disclosures of side effects. A product liability claim brought against us, may, regardless of merit or outcome, result in damages to our reputation, strain our financial resources and consume the time and attention of our management. If we are unable to defend ourselves against such claims, we may, among others, be subject to product recalls, civil liability for physical injury, death or other losses caused by our products, criminal liability and the revocation of our business licenses. We have not purchased product liability insurance and we may be unable to acquire such insurance at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

*We may grow our business in part through acquisitions, which may increase our capital requirements, dilute our shareholders, cause us to incur debt or assume contingent liabilities and have material adverse effect on our ability to manage our business, and we may fail to successfully complete such acquisitions or enhance post-acquisition performances in the future.*

To enhance our growth, we may acquire businesses, products, technologies or know-how or enter into strategic partnerships that we believe would benefit us in terms of product development, technology advancement or distribution network, among others. Any completed, in-process or potential acquisition or strategic partnership may entail numerous risks, including:

- inability to identify suitable acquisition targets and reach agreement on acceptable terms;
- lack of access to financing for acquisitions on acceptable terms or at all, or otherwise assumption of additional indebtedness or contingents and issuance of our equity securities;
- failure to obtain or secure the governmental approvals and third party consents necessary to consummate any proposed acquisition;
- increased operating expenses, including research and development expenses due to an increased number of product candidates, administrative expenses as well as selling and distribution expenses;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;

## RISK FACTORS

---

- diversion of our management's attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;
- difficulty in 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 products and product candidates;
- 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; and/or
- deficiencies in internal controls, data adequacy and integrity, product quality and regulatory compliance, and product liabilities in the acquired business we discover after such acquisition.

In any such event, our plan to grow our business through such acquisitions may not materialize as expected.

***Our internal risk management and control system may not be so adequate or effective to detect potential risks in our business as intended.***

We have an internal control system in place to monitor and control potential risk areas relevant to our business operations. However, due to the inherent limitations in the design and implementation of our internal control system, it may not be sufficiently effective in identifying, managing and preventing all risks if external circumstances change substantially or extraordinary events take place. Further, integration of various business operations from potential future acquisitions may give rise to additional internal control risks that are currently unknown to us, despite our efforts to anticipate such issues. Our risk management and internal controls also depend on effective implementation by our employees. There can be no assurance that such implementation by our employees will always function as intended, or such implementation will not be subject to human errors, mistakes or intentional misconduct.

***Breach, failure or disruption in or to our information system could compromise sensitive information related to our business and expose us to liability or reputational harm, and our ability to effectively manage our business operations could be adversely affected.***

Our information system may fail and is vulnerable to breakdown, breach, interruption or damage from computer viruses, computer hackers, malicious code, employee error or malfeasance, theft or misuse, denial-of-service attacks, sophisticated nation-state and nation-state-supported actors, unauthorized access, natural disasters, terrorism, war, telecommunication and electrical failures or other compromise. Any system damage or failure that interrupts data input, retrieval or transmission or increases service time could disrupt our normal operations, including the loss of clinical trial data from completed or future clinical trials that could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. There can be no assurance that we will be able to effectively handle a failure of our information systems, or that we will be able to restore our operational capacity in a timely manner to avoid disruption to our business. To the extent that any



## RISK FACTORS

---

disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate use, disclosure of or access to confidential or proprietary information, we could incur liability, our competitive position could be harmed and the further development and commercialization of our product candidates could be hindered or delayed.

Specifically, we may collect and store sensitive personal data in the ordinary course of our business. For more details, please see “— Risks Relating to Extensive Governmental Regulations — 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 our management of the medical data of subjects enrolled in our clinical trials and other personal or sensitive information” in this section. If such personal data are compromised due to a material breach of our information system, the market perception of the effectiveness of our security measures could be harmed and our reputation and credibility could be damaged. More importantly, we could be subject to regulatory actions and/or claims made by individuals and groups in private litigation involving privacy issues related to data collection and use practices and other data privacy laws and regulations.

***If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could materially and adversely affect the success of our business.***

As our operations involve the use of potentially harmful biological materials and other hazardous chemical materials and may produce hazardous waste, we are subject to numerous environmental, health and safety laws and regulations, including those governing air emissions, discharge of water, and the handling, use, storage, treatment and disposal of hazardous materials and wastes. While we have entered into hazardous waste disposal agreements 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 incur significant costs associated with civil or criminal fines and penalties. Further, we do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage, use or disposal of hazardous materials.

***Increased labor costs negatively affect our ability to operate efficiently and have an adverse impact on our revenues and profitability.***

Many aspects of our strategies and business growth may require us to have additional employees, and we may also have additional employees as a result of acquisitions or organic growth of our business. The average cost of labor in the PRC has been steadily increasing over the past years as a result of inflation, government-mandated wage increases and other changes in PRC labor laws, as well as competition for talents and qualified employees among pharmaceutical companies. As a result, increased labor costs could slow down our growth and affect our profitability.

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

We operate in the pharmaceutical industry, which involves numerous operating risks and occupational hazards. The insurance policies we maintain are required under the applicable laws and regulations as well as based on our assessment of our operational needs and industry practice. For more details, please see “Business — Insurance” in this document. However, there is no assurance that the

## RISK FACTORS

---

existing insurance coverage is sufficient to compensate for actual losses suffered or incurred. In line with industry practice in the PRC, we have elected not to maintain certain types of insurance, such as business interruption insurance or insurance to cover product and professional liability claims or lawsuits against us. In addition, there are certain types of losses, such as losses from war, acts of terrorism, health or public security hazards, earthquakes, typhoons, flooding and other natural disasters, as for which we cannot obtain insurance at a reasonable cost or at all. Should an uninsured loss or a loss in excess of insured limits occur, our business, results of operations and financial condition may be materially and adversely affected by such losses and associated liabilities. For details of the specific risks of inadequate insurance coverage in the event of product liability claims and environmental liabilities, see “— Risks Relating to Our General Operations — We may be subject to product liability claims that could expose us to costs and liabilities” and “— Risks Relating to Our General Operations — If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could materially and adversely affect the success of our business”, respectively, in this section.

### ***We are subject to risks associated with leasing space.***

As of the Latest Practicable Date, we leased two real properties in Zhuhai and one real property in Beijing as our office, manufacturing and/or research and development facilities. As our lease expires, we may fail to obtain renewals, either on commercially acceptable terms or at all, which could compel us to close such office and manufacturing facility. Our inability to enter into new leases or renew existing leases on terms acceptable to us could materially and adversely affect our business, results of operations or financial condition.

Further, as of the Latest Practicable Date, the lease agreements of the aforementioned real property in Beijing had not been registered with the relevant municipal land and real estate administration department in accordance with applicable PRC laws and regulations. As registration of the lease agreement will require the cooperation of the landlord, there is no assurance that you that we can complete the registration of such lease agreement in a timely manner or at all. Our PRC Legal Adviser advised us that the failure to register the lease agreement for our leased property in the PRC will not affect the validity of this lease agreement, but if we fail to complete the registration within the prescribed time frame as required by competent municipal land and real estate administration departments in the PRC, a penalty for the Company ranging from RMB1,000 to RMB10,000 may be imposed for each non-registered lease. During the Track Record Period and up to the Latest Practicable Date, we had not received any such request or suffered any such fine from the relevant PRC government authorities.

### ***Changes in the U.S. and international trade policies, particular with regard to China, may adversely impact our business and operating results.***

International market conditions and the international regulatory environment have historically been affected by competition among countries and geopolitical frictions. Changes to trade policies, treaties and tariffs of the jurisdictions in which we operate, or the perception that these changes could occur, could adversely affect the financial and economic conditions of the jurisdictions in which we operate, as well as our overseas expansion, our financial condition and results of operations.

For instance, it is notable that the United States government has recently made significant changes in its trade policy and has taken certain actions that may materially impact international trade, such as announcing import tariffs which have led to other countries, including China and members of the

## RISK FACTORS

European Union, imposing tariffs against the United States in response. It is also unknown whether and to what extent any such actions would have any significant effect on us or our industry.

***Our business, results of operations and financial position could be adversely affected by the SVB collapse.***

On March 10, 2023, Silicon Valley Bank (“SVB”), a commercial bank founded in 1983 and headquartered in Santa Clara, California, failed after a bank run. The collapse of SVB has had a significant impact on startups from the U.S. and abroad, with many unable to withdraw money from the bank for a limited period of time. The US federal government has stepped in to guarantee customer deposits, but SVB’s downfall continues to reverberate across global financial markets.

The SVB downfall will not have any direct or developing impact on our operations, cash flows, or research and development progress in China and overseas as we are not a customer or shareholder of SVB. However, given the SVB downfall continues to be an evolving development and going forward, it is uncertain whether the SVB downfall will have any adverse impact on Chinese financial market, which in turn may adversely affect our results of operations, financial position or prospects in the future.

### RISKS RELATING TO DOING BUSINESS IN CHINA

**The approval of, or filing with, CSRC or other regulatory authorities may be required in connection with the [REDACTED] and future [REDACTED] activities, and we cannot predict whether we will be able to obtain all necessary approval or complete such filing.**

The PRC Government has recently indicated an intent to exert more oversight and control over securities [REDACTED] and other capital markets activities that are conducted overseas and foreign investment in PRC-based companies like us.

On July 6, 2021, the General Office of the State Council together with another authority jointly promulgated the Opinion on Severely Punishing Illegal Activities in Securities Market (the “**Securities Activities Opinions**”) (《關於依法從嚴打擊證券違法活動的意見》), which calls for the enhanced administration and supervision of overseas-listed China-based companies, proposes to revise the relevant regulation governing the overseas issuance and listing of shares by such companies and clarifies the responsibilities of competent domestic industry regulators and government authorities.

On February 17, 2023, the CSRC released the Trial Administrative Measures of Overseas Securities Offering and Listing by Domestic Companies (《境內企業境外發行證券和上市管理試行辦法》) (the “**Overseas Listing Trial Measures**”), which will become effective on March 31, 2023 and stipulates that domestic companies that seek to offer or list securities overseas, both directly and indirectly, shall complete the filing procedures and report relevant information to the CSRC. On the same date, the CSRC also released the Circular on the Arrangements for the Filing-based Administration of Overseas Securities Offering and Listing by Domestic Companies (《關於境內企業境外發行上市備案管理安排的通知》), which stipulates that domestic enterprises that have obtained the approval documents issued by the CSRC for overseas offering and listing (including new issuance) by joint-stock companies may continue their overseas offering and listing during the valid term of the approval documents. If the domestic companies fail to complete overseas offering and listing upon expiry of the term of the approval documents issued by the CSRC for overseas offering and listing, they shall go through filing as per relevant regulations. Please see “Regulatory Overview — Regulatory Provisions — Laws and Regulations Related to Overseas Securities Offering and Listing” in this document.

## RISK FACTORS

---

We obtained the approval issued by the CSRC for the [REDACTED] and the [REDACTED] on November 11, 2022, and such approval is valid for twelve months. According to Overseas Listing Trial Measures and the Circular on the Arrangements for the Filing-based Administration of Overseas Securities Offering and Listing by Domestic Companies, if the [REDACTED] is not completed within the validity period of the approval of CSRC, we will be required to complete the necessary filing procedures for the [REDACTED] and the [REDACTED].

***The pharmaceutical industry in China is highly regulated and such regulations are subject to change, which may affect approval and commercialization of our product candidates.***

The pharmaceutical industry in China is subject to comprehensive government regulation and supervision, encompassing the approval, registration, manufacturing, packaging, licensing and marketing of new products. For details of a discussion of regulatory requirements that are applicable to our current and planned business in China, see “Regulatory Overview” in this document. We believe our strategy and approach are consistent with the PRC government’s policies, but we cannot ensure that our strategy and approach will continue to be consistent. Additionally, in recent years, the regulatory framework in China regarding the pharmaceutical industry has undergone significant changes, and we expect that it will continue to undergo significant changes. Any such changes or amendments may result in increased compliance costs on our business or cause delays in or prevent the successful development or commercialization of our product candidates and reduce the current benefits we believe are available to us from developing and manufacturing our product candidates in China. The PRC authorities have also become increasingly vigilant in enforcing laws in the pharmaceutical industry and any failure by us to maintain compliance with applicable laws and regulations may result in the suspension or termination of our business activities in China.

***Adverse changes in political, economic and other policies of the PRC government could have a material adverse effect on the overall economic growth of China, which could reduce the demand for our products, or otherwise materially and adversely affect our business, operations or competitive position.***

Our business, results of operations, financial condition and prospects may be influenced to a significant degree by economic, political, legal and social conditions in China. China’s economy differs from the economies of developed countries in many respects, including with respect to the amount of government involvement, level of development, growth rate, control of foreign exchange, allocation of resources and an evolving regulatory system. The PRC government has implemented various measures to encourage economic development and guide the allocation of resources, but some of these measures may have a negative effect on us. For example, our financial condition and results of operations may be adversely and affected by government control over capital investments or changes in tax regulations that are currently applicable to us. More generally, while the PRC economy has experienced significant growth over the past 40 years, growth has been uneven across different regions and among various economic sectors of China, and there is no assurance that future growth will be sustained at similar rates or at all. If the business environment or economic conditions in China deteriorates from the perspective of domestic or international investment, our business may also be adversely affected.

***There are uncertainties regarding the interpretation and enforcement of PRC laws, rules and regulations.***

The PRC legal system is a civil law system based on written codes and statutes. Unlike the common law system, prior court decisions may be cited as persuasive authority but have limited precedential

## RISK FACTORS

---

value. Since the late 1970s, the PRC government has promulgated a comprehensive system of laws, rules and regulations governing economic matters in general. However, as these laws and regulations are relatively new and the number of published decisions is limited, their interpretation and enforcement involve significant uncertainties, and can be inconsistent and unpredictable. Specifically, since the PRC administrative and court authorities have significant discretion in interpreting and implementing statutory and contractual terms, it may be more difficult to evaluate the outcome of administrative and court proceedings and the level of legal protection we enjoy than in more developed legal systems. These uncertainties may impede our ability to enforce the contracts we have entered into and could materially and adversely affect our business, financial condition and results of operation.

Furthermore, PRC laws and regulations afford significant protection to state-owned assets. Transactions that may lead to losses of state-owned assets are subject to heightened scrutiny by the competent authorities, and the competent authorities have significant discretion in interpreting and implementing the relevant laws and regulations. In the event we or our affiliates conduct transactions with state-owned enterprises or their affiliates, there might be risks and uncertainties involved that we might be found to have caused losses of state-owned assets, which may subject us to liabilities and could materially and adversely affect our business, financial condition and results of operation. Finally, the PRC legal system is based in part on government policies and internal rules, some of which are not published on a timely basis or at all, and which may have a retroactive effect. As a result, we may not be aware of our violation of these policies and rules until after the occurrence of the violation.

***You may experience difficulties in effecting service of legal process and enforcing judgments against us and our management.***

We are incorporated under the laws of the PRC with limited liability, and substantially all of our assets are located in the PRC. In addition, a majority of our Directors and Supervisors and all of our senior management personnel reside within the PRC, and substantially all their assets are located within the PRC. As a result, it may not be possible to effect service of process within the United States or elsewhere outside the PRC upon us or most of our Directors, Supervisors and senior management personnel.

When it comes to trans-jurisdictional recognition and enforcement of judgments, the PRC does not have treaties providing for the reciprocal recognition and enforcement of judgments of courts with the United States, the United Kingdom, Japan or many other countries. In addition, Hong Kong has no arrangement for the reciprocal enforcement of judgments with the United States. As a result, recognition and enforcement in the PRC or Hong Kong of judgments of a court obtained in the United States and any of the other jurisdictions mentioned above may be difficult or impossible.

As between the PRC and Hong Kong, the new arrangement entered into between the Supreme People's Court of the PRC and the government of the Hong Kong Special Administrative Region on January 18, 2019 has lifted the requirements for a choice of court agreement in writing in a civil or commercial case under the previous regime on bilateral recognition and enforcement. However, before such new arrangement becomes officially effective, it may be difficult or impossible to enforce a judgment rendered by a Hong Kong court in PRC if the parties in the dispute do not agree to enter into a choice of court agreement in writing. As a result, it may be difficult or impossible for investors seek recognition and enforcement of foreign judgments in the PRC.

## RISK FACTORS

*Fluctuations in exchange rates may result in foreign currency exchange losses and may have a material adverse effect on your [REDACTED].*

The change in the value of the Renminbi against the Hong Kong dollar and other currencies may fluctuate and is affected by, among other things, changes in China’s political and economic conditions and China’s foreign exchange policies, as well as supply and demand in the local market. As such, it is difficult to predict how market forces or government policies may impact the exchange rate between Renminbi, the US dollar, the Hong Kong dollar or other currencies in the future. Substantially all of our costs are denominated in Renminbi and most of our financial assets are also denominated in Renminbi. However, our proceeds from the [REDACTED] will be denominated in Hong Kong dollars. As a China-based company, any significant change in the exchange rates of the Hong Kong dollar against Renminbi may materially adversely affect any dividends payable on, our H Shares in Hong Kong dollars.

*Our operations are subject to and may be affected by changes in PRC tax laws and regulations.*

We are subject to periodic examinations on fulfillment of our tax obligation under the PRC tax laws and regulations by PRC tax authorities, and there is no assurance that any such examinations by PRC tax authorities would not result in fines, other penalties or actions that could adversely affect our business, financial condition and results of operations, as well as our reputation. Furthermore, the PRC government from time to time adjusts or changes its tax laws and regulations. For example, under the Individual Income Tax Law of the PRC (Revised in 2018) (《中華人民共和國個人所得稅法(2018年修訂)》) and the amended *Individual Income Tax Law* (《中華人民共和國個人所得稅法實施條例》) that took effect on January 1, 2019, foreign nationals have no domicile in China but have resided in the PRC for a total of 183 days or more in a tax year, would be subject to PRC individual income tax on their income gained within or outside the PRC. Should such rule be strictly enforced, our ability to attract and retain highly skilled foreign scientists and research technicians to work in China may be materially affected. Further adjustments or changes to PRC tax laws and regulations, together with any uncertainty resulting therefrom, could also have an adverse effect on our business, financial condition and results of operations.

*Gains on the sales of H Shares and dividends on the H Shares may be subject to PRC income taxes.*

Under the applicable PRC tax laws, both the dividends we pay to non-PRC resident individual holders of H shares (“**Non-Resident Individual Holders**”), and gains realized through the sale or transfer by other means of H shares by such shareholders, are subject to PRC individual income tax at a rate of 20%, unless reduced by the applicable tax treaties or arrangements. And the dividends we pay to, and gains realized through the sale or transfer by other means of H shares by non-PRC resident enterprise holders of H shares are both subject to PRC enterprise income tax at a rate of 10%, unless reduced by applicable tax treaties or arrangements. In addition, any non-resident enterprise registered in Hong Kong that holds directly at least 25% of the shares of our Company shall pay enterprise income tax for the dividends declared and paid by us at a tax rate of 5%.

With respect to Non-Resident Individual Holders in specific, income received from dividends and bonuses of a foreign-invested enterprise, as well as that from transfer of stocks of listed companies are currently exempt from individual income tax pursuant to applicable PRC regulations. However, the newly enacted regulations have stated the PRC government’s plan to cancel foreign individuals’ tax exemption for dividends obtained from foreign-invested enterprises, and the relevant governmental departments have been charged of making and implementing details of such plan. At present, no relevant

## RISK FACTORS

---

implementation rules or regulations have been promulgated, but there is no assurance that any gains on the sales of our H Shares and the dividend thereon will not be subject to PRC income taxes in the future.

*We may be restricted from transferring our scientific data abroad or using human genetic resources collected in China.*

On March 17, 2018, the General Office of the State Council promulgated the Measures for the Management of Scientific Data (《科學數據管理辦法》) (the “**Scientific Data Measures**”), which provides a broad definition of scientific data and relevant rules for the management of scientific data. According to the Scientific Data Measures, enterprises in China must seek governmental approval before any scientific data involving a state secret may be transferred abroad or to foreign parties. Upon approval by the competent authorities, the enterprise shall undergo the required procedures, and enter into the confidentiality agreements with the users of the scientific data. Further, any researcher conducting research funded at least in part by the PRC government is required to submit relevant scientific data for management by the entity to which such researcher is affiliated before such data may be published in any foreign academic journal. Given that the term “state secret” is not clearly defined, if and to the extent any data collected or generated in connection with our R&D of product candidates will be subject to the Scientific Data Measures and any subsequent laws as required by the relevant government authorities, there is no assurance that we can always obtain relevant approvals for sending scientific data (such as the results of our pre-clinical studies or clinical trials conducted within China) abroad or to our foreign partners in China. As a result, we may be subject to fines and other administrative penalties imposed by those government authorities.

In addition, on July 2, 2015, the Ministry of Science and Technology issued the Service Guide for Administrative Licensing Items concerning Examination and Approval of Sampling, Collecting, Trading or Exporting Human Genetic Resources, or Taking Such Resources out of the PRC (《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》) (the “**Service Guide**”), which became effective on July 2, 2015. According to the Service Guide, the sampling, collection or research activities of human genetic resources through clinical trials shall be required to be filled with the China Human Genetic Resources Management Office through the online system. Then, on May 28, 2019 the State Council promulgated the Regulations of PRC on the Administration of Human Genetic Resources (《中華人民共和國人類遺傳資源管理條例》), which became effective on July 1, 2019 (the “**Human Genetic Resources Regulation**”). The Human Genetic Resources Regulation stipulates that collecting human genetic resources of China’s important genetic families and specific regions, or collecting those human genetic resources in such categories and quantities as prescribed by the administrative department for science and technology under the State Council, preserving China’s human genetic resources and providing the basic platform for scientific research, utilization of China’s human genetic resources for international cooperation in scientific research, as well as transporting China’s materials of human genetic resources abroad shall be subject to the approval of the administrative department for science and technology under the State Council. If we are unable to obtain necessary approvals or comply with the regulatory requirements in a timely manner, or at all, our R&D of product candidates may be hindered. If the relevant government authorities consider the transmission of our scientific data or collection and usage of human genetic resources to be in violation of the requirements under applicable PRC laws and regulations, we may be subject to fines and other administrative penalties imposed by those government authorities.

## RISK FACTORS

***Governmental control of currency conversion, and restrictions on the remittance of Renminbi into and out of China, may adversely affect the value of your [REDACTED].***

Renminbi is currently not a fully freely convertible currency. The PRC government imposes controls on the convertibility of Renminbi into foreign currencies and, in certain cases, the remittance of currency out of China. A portion of our revenue may be converted into other currencies in order to meet our foreign currency obligations, e.g., to obtain foreign currency to make payments of declared dividends, if any, on our H Shares. Under China’s existing laws and regulations on foreign exchange, following the completion of the [REDACTED], we will be able to make dividend payments in foreign currencies by complying with certain procedural requirements and without prior approval from the State Administration of Foreign Exchange. However, in the future, the PRC government may, at its discretion, take measures to restrict access to foreign currencies for capital account and current account transactions under certain circumstances. As a result, we may not be able to pay dividends in foreign currencies to holders of our H Shares.

***The political relationships between China and other countries may affect our business operations.***

During the Track Record Period, we have relied on collaboration with entities in foreign countries and regions. We may also pursue partnerships with entities in foreign countries and regions in the future. Our business is therefore subject to constantly changing international economic, regulatory, social and political conditions, and local conditions in foreign countries and regions. As a result, China’s political relationships with those foreign countries and regions may affect development and commercialization of our product candidates.

Additionally, China’s political relationships with those foreign countries and regions may also affect the prospects of our relationship with third parties. There can be no assurance that our existing or potential collaborators will not alter their perception of us or their preferences as a result of adverse changes to the state of political relationships between China and the relevant foreign countries or regions, and such alteration may cause a decline in the demand for our products and adversely affect our business, financial condition, results of operations, cash flows and prospects.

### **RISKS RELATING TO THE [REDACTED]**

***There has been no prior public market for our H Shares and there can be no assurance that an active market would develop, and the [REDACTED] and [REDACTED] of our H Shares may be volatile.***

Prior to this [REDACTED], there has been no [REDACTED] market for our H Shares, and the [REDACTED] for our [REDACTED] was the result of negotiations among us, the [REDACTED] and the [REDACTED] (for themselves and on behalf of the [REDACTED]). However, a [REDACTED] on the Stock Exchange does not guarantee that an active and liquid [REDACTED] for the H Shares will develop, or if it does develop, that it will be sustained following the [REDACTED], or that the [REDACTED] of the H Shares will not decline following the [REDACTED]. In addition, the [REDACTED] and [REDACTED] of the H Shares may be subject to significant volatility in responses to various factors beyond our control, including the general market conditions of the securities in Hong Kong and elsewhere in the world. In particular, the business and performance and the market price of the shares of other companies engaging in similar business may affect the [REDACTED] and [REDACTED] of our H Shares. Further, the [REDACTED] and [REDACTED] of our H Shares may be highly volatile for specific business reasons, such as the results of clinical trials of our product candidates, the results of our applications for approval of our product candidates, regulatory developments affecting the relevant markets, health insurance and other related matters, fluctuations in our revenue, earnings, cash flows, investments and expenditures, relationships with our suppliers, movements or activities of key personnel, or actions taken by competitors.



## RISK FACTORS

*You will incur immediate and significant dilution and raising additional capital may cause further dilution or restrict our operation.*

The [REDACTED] of the [REDACTED] is higher than the net tangible asset value per H Share immediately prior to the [REDACTED]. Therefore, purchasers of the [REDACTED] in the [REDACTED] will experience an immediate dilution in [REDACTED] consolidated net tangible asset value. There can be no assurance that if we were to immediately liquidate after the [REDACTED], any assets will be distributed to Shareholders after the creditors’ claims. If we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a shareholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, limitations on our ability to acquire or license intellectual property rights or declaring dividends, or other operating restrictions.

*Any possible conversion of Domestic Shares into H Shares could increase the supply of H Shares in the market, which will negatively impact the [REDACTED] of H Shares.*

According to the stipulations by the State Council’s securities regulatory authority and the Articles of Association, our Domestic Shares may be converted into H Shares and such converted H Shares may be [REDACTED] or [REDACTED] on an overseas stock exchange, provided that prior to the conversion and [REDACTED] of such converted 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, have been obtained. In addition, such conversion, [REDACTED] and [REDACTED] must 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. We can apply for the [REDACTED] of all or any portion of our Domestic Shares on the Hong Kong Stock Exchange as H Shares in advance of any proposed conversion to ensure that the conversion process can be completed promptly upon notice to the Hong Kong Stock Exchange and delivery of shares for entry on the H Share register. This could increase the supply of H Shares in the [REDACTED], and [REDACTED], or [REDACTED], of the converted H Shares may adversely affect the [REDACTED] of H Shares.

*There will be a time gap between [REDACTED] and [REDACTED] of our H Shares, and the [REDACTED] of our H Shares when [REDACTED] begins could be lower than the [REDACTED].*

The [REDACTED] of our H Shares sold in the [REDACTED] is expected to be determined on the [REDACTED]. However, the H Shares will not commence [REDACTED] on the Stock Exchange until they are delivered, which is expected to be five Business Days after the [REDACTED]. As a result, investors may not be able to [REDACTED] or otherwise [REDACTED] in the H Shares before the commencement of [REDACTED]. Accordingly, holders of our H Shares are subject to the risk that the [REDACTED] of the H Shares when [REDACTED] begins could be lower than the [REDACTED] as a result of adverse market conditions or other adverse developments that may occur between the time of [REDACTED] and the time [REDACTED] begins.

*If securities or industry analysts do not publish research or reports about our business, or if they adversely change their recommendations regarding our H Shares, the [REDACTED] for our H Shares and [REDACTED] may decline.*

The [REDACTED] for our H Shares will be influenced by research or reports that industry or securities analysts publish about us or our business. If one or more analysts who cover us downgrade our

## RISK FACTORS

---

H Shares or publishes negative opinions about us, the [REDACTED] for our H Shares would likely decline regardless of the accuracy of the information. If one or more of these analysts cease coverage of us or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause the [REDACTED] or [REDACTED] of our H Shares to decline.

*Future [REDACTED] or [REDACTED] of a substantial number of our H Shares in the [REDACTED] following the [REDACTED] could materially and adversely affect the [REDACTED] of our H Shares and our ability to raise additional capital in the future, and may result in dilution of your shareholding.*

Prior to the [REDACTED], there has not been a public market for our H Shares. Future [REDACTED] or [REDACTED] by our existing Shareholders of our Shares after the [REDACTED] could result in a significant decrease in the prevailing [REDACTED] of our H Shares. Only a limited number of the Shares currently outstanding will be available for [REDACTED] or issuance immediately after the [REDACTED] due to contractual and regulatory restrictions on disposal and new issuance. Nevertheless, after these restrictions lapse or if they are waived, future [REDACTED] of significant amounts of our H Shares in the [REDACTED] or the perception that these [REDACTED] may occur could significantly decrease the prevailing [REDACTED] of our H Shares and our ability to raise equity capital in the future.

*There can be no assurance that we will declare and distribute any amount of dividends in the future.*

There can be no assurance that we will declare and pay dividends because the declaration, payment and amount of dividends are subject to the discretion of our Directors, depending on, among other considerations, our operations, earnings, cash flows and financial position, operating and capital expenditure requirements, our strategic plans and prospects for business development, our constitutional documents and applicable law. For more details on our dividend policy, see “Financial Information — Dividend” in this document.

*Our Controlling Shareholders have significant influence over our Company and their interests may not be aligned with the interest of our other shareholders.*

Our Controlling Shareholders will, through its voting power at the Shareholders’ meetings and its delegates on the Board, have significant influence over our business and affairs, including decisions in respect of mergers or other business combinations, acquisition or disposition of assets, issuance of additional shares or other equity securities, timing and amount of dividend payments, and our management. Our Controlling Shareholder may not act in the best interests of our minority Shareholders. In addition, without the consent of our Controlling Shareholder, we could be prevented from entering into transactions that could be beneficial to us. This concentration of ownership may also discourage, delay or prevent a change in control of our Company, which could deprive our Shareholders of an opportunity to receive a premium for the Shares as part of a [REDACTED] of our Company and may significantly reduce the [REDACTED] of our H Shares.

*Facts, forecasts and statistics in this document relating to the PRC economy and pharmaceutical industry may not be fully reliable.*

Facts, forecasts and statistics in this document relating to the PRC economic and pharmaceutical industry in and outside China 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. However, we cannot guarantee the quality or reliability of these sources. Neither we, the Sole Sponsor,

## RISK FACTORS

---

the [REDACTED] nor our or their respective affiliates or advisers have verified the facts, forecasts and statistics nor ascertained the underlying economic assumptions relied upon in those facts, forecasts and statistics obtained from these sources. Due to possibly flawed or ineffective collection methods or discrepancies between published information and factual information and other problems, the industry statistics in this document may be inaccurate and you should not place undue reliance on it. We make no representation as to the accuracy of such facts, forecasts and statistics obtained from various sources. Moreover, these facts, forecasts and statistics involve risk and uncertainties and are subject to change based on various factors and should not be unduly relied upon.

*You should read the entire document carefully and we strongly caution you not to place any reliance on any information contained in press articles or other media coverage regarding us or the [REDACTED].*

You should rely solely upon the information contained in this document, the [REDACTED] and any formal announcements made by us in Hong Kong when making your [REDACTED] decision regarding our H Shares. Subsequent to the date of this document but prior to the completion of the [REDACTED], there may be press and media coverage regarding us and the [REDACTED], which may contain, among other things, certain financial information, projections, valuations and other forward-looking information about us and the [REDACTED]. We have not authorized the disclosure of any such information in the press or media and do not accept any responsibility for the accuracy or completeness of any such press articles or other media coverage, nor the fairness or appropriateness of any forecasts, views or opinions expressed by the press or other media regarding our H Shares, the [REDACTED] or us. 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 in any such press articles or media coverage. Accordingly, prospective investors are cautioned to make their [REDACTED] decisions on the basis of the information contained in this document only and should not rely on any other information. By applying to [REDACTED] our H Shares in the [REDACTED], you will be deemed to have agreed that you will not rely on any information other than that contained in this document.

**WAIVERS FROM STRICT COMPLIANCE WITH THE LISTING RULES AND  
EXEMPTION FROM STRICT COMPLIANCE WITH THE COMPANIES  
(WINDING UP AND MISCELLANEOUS PROVISIONS) ORDINANCE**

---

In preparation for the [REDACTED], our Company has sought and [has been granted] the following waivers from strict compliance with the Listing Rules and the following exemption from compliance with the Companies (Winding Up and Miscellaneous Provisions) Ordinance.

**WAIVER IN RELATION TO MANAGEMENT PRESENCE IN HONG KONG**

Pursuant to Rule 8.12 and Rule 19A.15 of the Listing Rules, we must have a sufficient management presence in Hong Kong. This normally means that at least two of our executive Directors must be ordinarily resident in Hong Kong.

Our management, business operations and assets are primarily located outside Hong Kong. The principal management headquarters of our Group are primarily based in the PRC. Our Company considers that our Group’s management is best able to attend to its functions by being based in the PRC. None of our executive Directors is or will be ordinarily resident in Hong Kong after the [REDACTED] of our Company. Our Directors consider that relocation of our executive Directors to Hong Kong will be burdensome and costly for our Company, and it may not be in the best interests of our Company and our Shareholders as a whole to appoint additional executive Directors who are ordinarily resident in Hong Kong. As such, we do not have, and for the foreseeable future will not have, sufficient management presence in Hong Kong for the purpose of satisfying the requirements under Rule 8.12 and Rule 19A.15 of the Listing Rules.

Accordingly, we have applied to the Stock Exchange for, and the Stock Exchange [has granted] us, 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:

- (1) we have appointed two authorized representatives pursuant to Rule 3.05 of the Listing Rules, who will act as our principal channel of communication with the Stock Exchange. The two authorized representatives appointed are Mr. KONG Jian (our executive Director) and Ms. YUEN Wing Yan, Winnie (the joint company secretary of our Company). Ms. YUEN Wing Yan, Winnie is situated and based in Hong Kong. Each of our 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, facsimile and email;
- (2) our Company will implement a policy to provide the contact details of each Director (such as mobile phone numbers, office phone numbers and email addresses) to each of the authorized representatives and to the Stock Exchange. This will ensure that as and when the Stock Exchange wishes to contact our Directors on any matters, each of our authorized representatives has the means to contact all of our Directors (including the independent non-executive Directors) promptly at all times;
- (3) although our executive Directors are not ordinary residents in Hong Kong, each of our Directors possesses or can apply for valid travel documents to visit Hong Kong and is able to meet with the Stock Exchange within a reasonable period of time, when required;

**WAIVERS FROM STRICT COMPLIANCE WITH THE LISTING RULES AND  
EXEMPTION FROM STRICT COMPLIANCE WITH THE COMPANIES  
(WINDING UP AND MISCELLANEOUS PROVISIONS) ORDINANCE**

---

- (4) we have appointed Fosun International Capital Limited as our compliance advisor, pursuant to Rule 3A.19 of the Listing Rules, who will have access at all times to our authorized representatives, Directors and senior management, and will act as an additional channel of communication between the Stock Exchange and us; and
- (5) we have provided the Stock Exchange with the contact details of each Director (including their respective mobile phone number, office phone number and e-mail address).

Our Company will inform the Stock Exchange as soon as practicable in respect of any change in our authorized representatives, our Directors and/or our compliance advisor in accordance with the Listing Rules.

**WAIVER IN RELATION TO JOINT COMPANY SECRETARIES**

Pursuant to Rule 8.17 of the Listing Rules, an issuer must appoint a company secretary who satisfies the requirements under Rule 3.28 of the Listing Rules. According to Rule 3.28 of the Listing Rules, we must appoint an individual as the company secretary of our Company who, by virtue of his or her academic or professional qualifications or relevant experience, is, in the opinion of the Stock Exchange, capable of discharging the functions of company secretary.

Note 1 to Rule 3.28 of the Listing Rules provides that the Stock Exchange considers the following academic or professional qualifications to be acceptable:

- (a) a member of The Hong Kong Chartered Governance Institute;
- (b) a solicitor or barrister (as defined in the Legal Practitioners Ordinance); or
- (c) a certified public accountant (as defined in the Professional Accountants Ordinance).

Note 2 to Rule 3.28 of the Listing Rules provides that in assessing "relevant experience", the Stock Exchange will consider the individual's:

- (a) length of employment with the Company and other listed companies and the roles he/she played;
- (b) familiarity with the Listing Rules and other relevant law and regulations including the Securities and Futures Ordinance, the Companies Ordinance, the Companies (Winding Up and Miscellaneous Provisions) Ordinance and the Takeovers Code;
- (c) relevant training taken and/or to be taken in addition to the minimum requirement of taking not less than fifteen hours of relevant professional training in each financial year under Rule 3.29 of the Listing Rules; and
- (d) professional qualifications in other jurisdictions.

**WAIVERS FROM STRICT COMPLIANCE WITH THE LISTING RULES AND  
EXEMPTION FROM STRICT COMPLIANCE WITH THE COMPANIES  
(WINDING UP AND MISCELLANEOUS PROVISIONS) ORDINANCE**

---

We have appointed Mr. LIU Siyu (“**Mr. LIU**”) and Ms. YUEN Wing Yan, Winnie (“**Ms. YUEN**”) as the joint company secretaries of our Company.

Although Mr. LIU does not possess the qualifications set out in Rule 3.28 of the Listing Rules, we appointed him as the joint company secretary of our Company due to his familiarity with the internal administration and communications, corporate governance and legal compliance issues of our Group. As the secretary of our Board, Mr. LIU is primarily responsible for handling daily affairs and communications of our Board, assisting our Board in legal compliance and corporate governance matters, and handling external financing and public relations of our Group, including but not limited to liaising with our investors, relevant governmental authorities and the media. Through serving as the secretary of our Board, Mr. LIU has also familiarized himself with the relevant PRC laws and regulations related to the biopharmaceutical industry and applicable to our Company. He has also developed a close nexus and solid working relationship with our Directors and senior management team. Accordingly, our Directors consider Mr. LIU is a suitable candidate to act as the joint company secretary of our Company and believe that his appointment is in the interest of our Company and will facilitate our corporate governance and on-going compliance with the Listing Rules upon [REDACTED] given his relationship with our Board and familiarity with the matters of our Group.

On the other hand, Ms. YUEN is a Chartered Secretary, a Chartered Governance Professional and a fellow of both the Hong Kong Chartered Governance Institute (HKCGI) (formerly known as the Hong Kong Institute of Chartered Secretaries) and the Chartered Governance Institute (CGI) (formerly known as the Institute of Chartered Secretaries and Administrators) in the United Kingdom, and therefore meets the qualification requirements under Note 1 to Rule 3.28 of the Listing Rules. We have appointed Ms. YUEN as one of the joint company secretaries of our Company so as to fully comply with the requirements set forth under Rule 8.17 of the Listing Rules. Apart from discharging her functions in her role as one of the joint company secretaries of our Company, Ms. YUEN will work closely and assist Mr. LIU in enabling him to acquire the relevant company secretary experience as required under Rule 3.28 of the Listing Rules and to become familiar with the requirements of the Listing Rules and other applicable Hong Kong laws and regulations. In addition, Mr. LIU will attend relevant professional training during each financial year as required under Rule 3.29 of the Listing Rules. For more details of Mr. LIU’s and Ms. YUEN’s biographical information, see “Directors, Supervisors and Senior Management — Joint Company Secretaries” in this document.

Accordingly, we have applied to the Stock Exchange for, and the Stock Exchange [has granted] us, a waiver from strict compliance with the requirements under Rules 3.28 and 8.17 of the Listing Rules. Pursuant to Guidance Letter HKEX-GL108-20 issued by the Stock Exchange, the waiver is granted on the following conditions:

- (a) Mr. LIU must be assisted by Ms. YUEN, who possesses the qualifications and experience required under Rule 3.28 of the Listing Rules and shall remain appointed as a joint company secretary of our Company throughout the three-year waiver period;

**WAIVERS FROM STRICT COMPLIANCE WITH THE LISTING RULES AND  
EXEMPTION FROM STRICT COMPLIANCE WITH THE COMPANIES  
(WINDING UP AND MISCELLANEOUS PROVISIONS) ORDINANCE**

---

- (b) the waiver is valid for a period of three years from the [REDACTED] and will be revoked immediately if and when Ms. YUEN ceases to provide such assistance or if there are material breaches of the Listing Rules by our Company. Prior to the expiry of the three-year period, the qualifications and experience of Mr. LIU and his need for on-going assistance will be further evaluated by us. We will liaise with the Stock Exchange to enable it to assess whether Mr. LIU, having benefited from the assistance of Ms. YUEN for the preceding three years, will have acquired the skills necessary to carry out the duties of a company secretary and the relevant experience within the meaning of Note 2 to Rule 3.28 of the Listing Rules so that a further waiver will not be necessary;
- (c) Ms. YUEN will communicate regularly with Mr. LIU on matters relating to corporate governance, the Listing Rules, as well as other laws and regulations which are relevant to our Company and our other affairs. Ms. YUEN will work closely with, and provide assistance to, Mr. LIU in the discharge of his duties as company secretary and to acquire the relevant experience as required under Rule 3.28 of the Listing Rules;
- (d) Mr. LIU will also be assisted by our compliance advisor and our Hong Kong legal advisors, particularly in relation to Hong Kong corporate governance practices and regulatory compliance, on matters concerning our Company's ongoing compliance obligations under the Listing Rules and the applicable laws and regulations; and
- (e) Mr. LIU will endeavor to attend relevant training and familiarize himself with the Listing Rules and duties required for a company secretary of an issuer listed on the Stock Exchange, including briefing on the latest changes to the applicable Hong Kong laws and regulations and the Listing Rules as may be organized by our Hong Kong legal advisors or other professional bodies and seminars as may be organized by the Stock Exchange for issuers from time to time.

**EXEMPTION FROM COMPLIANCE WITH PARAGRAPH 27 OF PART I AND PARAGRAPH 31  
OF PART II OF THE THIRD SCHEDULE TO THE COMPANIES (WINDING UP AND  
MISCELLANEOUS PROVISIONS) ORDINANCE**

Section 342(1) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance requires all prospectuses to include matters specified in Part I of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance, and set out the report specified in Part II of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance.

Paragraph 27 of Part I of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance requires a company to include in its prospectus a statement as to the gross trading income or sales turnover (as the case may be) of such company during each of the three financial years immediately preceding the issue of the prospectus, as well as an explanation of the method used for the computation of such income or turnover and a reasonable breakdown of the more important trading activities.

**WAIVERS FROM STRICT COMPLIANCE WITH THE LISTING RULES AND  
EXEMPTION FROM STRICT COMPLIANCE WITH THE COMPANIES  
(WINDING UP AND MISCELLANEOUS PROVISIONS) ORDINANCE**

---

Paragraph 31 of Part II of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance further requires a company to include in its prospectus a report prepared by the auditors of the company with respect to (i) the profits and losses of the company for each of the three financial years immediately preceding the issue of the prospectus, and (ii) the assets and liabilities of the company as of the last date to which the financial statements were prepared.

Section 342A(1) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance provides that the SFC may issue, subject to such conditions (if any) as the SFC thinks fit, a certificate of exemption from compliance with the relevant requirements under the Companies (Winding Up and Miscellaneous Provisions) Ordinance if, having regard to the circumstances, the SFC considers that the exemption will not prejudice the interests of the investing public and compliance with any or all of such requirements would be irrelevant or unduly burdensome, or is otherwise unnecessary or inappropriate.

Rule 4.04(1) of the Listing Rules requires that the accountants' report contained in a prospectus must include, inter alia, the results of the company in respect of each of the three financial years immediately preceding the issue of the prospectus or such shorter period as may be acceptable to the Stock Exchange.

Rule 18A.06 of the Listing Rules requires that an eligible biotech company shall comply with Rule 4.04 of the Listing Rules modified so that references to "three financial years" or "three years" in that rule shall instead reference to "two financial years" or "two years", as the case may be.

In compliance with the abovementioned requirements under the Listing Rules, the Accountants' Report set out in Appendix I to this document is prepared to cover the two financial years ended December 31, 2022.

As such, we have applied to the SFC for, and the SFC [has granted], a certificate of exemption from strict compliance with the requirements under paragraph 27 of Part I and paragraph 31 of Part II of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance regarding the inclusion of an accountants' report covering the full three financial years immediately preceding the issue of this document on the following grounds:

- (a) our Company is primarily engaged in the research and development, application and commercialization of biotech products, and falls within the scope of biotech company as defined under Chapter 18A of the Listing Rules. Our Company will fulfill the additional conditions for [REDACTED] applicable to a Chapter 18A company;
- (b) the Accountants' Report for the two financial years ended December 31, 2022 has been prepared and is set out in Appendix I to this document in accordance with Rule 18A.06 of the Listing Rules;



**WAIVERS FROM STRICT COMPLIANCE WITH THE LISTING RULES AND  
EXEMPTION FROM STRICT COMPLIANCE WITH THE COMPANIES  
(WINDING UP AND MISCELLANEOUS PROVISIONS) ORDINANCE**

---

- (c) notwithstanding that the financial results set out in this document are only for the two financial years ended December 31, 2022 in accordance with Chapter 18A of the Listing Rules, other information required to be disclosed under the Listing Rules and requirements under the Companies (Winding up and Miscellaneous Provisions) Ordinance has been adequately disclosed in this document pursuant to the relevant requirements;
- (d) given that our Company is only required to disclose its financial results for the two financial years ended December 31, 2022 in accordance with Chapter 18A of the Listing Rules and the preparation of the financial results and audited financial report for the financial year ended December 31, 2020 would require additional work to be performed by our Company and the reporting accountants of our Company, strict compliance with the requirements of section 342(1)(b) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance and paragraph 27 of Part I and paragraph 31 of Part II of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance would be unduly burdensome for our Company; and
- (e) the Accountants' Report covering the two financial years ended December 31, 2022, together with other disclosures in this document, have already provided the potential investors with adequate and reasonable up-to-date information in the circumstances to form a view on the track record of our Company, and the Directors confirm that all information which is necessary for the investing public to make an informed assessment of the business, assets and liabilities, financial position, management and prospects has been included in this document. Therefore, the exemption would not prejudice the interest of the investing public.

The SFC [has granted] a certificate of exemption under section 342A of the Companies (Winding Up and Miscellaneous Provisions) Ordinance exempting our Company from strict compliance with section 342(1)(b) in relation to paragraph 27 of Part I and paragraph 31 of Part II of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance on the conditions that particulars of the exemption are set out in this document and this document will be issued on or before **[REDACTED]**.

Our Directors and the Sole Sponsor confirm that after performing all due diligence work which they consider appropriate, up to the date of this document, there has been no material adverse change to the financial and trading positions or prospects of our Company since December 31, 2022 (immediately following the date of the latest audited statement of financial position in the Accountants' Report set out in Appendix I to this document) to the date of this document and there has been no event which would materially affect the information shown in the Accountants' Report as set out in Appendix I to this document and the section headed "Financial Information" in this document and other parts of this document.

**INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]**

---

[REDACTED]

**INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]**

---

[REDACTED]

**INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]**

---

[REDACTED]

**INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]**

---

[REDACTED]

**INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]**

---

[REDACTED]

**DIRECTORS, SUPERVISORS AND PARTIES INVOLVED IN THE [REDACTED]**

**DIRECTORS**

<b>Name</b>	<b>Address</b>	<b>Nationality</b>
<b>Executive Directors</b>		
Mr. KONG Jian (孔健)	Room 301, Door 5, 14/F No. 4, Nanli, Sanjianfang Chaoyang District Beijing PRC	Chinese
Ms. ZHANG Yanping (張琰平)	Room 301, Door 5, 14/F No. 4, Nanli, Sanjianfang Chaoyang District Beijing PRC	Chinese
Ms. JIANG Xianmin (蔣先敏)	Building 26 Jingtong Court Chaoyang District Beijing PRC	Chinese
<b>Non-executive Directors</b>		
Mr. MA Biao (馬驥)	No. 8 Xingsheng Street Beijing Economic and Technological Development Zone Beijing PRC	Chinese
Mr. KONG Shuangquan (孔雙泉)	Unit 401 Building 2, Area 1, Zone 2 Tianhuayuan Beijing Economic and Technological Development Zone Beijing PRC	Chinese

**DIRECTORS, SUPERVISORS AND PARTIES INVOLVED IN THE [REDACTED]**

<b>Name</b>	<b>Address</b>	<b>Nationality</b>
<b>Independent non-executive Directors</b>		
Mr. LEUNG Wai Yip (梁偉業)	Room D, 29th floor Block 11, Royal Ascot Fo Tan Hong Kong	Canadian
Mr. LIANG Yeshe (梁冶矢)	Room 3-1903 Vanke Star Park Chaoyang District Beijing PRC	Chinese
Ms. HOU Aijun (侯愛軍)	Room 601 Building 36, District 13 Heping Street Chaoyang District Beijing PRC	Chinese

**SUPERVISORS**

<b>Name</b>	<b>Address</b>	<b>Nationality</b>
Ms. PENG Ling (彭玲)	Room 301, Unit 2 No. 125 Jinjiuhua Stonemason District Tuqiao Area Tongzhou District Beijing PRC	Chinese
Ms. KONG Xi (孔茜)	Room 1504, Unit 3, Building 1 West District Huanhu Town, Zhangjiawan Tongzhou District Beijing PRC	Chinese
Mr. CHEN Liang (陳亮)	6-3-502, Delin Garden Jiugong Town Daxing District Beijing PRC	Chinese

For the biographies and other relevant information of the Directors and Supervisors, see “Directors, Supervisors and Senior Management” in this document.



**DIRECTORS, SUPERVISORS AND PARTIES INVOLVED IN THE [REDACTED]**

---

**PARTIES INVOLVED IN THE [REDACTED]**

**Sole Sponsor, [REDACTED]  
[REDACTED] and [REDACTED]  
[REDACTED]**

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

[REDACTED]

**Financial Advisor**

**CCB International Capital Limited**  
12/F CCB Tower  
3 Connaught Road Central  
Central  
Hong Kong

**Legal Advisors to the Company**

*as to Hong Kong and U.S. laws:*

**O’Melveny & Myers**  
31/F, AIA Central  
1 Connaught Road Central  
Hong Kong

**DIRECTORS, SUPERVISORS AND PARTIES INVOLVED IN THE [REDACTED]**

---

*as to Hong Kong law:*

**Eric Chow & Co. in Association with  
Commerce & Finance Law Offices**

3401, Alexandra House  
18 Chater Road, Central  
Hong Kong

*as to PRC law:*

**Commerce & Finance Law Offices**

12-14/F, China World Office 2  
No. 1 Jianguomenwai Avenue  
Beijing  
PRC

**Legal Advisors to the Sole Sponsor  
and [REDACTED]**

*as to Hong Kong and U.S. laws:*

**Wilson Sonsini Goodrich & Rosati**

Suite 1509, 15/F, Jardine House  
1 Connaught Place  
Central  
Hong Kong

*as to PRC law:*

**Zhong Lun Law Firm**

6, 10, 11, 16, 17/F, Two IFC  
8 Century Avenue  
Pudong New Area  
Shanghai  
PRC

**Auditors and Reporting Accountants**

**Deloitte Touche Tohmatsu**

*Certified Public Accountants*  
35/F, One Pacific Place  
88 Queensway  
Hong Kong

**Industry Consultant**

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

Suite 2504, Wheelock Square  
1717 Nanjing West Road  
Shanghai  
PRC

**DIRECTORS, SUPERVISORS AND PARTIES INVOLVED IN THE [REDACTED]**

---

**Independent Property Valuer**

**Savills Valuation and Professional Services (China)**

**Limited**

1208, 12/F

1111 King's Road, Taikoo Shing

Hong Kong

**PRC Intellectual Property**

**Legal Advisor**

**Hiways Law Firm**

Room 703, Tower A, Oriental Media Center

4 Guanghua Road

Beijing 100026

PRC

**[REDACTED]**

## CORPORATE INFORMATION

---

**Registered Office, Headquarters and  
Principal Place of Business in the  
PRC**

No. 3 Guangtong Street  
Zhangjiawan  
Tongzhou District  
Beijing  
PRC

**Principal Place of Business in Hong  
Kong**

5/F, Manulife Place  
348 Kwun Tong Road  
Kowloon  
Hong Kong

**Company Website**

**[www.luzhubiotech.com](http://www.luzhubiotech.com)**

(Information contained on this website does not form part of this document)

**Joint Company Secretaries**

Mr. LIU Siyu (劉斯宇)  
2902, Block B, Building 8  
South Apple Community  
Shuangjing Street  
Chaoyang District  
Beijing  
PRC

Ms. YUEN Wing Yan, Winnie (袁穎欣) (FCG, HKFCG)  
5/F, Manulife Place  
348 Kwun Tong Road  
Kowloon  
Hong Kong

**Authorized Representatives**

Mr. KONG Jian (孔健)  
No. 4, Nanli  
Sanjianfang  
Chaoyang District  
Beijing  
PRC

Ms. YUEN Wing Yan, Winnie (袁穎欣) (FCG, HKFCG)  
5/F, Manulife Place  
348 Kwun Tong Road  
Kowloon  
Hong Kong

## CORPORATE INFORMATION

---

**Audit Committee**

Ms. HOU Aijun (侯愛軍) (*Chairlady*)  
Mr. KONG Shuangquan (孔雙泉)  
Mr. LEUNG Wai Yip (梁偉業)

**Remuneration Committee**

Mr. LIANG Yeshe (梁冶矢) (*Chairman*)  
Mr. KONG Jian (孔健)  
Mr. LEUNG Wai Yip (梁偉業)

**Nomination Committee**

Mr. KONG Jian (孔健) (*Chairman*)  
Mr. LIANG Yeshe (梁冶矢)  
Ms. HOU Aijun (侯愛軍)

**Compliance Advisor**

**Fosun International Capital Limited**  
Suite 2101-2105  
21/F, Champion Tower  
3 Garden Road  
Central  
Hong Kong

[REDACTED]

**Principal Bankers**

**Agricultural Bank of China Limited Beijing Free Trade Zone Zhangjiawan Design Town Branch**  
No. 7 Guanghua road  
Zhangjiawan town  
Tongzhou district  
Beijing  
PRC

**China Construction Bank Corporation Beijing Desheng Branch**  
Hesheng Fortune Plaza  
No. 13 Dewai Street  
Xicheng District  
Beijing  
PRC

## INDUSTRY OVERVIEW

*The information and statistics set out in this section and other sections of this document were extracted from the Frost & Sullivan Report, which was commissioned by us, and from various official government publications and other publicly available publications. We engaged Frost & Sullivan to prepare the Frost & Sullivan Report, an independent industry report, in connection with the [REDACTED]. The information from official government sources has not been independently verified by us, the [REDACTED], Sole Sponsor, [REDACTED], [REDACTED], any of the [REDACTED], any of their respective directors and advisers, or any other persons or parties involved in the [REDACTED], and no representation is given as to its accuracy.*

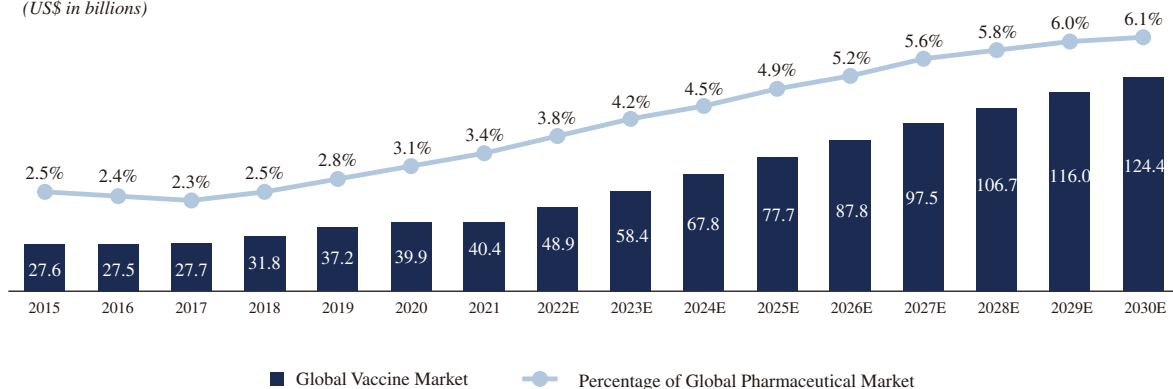
### OVERVIEW OF THE GLOBAL VACCINE MARKET

Vaccines are biological preparations that provide active acquired immunity against a particular disease. A vaccine typically contains one or several antigens from, or similar to, a disease-causing microorganism and improves immunity to a particular disease upon administration by inducing specific immune responses. Since the development of the first vaccine in 1798 to protect against smallpox, advances in biotechnology have promoted the development of vaccines. In the past two decades, the application of molecular genetics has furthered our understanding of immunology, microbiology and genomics, and their integration in vaccine research, which has led to the launch of innovative vaccines. The global vaccine market increased from US\$27.6 billion in 2015 to US\$40.4 billion in 2021 at a CAGR of 6.6%, and is expected to grow to US\$77.7 billion in 2025 at a CAGR of 17.8% from 2021 to 2025, and further grow to US\$124.4 billion in 2030 at a CAGR of 9.9% from 2025 to 2030. The chart below illustrates the historical and forecasted global vaccine market size for the periods indicated:

**Global Vaccine Market, 2015-2030E**

Period	CAGR
2015-2021	6.6%
2021-2025E	17.8%
2025E-2030E	9.9%

(US\$ in billions)



**Notes:**

- (1) The assumption of the global vaccine market size is based on the increasing proportion of vaccines in the global pharmaceutical market, as well as the revenue data disclosed by the major vaccine manufacturers. The COVID-19 vaccine market is not taken into consideration.
- (2) Percentage of global pharmaceutical market is calculated and forecasted based on 2020 data.

Source: Public disclosure of listed companies, expert interviews, Frost & Sullivan Analysis

## INDUSTRY OVERVIEW

The following table summarizes details of the top ten bestselling vaccines globally in 2022.

### Global Top Ten Best Selling Vaccines, 2022

Ranking	Vaccine	Manufacturer	Revenue, 2022	Vaccine Category
1	Comirnaty	Pfizer/BioNTech	USD 40.8 billion	Covid-19 mRNA vaccine
2	Spikevax	Moderna	USD 21.8 billion	Covid-19 mRNA vaccine
3	Gardasil, Gardasil 9	MSD	USD 6.9 billion	HPV vaccine
4	Prevnar Family	Pfizer	USD 6.3 billion	Pneumonia
5	Shingrix®	GSK	USD 3.6 billion***	Shingles
6	Fluzone, Flublok (flu vaccine)	Sanofi	USD 3.1 billion*	Influenza
7	Polio/Pertussis/Hib Vaccines	Sanofi	USD 2.4 billion**	Polio, Pertussis, and Hib Infection and etc.
8	ProQuad/M-M-R II/Varivax	MSD	USD 2.2 billion	Measles, Mumps, Rubella and Varicella
9	Ad26.COVS.2.S	J&J	USD 2.2 billion	Adenovirus-vectored Vaccines for COVID-19
10	Vaxzevria	AstraZeneca	USD 1.8 billion	Adenovirus-vectored Vaccines for COVID-19

Note: Exchange rate in 2022: 1 USD = 0.811GBP, 1 USD = 0.951 EUR

Source: Companies' 2022 annual reports, Frost & Sullivan analysis

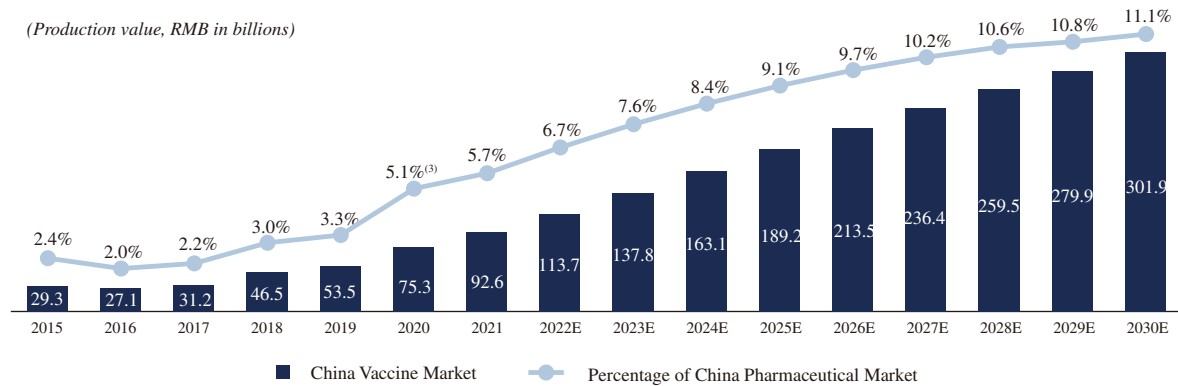
The vaccine market in China is expected to experience a stable growth in the forecast period, mainly due to (i) the population growth and urbanization: China's large population and increasing urbanization have led to a growing demand for vaccines; (ii) growing awareness of importance of vaccination: public awareness of the benefits of vaccination has been growing in China; (iii) increasing market competition and innovation: the increasing number of vaccine manufacturers in China has led to greater competition, driving innovation and improvements in vaccine offerings, which has helped expand the range of available vaccines and increased the accessibility to the public; (iv) improved vaccine quality and safety: after several incidents related to vaccine safety, the relevant authorities in China have tightened supervision on vaccine production, which has improved quality and safety of vaccines produced in China, increasing public trust and demand for domestically manufactured vaccines; (v) technological advancements: Chinese biopharmaceutical companies continue to adopt new technologies and innovations in vaccine production, which also contributes to the growth of the market; (vi) shifting marketing and distribution strategies: Chinese vaccine manufacturers are adopting new marketing and distribution strategies to reach a wider customer base, including working with healthcare providers, leveraging online platforms, and partnering with local governments and private healthcare providers to improve accessibility of vaccines. In terms of production value, the vaccine market in China increased from RMB29.3 billion in 2015 to RMB92.6 billion in 2021 at a CAGR of 21.2%, and is expected to grow to RMB189.2 billion in 2025 at a CAGR of 19.5% from 2021 to 2025, and further grow to RMB301.9 billion in 2030 at a CAGR of 9.8% from 2025 to 2030. The chart below illustrates the historical and forecasted vaccine market size in China for the periods indicated:

## INDUSTRY OVERVIEW

### Vaccine Market in China, 2015-2030E

Period	CAGR
2015-2021	21.2%
2021-2025E	19.5%
2025E-2030E	9.8%

(Production value, RMB in billions)



#### Notes:

- (1) China’s vaccine market size is measured by output value and forecasted based on annual batch issuance data. The COVID-19 vaccine market is not taken into consideration, as COVID-19 vaccines target specifically to the COVID-19 pandemic, which is temporary and unsustainable, and thus, it cannot reflect the true value of the vaccine market in China. The historical data is gathered from the National Institutes for Food and Drug Control (NIFDC). The forecasted data is based on the assumption the market is continuously driven by the unmet medical needs of the vaccine industry of China.
- (2) Percentage of China pharmaceutical market is calculated based on 2020 data.
- (3) The rapid growth of the vaccine market in 2020 was largely due to the promulgation of the Vaccine Administration Law of the PRC (《中華人民共和國疫苗管理法》) in 2019 and the increasing awareness of personal health and vaccines after the outbreak of COVID-19. In the previous years, the vaccine market in China grew in a relatively slow pace due to several vaccine safety incidents. However, after the promulgation of the Vaccine Administration Law of the PRC in 2019, which mainly aimed at encouraging innovation of vaccines, improving industry concentration and encouraging export, the vaccine market in China started to revitalize. In addition, due to the outbreak of COVID-19, the public awareness of personal health and vaccines has been improved.

Source: Expert interviews, NIFDC, Frost & Sullivan Analysis

In terms of government policies, the Chinese government has issued several favorable policies to incentivize the development of the vaccine industry. In China’s 14th 5-Year Plan, it sets out the aim to expand immunization plans. In 2017, Opinions of the General Office of the State Council on Further Strengthening the Management of Vaccine Circulation and Vaccination (國務院辦公廳關於進一步加強疫苗流通和預防接種管理工作的意見) set out principles to promote domestic vaccine manufacturers to scale up production of vaccines, independent R&D and to improve quality of vaccines to support R&D and industrialization of new vaccines, especially combination vaccines and multivalent vaccines; and financially support R&D of eligible vaccines through national science and technology programs, which also points out that the media should play a crucial role in educating the public for immunization knowledge, such as the importance, safety, and effectiveness of vaccination, and increasing vaccination rate of the public. These policies are in favor of developing new vaccines, as well as assist new vaccines to enter the market.



## INDUSTRY OVERVIEW

---

### Entry Barriers of the Human Vaccines Market in China

Entry barriers to the human vaccines market in China include (i) long development cycle, (ii) compliance with government regulations, (iii) production capacity, and (iv) capital requirement.

- *Long development cycle.* Vaccine development is an arduous process. The vaccine development process begins with initial preclinical research, followed by clinical trials to assess the efficacy and safety of the vaccine before the vaccine can obtain NMPA approval. The R&D cycle of a new vaccine can take 10-15 years to complete, which also requires large capital investment, with a low market success rate. Therefore, the complexity, time commitment and large capital requirement to effectively conduct R&D of vaccines establish high entry barriers for new market entrants in the vaccine industry.
- *Compliance with government regulations.* Due to vaccine related incidents in China in recent years, the Vaccine Administration Law of the People’s Republic of China (《中華人民共和國疫苗管理法》) (the “VAL”) was promulgated by the National People’s Congress Standing Committee on June 29, 2019, which updated vaccine management to the national level, reflecting the strictest supervision. According to the latest vaccine management law, the vaccine industry is subject to strong supervision in the R&D, production, circulation and vaccination of vaccines. Increasingly stringent regulatory policies will continue to increase the barriers to enter into the vaccine industry.
- *Production capacity.* The VAL stipulates that vaccine marketing license holders should have vaccine production capacity, and approval by the drug regulatory department of the State Council is required if vaccine production capacity exceeds a certain threshold. Those who accept commissioned production shall comply with the provisions of this law and relevant state regulations to ensure the quality of their vaccines. This regulation requires vaccine marketing license holders to have their own vaccine production facilities that meet GMP requirements. The technology and funds to build GMP compliant production facilities are also barriers to enter into the vaccine market.
- *Capital requirement.* The development of a new vaccine requires large capital investment. The construction of R&D facilities and manufacturing facilities require extensive capital resources. In addition, continuous funding is needed to conduct research and clinical trials.

### HERPES ZOSTER VACCINE MARKET

#### Overview

Herpes zoster also known as shingles, is a viral infection that causes a painful rash. It is caused by the reactivation of the varicella-zoster virus (VZV), the same virus that causes chickenpox (varicella). Symptoms include pain, itching, or tingling in the area which will later develop into a rash. Other symptoms of herpes zoster can include fever, headache, chills, and upset stomach. The most common complication of herpes zoster is postherpetic neuralgia (PHN). Approximately 9% to 34% of patients with herpes zoster have the potential risk of developing PHN. Other complications of herpes zoster may lead to serious complications involving the eye, including blindness. In rare occasions, it can also lead to pneumonia, hearing problems, brain inflammation or death.

## INDUSTRY OVERVIEW

There are three types of herpes zoster vaccines, namely live attenuated vaccines, recombinant vaccines and messenger RNA (mRNA) vaccines.

Category	Introduction	Advantages	Disadvantages
<b>Live attenuated herpes zoster vaccine</b>	Conventional vaccines using intact pathogens (bacteria or viruses) as antigens	<ul style="list-style-type: none"> <li>• Lower production costs</li> <li>• Fewer side effects</li> </ul>	<ul style="list-style-type: none"> <li>• Risk of residual virulence</li> <li>• Not applicable for people with weakened immune systems</li> </ul>
<b>Recombinant herpes zoster vaccine</b>	A vaccine produced through recombinant DNA technology. This involves inserting the DNA encoding an antigen (such as a bacterial surface protein) that stimulates an immune response into bacterial or mammalian cells, expressing the antigen in these cells and then purifying it from them.	<ul style="list-style-type: none"> <li>• Induces a human immune response while avoiding other components of the pathogen causing adverse effects on human body</li> <li>• Safe for people with weak immune systems</li> </ul>	<ul style="list-style-type: none"> <li>• Adjuvants are needed to help stimulate the body’s immune system response and booster shots are needed to achieve continuous protection</li> </ul>
<b>mRNA herpes zoster vaccine</b>	The latest vaccine technology. mRNA vaccines work by introducing a piece of mRNA that corresponds to a viral protein, usually a small piece of a protein found on the virus’s outer membrane. Using this mRNA blueprint, cells produce the viral protein.	<ul style="list-style-type: none"> <li>• Can be quickly designed and scaled up, and the manufacturing is sequence-independent, which makes it highly adaptable to different pathogens. The cost is lower than other platforms</li> <li>• Effective in avoiding the risk of virus leakage and infection</li> </ul>	<ul style="list-style-type: none"> <li>• Technology is relatively new and needs more studies to validate the immunogenicity and efficacy</li> </ul>

Source: Frost & Sullivan Analysis

According to the relevant clinical studies<sup>(1)</sup> of the herpes zoster vaccines on the market, the effective rate of recombinant vaccines in reducing herpes zoster and PHN is higher than that of live attenuated vaccines. In October 2017, the Advisory Committee on Immunization Practices (ACIP) recommended recombinant herpes zoster vaccines for the prevention of herpes zoster and related complications in immunocompetent adults aged 50 years old and above, and for the prevention of herpes zoster and related complications in immunocompetent adults who have previously received live attenuated herpes zoster vaccine. The ACIP states that recombinant herpes zoster vaccines are superior to live attenuated herpes zoster vaccines for the prevention of herpes zoster and related complications. Currently, the criteria of herpes zoster vaccine for ineligible patients include people who have severe allergic reaction to any of the component, and live attenuated herpes zoster vaccine is not recommended for patients with immunodeficiency or immunosuppressive diseases.

Note:

(1) Andrea Tricco, Wasifa Zarin, et al. Efficacy, effectiveness, and safety of herpes zoster vaccines in adults aged 50 and older: systematic review and network meta-analysis. *BMJ* 2018; 363:k4029.

## INDUSTRY OVERVIEW

Among global markets, the herpes zoster vaccination rate in the U.S. is the highest due to the earlier availability of the vaccine in the U.S., favorable reimbursement policies, high awareness of herpes zoster and lower cost of herpes zoster vaccines. The herpes zoster vaccination rate in China is relatively low compared to the rate of U.S. Given the large patient population in China, there is great potential for the herpes zoster vaccine market to grow in the future. The number of new cases of herpes zoster in people aged 50 years old and above in China increased from 2.5 million in 2015 to 3.9 million in 2021 at a CAGR of 7.8%. It is expected to increase to 4.9 million in 2025 at a CAGR of 6.0% from 2021 to 2025, and further increase to 6.0 million in 2030 at a CAGR of 4.2% from 2025 to 2030. The vaccination rate of herpes zoster vaccine among people aged 50 years and older is expected to reach 1.9% in 2025 and 12.6% in 2030 in China<sup>(1)</sup>. In comparison, the number of new cases of herpes zoster in people aged 50 years old and above in the U.S. is expected to grow at a slower rate compared to China. The number of new cases of herpes zoster in the U.S. increased from 1.0 million in 2015 to 1.1 million in 2021 at a CAGR of 2.4%. It is expected to increase to 1.2 million in 2025 at a CAGR of 1.8% from 2021 to 2025, and further increase to 1.3 million in 2030 at a CAGR of 1.5% from 2025 to 2030.

The recurrence rate of shingles for unvaccinated patients is approximately 4% to 6%, with the recurrence rate of shingles increasing with age. After receiving herpes zoster vaccination, the risk of recurrence of shingles is reduced by approximately 50% in vaccinated patients. For Shingrix<sup>®</sup>, two doses are recommend, and for Zostavax<sup>®</sup>, one dose is recommended. Currently, no booster is recommended for either Shingrix<sup>®</sup> or Zostavax<sup>®</sup> by the CDC, other clinical guidelines or medical organizations.

*Note:*

- (1) The key assumptions driving the forecasted growth in herpes zoster vaccination rate in China include:
  - (i) Increasing number of eligible patients: Herpes zoster vaccines are targeted for people aged 50 years and older. China’s population is aging faster than almost all other countries. By 2023, the number of people aged 50 years and older in China is expected to reach 515 million, and is expected to increase to 539 million in 2025 and further increase to 574 million in 2030.
  - (ii) Favorable government policies increasing public awareness: According to China’s 14th Five-Year Plan, it proposes improving the health of the elderly as a key task during this period. In addition, the NHC recommends people aged 50 years and older to obtain herpes zoster vaccination to prevent shingles<sup>(1)</sup>.
  - (iii) Lowered price can make the vaccine more affordable: Currently, Shingrix<sup>®</sup> and BCHT Biotechnology’s Gan Wei (感維) are the only two commercialized herpes zoster vaccines in China. Shingrix<sup>®</sup> is priced at approximately RMB1,600/dose with a total of two doses per treatment. Domestic vaccines tend to have lower prices due to their lower cost to manufacture and commercialize (sales, advertising, etc.). Therefore, the price for herpes zoster vaccines are expected to be reduced in China in the future, which may lead to eligible people becoming more willing to get vaccinated.
  - (iv) More herpes zoster vaccines will be commercialized in China which can provide continuous market education and increase public awareness and willingness to be vaccinated: By 2025, one to two new herpes zoster vaccines are expected to be commercialized in China, and by 2030, another two to three new herpes zoster vaccines are expected to be commercialized in China. Vaccine manufacturers generally conduct intense market education and advertisement. The increase in number of newly commercialized herpes zoster vaccines will provide continuous exposure of herpes zoster vaccine to increase public awareness and willingness to be vaccinated.

*Note:*

- (1) For details, please see the official micro-blog published by NHC on the designated website at [https://weibo.com/2834480301/4874560870548935?wm=3333\\_2001&from=10D3193010&sourcetype=weixin](https://weibo.com/2834480301/4874560870548935?wm=3333_2001&from=10D3193010&sourcetype=weixin). Please also see the article published by Shanghai Municipal Health Commission on the designated website at <https://wsjkw.sh.gov.cn/yfjz/20201218/6f8e16caf8b4edca5b5e7e06f986f30.html> and the article published by the Health Commission of Fengyang County at the designated website at <https://www.fengyang.gov.cn/public/161055498/1110317904.html>.

## INDUSTRY OVERVIEW

### Market for Herpes Zoster Vaccines

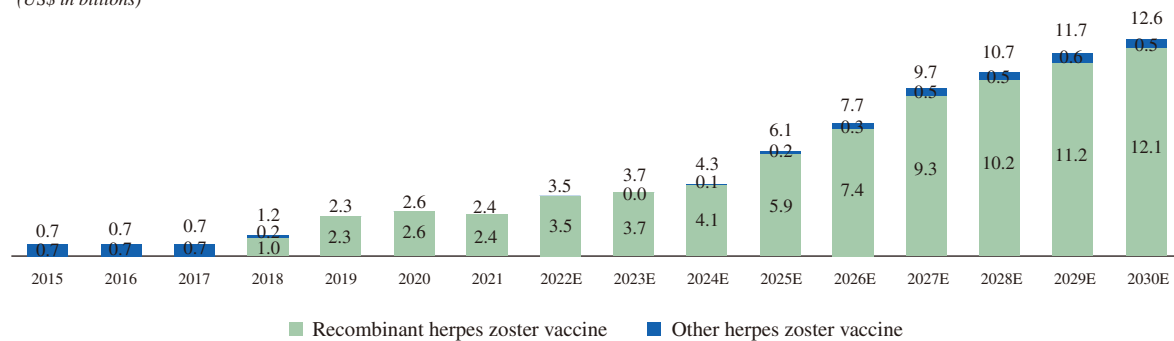
From 2020 to 2021, due to the impact of COVID-19, governments worldwide prioritized their attention and efforts on providing vaccination of COVID-19 for the elderly, thus affecting the market demand for herpes zoster vaccines. As new herpes zoster vaccines are expected to be marketed in the future and COVID-19 is gradually brought under control, the global herpes zoster vaccine market is expected to expand.

In terms of sales revenue, the global herpes zoster vaccine market increased from US\$0.7 billion in 2015 to US\$2.4 billion in 2021 at a CAGR of 21.2%, and is expected to grow to US\$6.1 billion in 2025 at a CAGR of 26.8% from 2021 to 2025, and further grow to US\$12.6 billion in 2030 at a CAGR of 15.5% from 2025 to 2030. The chart below illustrates the historical and forecasted global herpes zoster vaccine market for the periods indicated:

**Global Herpes Zoster Vaccine Market, 2015-2030E**

Period	Recombinant Herpes Zoster Vaccine	CAGR
2015-2021	N/A	21.2%
2021-2025E	25.6%	26.8%
2025E-2030E	15.5%	15.5%

(US\$ in billions)



Source: Public disclosure of listed companies, expert interviews, Frost & Sullivan Analysis

According to 2022 China Herpes Zoster Vaccine Expert Consensus (帶狀皰疹疫苗預防接種專家共識)<sup>(1)</sup>, herpes zoster vaccine is recommended in order to prevent herpes zoster, and individuals aged 50 years and older (regardless of whether the individual has a history of varicella infection or varicella vaccination) are recommended to receive herpes zoster vaccine. The complete immunization program consists of two doses, and the second dose is administered two to six months after the first dose of herpes zoster vaccination. Individuals who are or may have immunodeficiency or immunosuppression due to disease or treatment are recommended to receive the second dose within one to two months after the first dose.

Note:

(1) “2022 China Herpes Zoster Vaccine Expert Consensus”: Dermatology Branch of China Medical Care International Exchange Promotion Association, Senile Dermatology Research Center of Chinese Medical Association Dermatology Branch. Herpes Zoster Vaccine Expert Consensus. Medical Journal, 2022, 102(8): 538-543. DOI: 10.3760/cma.j.cn112137-20210828-01958.

## INDUSTRY OVERVIEW

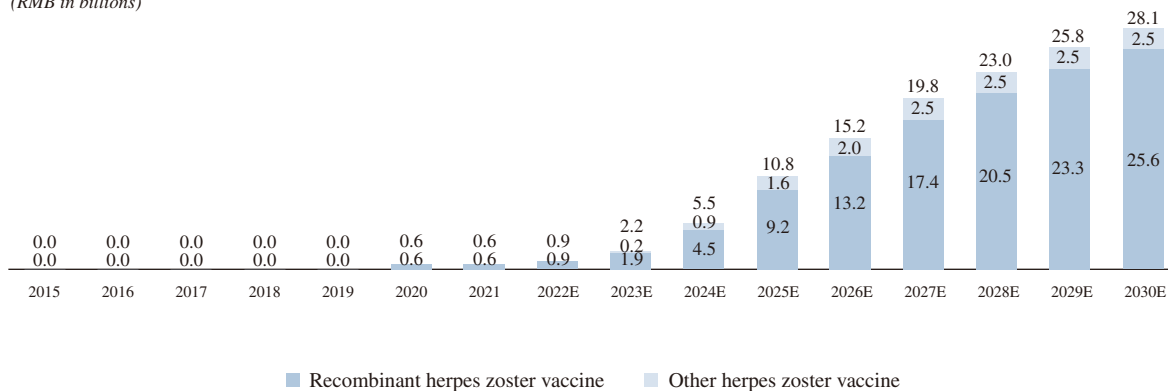
The U.S. CDC recommends that adults aged 50 years and older receive herpes zoster vaccine as a prevention regimen for shingles. The U.S. CDC recommends Shingrix® as the primary vaccine for shingles, and immunocompetent adults aged 50 years and older should obtain two doses of Shingrix® two to six months apart. The Background Paper on Herpes Zoster Vaccine authored by SAGE Working Group of WHO mentions the recommendations for herpes zoster vaccine administration in Europe and Asia, including Austria and Sweden for individuals aged 50 years and older, the U.S., Canada, Greece, Korea and Thailand for individuals aged 60 years and older, Australia for individuals aged between 60 to 79 years old and the U.K. for individuals aged between 70 to 79 years old.

The vaccination rate in people age 50 or above increased from 0.04% in 2020 to approximately 0.13% in 2022. As the public awareness of herpes zoster continues to grow and the number of available herpes zoster vaccines increases, the herpes zoster vaccine market in China is expected to grow significantly. In terms of sales revenue, the herpes zoster vaccine market in China increased from nil in 2015 to RMB0.6 billion in 2021, and is expected to grow to RMB10.8 billion in 2025 at a CAGR of 103.8% from 2021 to 2025, and further grow to RMB28.1 billion in 2030 at a CAGR of 21.1% from 2025 to 2030. The chart below illustrates the historical and forecasted herpes zoster vaccine market in China for the periods indicated:

### Herpes Zoster Vaccine Market in China, 2015-2030E

Period	Recombinant Herpes Zoster Vaccine	CAGR
2015-2021	N/A	N/A
2021-2025E	96.0% <sup>(1)</sup>	103.8% <sup>(2)</sup>
2025E-2030E	22.6%	21.1%

(RMB in billions)



Source: Expert interviews, Frost & Sullivan Analysis

Notes:

- The forecasted growth is largely due to an expected decrease in the price of recombinant herpes zoster vaccines. Domestic recombinant herpes zoster vaccines are expected to be more affordable as Domestic recombinant herpes zoster vaccine candidates are expected to become commercialized during this period and their average prices are expected to decrease from RMB1,600/dose in 2021 to RMB1,100/dose in 2025, with a decline of 31%, which is expected to increase domestic acceptance of recombinant herpes zoster vaccines and contributes to the high growth. In addition, the recombinant herpes zoster vaccine market was an emerging market as Shingrix® only entered China in 2020, and the market was RMB0.6 billion in 2021. With continuing market education and increasing acceptance of herpes zoster vaccine, the market size of herpes zoster vaccine in China is expected to increase rapidly. Since the market size of herpes zoster vaccine in China relatively was small in 2021, the rapid growth would lead to a higher CAGR.

## INDUSTRY OVERVIEW

- (2) The forecasted growth is largely due to (a) increasing vaccination rate: the vaccination rate of herpes zoster vaccine in China was only 0.1% in 2021 and the first herpes zoster vaccine, Shingrix<sup>®</sup>, was approved in China in May 2019. The vaccination rate is expected to increase to 1.9% in 2025. Given the large population base in China, the number of new cases of herpes zoster is relatively large, amounting to 3.9 million in 2021, which is expected to increase to 4.9 million in 2025 due to the growing aging population in China. The number of people who have received herpes zoster vaccine is expected to increase from 0.4 million in 2021 with an accumulative vaccination rate of 0.1% to 1.4 million in 2023 with an accumulative vaccination rate of 0.3%, and further to reach 10.4 million with an accumulative vaccination rate of 1.9% in 2025; (b) launch of new vaccines in the next few years: at present, Shingrix<sup>®</sup> and BCHT Biotechnology’s Gan Wei (感維) are the only two herpes zoster vaccines available in China while other domestic herpes zoster vaccine candidates are expected to be commercialized in this period, which will contribute to the growth of the market; (c) expansion of eligible patients: Shingrix<sup>®</sup> is used for adults aged 50 years and older in China. Domestic herpes zoster vaccine candidates are expected to expand to adults aged 40 years and older.

In the U.S., the vaccination rate of herpes zoster vaccine of people aged 50 or above in 2021 was approximately 26.8%, compared to approximately 0.1% in China. By 2030, the cumulative vaccination rate of people aged 50 or above in the U.S. is expected to be approximately 69.0%. In terms of sales revenue, the herpes zoster vaccine market in the U.S. increased from US\$0.5 billion in 2016 to US\$1.7 billion in 2021 at a CAGR of 27.2% from 2016 to 2021, and is expected to remain stable at US\$1.7 billion in 2025 at a CAGR of 0.2% from 2021 to 2025, and decrease to US\$1.6 billion in 2030 at a CAGR of -1.4% from 2025 to 2030. From 2023 to 2030, the herpes zoster vaccine market in the U.S. is expected to remain stable due to (i) the U.S. is a relatively mature market for herpes zoster vaccine compared to China. Shingrix<sup>®</sup> was approved in October 2017 in the U.S., and its vaccination rate among people aged 50 years and older in the U.S. increased from 0.1% in 2017 to 26.8% in 2021; and (ii) the number of people aged 50 years and older in the U.S. was 119 million in 2021 and is expected to reach 130 million in 2030, and the population of people aged 50 years old and above in the U.S. is expected to grow at a slower pace with an average year-over-year growth rate between 0.8% to 1.0%. Currently, Shingrix<sup>®</sup> is the only commercialized herpes zoster vaccine in the U.S. In terms of medical coverage, Shingrix<sup>®</sup> is covered by Medicare Part D in the U.S., which greatly reduce the financial burden of patient to be vaccinated, and Medicaid covers Shingrix<sup>®</sup> for people aged 50 and older in approximately two-thirds of the states in the U.S. The price of Shingrix<sup>®</sup> has remained stable in the U.S. at approximately US\$120 per dose. The price of herpes zoster vaccines is expected to increase in the future as mRNA herpes zoster vaccines featuring more advanced technology may be approved and sold at a higher price than Shingrix<sup>®</sup> in the U.S.

In Southeast Asia, the number of people aged 50 and over grew from 134.7 million in 2016 to 144.5 million in 2021, with a CAGR of 1.4%. It is expected to continue to grow in the future, reaching 156.2 million in 2026, with a CAGR of 1.6% from 2021 to 2026. The number of new cases of herpes zoster in Southeast Asia increased from 1.57 million in 2016 to 1.79 million in 2021, with a CAGR of 2.7% over this period. With the increase in the population over 50 years old, the number of new cases in Southeast Asia will reach 1.99 million in 2026, with a CAGR of 2.2% from 2021 to 2026. The growing population of people aged over 50 coupled with increasing new cases of herpes zoster in Southeast Asia implies that there is a large potential market for shingles vaccine in Southeast Asia. Southeast Asia consists of 11 countries including Singapore, the Philippines, Malaysia, Indonesia, etc, and each country currently has different national medical insurance coverages. The herpes zoster vaccines have been marketed in some Southeast Asian countries such as Singapore, Malaysia, and the Philippines, while the vaccines are not available in other Southeast Asian countries, such as Indonesia. There are two herpes zoster vaccines approved in Singapore, which are Shingrix<sup>®</sup> and Zostavax<sup>®(1)</sup>. Shingrix<sup>®</sup> was approved in Singapore in January 2022. There is only one herpes zoster vaccine approved in the Philippines, which is Zostavax<sup>®(1)</sup>.

*Note:*

- (1) There is no information available regarding the approval date of Zostavax<sup>®</sup> in Singapore and the Philippines.

## INDUSTRY OVERVIEW

---

There are two herpes zoster vaccines approved in Malaysia, which are Zostavax<sup>®</sup> and Skyzoster. Zostavax<sup>®</sup> was approved in November 2013 and Skyzoster was approved in January 2020 in Malaysia. The pricing of herpes zoster vaccines in different Southeast Asian countries vary which depends on the level of local medical development and the affordability of local people. For example, the price of Shingrix<sup>®</sup> is approximately US\$320 per dose in Singapore, the price of Zostavax<sup>®</sup> is approximately US\$150 to US\$200 per dose in Singapore, the Philippines and Malaysia, and the price of Skyzoster is approximately US\$100 to US\$110 per dose in Malaysia. In terms of medical insurance coverage, herpes zoster vaccines are generally not covered in the local vaccination schedule of Southeast Asian countries such as Singapore, Malaysia, and the Philippines. People have to pay it out-of-pocket when they want to get vaccinated. In addition, favorable government policies have promoted herpes zoster vaccines in Southeast Asia. For example, the Society of Infectious Disease (Singapore) Handbook (2020 edition) recommends herpes zoster vaccine for the prevention of shingles.

### Growth Drivers of the Global Herpes Zoster Vaccine Market

Growth drivers of the global herpes zoster vaccine market include (i) ongoing aging population, (ii) increasing number of new cases of shingles, (iii) increased public awareness and (iv) lack of effective treatment.

- *Ongoing aging population.* With declining fertility and increasing average life expectancy, the number of people aged 50 years old and above is growing at a considerable rate and is expected to continue to do so in the future, with the trend towards population aging becoming more pronounced. The global population of people aged 50 years old and above is expected to reach 2,330 million by 2030, representing approximately 27.3% of the total global population. By 2030, the number of people in China aged 50 years old and above is expected to reach 570 million, representing approximately 39.0% of the total population in China. The aging population is susceptible to the deterioration of the immune and metabolic system and is a high risk group for herpes zoster. An increasingly aging demographic will be one of the key drivers for the rapid growth of the herpes zoster vaccine market.
- *Increasing number of new cases of shingles.* Among the population over 50 years old, the number of new herpes zoster cases in China, the United States, and Europe reached 3.9 million, 1.1 million, and 2.0 million in 2021, respectively. Due to low vaccination rates, the number of new cases of herpes zoster still shows a growing trend, and the total number of patients with herpes zoster will continue to expand in the future. In addition, along with changing lifestyles, high work stress and low immunity, people under 50 years old are also prone to getting shingles.
- *Increased public awareness.* The steady growth in the global economy has led to increasing per capita disposable income, which in turn has increased the individual healthcare spending on vaccinations. In addition, the level of health awareness has been increasing in recent years, with the accumulation of knowledge and promotion of disease prevention. In the post-COVID-19 era, the health of the elderly has also attracted social attention. Shingles occurs frequently in people aged over 50. When people have weak immune systems, it can cause severe pain and seriously affect the quality of life of the elderly. In the past, vaccines mainly protected children's health and prevented various infectious diseases among children. With the continuous marketing of new vaccines, including herpes zoster vaccines, they will meet the prevention needs of different age groups. For instance, in a survey conducted in Shanghai, the awareness of herpes zoster vaccine in local people aged 50 and

## INDUSTRY OVERVIEW

above increased from 30% in 2020 to 42% in 2021. The awareness and acceptance of vaccination is expected to rise in the wake of the COVID-19 pandemic, further contributing to developing the vaccine market and increasing vaccination rates.

- *Lack of effective treatment.* Herpes zoster is accompanied by complications such as neuralgia. The pain can be dull, convulsive or throbbing, which disturbs sleep, mood, work and daily life. In severe cases, it may lead to depression. Elderly and frail patients may experience more pain. In addition, herpes zoster lacks quick and effective treatments. According to the *2018 Clinical Guideline for Herpes Zoster* in China, at present, there is no specific drug for herpes zoster. Current treatment goals for herpes zoster are to relieve acute pain, shorten the duration of skin lesions, prevent skin lesions from spreading and prevent or alleviate complications such as postherpetic neuralgia (“PHN”). Existing treatment methods primarily include antiviral drugs, glucocorticoid therapy and analgesic treatment. Antiviral drugs are commonly used in the clinical treatment of herpes zoster and can shorten the course of disease, accelerate the healing of rashes, prevent the formation of new rashes, and prevent the spread of viruses to the viscera. Glucocorticoid therapy, on the other hand, is still controversial. While systemic administration of glucocorticoids in the early stages of an acute herpes zoster attack can inhibit the inflammatory process, shorten the duration of acute pain and skin healing time, it is not effective for pain caused by PHN. Analgesic treatment primarily includes prescription of acetaminophen, nonsteroidal anti-inflammatory drugs, or tramadol, for mild to moderate pain, and prescription of morphine, oxycodone, or neuropathic pain medications such as calcium channel modulators like gabapentin and pregabalin, for moderate to severe pain. Vaccination can prevent herpes zoster and largely reduce the burden of related diseases.

### Competitive Landscape

As of the Latest Practicable Date, there were four herpes zoster vaccines marketed globally, namely Merck & Co., Inc.’s Zostavax<sup>®</sup>, GlaxoSmithKline plc’s Shingrix<sup>®</sup>, SK Chemicals Co., Ltd.’s SkyZoster and BCHT Biotechnology’s Gan Wei (感維). Among them, SkyZoster is sold in Korea with a market share accounted for approximately 1.0% of global herpes zoster market, and BCHT Biotechnology’s Gan Wei (感維) is only sold in China. Due to the low effectiveness of Zostavax<sup>®</sup> as a herpes zoster prophylaxis and its weakened market competitiveness, it has discontinued production in the U.S. LZ901 does not face the same risks of discontinued commercialization as Zostavax<sup>®</sup> because LZ901 is a recombinant vaccine while Zostavax<sup>®</sup> is a live attenuated vaccine and the cellular immune response and humoral response data from the Phase I clinical trial of LZ901 indicate the immunogenicity of LZ901 is not weaker than Shingrix<sup>®</sup>. In 2021, Shingrix<sup>®</sup> captured almost 100% of the global market share in terms of sales revenue, and is the only commercially available herpes zoster vaccine in China.



## INDUSTRY OVERVIEW

The following table sets forth details of Shingrix<sup>®</sup>, Zostavax<sup>®</sup> and BCHT Biotechnology’s Gan Wei (感維):

	GlaxoSmithKline	Merck & Co.	BCHT Biotechnology
<b>Product name</b>	Shingrix <sup>®</sup>	Zostavax <sup>®</sup>	Gan Wei (感維)
<b>Indications</b>	Herpes zoster and PHN	Herpes zoster	Herpes zoster
<b>Type of technology</b>	Recombinant	Live attenuated	Live attenuated
<b>Targeted age/gender group</b>	Immunocompetent male and female adults aged 50 years and older and immunodeficient male and female adults aged ≥19 years old	Males and females aged 50 years and older	Males and females aged 40 years and older
<b>Effectiveness reducing herpes zoster</b>	50-59 years old: 96.6% 60-69 years old: 97.4% 70+ years old: 91.3%	50-59 years old: 70% 60-69 years old: 64% 70-79 years old: 41% ≥80 years old: 18%	≥40 years old: 57.6% 40-49 years old: 37.4% 50-59 years old: 62.7% 60-69 years old: 64.4% ≥70 years old: 18.6%
<b>Effectiveness reducing postherpetic neuralgia</b>	≥50 years old: 91.2% ≥70 years old: 88.8%	≥60-69 years old: 65.7% ≥70 years old: 66.8%	≥45 years old: 62.8% ≥65 years old: 62.9%
<b>Long-term vaccine effectiveness against herpes zoster</b>	50 years and older: 81.6% (the first 6-10 years following vaccination)	50-59 years old: 60% (the first 3 years following vaccination); 60-69 years: 49% (the first 5 years following vaccination); 70-79 years: 46% (the first 5 years following vaccination); 80 years and older: 44% (the first 5 years following vaccination)	N/A
<b>Date of approval</b>	United States: October 20, 2017 Europe: March 28, 2018 China: May 22, 2019 <sup>(1)</sup>	United States: February 24, 2006 Europe: May 19, 2006	China: January 29, 2023 (expected commencement of sales in June 2023)
<b>Price</b>	RMB1,600/dose in China <sup>(2)</sup> approximately US\$120/dose overseas	Approximately US\$135/dose	RMB1,369/dose
<b>Vaccine administration procedure</b>	Two doses, second dose administered 2-6 months after first dose	One dose	One dose

Notes:

- (1) GlaxoSmithKline plc did not conduct clinical trials for Shingrix<sup>®</sup> in Mainland China but used overseas data to support the conditional approval for Shingrix<sup>®</sup> in China. After receiving conditional approval, GlaxoSmithKline plc had initiated a follow-up clinical trial for Shingrix<sup>®</sup> in Mainland China in 2021, which is expected to be completed in 2023.
- (2) For a new foreign vaccine to enter the Chinese market, clinical trials in China are required, which would result in additional expenses for GSK. In addition, Shingrix<sup>®</sup> is the first herpes zoster vaccine commercialized in China, which requires market education and establishment of the sales team to promote the new vaccine, and this would incur additional expenses as well. Therefore, based on the large initial investment, it is reasonable that the selling price of Shingrix<sup>®</sup> is higher in China. In the foreseeable future, it is expected that more herpes zoster vaccines will be commercialized and enter the market in China. In order to compete for more market share, it is reasonable that the price of Shingrix<sup>®</sup> will experience a decreasing trend. For overseas market, it is the similar situation for Shingrix<sup>®</sup> to lower the price in the future since more herpes zoster vaccines are expected to enter the global market.

Source: CDC, FDA, literature search, Frost & Sullivan Analysis

In a BALB/c mice study, our LZ901 induced a stronger cellular immune response with higher expression of multiple types of immune cell activating biomarkers compared to Shingrix<sup>®</sup>. In addition, based on immunogenicity data collected from the Phase I clinical trial for LZ901 in China, it has been demonstrated that there is no significant difference in the levels of anti-VZV antibodies after the full course of vaccination of LZ901 compared to Shingrix<sup>®</sup>, indicating that the immunogenicity of LZ901 is not weaker than Shingrix<sup>®</sup> and LZ901 provides strong protection against shingles.

LZ901 has a different antigen structure and a formulation that uses a different adjuvant compared to Shingrix<sup>®</sup>. The incidence of adverse reactions related to aluminum hydroxide adjuvant used in LZ901 is expected to be lower than the oil-based adjuvant used in Shingrix<sup>®</sup>. After receiving an injection of Shingrix<sup>®</sup>, the vast majority of subjects experience temporary nodules at the injection site or nodules that

## INDUSTRY OVERVIEW

take a long time to resolve and pain at the injection site. Similarly, the incidence of side reactions of our LZ901 is expected to be lower than that of Shingrix<sup>®</sup>, and the incidence of temporary nodules at the injection site or local pain should also be lower than that of Shingrix<sup>®</sup>.

As of the Latest Practicable Date, there was only one marketed herpes zoster vaccine, namely Shingrix<sup>®</sup>, and four herpes zoster vaccines under development in the U.S. In November 2020, Zostavax<sup>®</sup> was no longer available for use in the U.S. As of the Latest Practicable Date, there were no marketed herpes zoster vaccines and no clinical research information of herpes zoster vaccines under development in Indonesia. As of the Latest Practicable Date, there were two marketed herpes zoster vaccines, namely Shingrix<sup>®</sup> and Zostavax<sup>®</sup>, and no herpes zoster vaccines under development in Singapore. Vaccines approved in the U.S. require additional clinical trials and approval procedures in Southeast Asia. Each Southeast Asian country has different regulations on vaccine products. However, once a vaccine is approved by FDA, it will be highly recognized in Southeast Asia and the time required to conduct local clinical trials and approval procedures will be greatly reduced.

As of the Latest Practicable Date, there were four herpes zoster vaccines under development in China, including LZ901, and six other herpes zoster vaccine candidates at the clinical stage in Australia, the Philippines and the U.S. Wantai Biopharma strategically abandoned development of its live attenuated shingles vaccine as the Phase II clinical trial results demonstrated that its protective efficacy was inferior to Shingrix<sup>®</sup>. Currently, there is no public data about the Phase II clinical trial results of the live attenuated shingles vaccine of Waitai Biopharma. LZ901 does not face the same risks of discontinued research and development as Wantai Biopharma’s shingles vaccine because LZ901 is a recombinant vaccine while Wantai Biopharma’s shingles vaccine is a live attenuated vaccine and the cellular immune response and humoral response data from the Phase I clinical trial of LZ901 indicate the immunogenicity of LZ901 is not weaker than Shingrix<sup>®</sup>. The following chart sets forth details of the herpes zoster vaccines under development in China:

Vaccine Name	Technology	Company	R&D Progress	Clinical Application Country	Date of IND Approval	Date of Phase I Clinical Trial <sup>(1)</sup>	Ages/Gender Eligible for Clinical Trial	Sponsor Jurisdiction
Live attenuated herpes zoster vaccine	Live attenuated	Shanghai Institute of Biological Products (上海生物製品研究所)	Phase II (completed)	China	August 21, 2017	November 20, 2018	Males and females aged 40 years and older	China
Recombinant herpes zoster vaccine (CHO)	Recombinant	Luzhu Biotech (綠竹生物)	Phase II	China	August 4, 2021	January 15, 2022	Males and females aged 50 years and older	China
Recombinant herpes zoster vaccine (CHO)	Recombinant	Ab&B Bio-Tech (中慧元通)/ Easyway (上海怡道)	Phase I/II <sup>(2)</sup>	China	May 6, 2020	December 13, 2021	Males and females aged 40 years and older	China
Recombinant herpes zoster vaccine (CHO)	Recombinant	MAXVAX Biotechnology (邁科康生物)	Phase I	China	January 4, 2022	October 21, 2022	Males and females aged 18 years and older <sup>(3)</sup>	China

Note:

- (1) Date when the phase of clinical trial was first published.
- (2) Ab&B Bio-Tech/Easyway will conduct the Phase II clinical trial rightly after they complete the Phase I clinical trial without gap. A company can choose to conduct the seamless Phase I/II clinical trial based on its own commercial strategy.
- (3) The current enrollment of the Phase I clinical trial requires people aged 18 years and older, as the Phase I clinical trial is mainly focused on the safety test. The requirement may change with the progress of the clinical trials. The herpes zoster vaccine of MAXVAX Biotechnology may be still mainly recommended for people aged over 40 once commercialized because this group are susceptible to shingles.

Source: Center for Drug Evaluation (CDE), public disclosure of listed companies, Frost & Sullivan Analysis

## INDUSTRY OVERVIEW

The following chart sets forth details of the herpes zoster vaccines under development in Australia, the Philippines and the U.S.:

Vaccine Name	Technology	Company	R&D Progress	Clinical Application Country	Date of IND Approval	Date of Phase I Clinical Trial <sup>(1)</sup>	Ages/Gender Eligible for Clinical Trial	Sponsor Jurisdiction
Recombinant herpes zoster vaccine (CHO)	Recombinant	Luzhu Biotech (綠竹生物)	Phase I	U.S.	July 13, 2022	February 2023	Males and females aged 50 years and older	China
Recombinant Herpes Zoster Vaccine (CHO)	Recombinant	Curevo Inc.	Phase II	U.S.	N/A	January 2019	Males and females aged 50 years and older	U.S.
Recombinant Herpes Zoster Vaccine (CHO)	Recombinant	Eyegene Inc.	Phase I (completed)	Australia	N/A	January 2020	Males and females aged 50 years to 70 years	South Korea
Recombinant Herpes Zoster Vaccine (CHO)	Recombinant	Dynavax Technologies Corporation	Phase I	Australia	N/A	January 2022	Males and females aged 50 years to 69 years	U.S.
Recombinant Shingles Vaccine	Recombinant	Jiangsu Recbio Technology Co., Ltd. (瑞科生物)	Phase I	Philippines	December 19, 2022	N/A	N/A	China
RNA Herpes Zoster Vaccine JCXH-105	srRNA	Immorna (Hangzhou) Biotechnology Co., Ltd. (嘉晨西海)	FDA approved to initiate Phase I	U.S.	December 19, 2022	N/A	N/A	China
VZV modRNA	mRNA	Pfizer Inc. & BioNTech SE	Phase I/II <sup>(2)</sup>	U.S.	N/A	January 25, 2023	Males and females aged 50 years to 69 years	U.S.

Note:

- (1) Date when the phase of clinical trial was first published.
- (2) Pfizer Inc. & BioNTech SE will conduct the Phase II clinical trial right after they complete the Phase I clinical trial without gap. A company can choose to conduct the seamless Phase I/II clinical trial based on its own commercial strategy.

Source: Center for Drug Evaluation (CDE), public disclosure of listed companies, Frost & Sullivan Analysis

Curevo Inc. and Eyegene Inc. are unlikely to seek market approval for commercialization in China for their herpes zoster vaccines because Curevo Inc. is a subsidiary of a South Korean biopharma company, and Eyegene Inc. is also a South Korean company and South Korean biopharmaceutical companies rarely expand their vaccine business in China, as they have to comply with the regulations and approval procedures for new vaccines of the NMPA, which can be time-consuming and expensive. Meanwhile, they will face fierce competition from U.S. and European pharmaceutical companies, which are often larger-scale in Chinese market. South Korean companies may choose to focus on other markets, such as their domestic market and Southeast Asian markets, where they have better access or more significant competitive advantages. In addition, neither Curevo Inc. nor Eyegene Inc. has applied for CTA approval for their herpes zoster vaccines in China. As of the Latest Practicable Date, there were no approved vaccine in China manufactured by a South Korean company. Dynavax Technologies Corporation is also unlikely to seek market approval for commercialization in China for its Recombinant Herpes Zoster Vaccine (CHO), because as of the Latest Practicable Date, Dynavax had no product launched in China and had not registered any clinical trials for herpes zoster vaccine in China. Jiangsu Recbio Technology Co., Ltd. and Immorna (Hangzhou) Biotechnology Co., Ltd. are Chinese companies and may be more motivated than international companies to seek to commercialize their respective product candidates in China in the future. However, even if they have such plans, their respective product candidates are unlikely to enter the Chinese market in a short term, because in order to commercialize the relevant product candidates in China, they are required to complete new clinical trials in China, while as of the Latest Practicable Date, none of them had registered for any clinical trials in China for the relevant product candidates. Pfizer Inc. & BioNTech SE may have the possibility to seek for commercialization for its herpes zoster vaccine in China in the future because Pfizer Inc. & BioNTech SE have already expanded its business in China by selling other products. However, Pfizer Inc. & BioNTech SE have not registered any clinical trials for herpes zoster vaccine in China yet. Therefore, even if they have such plans, we expect that their herpes zoster vaccine will not enter the Chinese market in a short term.

## INDUSTRY OVERVIEW

### VARICELLA VACCINE MARKET

#### Overview

Varicella also known as chickenpox, is an acute infectious disease caused by VZV. Humans are the only host of VZV. VZV enters the host through the respiratory tract and conjunctiva. It replicates at the site of entry in the nasopharynx and in regional lymph nodes. A rash is often the first sign of disease in children. Adults may have 1 to 2 days of fever and malaise before a rash. In unvaccinated individuals, generalized and pruritic rash progresses rapidly.

Since varicella is a highly infectious disease and China has a higher population density compared to the U.S., the incidence rate of varicella in China is higher than that of the U.S. The incidence of varicella in China increased from 33.9 cases per 100,000 population in 2015 to 88.8 cases per 100,000 population in 2021 at a CAGR of 17.4%, and is expected to increase to 126.6 cases per 100,000 population in 2025 at a CAGR of 9.3% from 2021 to 2025, and further increase to 154.0 cases per 100,000 population in 2030 at a CAGR of 4.0% from 2025 to 2030. In comparison, the incidence rate of varicella in the U.S. is lower since the U.S. was the first country to recommend universal routine varicella vaccination. The incidence rate of varicella in the U.S. decreased from 3.8 cases per 100,000 population in 2015 to 2.8 cases per 100,000 population in 2021 at a CAGR of -4.8%, and is expected to decrease to 2.3 cases per 100,000 population in 2025 at a CAGR of -4.6% from 2021 to 2025, and further decrease to 1.9 cases per 100,000 population in 2030 at a CAGR of -4.6% from 2025 to 2030.

#### Types of Varicella Vaccines

There are two types of commercialized varicella vaccines, monovalent vaccines, consisting of live attenuated vaccines and recombinant vaccines, and combination vaccines. Live attenuated vaccines and combination vaccines contain the Oka strain of live attenuated virus. Monovalent vaccines have demonstrated less severe side effects while combination vaccines have demonstrated higher efficacy. As of the Latest Practicable Date, there was no recombinant varicella vaccine approved in the market. The recombinant varicella vaccine has a higher protective effect. While inducing a human immune response, it can prevent other components of the pathogen from causing adverse effects on the human body.

#### Market for Varicella Vaccines

In China, children aged five to seven years old are most likely to be infected with varicella. Currently, varicella vaccines are mostly for children aged from 12 months to 12 years old, which covered approximately 213.1 million population in China in 2021 and is expected to decrease to 190.0 million in 2030. In 2020, the vaccination rate among children aged 1 to 14 years old was approximately 52.7% and 11.4% for first and second dose, respectively. Prior to 2012, China recommended only one dose of varicella vaccine. Since 2012, the PRC government began to promote the administration of two doses of varicella vaccine, which contributed to the growth of the varicella vaccine market in China in the past few years. However, the decline in birth rate will impact the future growth of the varicella vaccine market in China. The criteria of varicella vaccine for ineligible patients are people who have severe allergic reaction to any of the component, patients with immunodeficiency or immunosuppressive diseases, people with encephalopathy, uncontrolled epilepsy and other progressive neurological diseases, etc.

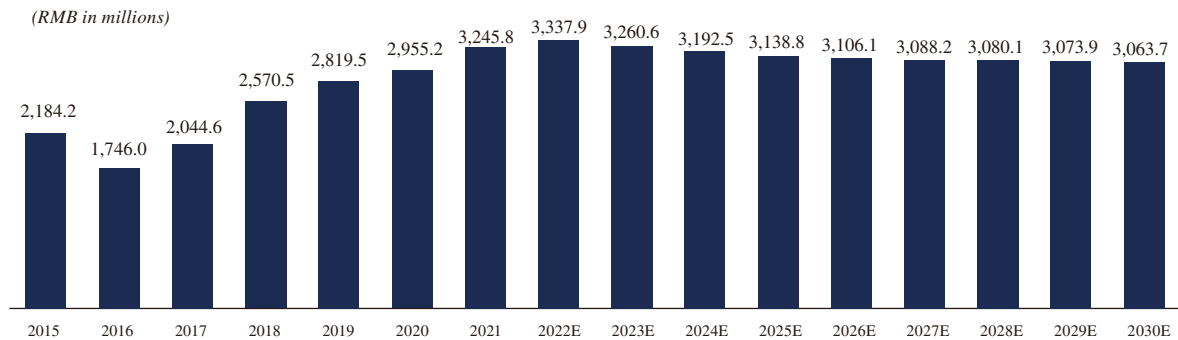
The varicella vaccine market in China increased from RMB2,184.2 million in 2015 to RMB3,245.8 million in 2021 at a CAGR of 6.8%, and is expected to decline to RMB3,138.8 million in 2025 at a CAGR of -0.8% from 2021 to 2025, and further decline to RMB3,063.7 million in 2030 at a CAGR of -0.5% from 2025 to 2030. The expected decline from 2021 to 2030 is largely due to the declined birth rate as varicella vaccines in China are for children aged under 12, partially offsetting the expected increase in vaccination

## INDUSTRY OVERVIEW

rate. The chart below illustrates the historical and forecasted varicella vaccine market in China for the periods indicated:

### Varicella Vaccine Market in China, 2015-2030E

Period	CAGR
2015-2021	6.8%
2021-2025E	-0.8%
2025E-2030E	-0.5%



Source: Public disclosure of listed companies, expert interviews, NIFDC, Frost & Sullivan Analysis

### Competitive Landscape

As of the Latest Practicable Date, there were five commercialized varicella vaccines marketed in China, which are all based on the technology of live, attenuated varicella-zoster virus derived from the Oka strain. The following table sets forth details of the approved varicella vaccines in China:

#### Commercialized Varicella Vaccines in China

Company	Technology	Vaccine Administration Procedure	Approval Date	Price, per Dose, 2021	Sales Revenue, 2021 (RMB million)	Market Share, 2021
Changchun Keygen Biological Products	Live attenuated	One dose administered for 12 month and older	March 30, 2007	RMB145.5-160.5	1,078.2	33.2%
BCHT Biotechnology	Live attenuated	One dose administered for 1-12 years of age; 2 dose administered for 13 years and older	February 4, 2008	RMB90-160.5	1,020.3	31.4%
Shanghai Institute Of Biological Products	Live attenuated	One dose administered for 12 month – 12 years old	November 7, 2006	RMB90-160.5	674.7	20.8%
RongSheng Biotech	Live attenuated	One dose administered for 12 months – 12 years old	October 25, 2016	RMB136-157	270.6	8.3%
Sinovac	Live attenuated	12 months – 12 years of age: One dose One booster dose can be administered when deemed necessary	December 18, 2019	RMB90	202.0	6.3%

Source: Public disclosure of listed companies, NMPA, Frost & Sullivan Analysis

## INDUSTRY OVERVIEW

Currently, all the varicella vaccines in the global market are developed by live attenuated technology. In 2021, major manufacturers of varicella vaccine included Merck & Co., GSK, Changchun Keygen Biological Products, BCHT Biotechnology and SK Bioscience. Merck & Co. had the largest global market share of 55.7% in 2021. The following table sets forth details of major manufacturers of varicella vaccine:

Company Name	Product	Technology	Market Share, in 2021	Price, per Dose, in 2021
Merck & Co.	Varivax & ProQuad	Live attenuated	55.7%	U.S. CDC Price: Varivax: \$122.67-150.98 ProQuad: \$153.507-250.02
GSK	Varilrix & Priorix Tetra	Live attenuated	9.3%	Price in Australia: Varilrix: AUD 64.95 Priorix Tetra: AUD 68.95
Changchun Keygen Biological Products	Varicella Vaccine, Live	Live attenuated	5.3%	RMB145.5–160.5
BCHT Biotechnology	Varicella Vaccine, Live	Live attenuated	5.1%	RMB90-160.5
SK Bioscience	Sky Varicella	Live attenuated	3.9%	RMB90-160.5
Others	NA	NA	20.7%	NA

## HUMAN RABIES VACCINE MARKET

### Overview

Rabies is a vaccine-preventable viral disease often transmitted through the bite of a rabidly infected animal. Rabies is caused by the *Rabies lyssavirus*, which includes the rabies virus and the Australian bat rabies virus. The rabies virus infects the central nervous system of mammals, eventually leading to brain disease and death. Rabies is a contagious disease with a very high mortality rate, which is why countries around the world are dedicated to eliminating rabies. The disease, which is nearly always fatal, is preventable by vaccines given either before and/or after exposure to a rabid animal. Numerous factors including the high cost of vaccines, the relative complexity of post-exposure vaccination protocols requiring multiple doses of vaccine, and insufficient surveillance contribute to the estimated 59,000 human deaths caused by rabies each year, according to the WHO.

According to the Center for Disease Control and Prevention (CDC) in China and in the U.S., the number of new human rabies cases in China and the U.S. was 2,048 cases and 2 cases in 2010, respectively, and decreased to 157 cases and 5 case in 2021, respectively. In the U.S., rabies is prevented through the vaccination of animals, while in China, humans are vaccinated. Despite the rapid decline in the number of cases in China, the number of rabies cases in China is still at a higher level compared to that of the U.S.

## INDUSTRY OVERVIEW

### Types of Human Rabies Vaccines

Currently there are four types of commercialized rabies vaccines, including hamster kidney cell vaccine, purified chick embryo cell vaccines (PCEC), purified Vero cell vaccines (PVCV) and human diploid cell vaccines (HDCV), of which hamster kidney cell vaccines are less popular in the global market. In 2021, there was no purified chick embryo cell (PCEC) human rabies vaccines in China. As for purified Vero cell vaccines (PVCV), the key manufactures are Liaoning Chengda Biotechnology (with market share of 54.3%) and Rongan Biological (with market share of 24.4%). As for human diploid cell vaccines (HDCV), Chengdu Kanghua Biological Products captures 100% market share. The following tables set forth the various types of cell culture vaccines:

Cell Line	Hamster Kidney Cell	PCEC	PVCV
<b>Features</b>	The first approved cell culture rabies vaccine was the hamster kidney cell rabies vaccine, which was developed in China in 1980 with an aluminum adjuvant and the strain being the Beijing aG strain, inactivated with formaldehyde.	PCEC vaccine was cultured in primary chicken embryo fibroblasts with the Flury LEP-C25 virus strain, inactivated with 0.025% β-propiolactone and then concentrated and purified using density gradient centrifugation.	The Vero cell line, was established in 1962 and supports infection with multiple genotypes of the Lisa virus genus. PVCV vaccine was first approved in Europe and now are being massively producing in many developing countries.
<b>Advantages</b>	Mild adverse effects, relatively good efficacy and safety, as well as relatively low price.	Clinical experience in over 60 countries over the last 30 years has shown that the vaccine is immunogenic, effective and safe.	Can be grown and infected on microcarriers and cultured in fermentation instillations, immortalized cell lines have an almost unlimited growth capacity and can be produced on a large scale.
<b>Disadvantages</b>	Less effective in terms of safety and efficacy comparing to HDCV and PVCV rabies vaccines.	Currently no PCEC vaccine available in China. It is difficult to be massively produced and relatively expensive.	Immortalized cell lines have potential cancer risk.
<b>Mainly Used in</b>	China	Australia, Europe, India and U.S.	China, India
<b>Major manufactures</b>	Henan Grand Biopharmaceutical, Zhongke Biopharm	GSK, ChiroRab	Liaoning Chengda Biotechnology, Rongan Biological, Sanofi Pasteur, Indian Immunologicals, Serume Institute of India

## INDUSTRY OVERVIEW

Cell Line	HDCV	Recombinant Protein
<b>Features</b>	The first human diploid cell line, WI38, was established in 1961 to avoid problems arising from the use of primary tissue culture, such as allergy to animal proteins. It is currently produced using MRC5 human embryonic fibroblasts, inoculated with the Pitman Moor L503 3M strain.	Currently, there is no recombinant rabies vaccine launched in the market. All the products are in R&D. Only the product from CPL Biologicals, a biopharma company in India is recorded to enter Phase III clinical experiments.  The non-replicating virus-based vaccine uses a viral vector that cannot be replicated in the host and can express the G protein of the rabies virus, thereby causing an immune response.
<b>Advantages</b>	Recommended by the WHO as the “gold standard” rabies vaccine. HDCV vaccine induces a more intense immune response in test animals and humans and is less likely to cause adverse reactions.	The vaccine produced by this technology has a high degree of safety for the host body.
<b>Disadvantages</b>	It has high cost, therefore, is mainly used in developed countries. In China, there is only one manufacturer, Chengdu Kanghua Bio, which listed its HDCV rabies vaccine in 2015.	The production cost of the vaccine produced by this technology will be higher, so the price will be higher in the future.
<b>Mainly Used in</b>	China, Europe, U.S., Australia	/
<b>Major manufactures</b>	Chengdu Kanghua Biological Products, Sanofi Pasteur	/

Source: Frost & Sullivan Analysis

### Market for Pre-Exposure Human Rabies Vaccine in China

Currently, most human rabies vaccines marketed in China are for post-exposure prophylaxis (PEP). Although this type of vaccine can also be given prior to exposure, most people still receive rabies vaccines after being bitten or scratched by animals such as cats and dogs. In addition, human rabies vaccination is used for pre-exposure prophylaxis (PrEP) for populations at high risk of rabies virus exposure, including sub-populations in highly endemic settings with limited access to timely and adequate PEP, individuals at occupational risk, and travelers who may be at risk of exposure. People who are at an occupational risk of rabies virus exposure account for a small portion of the total vaccine recipients, including Centers for Disease Control and Prevention staff, veterinary clinic staff and dog trainers. In 2021, approximately 15 million people in China received human rabies vaccine. In the future, the market for human rabies vaccines as a PrEP can be expanded to other groups of people with a potential risk of rabies virus exposure, including courier and food delivery staff and other potential target groups. Since rabies is nearly always fatal, there is no criteria for post-exposure vaccination. The criteria of pre-exposure human rabies vaccine for ineligible patients include people who have severe allergic reaction to any of the component, patients with immunodeficiency or immunosuppressive diseases, etc.

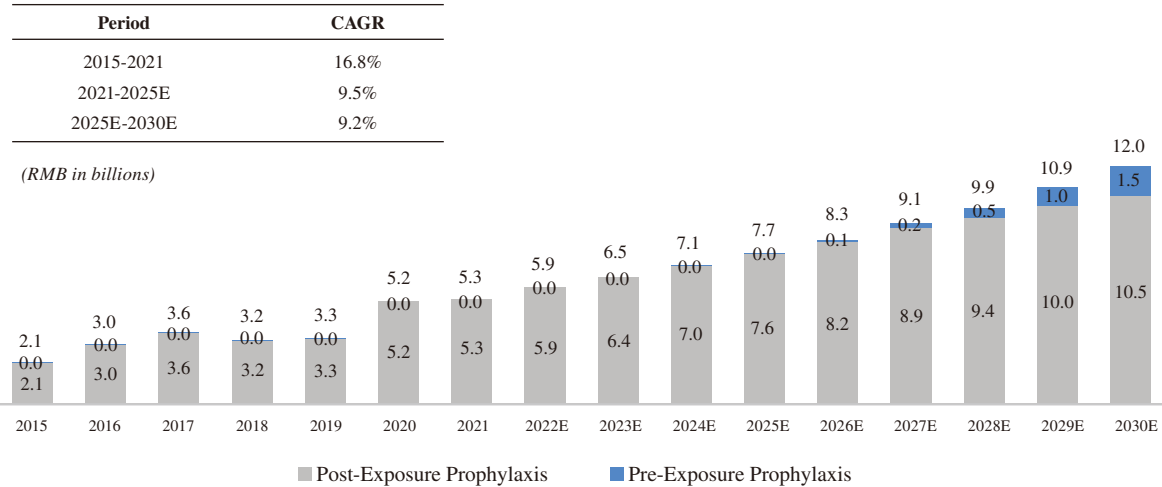
The human rabies vaccine market in China increased from RMB2.1 billion in 2015 to RMB5.3 billion in 2021 at a CAGR of 16.8% and is expected to grow to RMB7.7 billion at a CAGR of 9.5% from 2021 to 2025, and further increase to RMB12.0 billion in 2030 at a CAGR of 9.2% from 2025 to 2030. The growth of human rabies vaccine market in China is largely due to the increasing demand of human rabies vaccine. The number of pet cats and pet dogs has been growing rapidly these years and is expected to grow in the future, generating demand for human rabies vaccine. The pre-exposure human rabies vaccine market in China increased from RMB4.2 million in 2015 to RMB10.7 million in 2021 at a CAGR of 16.8% from 2015 to 2021, and is expected to increase to RMB2,960.2 million in 2035 at a CAGR of



## INDUSTRY OVERVIEW

49.4% from 2021 to 2035. The chart below illustrates the historical and forecasted rabies vaccine market in China for the periods indicated:

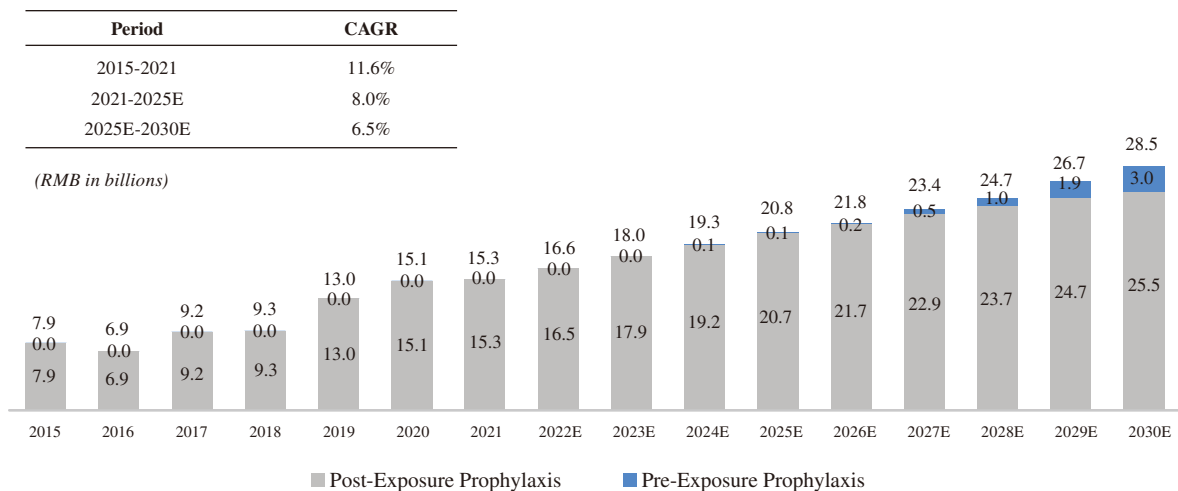
### Human Rabies Vaccine Market in China, 2015-2030E



Source: Company public disclosure, NMPA, DataYes Inc., Frost & Sullivan Analysis

The global human rabies vaccine market increased from RMB7.9 billion in 2015 to RMB15.3 billion in 2021 at a CAGR of 11.6% and is expected to grow to RMB20.8 billion at a CAGR of 8.0% from 2021 to 2025, and further increase to RMB28.5 billion in 2030 at a CAGR of 6.5% from 2025 to 2030. The chart below illustrates the historical and forecasted global rabies vaccine market for the periods indicated:

### Global Human Rabies Vaccine Market, 2015-2030E



Source: Company public disclosure, Frost & Sullivan Analysis

## INDUSTRY OVERVIEW

### Growth Drivers of Pre-Exposure Human Rabies Vaccine Market in China

Growth drivers of the Pre-Exposure human rabies vaccine market include (i) increasing number of pet owning families creating large potential demand (ii) favorable policies and (iii) enhanced awareness of preventative immunization.

- Increasing number of pet owning families creating large potential demand.* In recent years, with the continuous growth of consumption and increasing attention to pets, the number of pet dogs and cats in China has been increasing and approaching 100 million. Since dogs are the main source of human rabies deaths in China, the high number of pet dogs exposes dog-owning families to the potential risk of rabies.
- Favorable policies.* Countries around the world have been working to eliminate rabies. In 2018, the WHO released “Zero by 30” with the goal of effectively using vaccines, medicines, tools and technologies to block rabies transmission and reduce the risk of death and implement the Global Strategic Plan to end human deaths from dog-mediated rabies by 2030. In China, the Technical Guidelines for Rabies Prevention and Control (2016 edition), published by the CDC in 2016, provided the guidance and recommendations for pre- and post-exposure vaccination and the use of passive immunization preparations. Meanwhile, in 2021, China’s 14th Five-Year Plan proposes to improve the fast-track review and approval mechanism for innovative drugs, vaccines and medical devices. Favorable policies will facilitate the promotion of rabies vaccines, thus promoting the sustainable development of the human rabies vaccine industry.
- Enhanced awareness of preventative immunization.* Rabies is a disease with a nearly 100% mortality rate after onset of symptoms, causing a heavy disease burden in countries such as China. Therefore, increasing awareness of the hazard of rabies and the preventative immunization of human rabies vaccines are important for the control and elimination of rabies.

### Competitive Landscape

In 2021, Liaoning Chengda Biotechnology and Chengdu Kanghua Biological Products had more than half of the market share of the human rabies vaccine market in China. The following table sets forth details of the competitive landscape of the human rabies vaccine industry in terms of sales revenue and market share in China in 2021:

Company Name	Product	Sales Revenue in 2021 (billion RMB)	Market Share in 2021 (%)
Liaoning Chengda Biotechnology	Rabies Vaccine (Vero Cell) for Human Use	2.1	39.0%
Chengdu Kanghua Biological Products	Rabies Vaccine (Human diploid cell) for Human Use, Freeze-dried	1.3	23.7%
Rongan Biological	Rabies Vaccine (Vero Cell) for Human Use	0.9	17.5%
Changchun Zhuoyi Biological	Rabies Vaccine (Vero Cell) for Human Use, Freeze-dried	0.4	7.8%
Zhongke Biopharm	Rabies Vaccine (Hamster Kidney Cell) for Human Use	0.1	2.0%
Others	/	0.5	10.0%

*Notes:*

- As of the Latest Practicable Date, there were 13 human rabies vaccines registered in the CDE, while 3 of them had not generated any revenue in 2021. This excludes human rabies vaccines which did not have any batches issued by the NMPA in the last five years.
- Market share is calculated in terms of total market size of human rabies vaccine in China.

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

## INDUSTRY OVERVIEW

As of the Latest Practicable Date, there were 13 commercialized human rabies vaccines marketed in China (three of them have not generated any revenue in 2021 and one was approved in January 2023), which can be injected in both adults and children. The following table sets forth details of the commercialized human rabies vaccines in China:

### Commercialized Human Rabies Vaccines in China

Manufacturer	Cell Line	Administration	Approval Date	Price, 2021
Hualan Bio	PVCV	Pre-exposure: Three doses Post-exposure: Four doses (2-1-1) or five doses	January 29, 2023	/
Shandong Yidu Biotechnology		Pre-exposure: Three doses Post-exposure: Four doses (2-1-1) or five doses	July 12, 2021	/
Changchun Institute of Biological Products		Four-dose or five dose	April 30, 2021	/
Changchun Zhuoyi Biological		Pre-exposure: Three doses Post-exposure: Five doses	November 23, 2016	RMB65-93
Dalian Aleph Biomedical		Pre-exposure: Three doses Post-exposure: Five doses	September 28, 2016	RMB58.5-91.0
Liaoning Chengda Biotechnology	PVCV	Pre-exposure: Three doses Post-exposure: Four doses (2-1-1) or five doses	March 6, 2007	Frozen-dried: RMB60-258.5 Non-frozen-dried: RMB42.09-104
Rongan Biological		Pre-exposure: Three doses Post-exposure: Five doses	September 30, 2007	RMB53.85-87
Promise Biological		Pre-exposure: Three doses Post-exposure: Five doses	May 8, 2008	RMB53
Jilin Maifeng Biopharmaceutical		Pre-exposure: Three doses Post-exposure: Five doses	January 9, 2008	/
Liaoning Yisheng Biopharma		Pre-exposure: Three doses Post-exposure: Five doses	November 6, 2006	RMB68.5-243.5
Henan Grand Biopharmaceutical	Hamster Kidney Cell	Pre-exposure: Three doses Post-exposure: Five doses	June 12, 2007	RMB46.2-89.5
Zhongke Biopharm		Pre-exposure: Three doses Post-exposure: Five doses	May 28, 2007	RMB58.8-95
Chengdu Kanghua Biological Products	HDCV	Pre-exposure: Three doses Post-exposure: Five doses	April 28, 2012	RMB275-320

Note:

\* Excluding human rabies vaccines in China that did not have any batches issued by the NMPA in the last five years.

Source: Public disclosure of listed companies, DataYes Inc., NMPA, Frost & Sullivan Analysis

## INDUSTRY OVERVIEW

### ADALIMUMAB INJECTABLE MARKET

#### Overview of Anti-tumor Necrosis Factor (TNF)- $\alpha$ Monoclonal Antibody (mAb) and Immune-Mediated Inflammatory Diseases (IMIDs)

TNF- $\alpha$  is a key regulator of innate immunity and plays an important role in the regulation of the immune responses against intracellular bacteria and certain viral infections. However, the natural occurring cytokines, such as TNF, can contribute to numerous pathological situations in related to inflammatory and immune responses. These include IMIDs including rheumatoid arthritis, Crohn’s disease, psoriatic arthritis, ankylosing spondylitis, ulcerative colitis and severe chronic plaque psoriasis.

Rheumatoid arthritis is an autoimmune disease that causes chronic inflammation of the joints and other areas of the body, for which there is currently no cure. The incidence of rheumatoid arthritis in China increased from 5,773.4 thousand in 2015 to 6,001.6 thousand in 2021 at a CAGR of 0.6% from 2015 to 2021, and is expected to increase to 6,161.3 thousand in 2025 at a CAGR of 0.7% from 2021 to 2025, and further increase to 6,409.1 thousand in 2030 at a CAGR of 0.8% from 2025 to 2030.

Crohn’s disease is an incurable chronic inflammatory bowel disease. It is characterized by mucosal ulceration and inflammation, which may occur anywhere along the gastrointestinal tract but most commonly affect the distal small intestine. The inflammation caused by Crohn’s disease often spreads deep into the layers of the affected bowel tissue and can be both painful and debilitating, and sometimes may lead to life-threatening complications. The incidence of Crohn’s disease in China increased from 81.1 thousand in 2015 to 160.9 thousand in 2021 at a CAGR of 12.1% from 2015 to 2021, and is expected to increase to 215.9 thousand in 2025 at a CAGR of 7.6% from 2021 to 2025, and further increase to 282.7 thousand in 2030 at a CAGR of 5.5% from 2025 to 2030.

Psoriasis is a common skin condition that speeds up the life cycle of skin cells. Psoriasis is a chronic disease for which there is currently no cure. It causes cells to build up rapidly on the surface of the skin. The extra skin cells form scales and red patches that are itchy and sometimes painful. The incidence of psoriasis in China increased from 6,460.7 thousand in 2015 to 6,672.3 thousand in 2021 at a CAGR of 0.5% from 2015 to 2021, and is expected to increase to 6,789.0 thousand in 2025 at a CAGR of 0.4% from 2021 to 2025, and further increase to 6,853.0 thousand in 2030 at a CAGR of 0.2% from 2025 to 2030.

Ankylosing spondylitis is a type of arthritis that causes inflammation in certain parts of the spine, for which there is currently no clear cause or cure. The incidence of ankylosing spondylitis in China increased from 3,780.3 thousand in 2015 to 3,916.1 thousand in 2021 at a CAGR of 0.6% from 2015 to 2021, and is expected to increase to 3,986.0 thousand in 2025 at a CAGR of 0.4% from 2021 to 2025, and further increase to 4,054.2 thousand in 2030 at a CAGR of 0.3% from 2025 to 2030.

Anti-TNF- $\alpha$  mAb is a new generation therapy that treats IMIDs with high effectiveness, safety and convenient administration methods. The interaction of soluble and transmembrane bioactive forms of human TNF- $\alpha$  binding prevents the binding of TNF- $\alpha$  to its receptors, thereby inhibiting the biological activity of TNF- $\alpha$ . Anti-TNF- $\alpha$  mAb can restrict TNF- $\alpha$ ’s ability to activate T cells, effectively neutralizing TNF- $\alpha$  bioactivity and inducing the apoptosis of TNF-expressing cells.

## INDUSTRY OVERVIEW

### Market for Adalimumab

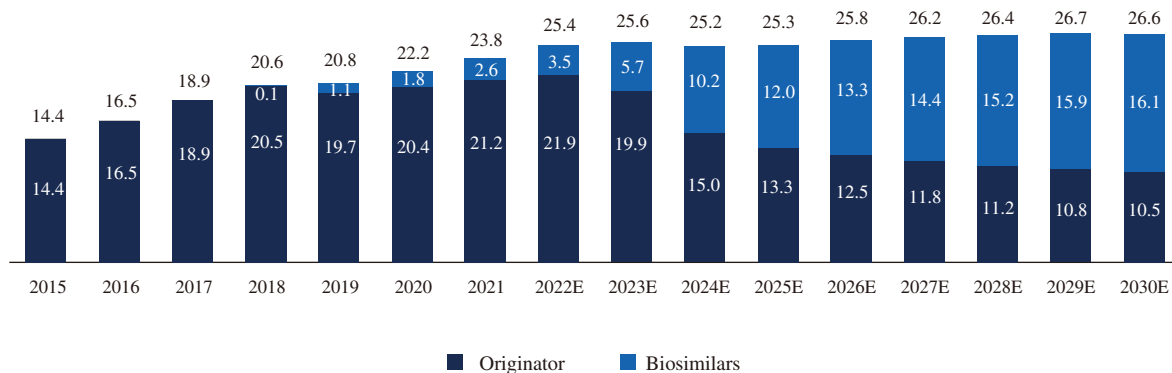
Humira<sup>®</sup>, generically known as adalimumab, is a TNF- $\alpha$  inhibitor for the treatment of autoimmune diseases. In December 2002, Humira<sup>®</sup> was approved by the U.S. Food and Drug Administration (“FDA”) for the treatment of rheumatoid arthritis. Subsequent indications approved by the FDA include psoriatic arthritis, ankylosing spondylitis and Crohn’s disease. Most of the indications are chronic diseases that require long-term regular treatment. Given the wide range of indications, Humira<sup>®</sup> has been ranked first in global prescription drug sales for nine consecutive years and its efficacy in the treatment of autoimmune diseases has been widely verified. Adalimumab and its biosimilars and biosimilar candidates are facing fierce competition against each other in their therapeutic segments. K3, also a biosimilar of adalimumab, is expected to compete with Humira<sup>®</sup>, Anjianning (安建寧), Handayuan (漢達遠), Taibowei (泰博維), Junmaikang (君邁康) and other adalimumab biosimilars that have been launched or currently under development in China.

In terms of sales revenue, the global adalimumab market increased from US\$14.4 billion in 2015 to US\$23.8 billion in 2021 at a CAGR of 8.7%, and is expected to grow to US\$25.3 billion in 2025 at a CAGR of 1.5% from 2021 to 2025, and further grow to US\$26.6 billion in 2030 at a CAGR of 1.0% from 2025 to 2030. The chart below illustrates the historical and forecasted global adalimumab market for the periods indicated:

**Global Adalimumab Market, 2015-2030E**

Period	Originator	Biosimilars	Total
2015-2021	6.7%	/	8.7%
2021-2025E	-11.0%	46.6%	1.5%
2025E-2030E	-4.6%	6.1%	1.0%

(US\$ in billions)



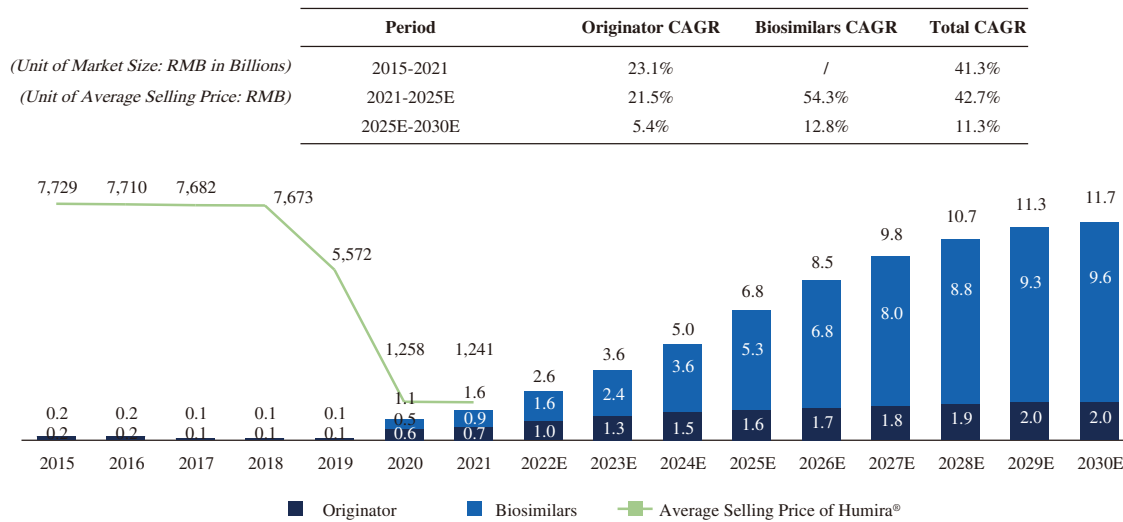
Source: Public disclosure of listed companies, expert interviews, Frost & Sullivan Analysis

Humira<sup>®</sup> was approved by the NMPA in 2010 and included in the National Reimbursement Drug List (NRDL) in 2019. Its average selling price was originally RMB7,729 per unit in 2015, and decreased from RMB5,572 in 2019 to RMB1,258 in 2020, directly contributing to a 440% increase in sales in 2020 compared to 2019.

## INDUSTRY OVERVIEW

Due to the wide range of indications for adalimumab, large market demand and continuous availability of new biosimilar products, the adalimumab market size is growing rapidly in China. In terms of sales revenue, the adalimumab market in China increased from RMB0.2 billion in 2015 to RMB1.6 billion in 2021 at a CAGR of 41.3%, and is expected to grow to RMB6.8 billion in 2025 at a CAGR of 42.7% from 2021 to 2025, and further grow to RMB11.7 billion in 2030 at a CAGR of 11.3% from 2025 to 2030. The chart below illustrates the historical and forecasted adalimumab market in China for the periods indicated:

### Adalimumab Market in China, 2015-2030E



Source: Public disclosure of listed companies, expert interviews, Frost & Sullivan Analysis

### Growth Drivers of the Adalimumab Injection Market

Growth drivers of the adalimumab injection market include (i) improving regulatory landscape, (ii) expiration of the core patents of originator drugs and (iii) wide range of indications.

- Improving regulatory landscape.** As biosimilars are not exact replicas of the originator drugs, the development of regulations governing the approval and market launch of biosimilars is a complex process. Health authorities around the world are working to establish clear regulatory pathways to ensure market access for qualified biosimilars. In 2006, the first biosimilar was approved for the European market. In March 2010, the U.S. government set out regulations of biosimilars for the first time in the Affordable Care Act. It was not until March 2015 that the first class of biosimilars was officially approved for the U.S. market via 315(k). Similar changes have been made in other countries and regions around the world, which has helped biosimilars enter the market.
- Expiration of the core patents of originator drugs.** Patent protection for the antibody molecule of the originator (Humira®) expired in the U.S. in 2016, in China in 2017 and in the EU in 2018. The expiry of the aforementioned core patent protection for Humira® has enriched the competitive landscape of the adalimumab industry and provided opportunities for the development of a more affordable biosimilar market for adalimumab. According to the latest publicly disclosed price in February, 2023, the average price of adalimumab biosimilars (40mg) is RMB992/40mg, which is almost a quarter of the price of Humira

## INDUSTRY OVERVIEW

before it was covered by NRDL and RMB300 lower than Humira’s price as of the Latest Practicable Date. Six Humira<sup>®</sup> biosimilars have been approved for marketing in China. In addition, Humira<sup>®</sup> was approved by the State Drug Administration of China in 2010 and included in the Class B list of the NRDL in 2019. Its price decreased from RMB5,572 in 2019 to RMB1,258 in 2020. The significant price reduction of Humira<sup>®</sup> is expected to stimulate potential clinical demand that has been suppressed due to high healthcare costs. QLETLI<sup>®</sup> (格樂立) of Bio-Thera Solutions, Ltd., Anjianning of Hisun Pharmaceutical, SULINNO<sup>®</sup> (蘇立信) of Innovent Bio, and Handayuan of Henlius Biotech are covered by the NRDL. However, Chia Tai Tianqing’s Taibowei and Junshi Biosciences/Mabwell’s Junmaikang were approved in 2022 but are not covered by NRDL. When Humira<sup>®</sup> was included in NRDL in 2019, three indications were covered, and another five indications were covered in 2021. According to NRDL in 2022, the restrictions on medical insurance of eight indications of adalimumab had been completely removed, such as no longer requiring patients to have moderate and severe diseases, thereby benefiting an increasing number of patients. In addition, the change of reimbursement for adalimumab applies to biosimilars. With increased medical insurance coverage, patients’ ability to pay will also be greatly enhanced, which will provide strong support for the development of biosimilars in China and accelerate the pace of market release. According to the Interim Measures for the Administration of Use of Drugs Covered by the Basic Medical Insurance (《基本醫療保險用藥管理暫行辦法》), during the period of the negotiated drug agreement, if there is a negotiated drug with the same generic name (generic drug) listed, the medical insurance department can adjust the payment standard of the drug according to its price level, and can also include the generic name into the scope of centralized procurement. Therefore, with the increased medical insurance coverage, if the generic name of biosimilar drugs is included in the coverage of medical insurance, the medical insurance department can adjust relevant payment standard of these biosimilar drugs according to their price level. The patient penetration rate of such biosimilars will increase with the decrease of drug price, thus improving the sales of these biosimilars, and the clinical demand suppressed by the non-reimbursement of medical insurance will be released, which will support the development of biosimilars in China.

- *Wide range of indications.* In December 2002, the U.S. Food and Drug Administration approved Humira<sup>®</sup> for the treatment of rheumatoid arthritis and subsequently approved indications including psoriatic arthritis, ankylosing spondylitis, Crohn’s disease, ulcerative colitis, chronic psoriasis, septic sweat gland inflammation and juvenile idiopathic arthritis. In 2020, the number of approved indications for Humira<sup>®</sup> expanded to 17 worldwide. Most of these are chronic conditions require long-term regular treatment. In February 2010, the State Drug Administration of China first approved Humira<sup>®</sup> for the treatment of rheumatoid arthritis, and to date, eight indications have been approved in China, including rheumatoid arthritis, ankylosing spondylitis, psoriasis and uveitis.

## INDUSTRY OVERVIEW

### Competitive Landscape

In 2021, Humira® recorded sales revenue of US\$21.2 billion globally. The following table sets forth details of the global adalimumab injection market in terms of sales revenue in 2021:

#### Market Share of Global Adalimumab Market, 2021

Company Name	Product	Sales Revenue in 2021 (US\$ million)	Market Share in 2021 (%)
AbbVie	Humira®	20,694.0	86.9%
Eisai	Humira®	552.9	2.3%
Amgen Inc.	Amgevita®	439.0	1.8%
Biogen Inc.	Imraldi®	233.0	1.0%
Others	/	1,896.0	8.0%

*Notes:*

- (1) In February 2007, Eisai and Abbott announced an amendment to their agreement to co-market Humira® in Taiwan and Korea, with sales credited to Eisai’s subsidiaries in Taiwan and Korea.
- (2) In January 2008, Eisai and Abbott began to co-market the Humira® brand in Japan, using one brand, one channel and two promotional programs.
- (3) In Europe and the U.S., adalimumab is exclusively distributed by Abbott (later spun off as AbbVie). In Korea and Taiwan, Eisai and Abbott jointly promote and distribute Humira® using a similar program to that in Japan.

In China, the high selling price of Humira® when it entered the market and the lack of education in autoimmune diseases led to low penetration and a declining sales trend from 2013 to 2019. With the inclusion of Humira® in the NRDL, Humira® sales increased significantly in the adalimumab injection market in China in 2020. The following chart and table set forth details of the adalimumab injection market in China in terms of sales revenue and market share in 2021:

Company Name	Product	Sales Revenue in 2021 (million RMB)	Market Share in 2021 (%)
AbbVie Inc.	Humira®	720.0	43.6%
Hisun Pharmaceutical (海正藥業)	Anjianning (安建寧)	450.0	27.3%
Bio-Thera Solutions, Ltd. (百奧泰)	QLETLI®/格樂立	306.3	18.6%
Innovent Bio (信達生物)	SULINNO®/蘇立信	110.0	6.7%
Henlius Biotech (復宏漢霖)	Handayuan (漢達遠)	62.5	3.8%

*Note:* Henlius Biotech (復宏漢霖) signed a cooperation agreement with Fosun Pharmaceutical (復星醫藥) regarding Handayuan (漢達遠). In 2021, Henlius Biotech received a profit share of RMB21.8 million from Handayuan under the cooperation agreement, and the sales revenue of Handayuan in 2021 is estimated to be RMB62.5 million with reference to the profit of similar products, as verified by expert interviews.

*Source:* Public disclosure of listed companies, expert interviews, Frost & Sullivan Analysis



## INDUSTRY OVERVIEW

As of the Latest Practicable Date, there were six Humira® biosimilar drugs approved and ten Humira® biosimilar drugs under development in China. The following tables set forth details of the Humira® biosimilars approved and under development in China:

### Approved Products in China

Company Name	Product	NMPA Approval Date	Indications	Price
Bio-Thera Solutions, Ltd. (百奥泰)	QLETLI®/ 格樂立	November 6, 2019	Rheumatoid arthritis, ankylosing spondylitis, psoriasis, Crohn's disease, uveitis, childhood plaque psoriasis, polyarticular juvenile idiopathic arthritis, Crohn's disease in children	RMB1,080/40mg RMB676/20mg
Hisun Pharmaceutical (海正藥業)	Anjianning (安建寧)	December 6, 2019	Rheumatoid arthritis, ankylosing spondylitis, psoriasis, Crohn's disease, non-infectious uveitis, polyarticular juvenile idiopathic arthritis, childhood plaque psoriasis	RMB1,090/40mg
Innovent Bio (信達生物)	SULINNO®/ 蘇立信	September 2, 2020	Rheumatoid arthritis, ankylosing spondylitis, psoriasis, polyarticular juvenile idiopathic arthritis, childhood plaque psoriasis, non-infectious uveitis	RMB1,088/40mg
Henlius Biotech (復宏漢森)	Handayuan (漢達遠)	December 2, 2020	Rheumatoid arthritis, ankylosing spondylitis, psoriasis, uveitis	RMB899/40mg
Chia Tai Tianqing (正大天晴)	Taibowei (泰博維)	January 18, 2022	Rheumatoid arthritis, ankylosing spondylitis, psoriasis	RMB799/40mg
Junshi Biosciences (君實生物)/ Mabwell (邁威生物)	Junmaikang (君邁康)	March 1, 2022	Rheumatoid arthritis, ankylosing spondylitis, psoriasis	RMB998/40mg

Source: CDE, public disclosure of listed companies, Frost & Sullivan Analysis

## INDUSTRY OVERVIEW

### Products Under Development in China

Company Name	Products	R&D Progress	Indication	Date of Phase I Clinical Trial*
SinoCellTech (神州細胞)	SCT630	Phase III completed, pending approval	Moderate-to-severe plaque psoriasis	January 29, 2019
Wuhan Institute of Biological Products (武漢生物製品研究所)	Recombinant fully human anti-human TNF- $\alpha$ monoclonal antibody injection	Phase III	Moderate-to-severe plaque psoriasis	May 24, 2019
Shandong Danhong Pharmaceutical Co., Ltd (山東丹紅)	BC002	Phase III	Ankylosing spondylitis	April 25, 2019
Huaota Biopharm (華奧泰生物)	HOT-3010	Phase III	Moderate-to-severe plaque psoriasis	September 21, 2018
Hualan Bio (華蘭生物)	HL01	Phase III	Rheumatoid arthritis, ankylosing spondylitis, psoriasis	May 21, 2018
Tonghua Dongbao Pharmaceutical (通化東寶)	DB101	Phase III	Moderate-to-severe plaque psoriasis	August 18, 2017
Luzhu Biotech (綠竹生物)	K3	Phase I (completed)	Rheumatoid arthritis, ankylosing spondylitis, plaque psoriasis	November 13, 2018
Eastern Biotech (北京東方百泰生物/ 北京精益泰翔)	JY026	Phase I (completed)	Rheumatoid arthritis, ankylosing spondylitis	October 29, 2019
Anhui Weiming Damu Biomedicine Co., Ltd. (安徽未名達木生物醫藥有限公司)	Recombinant anti-TNF- $\alpha$ fully human monoclonal antibody injection	Phase I	Rheumatoid arthritis, ankylosing spondylitis	July 5, 2021
North China Pharmaceutical Company Ltd. (華北製藥)	Recombinant human anti-human tumour necrosis factor (TNF- $\alpha$ ) monoclonal antibody injection	Phase I	Rheumatoid arthritis, ankylosing spondylitis, psoriasis	January 15, 2020

*Note:*

\* Date when the Phase I clinical trial was first published by the CDE.

*Source:* CDE, public disclosure of listed companies, Frost & Sullivan Analysis

## INDUSTRY OVERVIEW

---

### RELAPSED OR REFRACTORY B CELL NON-HODGKIN LYMPHOMAS (NHL)/ACUTE LYMPHOBLASTIC LEUKEMIA (ALL) TREATMENT MARKET

#### Overview

B cell malignancies originate from different stages of B cell differentiation and constitute a heterogeneous group of cancers, including B cell lymphoma, B cell leukemia and plasma cell malignancy. B cell type non-Hodgkin lymphoma (“**NHL**”) and B cell type acute lymphoblastic leukemia (“**ALL**”) are the most common B cell malignancy.

#### **NHL**

Lymphomas are malignant neoplasms that originate in the lymphopoietic system and are the most common hematologic neoplasms worldwide. NHL is the most common type of lymphoma, accounting for 90% of newly diagnosed cases of lymphoma. There are several subtypes of non-Hodgkin’s lymphoma, which are identified on the basis of their phenotype, surface proteins and genetic characteristics.

The number of new cases of NHL in China increased from approximately 81,000 in 2015 to 95,000 in 2021 at a CAGR of 2.6%, and is expected to increase to 104,000 in 2025 at a CAGR of 2.4% from 2021 to 2025, and further increase to 116,000 in 2030 at a CAGR of 2.1% from 2025 to 2030. The global number of new cases NHL increased from approximately 475,000 in 2015 to 546,000 in 2021 at a CAGR of 2.3%, and is expected to increase to 599,000 in 2025 at a CAGR of 2.3% from 2021 to 2025, and further increase to 669,000 in 2030 at a CAGR of 2.2% from 2025 to 2030.

#### **ALL**

ALL is a heterogeneous hematologic malignancy that can develop in people of different ages groups, of which 80% of ALL cases occur in children. ALL is divided into two main categories, B-lymphocytic leukemia (B-ALL) and T-lymphocytic leukemia (T-ALL). In adults, approximately 75% of ALL cases are B-ALL and the rest are T-ALL.

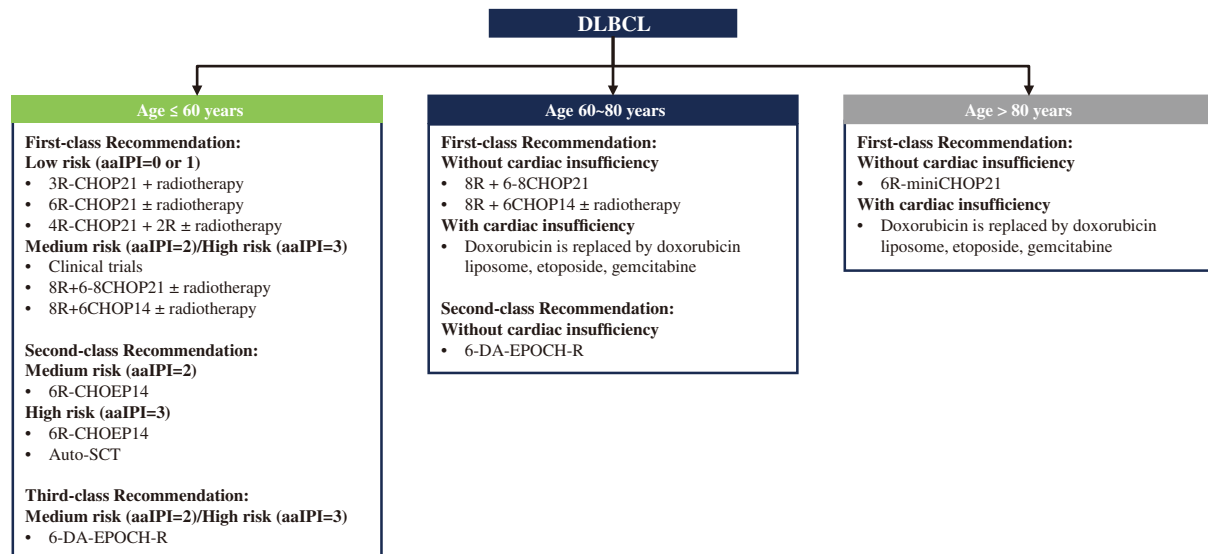
The number of new cases of ALL in China increased from approximately 11,800 in 2015 to 13,000 in 2021 at a CAGR of 1.6%, and is expected to increase to 13,800 in 2025 at a CAGR of 1.5% from 2021 to 2025, and further increase to 14,700 in 2030 at a CAGR of 1.3% from 2025 to 2030. The global number of new cases NHL increased from approximately 62,200 in 2015 to 68,800 in 2021 at a CAGR of 1.7%, and is expected to increase to 73,300 in 2025 at a CAGR of 1.6% from 2021 to 2025, and further increase to 79,000 in 2030 at a CAGR of 1.5% from 2025 to 2030.

## INDUSTRY OVERVIEW

### Relapsed or Refractory B cell NHL/ALL Treatment Modalities

Approximately 50% of those with NHL type B are relapsed-refractory, and approximately 15% of those with ALL type B are relapsed-refractory. The following table sets forth details of the treatment paradigm of B-NHL in China.

#### Treatment Paradigm of B-NHL in China (with DLBCL as an Example)



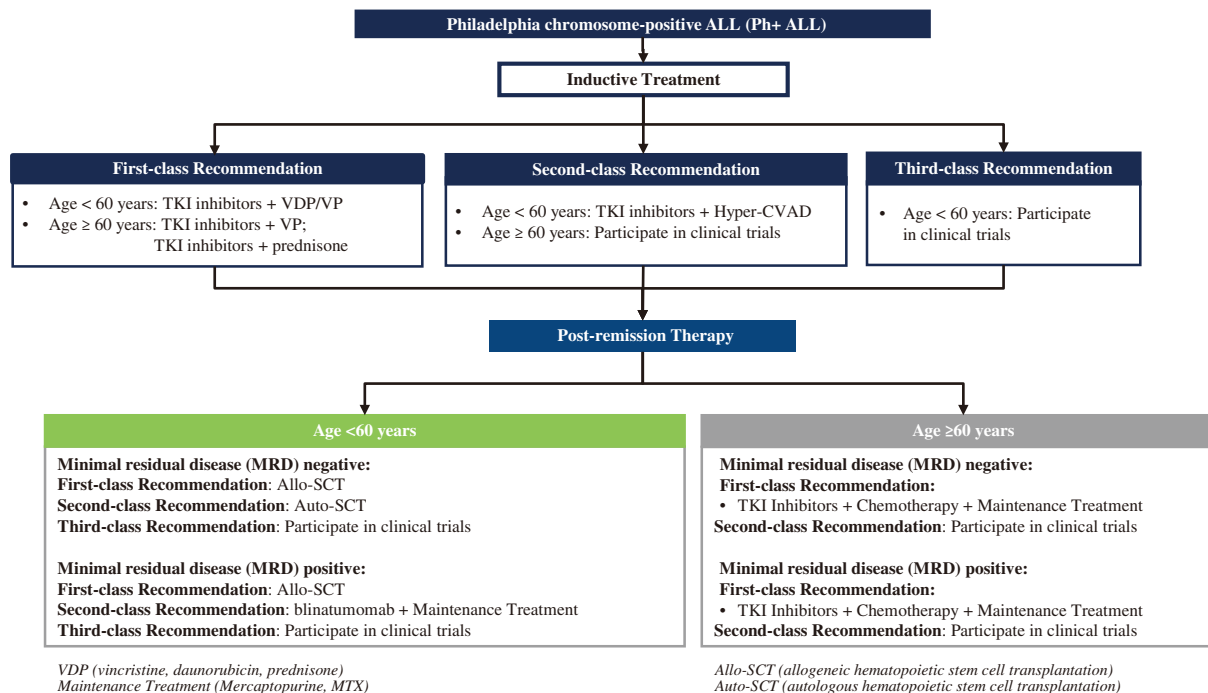
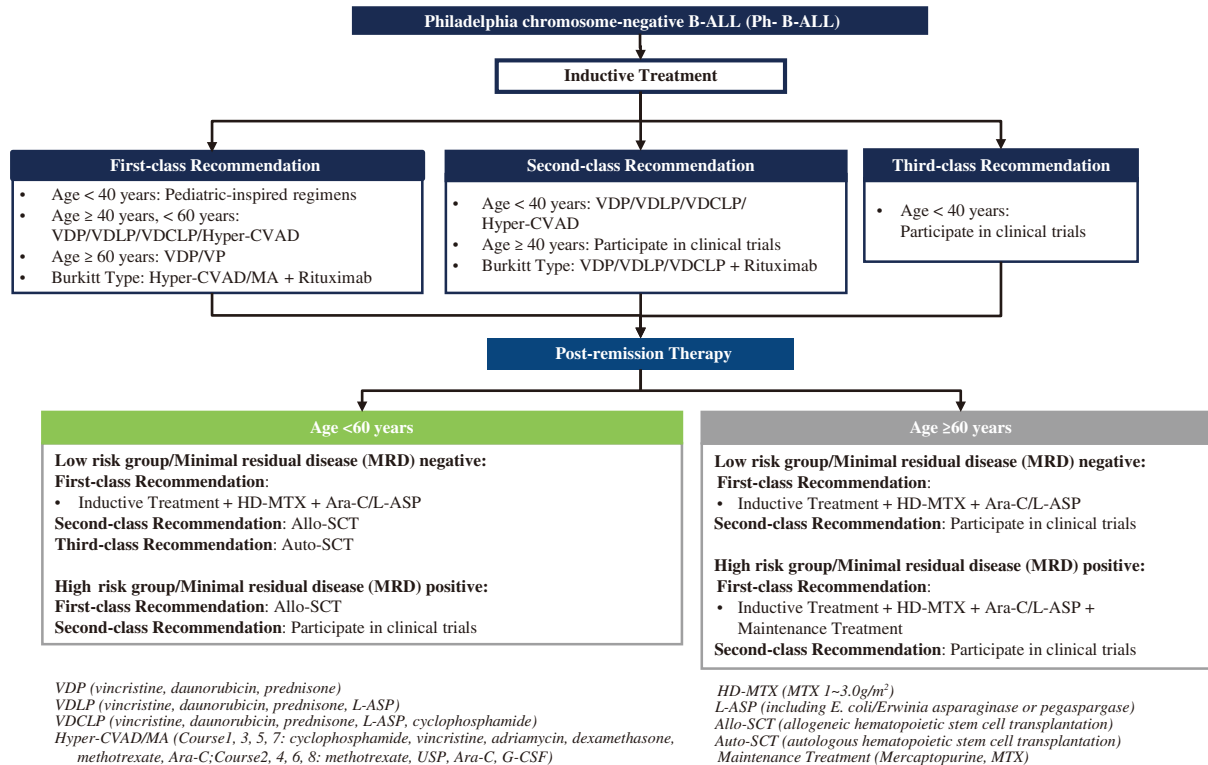
*R-CHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone)*  
*CHOEP (cyclophosphamide, doxorubicin, vincristine, prednisone, etoposide)*  
*EPOCH (etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin)*

Source: 《2021CSCO淋巴瘤診療指南》, Frost & Sullivan Analysis

## INDUSTRY OVERVIEW

The following table sets forth details of the treatment paradigm of B-ALL in China.

### Treatment Paradigm of B-ALL in China

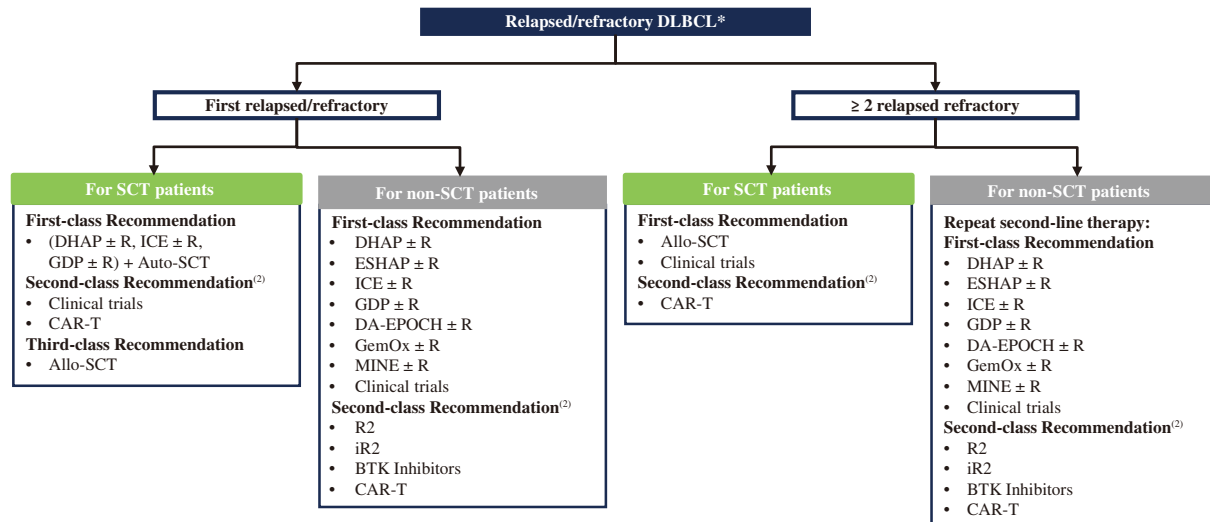


Source: 《2021CSCO恶性血液病診療指南》, Frost & Sullivan Analysis

## INDUSTRY OVERVIEW

The following table sets forth details of the treatment paradigm of relapsed/refractory B-NHL in China. K193 and K1932 are recommended for patients with relapsed or refractory B cell leukemia and lymphoma, who have received at least two failed chemotherapy and/or at least one failed combination therapy with CD20 monoclonal antibody, or for patients who are ready to receive CAR-T treatment. K193 and K1932 are expected to be included in the second-class recommendation of the treatment paradigm.

### Treatment Paradigm of Relapsed/Refractory B-NHL in China (with DLBCL as an Example)



DHAP (dexamethasone, cisplatin, cytarabine)

ESHAP (etoposide, methylprednisolone, cytarabine, cisplatin)

GDP (gemcitabine, dexamethasone, cisplatin)

R2 (rituximab, lenalidomide)

EPOCH (etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin)

iR2 (ibrutinib, rituximab, lenalidomide)

GemOx (gemcitabine, oxaliplatin)

ICE (ifosfamide, carboplatin, etoposide)

MINE (mesna, ifosfamide, mitoxantrone, etoposide).

Auto-SCT (autologous hematopoietic stem cell transplantation)

Allo-SCT (allogeneic hematopoietic stem cell transplantation)

Note:

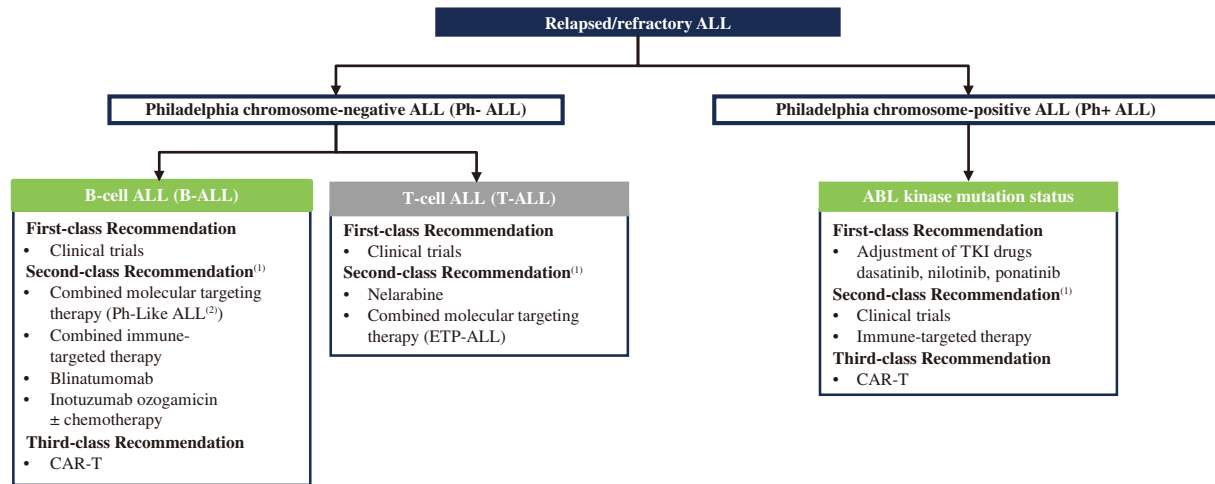
- (1) Applicable for patients receiving adequate doses of rituximab and anthraquinone-based chemotherapy during first-line therapy.
- (2) We expect that both K193 and K1932 will be included in the second-class recommendation once commercialized. However, as the half-life of K1932 is expected to be longer than that of K193, patients are recommended to be administered K193 before the administration of K1932. For details, please see “Business — Our Products and Product Candidates — Our Core Product and Clinical-Stage Product Candidates — 4. K1932 — Competitive Advantages” in this document.

Source: 《2021CSCO淋巴瘤診療指南》, Frost & Sullivan Analysis

## INDUSTRY OVERVIEW

The following table sets forth details of the treatment paradigm of relapsed/refractory ALL in China. When used for patients with relapsed/refractory ALL, K193 and K1932 are expected to be included in the second-class recommendation of the treatment paradigm.

### Treatment Paradigm of Relapsed/Refractory ALL in China



Note:

- (1) We expect that both K193 and K1932 will be included in the second-class recommendation once commercialized. However, as the half-life of K1932 is expected to be longer than that of K193, patients are recommended to be administered K193 before the administration of K1932. For details, please see “Business — Our Products and Product Candidates — Our Core Product and Clinical-Stage Product Candidates — 4. K1932 — Competitive Advantages” in this document.
- (2) Detection of mutations with abnormal molecular biology in Ph-like ALL, ETP-ALL may benefit from combining molecularly targeted drugs.

Source: 《2021CSCO恶性血液病診療指南》, Frost & Sullivan Analysis

## INDUSTRY OVERVIEW

Currently, the main treatment modalities for relapsed or refractory B cell NHL and B cell ALL are CD3/CD19 bispecific antibodies, anti-CD19 antibody drug conjugate (ADC), chimeric antigen receptor (CAR) T-cell therapy, and hematopoietic stem cell transplantation. The following table sets forth details of the immunotherapy modalities for relapsed or refractory B cell NHL and B cell ALL:

Drug	Mechanism of actions	Advantage	Disadvantage	Representative Drug/Fees	First to Market	Treatment duration	Dosage
CD19-CD3 Bispecific Antibodies	The CD19-CD3 bispecific antibody can bind to CD19 expressed on the surface of B cells at one end and to CD3 expressed on the surface of T cells at the other end. By linking CD19 malignant B lymphocytes to CD3+ T lymphocytes, the CD19-CD3 bispecific antibody mediates the lysis of tumor cells by T cells.	<ul style="list-style-type: none"> <li>Compared to single-antibody conjugation, bispecific antibodies have potential ease of drug combination, higher potential safety and better potential efficacy</li> </ul>	<ul style="list-style-type: none"> <li>Weak market performance and clinical data of previous anti-tumor dual antibodies</li> </ul>	Blincyto®/ US\$178,000	2014	Each treatment includes (a) up to two cycles of a 42-day induction treatment, (b) up to three cycles of a 42-day consolidation treatment, and followed by (c) up to four cycles of a 84-day continued treatment	<p>For individuals weighing 45kg or more</p> <p>First induction treatment: Day 1-7: 9 µg/d, Day 8-28: 9 µg/d, Day 29-42: no drugs provided during this period</p> <p>Second induction treatment: Day 1-28: 28 µg/d, Day 29-42: no drugs provided during this period</p> <p>Consolidation treatment: Day 1-28: 28 µg/d, Day 29-42: no drugs provided during this period</p> <p>Continued treatment: Day 1-28: 28 µg/d, Day 29-84: no drugs provided during this period</p> <p>For individuals weighing under 45kg, dosage is based on the individual's body surface area</p>
Anti-CD19 ADCs	Made from a humanized anti-human CD19 monoclonal antibody coupled to a pyrrolbenzodiazepine (PBD) dimeric cytotoxin via Linker. Once bound to CD19-expressing cells, Zynlonta® is internalized by the cells and subsequently releases a cytotoxin that irreversibly binds to DNA, resulting in strong interstrand crosslinks that prevent DNA strand separation, thereby disrupting essential DNA metabolic processes such as replication and ultimately leading to cell death.	<ul style="list-style-type: none"> <li>Compared to single antibody drugs, ADC drugs have better early therapeutic efficacy, greater resistance to drug resistance, and greater clinical potential</li> </ul>	<ul style="list-style-type: none"> <li>Overall technical complexity and high requirements for production technology</li> </ul>	Zynlonta® (entering Phase I clinical trial in China)/ US\$235,000	2021	Intravenous infusion administered over 30 minutes on day 1 of each cycle (every 3 weeks)	<p>0.15 mg per kg of body weight every 3 weeks for 2 cycles</p> <p>0.075 mg per kg of body weight every 3 weeks for subsequent cycles</p>
CAR-T-cell Therapy	CAR-T cell technology is a T cell-based cellular immunology technology where T cells are genetically edited to incorporate chimeric antigen receptors to form CAR-T cells that can effectively capture and kill tumor cells to achieve therapeutic results.	<ul style="list-style-type: none"> <li>Good efficacy and high remission rate</li> <li>May provide patients with long-lasting anti-tumor mechanisms</li> </ul>	<ul style="list-style-type: none"> <li>Technology not yet mature, CRS side effects need to be addressed</li> <li>Difficult to mass produce, high price</li> </ul>	Yescarta®/ RMB1.2 Million	2017	Subject to doctor's evaluations, generally one to two treatments and each treatment lasts for two weeks	A suspension of 2×10 <sup>6</sup> CAR-positive viable T cells per kg of body weight, with a maximum of 2 × 10 <sup>6</sup> CAR-positive viable T cells in approximately 68 mL
Hematopoietic Stem Cell Transplantation	Hematopoietic stem cell transplantation is a process whereby hematopoietic stem cells from the donor are removed from the body as a graft and then transfused back to the pre-treated recipient to rebuild the recipient's hematopoietic and immune systems. Pre-treatment with ultra-lethal doses of chemoradiotherapy has a bone marrow-clearing effect and the graft has anti-leukemic and anti-tumor effects.	<ul style="list-style-type: none"> <li>Main treatment modality for many years in the past, clinically mature</li> <li>Relatively low cost of treatment</li> <li>Good postoperative results</li> </ul>	<ul style="list-style-type: none"> <li>Mating restrictions</li> <li>Graft-versus-host disease</li> <li>Severe complications</li> </ul>	—*/RMB300,000	—	Median treatment duration: four months	<p>Peripheral blood mononuclear cells: 3 to 5 ×10<sup>6</sup> per kg of body weight, with peripheral blood CD34+ cells ≥ 2 ×10<sup>6</sup> cells per kg of body weight, or</p> <p>bone marrow nucleated cells: 1 to 3 ×10<sup>6</sup> per kg of body weight, with bone marrow CD34+ cells equal to 1 to 2 ×10<sup>6</sup> cells per kg of body weight</p>

Note:

\* Since hematopoietic stem cell transplantation refers to a process, no representative drugs are applicable.

Source: Chinese Society of Clinical Oncology (CSCO), Frost & Sullivan Analysis



## INDUSTRY OVERVIEW

The following table sets forth the total fees for each treatment:

Drug	Representative drug	Per dose price	Total fees
CD19-CD3 Bispecific Antibodies	Blinicyto <sup>®</sup>	RMB12,900/dose <sup>(1)</sup>	~US\$178,000/course <sup>(3)</sup>
Anti-CD19 ADCs	Zynlonta <sup>®</sup>	US\$25,415/injection <sup>(2)</sup>	~US\$235,000/year <sup>(4)</sup>
CAR-T-cell Therapy	Yescarta <sup>®</sup>	RMB1.2 million/injection	~RMB1.2 million <sup>(5)</sup>

*Notes:*

- (1) RMB12,900/dose is the bidding price of Blincyto<sup>®</sup>.
- (2) US\$25,415/injection is the price of Zynlonta<sup>®</sup> in the United States.
- (3) For Blincyto<sup>®</sup>, the doctor will give a personalized treatment based on comprehensive diagnosis and analysis of the patient’s condition. According to the instructions of Blincyto<sup>®</sup>, a course of treatment includes at most 2 cycles of induction therapy, 3 cycles of consolidation therapy and at most 4 cycles of maintenance therapy.
- (4) For Zynlonta<sup>®</sup>, patients receive treatment until progressive disease or unacceptable toxicity.
- (5) For Yescarta<sup>®</sup>, The frequency of treatment is subject to the the doctor’s evaluation (generally 1-2 times in total).

CD19 has advantages which make it an important therapeutic target for relapsed-refractory B cell malignancies, including high expression on the surface of B cells and low expression on the surface of other cells, CD19 is not lost during the malignant transformation of B cells and remains effective in refractory/relapsed cases, and B cells can be effectively replenished after treatment is stopped.

### *Bispecific Antibodies*

A bispecific antibody is an artificial protein that recognizes and specifically binds two antigens or epitopes. It simultaneously blocks the biological functions mediated by both antigens/epitopes or draws the cells of both antigens closer together and enhances the interaction. In recent years, a better understanding of the pathogenesis of various diseases and the rapid development of therapeutic monoclonal antibodies have also contributed to the development and advancement of bispecific antibodies. With the development of antibody construction, expression and purification techniques, dozens of structures have emerged from bispecific antibodies. The applications and research of existing bispecific antibodies are mainly focused on the field of oncology therapy.

### *CAR T-cell Therapy*

CAR T-cell therapy uses a delivery vehicle such as a lentivirus (LV) to transfer therapeutic gene sequences to the T cell genome, enabling the patient’s T cells to specifically recognize and bind to tumor cells, and subsequently kill them by releasing factors such as perforin. The therapy also results in the formation of memory T cells, providing patients with a long-lasting mechanism to fight tumors, effectively extending their survival rate and possibly even achieving a cure. Clinically, CAR T-cell therapy has shown significant efficacy in leukemia and non-Hodgkin’s lymphoma.

## INDUSTRY OVERVIEW

### *Hematopoietic Stem Cell Transplantation*

Hematopoietic stem cell transplantation (HSCT) is a process in which donor hematopoietic stem cells are removed from the body as a graft and then returned to the pre-treated recipient for transplantation to rebuild the recipient’s hematopoietic and immune systems. Pre-treatment with super lethal doses of chemoradiotherapy has a bone marrow scavenging effect and the graft has an anti-leukemic (graft versus leukemia, GVL) and anti-tumor (graft versus tumor, GVT) effect and is used clinically to treat hematologic disorders and certain malignant solid tumors associated with hematopoietic stem cells.

### **Market for Relapsed or Refractory B cell NHL/ALL Treatment**

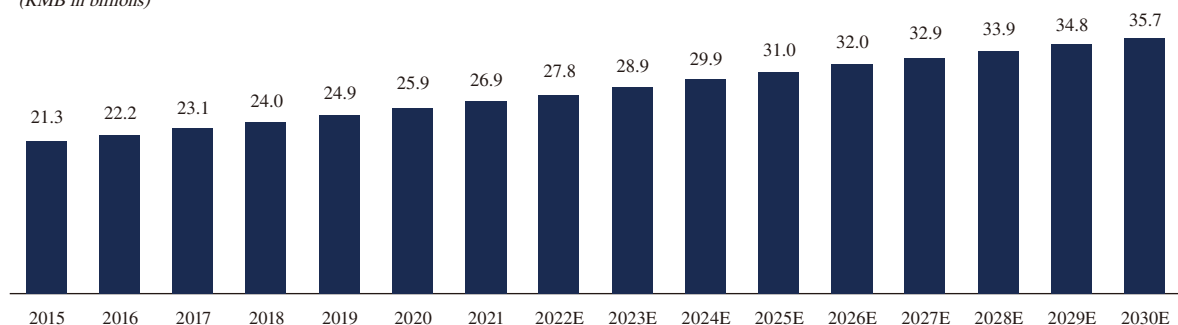
The incidence of hematologic malignancies such as lymphoma, myeloma and leukemia is increasing yearly, and although the application of various new drugs and protocols has greatly improved clinical treatment outcomes, the challenge in refractory recurrent hematologic tumors remains prominent. In China, the number of new cases of NHL was 95,000 in 2021. The majority of clinical NHL is of the B-cell type, accounting for 70%~85% of the total. In China, the number of new cases of ALL was about 13,000 in 2021. ALL is divided into two main categories, B-lymphocytic leukaemia (B-ALL) and T-lymphocytic leukaemia (T-ALL). According to the 2019 China Lymphoma Patient Survival White Paper, the average cost of non-first-time treatment is approximately RMB300,000 higher than the average cost of first-time treatment.

The relapsed or refractory B cell NHL/ALL treatment market in China increased from RMB21.3 billion in 2015 to RMB26.9 billion in 2021 at a CAGR of 4.0%, and is expected to increase to RMB31.0 billion in 2025 at a CAGR of 3.7% from 2021 to 2025, and further increase to RMB35.7 billion in 2030 at a CAGR of 2.9% from 2025 to 2030. K193 is expected to be launched in the market in year 2028 and the number of end-users is expected to reach 6.4 thousand in 2034. The chart below illustrates the historical and forecasted relapsed or refractory B cell NHL/ALL treatment market in China for the periods indicated:

### **Relapsed or Refractory B cell NHL/ALL Treatment Market in China, 2015-2030E**

Period	CAGR
2015-2021	4.0%
2021-2025E	3.7%
2025E-2030E	2.9%

(RMB in billions)



Source: Frost & Sullivan Analysis

## INDUSTRY OVERVIEW

### Growth Drivers of the Relapsed or Refractory B cell NHL/ALL Treatment Market

Growth drivers of the relapsed or refractory B cell NHL/ALL treatment market include (i) incurability of relapsed or refractory hematologic malignancies, (ii) limited treatment options, (iii) major flaws in treatment methods and (iv) favorable policies.

- *Incurability of relapsed or refractory hematologic malignancies.* Currently, there are poor treatment options for relapsed or refractory B cell NHL/ALL, which represent an area of significant unmet medical need. Patients with relapsed/refractory B-cell NHL/ALL are those who have failed first-line therapy and need to continue second-or third-line therapy. Although conventional first-line treatments are proved to be beneficial, the five-year survival rates do not exceed 70%, whereas, simultaneously, almost half of the patients become resistant to or experience a relapse following treatment. For second-line treatment of NHL, there is a high degree of overlap between second-line and first-line treatment drugs in China, and in the area of end-line treatment, there are fewer drugs on the market, relying on stem cell transplantation. In addition, high-dose chemotherapy and autologous hematopoietic stem cell transplantation (Auto-HCT) offer a chance of cure for chemotherapy-sensitive patients with R/R DLBCL. However, only 50% of patients with R/R DLBCL are usually suitable for HCT treatment due to their advanced age and the presence of comorbidities. Patients with recurrent or refractory acute ALL have a poor prognosis, with less than 10% surviving 5 years. Related studies have shown that patients with Philadelphia chromosome-negative (Ph-) R/R ALL have poor survival outcomes, with a median overall survival (OS) of only 3.3 months and a 1-year OS rate of only 22%-24%. According to the 2021 CSCO Guidelines for the Diagnosis and Treatment of Lymphoma and the 2021 CSCO Guidelines for the Diagnosis and Treatment of Hematological Malignancies, there is no specific drug for patients with relapsed/refractory B-cell NHL/ALL. Grade I recommended treatment for relapsed/refractory B-cell NHL includes clinical trials of autologous hematopoietic stem cell transplantation and allogeneic hematopoietic stem cell transplantation. Patients who are ineligible for transplantation are encouraged to participate in clinical trials such as non-cross-resistant combination chemotherapy. Grade II recommended therapies include CAR-T therapy, BTK inhibitors combined with chemotherapy and radiotherapy. Patients who fail rescue therapy can also choose biological products for treatment, such as monoclonal antibodies. Patients are encouraged to participate in clinical trials. Treatment options include monoclonal immunotherapy targeting CD22 and CD19, CAR-T therapy targeting CD19 and CD22 in B-ALL, and hematopoietic stem cell transplantation. Current treatment options for relapsed/refractory B cell NHL/ALL are still in clinical trials. Autologous hematopoietic stem cell transplantation has been a major treatment for relapsed/refractory B-cell NHL/ALL for many years. It is clinically mature and the postoperative effect is good. However, transplant failure, recurrence after transplantation, or serious complications may still occur. Autologous hematopoietic stem cell transplantation was first launched in 1956, and its treatment cost is approximately RMB300,000. CAR-T cell technology is a cellular immune technology based on T cells. T cells add chimeric antigen receptors through gene editing to form CAR-T cells, which can effectively capture and kill tumor cells to achieve therapeutic effect. The marketed CAR-T therapy products in China include Yescarta<sup>®</sup> (launched by Fosun Kite in China in 2021, targeting CD19 and priced at RMB1.2 million per injection and Carteyva<sup>®</sup> (launched by JW Therapeutics in China in 2021, targeting CD19 and priced at RMB1.3 million per injection). In addition, other globally marketed CAR-T

## INDUSTRY OVERVIEW

---

products include Novartis’ Kymriah, Gilead’s Tecartus, BMS’s Breyanzi and Abecma, and Legendary Bio/Johnson & Johnson’s Carvykti. Although CAR-T therapy products are effective, the technology is not yet mature, and CRS side effects need to be addressed. CAR-T therapy products are difficult to mass produce and less accessible to patients due to the high cost of treatment. CD19-CD3 bispecific antibody therapy is a prospective treatment. One end of the CD19-CD3 bispecific antibody can bind to CD19 expressed on the surface of B cells, and the other end can bind to CD3 expressed on the surface of T cells. By connecting CD19 malignant B lymphocytes with CD3+T lymphocytes, CD19-CD3 bispecific antibodies can mediate the lysis of T cells to tumor cells. The first commercialized bispecific antibody product in China is Amgen’s Blincyto<sup>®</sup> (launched in China in 2021, targeting CD19×CD3 and priced at RMB12,900 per dose, and RMB361,200 per course). Compared with monoclonal combination therapies, bispecific antibody therapies have higher potential safety and better potential efficacy. Up to 50% of patients with diffuse large B cell lymphoma are difficult to cure with rituximab, cyclophosphamide, doxorubicin hydrochloride, vincristine and prednisone (R-CHOP) therapy or relapse after achieving complete remission with first-line therapy. Approximately 60% to 70% of patients do not respond to current second-line therapy after first-line treatment, and of those who do respond to second-line therapy, approximately 50% will eventually relapse. Patients with relapsed or refractory B cell NHL have poor prognosis, and no treatment options are available for NHL. Patients with relapsed or refractory acute ALL have a dismal prognosis with less than 10% of patients surviving 5 years. With NHL causing approximately 54,351 deaths in China in 2020, there remains a significant unmet medical need for patients who have relapsed or are refractory to cure after receiving available therapies.

- *Limited treatment options.* Due to limited choices of mechanisms of action, existing therapies are unable to provide effective treatment for patients with different relapsed or refractory diffuse large B cell lymphomas. For example, rituximab maintenance therapy has no significant effect on patients with relapsed or refractory diffuse large B cell lymphomas who have relapsed after autologous stem cell transplantation. Second-line treatment options other than chemotherapy are also extremely limited in China compared to the U.S. Therefore, second-line patients eligible for transplantation in China are more likely to be treated with stem cell transplantation than in the U.S.
- *Major flaws in treatment methods.* The diagnosis of hematologic malignancies is usually through bone marrow examination and imaging. Most patients will opt for chemotherapy, targeted drugs, immunotherapy and, for those with the right conditions, bone marrow transplantation. The main drawbacks of current therapies are reflected in low overall response rates, high recurrence rates, side effects, long treatment cycles and high prices. Due to the lack of key drugs, inadequate adjuvant therapies and low early diagnosis rates, the five-year survival rates for hematologic malignancies in China are low, with NHL and multiple myeloma having five-year survival rates of approximately 37% and 25% respectively, which are lower than the survival rates for the same indications in the U.S. Curable immunotherapies have the potential to increase the market for relapsed or refractory B cell NHL/ALL treatment and are in high demand.

## INDUSTRY OVERVIEW

- Favorable policies.** Economic, social and legal factors will have a significant impact on growth of the relapsed or refractory B cell NHL/ALL treatment market, as the market is heavily influenced by price, drug safety and the regulatory environment. The PRC government is implementing favorable policies and regulations to facilitate the development of new therapies. Special review channels such as priority review are also enabling accelerated launch of anti-tumor drugs. Policies such as the expansion of medical insurance, zero tariff on imported anti-cancer drugs and the negotiation of anti-cancer drugs into medical insurance will reduce the cost of anti-cancer drugs, further increasing the accessibility of innovative oncology immunology drugs.

### Competitive Landscape

As of the Latest Practicable Date, there were three marketed drugs in China for third-line treatment of relapsed or refractory B cell NHL/ALL, comprising one bispecific antibody and two CAR T-cell therapies. The following table sets forth details of the marketed drugs in China for third-line treatment of relapsed or refractory B cell NHL/ALL:

#### Bispecific Antibodies

Year	Product	Company	Indication	Target	Effectiveness	Safety	Price
2020	Blinicyto®	Amgen	Adults r/r ALL	CD19 × CD3	ORR: 44%, CR: 34%, mDOR: 7.3 month	CRS:15% (≥grade 3: 7%) NT: 65%	US\$178,000

#### CAR-T

Year	Product	Company	Indication	Target	Effectiveness	Safety	Price
2021	Yescarta®	Fosun Kite Biotechnology	Adult r/r DLBCL, Adult r/r FL	CD19	Best ORR: 82%, Best CR: 58%, CR at 2 years: 37%, 2-yr PFS: 39%, 2-yr OS: 51%	CRS:93% (≥grade 3: 13%) ICANS : 64% (≥grade 3: 28%)	~RMB1.2 million
2021	Carteyva®	JW Therapeutics	r/r LBCL, r/r FL	CD19	Best ORR: 76%, Best CR: 52%	CRS:48% (≥grade 3: 5%) NT:20% (≥grade 3: 5%)	~RMB1.3 million

#### Notes:

- DLBCL = diffuse large B cell lymphoma; LBCL = large B cell lymphoma; FL = follicular lymphoma.
- For Carteyva®, the treatment duration varies depending on the doctor’s evaluations, and the recommended dosage is  $100 \times 10^6$  CAR-T cells.

Source: *Guangdong Medicine Exchange, Frost & Sullivan Analysis*

As of the Latest Practicable Date, there were over 30 drugs under development in China for third-line treatment of relapsed or refractory B cell NHL/ALL.

## INDUSTRY OVERVIEW

As of the Latest Practicable Date, there was one marketed CD3/CD19 bispecific antibody in China for the treatment of relapsed or refractory B cell NHL/ALL, five CD3/CD19 bispecific antibodies and one CD3/CD19/CD20 trispecific antibody under development in China for the treatment of relapsed or refractory B cell NHL/ALL. The following chart sets forth details of CD3/CD19 bispecific antibodies and CD3/CD19/CD20 trispecific antibody that are marketed or under development in China for the treatment of relapsed or refractory B cell NHL/ALL:

Name of Drug	Company Name	Indication	Target	Clinical Progress	Date of Clinical Publication <sup>(1)</sup>
Blincyto®	Amgen	Relapsed or refractory diffuse large B cell lymphoma	CD19 × CD3	Listed	2014 FDA 2020 NMPA
A-319	Generon Biomed <sup>(2)</sup>	Refractory or relapsed B cell lymphoma	CD19 × CD3	Phase I	April 8, 2019
K193	Luzhu Biotech	Refractory/relapsed B cell non-Hodgkin's lymphoma	CD19 × CD3	Phase I	November 18, 2019
CN201	Curon Biopharma	r/r-B-NHL	CD19 × CD3	Phase I	January 11, 2021
LNF1904	Shandong Xinshidai Pharmaceutical Co., Ltd	Refractory/relapsed B cell malignant tumor	CD19 × CD3	Phase I	September 15, 2022
CMG1A46	BioRay Pharmaceutical Chimagen Biosciences	B cell NHL	CD19 × CD20 × CD3	Phase I	April 27, 2022
YK012	iEcyte	r/r-B-NHL	CD19 × CD3	Phase I	February 1, 2023

*Notes:*

- (1) Date of clinical publication is defined as the date of first publication of information based on clinical progress.
- (2) Generon Biomed has changed its name to Evive Biotech.

*Source: Frost & Sullivan Analysis*

## MYELOID LEUKEMIA TREATMENT MARKET

### Overview

Acute myeloid leukemia (AML) is a disorder characterized by a clonal proliferation derived from primitive hematopoietic stem cells or progenitor cells. Abnormal differentiation of myeloid cells results in a high level of immature malignant cells and fewer differentiated red blood cells, platelets and white blood cells. The disease occurs at all ages, but predominantly occurs in older people (>60 years of age). Symptoms may include fatigue, difficulty breathing, easy bruising and bleeding, and increased risk of infection. AML typically presents with a rapid onset of symptoms that are attributable to bone marrow failure and may be fatal within weeks or months when left untreated.

The number of new cases of AML in China increased from approximately 28,000 cases in 2015 to 30,000 cases in 2021 at a CAGR of 1.6%, and is expected to increase to 32,000 cases in 2025 at a CAGR of 1.5% from 2021 to 2025, and further increase to 34,000 cases in 2030 at a CAGR of 1.3% from 2025 to 2030. The global number of new cases of AML increased from approximately 115,600 in 2015 to 127,800 in 2021 at a CAGR of 1.7%, and is expected to increase to 136,200 in 2025 at a CAGR of 1.6% from 2021 to 2025, and further increase to 146,700 in 2030 at a CAGR of 1.5% from 2025 to 2030.

## INDUSTRY OVERVIEW

---

The main treatment for most types of AML is chemotherapy, sometimes along with a targeted therapy drug. This might be followed by a stem cell transplant. Surgery and radiation therapy are not major treatments for AML, but they may be used in special circumstances. Patients with AML have the lowest five-year survival rate of any leukemia type. The proportion of patients suitable for stem cell transplant is low in terms of current treatment, and most patients fail to respond to chemotherapy and progress to relapsed/refractory AML. Relapsed/Refractory AML is difficult to treat due to its inherent difficulty in achieving complete remission, multiple complications and short survival.

### THE FROST & SULLIVAN REPORT

In connection with the [REDACTED], we commissioned Frost & Sullivan, an Independent Third Party, to prepare a report on the vaccine market, relapsed or refractory B cell NHL/ALL treatment market, adalimumab injectable market and myeloid leukemia treatment market in China and globally. Frost & Sullivan is an independent global market research and consulting company which was 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. We have agreed to pay a total of RMB0.9 million in fees for the preparation of the Frost & Sullivan Report. The payment of such amount was not contingent upon our successful [REDACTED] 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 [REDACTED]. We have included certain information from the Frost & Sullivan Report in this document because we believe such information facilitates an understanding of the market where we operate our businesses for potential investors. 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 has exercised due care in collecting and reviewing the information so collected and 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. The market projections in the commissioned report are based on the following key assumptions: (i) the overall social, economic and political environment in China and globally is expected to remain stable during the forecast period; (ii) the pharmaceutical industry is expected to maintain a robust growth over the next few years; and (iii) no extreme force majeure or industry regulation will dramatically or fundamentally affect the market. Frost & Sullivan research may be affected by the accuracy of these assumptions and the choice of these primary and secondary sources. Except as otherwise noted, all data and forecasts in this section come from the Frost & Sullivan Report.

## REGULATORY OVERVIEW

---

### PRC LAWS AND REGULATIONS

Our business operations are subject to extensive supervision and administration by the Chinese government. This section sets out: (i) the introductions of the Chinese governmental agencies with jurisdiction over our operation; and (ii) the overview of the laws, regulations and policies we must comply with.

### REGULATORY AUTHORITIES

#### NMPA and Its Evaluation Center

China National Medical Products Administration (國家藥品監督管理局) (hereinafter referred to as “NMPA”), successor to the China Food and Drug Administration (國家食品藥品監督管理局) 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 policy planning, formulating departmental regulations, organizing the development and issuance of pharmaceutical and medical device standards, classification and management systems, such as national formulary, and supervising the implementation.

The 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 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), (the “NHC”), is primary national regulator 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 formulation of national drug policies and national essential medicine system, launching an early warning mechanism for the monitoring of the use and clinical comprehensive evaluation of medicine as well as the drug shortage, giving suggestions on the pricing policy of national essential medicine, and regulating the operation of medical institutions and practicing of medical personnel.

#### NIFDC

The National Institutes for Food and Drug Control (中國食品藥品檢定研究院) (the “NIFDC”) is a public institution directly subordinate to NMPA and the statutory authority and supreme technical arbitration institution for inspecting the quality of pharmaceuticals and biological products. It is responsible for the approval and registration inspection, import inspection, supervision and inspection, safety evaluation of drugs, biological products, medical devices, foods, dietary supplements, cosmetics, laboratory animals and package materials and the batch release of biological products, the research, distribution and management of the national drug and medical device reference materials and bacterial and viral strains for production verification, as well as the relevant technical research.



## REGULATORY OVERVIEW

---

In accordance with the Drug Registration Regulation (《藥品註冊管理辦法》) (the “**Drug Registration Regulation**”), the NIFDC shall undertake the drug registration inspection and other relevant work which are required for implementation of drug registration administration. Specifically, the NIFDC or a drug inspection institution designated by the NMPA shall undertake inspection for registration of the following drugs: innovative drugs; modified new drugs (except for traditional Chinese medicine); biological products, radioactive drugs and in-vitro diagnostic reagents subject to drug management; and other drugs stipulated by the NMPA.

### China CDC

Under the leadership of National Health Commission, Chinese Center for Disease Control and Prevention (中國疾病預防控制中心) (the “**CDC**”) exerts its function in technical guidance and support of public health. Focusing on the key tasks of national disease prevention and control, China CDC studies on the strategies and measures for disease prevention and control, organizing and implementing the work plan for various kinds of disease prevention and control. It takes care of management of public health services, including food safety, occupational safety, health related product safety, radiological health, environmental health, as well as women and children’s health. China CDC forcefully carries out operational researches, and enhances technical instruction, training and quality controls in national disease prevention and control, as well as in public health service and plays the leading role nationwide in disease prevention and control, health emergency response and capacity building of public health information.

### MOFCOM

Ministry of Commerce (商務部) (the “**MOFCOM**”) is responsible for guiding and managing the foreign investment absorption in the country, drawing up the laws and regulations related to foreign investment, formulating the relevant rules, policies and reform schemes, organizing the implementation, supervising and inspecting the implementation status; participating in the formulation and joint issuance of Special Management Measures for the Access of Foreign Investment (Negative List) (《外商投資准入特別管理措施(負面清單)》) and Encouraging Foreign Investment Industries Catalogue (《鼓勵外商投資產業目錄》) with the National Development and Reform Commission; managing and guiding the foreign investment review, approval and filing works.

### NDRC

National Development and Reform Commission (國家發展和改革委員會) (the “**NDRC**”) is mainly responsible for participating in the formulation of health development policies, the establishment of technical reform investment projects, the macro guidance and management of the economic operation of pharmaceutical enterprises, and the supervision of the implementation of relevant policies and regulations. NDRC also regulate the price of drugs circulated in the market.

### NHSA

National Healthcare Security Administration (國家醫療保障局) (the “**NHSA**”) is mainly responsible for formulating and organizing the implementation of policies, plans and standards for medical insurance, maternity insurance, medical aid and other medical security systems, organizing the formulation and adjustment of prices and charging standards for drugs and medical services, and formulating and supervising the implementation of the bidding and procurement policies for drugs and medical consumables.

## REGULATORY OVERVIEW

### REGULATORY PROVISIONS

#### Laws and Regulations Related to Drugs

##### *Introduction*

In 2017, the drug regulatory system entered a new and significant period of reform. In October 2017, the General Office of the State Council and the General Office of the Central Committee of the China Communist Party jointly issued the Opinions on Deepening the Reform of the Evaluation and Approval System to Encourage Innovation in Drugs and Medical Devices (《關於深化審評審批制度改革鼓勵藥品醫療器械創新的意見》) (the “**the Innovation Opinion**”) to encourage, among others, the reform of clinical trial management and acceleration of the review and approval for drugs and medical devices marketing.

To implement the regulatory reform introduced by the Innovation Opinion, the National People’s Congress, or the NPC and the NMPA has been revising the fundamental laws, regulations and rules regulating pharmaceutical products and the industry, which include the framework law known as the PRC Drug Administration Law (《中華人民共和國藥品管理法》), or the Drug Administration Law. The Drug Administration Law was promulgated by the Standing Committee of the NPC, or the SCNPC, on September 20, 1984 and latest amended on August 26, 2019 and took effect as of December 1, 2019. The State Council issued the Regulations for Implementation of the Drug Administration Law of the PRC (《中華人民共和國藥品管理法實施條例》), which was promulgated on August 4, 2002 and latest amended on March 2, 2019, to further implement the Drug Administration Law. The NMPA also has its own set of regulations for the Drug Administration Law, and the primary one governing clinical trial applications, marketing approval, and post-approval amendment and renewal is known as the Drug Registration Regulation (《藥品註冊管理辦法》), which was latest amended by the NMPA on January 22, 2020 and effective from July 1, 2020.

##### *Clinical Trials Approval*

Before registering a new drug, a sponsor shall complete clinical trials according to the Drug Registration Regulation. To start the clinical trial, a sponsor needs to apply for clinical trial approval first, and the Administrative Regulations of Quality of Drug Clinical Practice (《藥物臨床試驗質量管理規範》), or the DCP, has been promulgated to further promote the research into good practice for clinical trials of drugs and enhance the quality thereof. The DCP was promulgated by NMPA on August 6, 2003 and latest amended by NMPA and NHC which came into effect on July 1, 2020. All clinical trials conducted in China for new drug registration purposes must be approved and conducted at pharmaceutical clinical trial institutions filed according to the Regulations on the Administration of Drug Clinical Trial Institutions (《藥物臨床試驗機構管理規定》) promulgated by NMPA and NHC on November 29, 2019.

According to the Announcement of Several Policies on the Evaluation and Examination for Drug Registration (《關於藥品註冊審評審批若干政策的公告》) promulgated by NMPA on November 11, 2015, an umbrella approval would be issued by NMPA for all phases (typically three) of a new drug clinical trial, instead of approvals phase by phase. Provided by the Announcement of the Adjustment of Procedures of the Evaluation and Examination for Drug Clinical Trial (《關於調整藥物臨床試驗審評審批程序的公告》) issued by NMPA on July 24, 2018, applicants could proceed with their clinical trials if they have not received any denial or query from the CDE within 60 business days after the application has been accepted and the relevant application fees have been paid. The newly revised Drug Administration

## REGULATORY OVERVIEW

Law further confirms that the CDE under the State Council shall, within 60 working days from the date on which the application for a clinical trial is accepted, decide on whether to approve it and then notify the clinical trial applicant. In the case of failure to notify the applicant within the prescribed time limit, it shall be deemed as approved. On May 22, 2017, NMPA issued the Announcement of the Opinions on Handling Issues Related to Verification of Drug Clinical Trial Data (《關於藥物臨床試驗數據核查有關問題處理意見的公告》), according to which, if the clinical trial data is incomplete, ill-formed and insufficient to prove the safety and efficacy of the drug, the registration application of the drug will be rejected.

### *Drug Clinical Trial Registration*

Pursuant to the Drug Registration Regulation, upon obtaining the clinical trial approval and before commencing a clinical trial, the sponsor shall register the scheme of the clinical trial and other information on the Drug Clinical Trial Registration and Information Platform for clinical trials of drugs. During the clinical trial of drugs, the sponsor shall update registration information continuously, and register information on the outcome of the clinical trial of drugs upon completion of the clinical trial of drugs. The registration information shall be published on the platform and the sponsor shall be responsible for the veracity of such information. More details are provided in the Announcement on Drug Clinical Trial Information Platform (《關於藥物臨床試驗信息平台的公告》) released by the NMPA on September 6, 2013, providing that for all clinical trials approved by the NMPA and conducted in China shall be published through the Drug Clinical Trial Registration and Information Platform. The applicant shall complete trial pre-registration within one month after obtaining the clinical trial approval to obtain the trial’s unique registration number and shall complete certain follow-up information and first submission for publication before the first subject’s enrollment in the trial. If the foregoing first time of publication has not been submitted within one year after obtaining the clinical trial approval, the applicant shall submit an explanation, and if the procedure is not completed within three years, the clinical trial approval shall automatically be annulled.

### *Clinical Trial Process and Good Clinical Practices*

Pursuant to the Drug Registration Regulation, drug clinical trials in China shall go through four phases. Based on the characteristics of drugs and research objective, the research contents shall include clinical pharmacology research, exploratory clinical trial, confirmatory clinical trial and post-marketing research clinical. The NMPA requires that the different phases of clinical trials in China shall receive ethics committee approval respectively and comply with the relevant requirements of quality management standards for clinical trial of drugs in PRC. The sponsor shall submit safety update reports on the CDE website regularly during the research and development period. The sponsor shall promptly report to the CDE regarding suspicious and unexpected serious adverse reaction and other potential serious safety risks arising in the course of the clinical trial. Based on the severity of the safety risks, the sponsor may be required to adopt measures to strengthen risk control, and may be required to suspend or terminate the clinical trial of drugs where necessary.

According to the DCP, the sponsor shall provide investigators and the clinical trial institution with legal and economic insurance or guarantee relating to the clinical trial, and ensure that such insurance or guarantee is appropriate to the nature and degree of risks of the clinical trial, excluding the damages caused by the negligence of investigators or the clinical trial institution. Pursuant to the Innovation Opinion, the accreditation of the institutions for drug clinical trials shall be subject to record-filing administration. The conduct of clinical trials must adhere to the DCP, and the protocols must be approved

## REGULATORY OVERVIEW

---

by the ethics committees. Pursuant to the newly amended Drug Administration Law and the Regulations on the Administration of Drug Clinical Trial Institution (《藥物臨床試驗機構管理規定》) jointly promulgated by NMPA and NHC on November 29, 2019 and effective from December 1, 2019, drug clinical trial institutions shall be subject to filing administration. Entities that only conduct analysis of biological samples related to clinical trials of drugs are not required perform filing procedures.

### *Human Genetic Resources Approval and Registration*

The Ministry of Science and Technology promulgated the Service Guide for Administrative Licensing Items concerning Examination and Approval of Sampling, Collecting, Trading or Exporting Human Genetic Resources, or Taking Such Resources out of the PRC (《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》) in July 2015, according to which, if the sampling, collection or research activities of human genetic resources by a foreign-invested sponsor fall within the scope of international cooperation, and the cooperating organization of China shall apply for approval of the China Human Genetic Resources Management Office through the online system. On October 26, 2017, the Ministry of Science and Technology issued the Announcement on Optimizing the Administrative Examination and Approval of Human Genetic Resources (《關於優化人類遺傳資源行政審批流程的通知》), which simplified the approval for utilizing human genetic resources for the purpose of obtaining the marketing license of a drug in the PRC.

On May 28, 2019, the State Council of PRC issued the Administrative Regulations on Human Genetic Resources (《人類遺傳資源管理條例》) (the “**Human Genetic Resource Regulation**”), which became effective on July 1, 2019. According to the Human Genetic Resource Regulation, human genetic resource includes human genetic resource materials and information. Human genetic resource materials refer to organs, tissues, cells and other genetic materials containing human genome, genes and other genetic materials. Human genetic resource information refers to information, such as data, generated by human genetic resources materials. The Human Genetic Resource Regulation formalized the approval requirements pertinent to research collaborations between Chinese and foreign-owned entities, under which, a new filing system (as opposed to the advance approval approach originally in place) is put in place for clinical trials utilizing China’s human genetic resources in order to obtain market license at clinical institutions without involving the export of human genetic resources materials outside of China. Foreign organizations, individuals and institutions established or actually controlled by foreign organizations and individuals are not allowed to collect or preserve human genetic resources in China or provide human genetic resources abroad.

### *New Drug Application and Approval*

According to the Drug Registration Regulation, an applicant shall, upon completion of studies including pharmacy, pharmacology and toxicology and clinical trial of drugs which support the registration of drug marketing, determination of quality standards, verification of commercial scale manufacturing process, and preparation to undergo examination and inspection for drug registration, submit an application for drug marketing authorization, and submit the relevant research materials in accordance with the submission requirements. The CDE shall organize pharmacist, medical and other technical personnel to comprehensively review the application regarding the safety, effectiveness and quality control of the drug. Where the application is cleared by the comprehensive review, the drug shall be approved for marketing and a drug registration certificate shall be issued.

## REGULATORY OVERVIEW

---

In accordance with Drug Registration Regulation, during drug clinical trials, applications for conditional approval may be submitted for drugs falling under any of the following circumstances: (1) the drugs are used for treatment of diseases that seriously endanger life and have no effective measure of treatment, and the data of drug clinical trials can prove the efficacy and forecast the clinical value of the drugs; (2) the drugs are urgently needed for public health, and the data of drug clinical trials can prove the efficacy and forecast the clinical value of the drugs; or (3) vaccines are urgently needed to deal with major public health emergencies or other vaccines which the NHC deems to be urgently needed, and it is assessed that the benefits thereof outweigh the risks therein.

An applicant that applies for conditional approval shall communicate with the CDE about the conditions for marketing with conditional approval and the research work to be completed after marketing, among others, and submit an application for marketing authorization after making confirmation through communication. If it is reviewed that the requirements for conditional approval are satisfied, the drug registration certificate shall indicate the validity period of the conditional approval drug registration certificate, the research work to be completed after marketing, time limit for completion, and other relevant matters.

With respect to drugs with conditional approval, MAHs shall take corresponding risk management measures after the drugs are marketed, complete drug clinical trials and relevant research as required within the specified time limit, and submit an application in the form of a supplementary application. If any further research is required during approval of an application for vaccine registration, the vaccine holder shall complete the research within the specified time limit.

Under the Drug Registration Regulation, drugs are classified into Chinese medicine, chemical medicine, biological products and others. Biological products are further divided in 3 categories in the Registration Classification and Application Documents Requirements of Biological Products (《生物製品註冊分類及申報資料要求》) (the “**Registration Category**”), which was promulgated by the NMPA on June 29, 2020 and replaced the previous version issued in 2007. Pursuant to the Registration Category, Category I therapeutic biological products or vaccines refer to those have not been marketed in the PRC or abroad. Category 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. Category III therapeutic biological products or vaccines refer to those have been marketed in the PRC or abroad.

Pursuant to the newly amended Drug Administration Law, an applicant who has obtained a drug registration certificate shall be recognized as a drug marketing authorization holder, responsible for non-clinical laboratory studies, clinical trials, production and distribution, post-market studies, and the monitoring, reporting, and handling of adverse reactions in connection with pharmaceuticals in accordance with the provisions of the Drug Administration Law. The drug marketing authorization holder may engage in manufacturing or distribution on their own or to entrust a licensed third party. At the time of application for drug marketing authorization, the applicant and the manufacturing enterprise shall have held the corresponding Pharmaceutical Manufacturing Permit.

### **Biosimilars Application and Approval**

Biosimilars refer to therapeutic biological products that are similar to approved and registered reference drugs in terms of quality, safety and efficacy. In accordance with the Announcement of the CFDA on Promulgating the Guiding Principles for the Research and Development and Evaluation

## REGULATORY OVERVIEW

---

Techniques concerning biosimilars (《國家食品藥品監督管理總局關於發佈生物類似藥研發與評價技術指導原則的通告》) on 28 February 2015, biosimilars shall be declared according to the application procedures for new drugs. Application materials for therapeutic biological products shall be submitted following specific requirements in the Guidelines for the R&D and Evaluation of Biosimilar Drugs (for Trial Implementation) (《生物類似藥研發與評價技術指導原則(試行)》) (the “**Guiding Principles**”).

In February 2015, the CFDA released the Guiding Principles, 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 Guiding Principles, 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, dose-escalation principle, consistency principle and equivalence principle) and should cover pharmaceutical, non-clinical and clinical research and evaluation. The Guiding Principles set out provisions for the expansion 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 expanded 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 expanded indications. The expansion of indications shall be considered according to product features on case basis. However, caution shall be taken in expanding indications for groups with combined medication, patients with different combined diseases and different recommended dosage.

With respect to the application and approval process for imported biosimilars developed overseas, according to the PRC Drug Administration Law (《中華人民共和國藥品管理法》), the importation of biosimilars which have been approved overseas shall be examined by the drug regulatory authority of the State Council. Import approval shall be granted only after the examination confirms that the drugs comply with quality standards and are safe for use. A Registration Certificate for Imported Drugs shall then be issued. According to the Drug Registration Regulation (《藥品註冊管理辦法》), the application for registration of drugs produced overseas shall be filed in accordance with the requirements for the detailed classification and the corresponding application materials. In order to cooperate with the implementation of the Drug Registration Regulation, the NMPA formulated the Registration Category, and the Registration Classification of Biological Products part came into effect on July 1, 2020 while the Requirements for Application Materials part came into effect on October 1, 2020. According to the Registration Category, the biosimilars are classified as category 3.3.

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》) (the “**Technical Guidelines**”) to further standardize the development and evaluation of biosimilars, which came into effect on the same day. According to the Technical Guidelines, 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 the similarity evaluation should be carried out on different stages of biopharmaceutical studies.

## REGULATORY OVERVIEW

---

### *Drug Manufacturing*

According to the Drug Administration Law and Administrative Measures on Supervision of Pharmaceutical Manufacturing (《藥品生產監督管理辦法》) which was promulgated by the NMPA on December 11, 2002 and last amended on January 22, 2020 and effective on July 1, 2020, all facilities that manufacture drugs in China must apply for a Pharmaceutical Manufacturing Permit which are issued by the drug supervision and administration department of the province, autonomous region or municipality directly under the central government where it is domiciled. The Pharmaceutical Manufacturing Permit is valid for five years and shall be renewed six months before the expiry date. The drug marketing authorization holder who entrusts another party to produce preparations shall meet the requirements as specified in Administrative Measures on Supervision of Pharmaceutical Manufacturing, sign an entrustment agreement and a quality agreement with a qualified drug producer, and submit the relevant agreements and the application materials of the actual production site to provincial drug administrative departments where the drug marketing authorization holder is located to apply for the drug production license. When an application for marketing authorization is submitted, the applicant and the manufacturer shall have obtained the corresponding Pharmaceutical Manufacturing Permit.

### *Drug Operation*

As required by Drug Administration Law and Administrative Measures for Drug Business Permits (《藥品經營許可證管理辦法》) which was promulgated by the NMPA on February 4, 2004 and amended on November 17, 2017, operation of drug business, including drug wholesale and drug retail, is prohibited without a Drug Business Permit. A Drug Business Permit shall state the validity period and the scope of business and be subject to review and reissuance upon expiry of the validity period. Drug business operators shall comply with the drug operation quality management norms, establish and improve their business operation quality management system, and ensure that the whole drug business process continuously comply with statutory requirements.

In China, governmental pricing controls on drugs (other than narcotic and certain psychiatric drugs) have been lifted since May 2015 when the Opinions on Advancing Drug Price Reform (《推進藥品價格改革意見》) came into effect. Instead of direct governmental controls, the government exercises control over the drugs through establishing a centralized tender process or centralized procurement mechanism, revising the National Reimbursement Drug List or provincial medical insurance drug catalogs and strengthening regulation of medical and pricing practices. Also, according to the Opinions on the Reform of Review and Approval System for Drugs and Medical Devices (《關於改革藥品醫療器械審評審批制度的意見》) promulgated by the State Council in August 2015, enterprises which apply for the registration of new drugs should promise that the prices of their products on the PRC market should not be higher than the comparable market prices in original countries or the surrounding area of the PRC.

According to the Interim Measures for the Administration of Use of Drugs Covered by the Basic Medical Insurance (《基本醫療保險用藥管理暫行辦法》), western drugs and Chinese drugs in the national Drug Catalog are divided into “drugs of Category A” and “drugs of Category B”. “Drugs of Category A” are drugs which are necessary for clinical treatment, are widely used, have a definite effect, and have a lower price or treatment cost among similar drugs. “Drugs of Category B” are drugs which may be selected for clinical treatment, have definite effect, and have a slightly higher price or treatment cost than “drugs of Category A” among similar drugs. The expenses for “drugs of Category A” used by the insured shall be paid according to the payment standards and sharing measures stipulated for basic medical insurance, while those for “drugs of Category B” shall be first paid by the insured in a certain

## REGULATORY OVERVIEW

percentage, and then paid according to the sharing measures stipulated for basic medical insurance. The percentage of expenses paid by individuals for “drugs of Category B” is determined by the provincial or pooling region’s healthcare security administrative department.

### Laws and Regulations Related to Vaccines

#### *Vaccine Policies*

The Laws on Prevention and Treatment of Infectious Diseases (《中華人民共和國傳染病防治法》), issued in February 1989 and amended in August 2004 and June 2013, stipulates that a planned prophylactic vaccination system is performed in the PRC. The health administration department under the State Council and such departments under the people’s governments of provinces, autonomous regions, and municipalities directly under the central government shall, in accordance with the requirements of prevention and control of infectious diseases, draw up plans for prophylactic vaccination against infectious diseases and coordinate efforts for their implementation. Vaccines used for prophylactic vaccination shall conform to the quality standards of the PRC.

According to the Vaccine Administration Law of the PRC (《中華人民共和國疫苗管理法》) (the “**Vaccine Administration Law**”), which was promulgated by the SCNPC on June 29, 2019 and came into effect on December 1, 2019, the State applies the most stringent management system for vaccines, and adheres to the principles of safety first, risk management, whole-process control, scientific supervision and social co-governance. Also, a National Immunization Program system is applied in the PRC, under which the government would provide vaccines under the immunization program to the residents free of charge.

According to Biosecurity Law of the PRC (《中華人民共和國生物安全法》) (the “**Biosecurity Law**”), which was promulgated by the SCNPC on October 17, 2020 and came into effective on April 15, 2021, organizations engaged in biotechnology research and development shall comply with the national safety administration norms for biotechnology research and development. The high- or medium-risk biotechnology research and development activities shall be carried out by corporate bodies lawfully established within the territory of China and shall be approved or filed for record in accordance with the law. The corporate bodies engaged in high- or medium-risk biotechnology research and development activities shall conduct risk assessment, formulate risk prevention and control plans and emergency plans for biosafety incidents, and reduce the risks in the implementation of the research and development activities. The clinical research of new biomedical technologies shall pass the ethical review and be conducted in the medical institutions with corresponding qualifications; the operation of human clinical research shall be conducted by the professional medical workers with corresponding qualifications.

#### *Vaccine Administration*

On January 15, 2017, the General Office of State Council issued Opinions on Further Enhancing Administration of Circulation and Vaccination of Vaccines (《關於進一步加強疫苗流通和預防接種管理工作的意見》) (the “**Vaccine Opinion**”) among others, to improve the work mechanism for the management of vaccines and promote the independent R&D and quality improvement of vaccines. On June 29, 2019, the SCNPC released the Vaccine Administration Law, which requires the most stringent management system for vaccines, and at the same time, supports the basic research and applied research on vaccines, promotes the development and innovation of vaccines, including the development, production and reserve of vaccines for the prevention and control of serious diseases in the national



## REGULATORY OVERVIEW

---

strategy. Entities and individuals engaged in vaccine development, production, circulation and vaccination shall abide by the laws, regulations, rules, standards and specifications, ensure that the information during the whole process is true, accurate, complete and traceable, assume responsibilities in accordance with the law and accept social supervision.

Pursuant to the Vaccine Administration Law, vaccine marketing authorization holders shall establish an electronic vaccine traceability system, which is connected with the national electronic vaccine traceability collaboration platform to realize the traceability and verifiability of the smallest packaging units of vaccines in the whole process of production, circulation and vaccination. In addition, vaccine marketing authorization holders are required to purchase compulsory liability insurance for their vaccines. Where an inoculated person suffers any damage due to vaccine quality problems, the insurance company shall pay compensation within the limit of liability insured.

### *Development and Registration of Vaccines*

On October 14, 2005, the NMPA promulgated the Notice on Issuing Six Technical Guidelines including the Technical Guidelines on Preclinical Study of Preventive Vaccines (《關於印發〈預防用疫苗臨床前研究技術指導原則〉等6個技術指導原則的通知》), which specified the requirements on preclinical research, change of production process, quality control in clinical stages of vaccine to ensure its safety and efficacy.

According to the Vaccine Administration Law, clinical trials of vaccines shall not be conducted without obtaining the approval of the drug administrative department under the State Council. Clinical trials of vaccines shall be conducted or organized for implementation by Grade III medical institutions that meet the conditions prescribed by the drug administrative department under the State Council and the competent health department under the State Council, or by disease prevention and control institutions at or above the provincial level.

A vaccine to be marketed within the territory of China shall be approved by the drug administrative department under the State Council and obtain a drug registration certificate; when applying for registration of a vaccine, an applicant shall provide true, sufficient and reliable data, information and samples. With respect to the vaccines urgently needed for disease prevention and control as well as the innovative vaccines, the drug administrative department under the State Council shall prioritize their evaluation and approval.

According to the Vaccine Administration Law, for vaccines urgently needed for disease prevention and control as well as the innovative vaccines, the NMPA shall prioritize the evaluation and approval work. With respect to a vaccine urgently needed for responding to a major public health emergency or any other vaccines urgently needed as determined by the health department under the State Council, if the benefits outweigh the risks upon assessment, the drug administrative department under the State Council may conditionally approve the vaccine registration application.

According to the Drug Registration Regulation, before the applicant submits an application for drug marketing authorization, it shall communicate with the CDE and, upon communication and confirmation, submit the application for drug marketing authorization and simultaneously submit an application for prioritized review and approval. Upon included in the procedures for prioritized review and approval, the sponsors could enjoy, among others, a shortened review period for drug marketing authorization within 130 days.

## REGULATORY OVERVIEW

---

### *Production and Batch Release of Vaccines*

According to the Vaccine Administration Law, whoever engages in vaccine production activities shall, in addition to meeting the conditions for engaging in drug production activities as prescribed in the Drug Administration Law, also meet the following conditions: (1) Having moderate scale and sufficient capacity reserves; (2) Having systems, facilities and equipment for ensuring bio-safety; and (3) Meeting the needs of disease prevention and control. A vaccine marketing authorization holder shall have the capacity for production of vaccines. If it is really necessary to entrust the production of vaccines in excess of its capacity, the vaccine marketing authorization holder shall obtain the approval of the drug administrative department under the State Council. When it accepts the entrustment to produce vaccines, it shall abide by the provisions of the Vaccine Administration Law and the relevant provisions of the State, so as to guarantee the quality of vaccines.

The State adopts a batch release system for vaccines. Each batch of vaccines shall, before being sold or imported, be examined and inspected according to the relevant technical requirements by the batch release institution designated by the drug administrative department under the State Council. If the requirements are met, a batch release certificate shall be issued; otherwise, a notice on rejecting batch release shall be issued. According to the Measures for Administration of Batch Release of Biological Products (《生物製品批簽發管理辦法》) issued on December 13, 2002 and latest amended on December 11, 2020 and effective on March 1, 2021, the vaccine products with marketing approval shall be subject to document review and sample inspection by the drug batch release institution designated by NMPA and pass the biological product batch release approval before the marketing and sales of each batch of products. Vaccines that are urgently needed for infectious disease prevention and control or for emergencies shall be exempted from the biological product batch release approval upon approval by the NMPA.

According to Notice on further strengthening supervision of vaccine quality and safety (關於進一步加強疫苗質量安全監管工作的通知) which was promulgated by the NMPA on December 31, 2010 and came into effective on the same day, approval of new production of already marketed vaccine products is strictly controlled, which further improve the quality standards of products on the market. Strict quality standards will be applied to vaccines produced by multiple companies, and vaccines produced with outdated production methods, preservatives and excipients with safety risks will be phased out.

### *Circulation of Vaccines*

According to the Vaccine Opinion, vaccines should be procured online on the provincial public resource trading platform in accordance with the principles of transparency, competition, and fair trade.

According to the Vaccine Administration Law, the competent health department under the State Council shall, in concert with the finance department under the State Council and other departments, organize centralized bidding or unified negotiation to form and publish the bid-winning price or transaction price of vaccines under the National Immunization Programs, and all provinces, autonomous regions and municipalities directly under the central government shall implement centralized procurement for such vaccines. The procurement of vaccines under other immunization programs other than those under the National Immunization Program and vaccines not under any immunization program shall be organized by provinces, autonomous regions and municipalities directly under the central government through provincial public resources trading platforms.

## REGULATORY OVERVIEW

According to the Vaccine Administration Law, the price of vaccines shall be set reasonably and independently by the vaccine marketing authorization holder according to law. The price level, price difference rate and profit rate of vaccines shall be kept within a reasonable range. A vaccine marketing authorization holder shall, as agreed upon in the procurement contract, supply vaccines to the disease prevention and control institution. A vaccine marketing authorization holder shall, as agreed upon in the procurement contract, deliver vaccines to the disease prevention and control institution or the inoculation entity designated thereby. The vaccine marketing authorization holder and disease prevention and control institution that distribute vaccines themselves shall have the conditions for cold chain storage and transport of vaccines or may entrust eligible vaccine distribution entities to distribute vaccines. A vaccine marketing authorization holder shall, in accordance with the provisions, set up true, accurate and complete sales records, and preserve them for inspection for at least five years after expiry of the validity of the vaccines.

With regard to storage and transportation of vaccines, the present Notice for Distributing Regulations on Administration of Vaccine Storage and Transportation (2017 Edition) (《疫苗儲存和運輸管理規範(2017年版)》), which promulgated by the NMPA and NHC on December 15, 2017 and effective on the same day, requires that, among others, vaccine production enterprises shall be equipped with full-time staff for vaccine management, establish a management system for vaccine storage and transport, maintain cold chain facilities and equipment for storage and transport of vaccines to ensure the quality of vaccines, and must store and transport vaccines in light of the instructions for use of vaccines, the vaccination work rules and other relevant requirements on temperature for storage and transport of vaccines.

### Laws and Regulations Related to Foreign Investment

Since January 1, 2020, the Foreign Investment Law of the People’s Republic of China (《中華人民共和國外商投資法》) (the “**Foreign Investment Law**”) promulgated by the National People’s Congress has come into effect. The Law of the People’s Republic of China on Sino-Foreign Equity Joint Ventures and the Law of the People’s Republic of China on Wholly Foreign-Owned and Law of the People’s Republic of China on Sino-Foreign Cooperative Joint Ventures were abolished at the same time. Since then, the Foreign Investment Law has become the basic law regulating foreign-invested enterprises wholly or partially invested by foreign investors. While the organization form, institutional framework and standard of conduct of foreign-invested enterprises shall be subject to the provisions of the Company Law of the PRC and other laws. The PRC government will implement the management system of pre-entry national treatment and the Negative List for foreign investment abolished the original approval and filing administration system for the establishment and change of foreign-invested enterprises. Pre-entry national treatment refers to the treatment accorded to foreign investors and their investments at the stage of investment entry which is no less favorable than the treatment accorded to domestic investors and their investments. Negative List refers to a special administrative measure for the entry of foreign investment in specific sectors as imposed by the PRC. The PRC accords national treatment to foreign investment outside of the Negative List. The current Negative List is the Special Management Measures (the “**Negative List**”) for the Access of Foreign Investment (2021 Revision) (《外商投資准入特別管理措施(負面清單)(2021年版)》) issued by the NDRC and the MOFCOM on December 27, 2021, and came into effect on January 1, 2022 which lists the special management measures for foreign investment access for industries regulated by the Negative List, such as equity requirements and senior management requirements. In the current implementation of the negative list, the vaccine industry is not explicitly listed as a negative regulatory object.

## REGULATORY OVERVIEW

While strengthening investment promotion and protection, the Foreign Investment Law further regulates foreign investment management and proposes the establishment of a foreign investment information reporting system that replaces the original foreign investment enterprise approval and filing system of the Ministry of Commerce. The foreign investment information reporting is subject to the Foreign Investment Information Reporting Method (《外商投資信息報告辦法》) jointly developed by the MOFCOM and the SAMR, which came into effect on January 1, 2020. According to the Foreign Investment Information Reporting Method, foreign investors who directly or indirectly carry out investment activities in China shall submit investment information to the competent commercial department through the enterprise registration system and the National Enterprise Credit Information Publicity System and the reporting methods include initial reports, change reports, cancellation reports, and annual reports.

### **Laws and Regulations Related to Product Liability**

Pursuant to the Product Quality Law (《中華人民共和國產品質量法》) promulgated on February 22, 1993 and amended on July 8, 2000, August 27, 2009 and December 29, 2018 respectively by SCNPC, Seller shall be responsible for the repair, replacement or return of the product sold if (1) the product sold does not possess the properties for use that it should possess, and no prior and clear indication is given of such a situation; (2) the product sold does not conform to the applied product standard as carried on the product or its packaging; or (3) the product sold does not conform to the quality indicated by such means as a product description or physical sample. If a consumer incurs losses as a result of purchased product, the seller shall compensate for such losses.

Pursuant to the PRC Civil Code (《中華人民共和國民法典》) promulgated by the NPC on May 28, 2020 and coming into effect on January 1, 2021, where a patient suffers damage due to defects in drugs, he may seek compensation from the drug marketing authorization holder or also from the medical institution. Where the patient seeks compensation from the medical institution, the medical institution, after it has made the compensation, shall have the right to recover the compensation from the liable drug marketing authorization holder.

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. Under the amendments made on October 25, 2013, all business operators must pay high attention to protecting customers' personal information and must strictly keep confidential any consumer information they obtain during their business operations.

### **Laws and Regulations Related to Environmental Protection and Fire Prevention**

#### ***Environment Protection***

The Environmental Protection Law of the PRC (《中華人民共和國環境保護法》), 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 Environmental Protection 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.

## REGULATORY OVERVIEW

### *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》), 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.

### *Pollutant Discharge Licensing*

Pursuant to the Administrative Measures for Pollutant Discharge Licensing (for Trial Implementation) (《排污許可管理辦法(試行)》) promulgated on January 10, 2018 and partially revised on August 22, 2019 by the Ministry of Ecology and Environment, or the MEE, enterprises and public institutions as well as other producers and operators included in the Catalog of Classified Administration of Pollutant Discharge License for Stationary Pollution Sources shall apply for and obtain a pollutant discharge license within a prescribed time limit. Any enterprise that fails to obtain a pollutant discharge license as required shall not discharge pollutants.

According to the Catalog of Classified Administration of Pollutant Discharge License 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 MEE on December 20, 2019, key management, simplified management and registration management of pollutant discharge permits are implemented according to factors such as the amount of pollutants generated, the amount of emissions, the degree of impact on the environment, etc., and only pollutant discharge entities that implement registration management do not need to apply for a pollutant discharge permit.

The State Council issued the Regulation on Pollutant Discharge Permit Administration (《排污許可管理條例》) on January 24, 2021 to further enhance the pollutant discharge administration. The administration on pollutant discharge units are divided into key management and simplified management pursuant to the amount of pollutant caused and discharged and the impact on the environment. The review, decision and information disclosure of pollutant discharge licenses shall be handled through the national pollutant discharge license management information platform. The pollutant discharge license is valid for 5 years and the discharging units should apply for renewal 60 days before the expiry for continues pollutant discharge.

## REGULATORY OVERVIEW

---

### *Acceptance Inspection on Environmental Protection Facilities*

Interim Measures for Acceptance inspection of Environmental Protection upon Completion of Construction Projects (《建設項目竣工環境保護驗收暫行辦法》) also requires that upon completion of construction for which an environment impact report or environment impact statement is formulated, the constructor shall conduct acceptance inspection of the environmental protection facilities pursuant to the standards and procedures stipulated by the environmental protection administrative authorities of the State Council, formulate the acceptance inspection report, and announce the acceptance inspection report pursuant to the law except for circumstances where there is a need to keep confidentiality pursuant to the provisions of the State. Where the environmental protection facilities have not undergone acceptance inspection or do not pass acceptance inspection, the construction project shall not be put into production or use.

### *Fire Prevention Design and Acceptance*

The Fire Prevention Law of the PRC (《中華人民共和國消防法》) (“**the Fire Prevention Law**”), was issued on April 29, 1998, then became effective on September 1, 1998 and latest amended on April 29, 2021. According to the Fire Prevention Law, for special construction projects stipulated by the housing and urban-rural development authority of the State Council, the developer shall submit the fire safety design documents to the housing and urban-rural development authority for examination, while for construction projects other than those stipulated as special development projects, the developer shall, at the time of applying for the construction permit or approval for work commencement report, provide the fire safety design drawings and technical materials which satisfy the construction needs. According to Interim Regulations on Administration of Examination and Acceptance of Fire Control Design of Construction Projects (《建設工程消防設計審查驗收管理暫行規定》) issued by the Ministry of Housing and Urban-Rural Development of the PRC on April 1, 2020, an examination system for fire prevention design and acceptance only applies to special construction projects, and for other projects, a record-filing and spot check system would be applied.

### **Laws and Regulations Related to Intellectual Property**

#### *Patent*

The Patent Law of the People’s Republic of China (《中華人民共和國專利法》) (the “**Patent Law**”) is revised by the SCNPC on October 17, 2020 and came into effect on June 1, 2021. According to the current Patent Law, when the invention or utility model patent is granted, unless otherwise stipulated in the Patent Law, without the approval of the patent owner, no entity or person shall implement the relevant patent, that is, manufacture, use, offer to sell, sell or import the patented products for business purpose, or use the patented method and use, offer to sell, sell or import the products directly obtained with the patented method. Implementing the patent without the approval of the patent owner constitutes the infringement of patent rights. Any dispute in connection with this shall be resolved by the relevant parties through negotiation. If the relevant parties refuse to negotiate or the negotiation fails, the patent owner or the relevant stakeholders may file a lawsuit in the people’s court or turn to the patent administration authorities for handling.

## REGULATORY OVERVIEW

---

Pursuant to the Rules for Implementation of the Patent Law of the People’s Republic of China (《中華人民共和國專利法實施細則》), which was amended by the State Council on 9 January 2010 and became effective on 1 February 2010, where the entity to which a patent right is granted fails to agree with the inventor or the designer on, or to specify in its legitimately enacted company rules the way and amount of reward and remuneration specified in its rules and regulations established by law, the entity shall reward to the inventor or designer within 3 months from the announcement of granting the patent. The minimum reward for one invention patent shall not be less than RMB3,000; and the minimum reward for one utility model or design patent shall not be less than RMB1,000. The entity shall, after exploiting the patent for invention-creation within the term of the patent right, pay the inventor or designer remuneration at a percentage of not less than 2% each year from the profits generated from the exploitation of the invention or utility model patent, or at a percentage of not less than 0.2% from the profits gained from the exploitation of the design, or pay the inventor or creator a lump sum of remuneration by reference to the above percentages; where the entity to which a patent right is granted authorize other entity or individual to exploit its patent, it shall reward the inventor or designer at a percentage no less than 10% from the license and royalty fee.

### *Trademark*

According to the Trademark Law of the People’s Republic of China (《中華人民共和國商標法》) revised by the SCNPC on April 23, 2019 and taking effect on November 1, 2019 (the “**Trademark Law**”), the registered trademark has a validity period of 10 years starting from the registration date. The trademark registrant enjoys the exclusive right to use the trademark. Any dispute in connection with the activities the infringe the exclusive right to use a registered trademark set out in Article 57 of the Trademark Law shall be resolved by the relevant parties through negotiation. If the relevant parties refuse to negotiate or the negotiation fails, the trademark registrant or the relevant stakeholders may file a lawsuit in the people’s court or turn to the industrial and commercial administrative department for handling.

### *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 Ministry of Information Industry is responsible for supervision and administration of domain name services in the PRC. Communication 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.

## REGULATORY OVERVIEW

---

### Laws and Regulations Related to Employment and Social Securities

#### *Employment*

According to the Labor Law of the People's Republic of China (《中華人民共和國勞動法》) taking effect on January 1, 1995 and revised on December 29, 2018 and the Labor Contract Law of the People's Republic of China (《中華人民共和國勞動合同法》) taking effect on January 1, 2008 and revised on December 28, 2012, a labor contract shall be signed when the employer establishes labor relationship with the worker. The labor contracts shall be signed in written. When agreement is reached after negotiation, labor contracts, including fixed term labor contract, open term labor contract or labor contract based on the completion of work, shall be signed, and the salary shall be no less than the local minimum wage standard. The employer and the worker shall each fully perform its/his obligations in accordance with the labor contract.

#### *Social Securities*

According to the Social Insurance Law of PRC (《中華人民共和國社會保險法》), which issued by the SCNPC on October 28, 2010 and came into effect on July 1, 2011 and was newly revised on December 29, 2018, enterprises and institutions in the PRC shall provide their employees with welfare schemes covering basic pension insurance, unemployment insurance, maternity insurance, work-related injury insurance and basic medical insurance. The employer shall apply to the local social insurance agency for social insurance registration within 30 days from the date of its formation. And it shall, within 30 days from the date of employment, apply to the social insurance agency for social insurance registration for the employee. Any employer who violates the regulations above shall be ordered to make correction within a prescribed time limit; if the employer fails to rectify within the time limit, the employer and its directly liable person will be fined. If the employer fails to pay social insurance contributions on time and in full, the social insurance agency shall place an order with the employer demanding full payment within a prescribed period, and an overdue payment fine at the rate of 0.5% shall be levied as of the date of indebtedness. When the payment is not made at the expiry of the prescribed period, a fine above the overdue amount but less than its triple shall be demanded by the authoritative administrative department. Meanwhile, the Interim Regulation on the Collection and Payment of Social Insurance Premiums (《社會保險費徵繳暫行條例》) (issued by the State Council on January 22, 1999 and came into effect on the same day and was recently revised on March 24, 2019) prescribes the details concerning the social securities.

#### *Housing Provident Fund*

According to Regulations on Management of Housing Provident Fund (《住房公積金管理條例》) issued by the State Council on April 3, 1999 and revised and implemented on March 24, 2019, the enterprises shall fully pay the housing provident fund contribution for the employees on time, with the contribution ratio no less than 5% of the average monthly salary of the relevant employee in the previous year. The housing provident fund contribution paid by the employees and the employers shall be owned by the employees.



## REGULATORY OVERVIEW

### Laws and Regulations Related to Tax

#### *Enterprise Income Tax*

According to the Corporate Income Tax Law of the People's Republic of China (《中華人民共和國企業所得稅法》), which was promulgated on March 16, 2007, came into effect on January 1, 2008 and amended by the SCNPC on February 24, 2017 and December 29, 2018, and Implementation Regulations for the Corporate Income Tax Law of the People's Republic of China (《中華人民共和國企業所得稅法實施條例》), which was promulgated by the State Council on December 6, 2007 and came into effect on January 1, 2008, and amended by the State Council on April 23, 2019 and came into effect on the same date, all the domestic enterprises in China (including foreign-invested enterprises) shall be subject to enterprise income tax at the uniform tax rate of 25%, except for the high-tech enterprises certificated by the state, which will be subject to enterprise income tax at the reduced rate of 15%, or the qualified small low-profit enterprises, which will enjoy the reduced enterprise income tax rate of 20%.

#### *Value-added Tax*

The Provisional Regulations on Value-added Tax of the People's Republic of China (《中華人民共和國增值稅暫行條例》), which was promulgated on December 13, 1993, came into effect on January 1, 1994, and last amended on November 19, 2017, and the Detailed Implementing Rules of the Provisional Regulations on Value-added Tax of the People's Republic of China (《中華人民共和國增值稅暫行條例實施細則》), which was promulgated on December 25, 1993 and came into effective on the same date, and was amended on December 15, 2008 and October 28, 2011, came into effect on November 1, 2011 set out that all taxpayers selling goods or providing processing, repairing or replacement services, sales of services, intangible assets and immovable assets and importing goods in China shall pay a value-added tax. A tax rate of 17% shall be levied on general taxpayers selling goods and services, leasing of tangible movable assets or importing goods whereas the applicable rate for the export of goods by taxpayers shall be nil, unless otherwise stipulated. According to the Notice of the Ministry of Finance and the SAT on Adjusting Value added Tax Rates (《財政部、國家稅務總局關於調整增值稅稅率的通知》) issued on April 4, 2018 and became effective on May 1, 2018, the deduction rates of 17% and 11% applicable to the taxpayers who have VAT taxable sales activities or imported goods are adjusted to 16% and 10%, respectively. According to the Notice of the Ministry of Finance, the SAT and the General Administration of Customs on Relevant Policies for Deepening Value Added Tax Reform (《關於深化增值稅改革有關政策的公告》) issued on March 20, 2019 and became effective on April 1, 2019, the VAT rate was reduced to 13% and 9%, respectively.

### Laws and Regulations Related to Foreign Exchange

The Regulations on Foreign Exchange Control of the PRC (《中華人民共和國外匯管理條例》) issued by the State Council on January 29, 1996 and implemented on April 1, 1996, which was revised on January 14, 1997 and August 5, 2008 respectively, is the key foreign exchange control regulation in force, applicable to the foreign exchange income and payment and foreign exchange operation activities of the domestic institutions and domestic individuals in China and the foreign exchange payment and collection and foreign exchange operation activities of the overseas institutions and overseas individuals in China.

The Regulations on Foreign Exchange Settlement, Sale and Payment (《結匯、售匯及付匯管理規定》) issued by PBOC on June 20, 1996 and implemented on July 1, 1996 set out requirements on the foreign exchange settlement, purchase, payment, opening of foreign exchange account and external payment by the domestic institutions, individual citizens, foreign institutions in China and foreigners in China.

## REGULATORY OVERVIEW

According to the Decision of the State Council on Canceling and Adjusting A Batch of Items Requiring Administrative Approval (《國務院關於取消和調整一批行政審批項目等事項的決定》) issued by the State Council on October 23, 2014, SAFE and its branches canceled the review and approval on the foreign exchange settlement for the repatriation of funds raised abroad under the overseas listed foreign capital stock account.

In addition, according to the Notice of SAFE on Relevant Issue Concerning the Administration of Foreign Exchange for 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, the domestic companies shall register the overseas listing with the foreign exchange control bureau located at its registered address in 15 working days after the completion of the overseas listing and issuance. The funds raised by the domestic companies through overseas listing may be repatriated to China or deposited overseas, provided that the intended use of the fund shall be consistent with the contents of the document and other public disclosure documents.

According to the Notice of SAFE on Reforming and Standardizing Capital Account Foreign Exchange Settlement Administration Policies (《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》) issued by SAFE on June 9, 2016, it has been specified clearly in the relevant policies that, for the capital account foreign exchange income subject to voluntary foreign exchange settlement (including the repatriation of the proceeds from overseas listing), the domestic institutions may conduct the foreign exchange settlement at the banks according to their operation needs. The proportion of the capital account foreign exchange income subject to voluntary foreign exchange settlement was tentatively set as 100%, provided that SAFE may adjust the aforesaid proportion according to the international payment balance status in good time.

### **Laws and Regulations Related to Overseas Securities Offering and Listing**

On February 17, 2023, the CSRC released the Trial Administrative Measures of Overseas Securities Offering and Listing by Domestic Companies (《境內企業境外發行證券和上市管理試行辦法》) (the “**Overseas Listing Trial Measures**”), which will become effective on March 31, 2023 and stipulates that domestic companies that seek to offer or list securities overseas, both directly and indirectly, shall complete the filing procedures and report relevant information to the CSRC. On the same date, the CSRC also released the Circular on the Arrangements for the Filing-based Administration of Overseas Securities Offering and Listing by Domestic Companies (《關於境內企業境外發行上市備案管理安排的通知》), which stipulates that domestic enterprises that have obtained the approval documents issued by the CSRC for overseas offering and listing (including new issuance) by joint-stock companies may continue their overseas offering and listing during the valid term of the approval documents. If the domestic companies fail to complete overseas offering and listing upon expiry of the term of the approval documents issued by the CSRC for overseas offering and listing, they shall go through filing as per relevant regulations.

## HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

### OVERVIEW

We are a biotechnology company committed to developing innovative human vaccines and therapeutic biologics to prevent and control infectious diseases and treat cancer and autoimmune diseases. Since our inception in 2001, we have focused on human medicine and have established technology platforms with our understanding of immunology and protein engineering. Since our inception in 2001 and prior to the Series A Financing (as defined below) in 2019, we primarily relied on (1) capital injection from our Shareholders, (2) one-off or milestone payments received from the historically developed products that had been transferred or out-licensed to third parties prior to the Track Record Period, and (3) revenue generated from the sales of immunoreagent testing kits to support our business operations. For details, please refer to “Business — Our Products and Product Candidates — Our Other Historically Developed Products — 3. Immunoreagent Testing Kits” in this document.

Our predecessor company, Beijing Luzhu Biotechnology Limited Liability Company (北京綠竹生物技術有限責任公司), was established in Beijing on November 9, 2001 as a limited liability company under the PRC Company Law. After several changes in our shareholding structure, our predecessor company was converted into a joint stock limited company under the laws of the PRC on July 19, 2013 by Mr. KONG, Ms. ZHANG, and Ms. JIANG as our promoters, who are also our executive Directors, and our predecessor company thereby became our Company. For details of the background and experience of Mr. KONG, Ms. ZHANG, and Ms. JIANG, see “Directors, Supervisors and Senior Management” in this document.

### KEY MILESTONES

The following table illustrates the key milestones of our business development:

Year	Event
2001	Our predecessor company was established in Beijing.
2003	We submitted a clinical trial application for Meningococcal Group A and C Polysaccharide Conjugate Vaccine to Beijing Medical Product Administration and received NMPA clinical trial approval in 2003 <sup>(Note 1)</sup> .
2005	We received clinical trial approval for our Group ACYW <sub>135</sub> Meningococcal Polysaccharide Vaccine <sup>(Note 1)</sup> .
2007	Our product, Group ACYW <sub>135</sub> Meningococcal Polysaccharide Vaccine obtained new drug approval <sup>(Note 1)</sup> .
2009	We initiated the study of recombinant human monoclonal antibody and bispecific antibody.
2013	Our predecessor company was converted into a joint stock company with limited liability, and was renamed as Beijing Luzhu Biotechnology Co., Ltd. (北京綠竹生物技術股份有限公司).
2017	We obtained NMPA clinical trial approval for (i) K3; and (ii) K11.
2018	We commenced the development of LZ901, our Core Product, in March 2018.  We established our wholly-owned subsidiary, Zhuhai Luzhu.  We submitted pre-IND data for K193 Antibody Injection to Center for Drug Evaluation at NMPA.  We obtained NMPA clinical trial approval for Inactivated Enterovirus Type 71 vaccine (“ <b>Inactivated EV71 Vaccine</b> ”) <sup>(Note 2)</sup> .

## HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Year	Event
2019	<p>We initiated Phase I clinical trials of K193 in the PRC in December 2019.</p> <p>We completed the Series A Financing in the third quarter of 2019.</p> <p>We completed the Phase I clinical trial of K3 in the PRC.</p>
2020	<p>We submitted a PCT patent for LZ901 (Ref. No: PCT/CN2020/090200).</p>
2021	<p>We received clinical trial application approval for LZ901 from the NMPA in August 2021.</p> <p>We completed the Series B Financing in the third quarter of 2021.</p> <p>We established our wholly-owned subsidiary, Hong Kong Luzhu.</p>
2022	<p>We submitted an IND application for LZ901 to the FDA in January 2022 and received IND approval from the FDA in July 2022.</p> <p>We completed the Series B+ Financing in the first quarter of 2022.</p> <p>We were recognized as a Professional, Specialized and New Small and Medium Enterprise (專精特新中小企業) by the Beijing Municipal Bureau of Economy and Information Technology (北京市經濟和信息化局) in the PRC.</p> <p>We established our wholly-owned subsidiary, Beijing Luzhu.</p> <p>We completed Phase I clinical trials and initiated Phase II clinical trials for LZ901 in the PRC.</p> <p>We completed the Series C Financing in the second quarter of 2022.</p>
2023	<p>The Phase I clinical trial report for LZ901 in the PRC was issued in February 2023 with head-to-head immunogenicity study comparing Shingrix<sup>®</sup> being disclosed.</p> <p>We initiated Phase I clinical trial for LZ901 in the U.S. in February 2023.</p>

### Notes:

- (1) In 2008, our Company assigned Beijing Zhifei Luzhu Biological Products Co., Ltd. (北京智飛綠竹生物製藥有限公司) (“**Zhifei Biopharma**”) the intellectual property rights in and to the Group ACYW<sub>135</sub> Meningococcal Polysaccharide Vaccine and Meningococcal Group A and C Polysaccharide Conjugate Vaccine, and transferred technical data and materials to produce the aforementioned vaccines to Zhifei Biopharma. For details, see “Business — Our Products and Product Candidates — Our commercialized vaccine products” in this document.
- (2) Pursuant to a technology transfer agreement entered into between our Company and Zhifei Biopharma in July 2011, we transferred all test results and research data in relation to pre-clinical studies of Inactivated EV71 Vaccine, proprietary technology related to Inactivated EV71 Vaccine pilot-scale manufacturing and testing, and relevant testing technologies that are not disclosed in the invention patent of Inactivated EV71 Vaccine to Zhifei Biopharma. For details, see “Business — Our Products and Product Candidates — Our Other Historically Developed Products” in this document.

## OUR CORPORATE DEVELOPMENTS

The following sets forth the corporate history and shareholding changes of our Company.

### Establishment of our Company

Our predecessor company, Beijing Luzhu Biotechnology Limited Liability Company (北京綠竹生物技術有限責任公司), was established on November 9, 2001, with an initial registered capital of RMB500,000, which was fully paid up as of the date of establishment. As of the date of establishment, our predecessor company was owned as to 45.00% by Ms. ZHANG and 55.00% by two other Independent Third Parties, respectively.

## HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

### Conversion into Joint Stock Limited Company and Major Shareholding Changes after the Conversion

After a series of equity transfers and capital injections and immediately prior to our conversion into a joint stock limited liability company, our predecessor company was owned as to 61.00% by Mr. KONG, 35.00% by Ms. ZHANG, and 4.00% by Ms. JIANG, respectively, with its sole director being Mr. KONG and sole supervisor being Ms. ZHANG. On June 28, 2013, Mr. KONG, Ms. ZHANG, and Ms. JIANG, as our promoters, resolved at a shareholders’ general meeting to convert our predecessor company into a joint stock company with limited liability, with a registered capital of RMB55.0 million. According to the capital verification report prepared by an Independent Third Party auditor, the total equity value of our Company as of May 31, 2013 amounted to approximately RMB55.8 million, of which (i) RMB55.0 million was converted into Shares of RMB1.00 par value each; and (ii) the remaining amount of approximately RMB0.8 million was converted into capital reserve. Upon the completion of registration with Beijing Administration for Industry and Commerce (北京市工商行政管理局) on July 19, 2013, our Company was converted into a joint stock company with limited liability, and was renamed as Beijing Luzhu Biotechnology Co., Ltd. (北京綠竹生物技術股份有限公司). Immediately upon completion of the said conversion, the shareholding structure of our Company was as follows:

<u>Shareholders</u>	<u>Number of Shares</u>	<u>Approximate percentage of shareholding in our Company</u> (%)
Mr. KONG	33,550,000	61.00
Ms. ZHANG	19,250,000	35.00
Ms. JIANG	2,200,000	4.00
<b>Total</b>	<b>55,000,000</b>	<b>100.00</b>

Pursuant to an investment framework agreement entered into between our Company and Shenzhen Qianhai Qilin Xinsheng Investment (Limited Partnership) (深圳前海麒麟鑫盛投資企業(有限合夥)) (“**Shenzhen Qianhai Qilin**”) on March 19, 2014, Shenzhen Qianhai Qilin invested into our Company and subscribed for 23,580,000 Shares, representing 30.00% of the post-subscription issued share capital of our Company at a total consideration of RMB60.0 million. The funds were irrevocably settled and received by our Company as of September 17, 2014. The consideration was determined after arm’s length negotiations between the relevant parties. Shenzhen Qianhai Qilin is a limited partnership established in the PRC and is principally engaged in investment holding.

In July 2014, with the intention to incentivize certain employees of our Group by offering them an opportunity to invest in our Company, Mr. KONG entered into an equity transfer agreement with each of the five selected staff members to transfer certain Shares at nominal consideration of RMB1.00, namely (i) 1,100,000 Shares to Ms. HUANG Ying (黃穎), our then deputy general manager; (ii) 550,000 Shares to Mr. ZOU Qiang (鄒強), our then Director; (iii) 550,000 Shares to Ms. KONG Xi (孔茜), our Supervisor, who is also the niece of Mr. KONG and Ms. ZHANG; (iv) 300,000 Shares to Mr. ZHOU Peng (周朋), our then Director; and (v) 250,000 Shares to Ms. YE Yi (葉藝), our then Supervisor, subject to a condition of minimum service period of five years, failing the fulfillment of which, Mr. KONG shall be entitled to buy back the Shares at nominal consideration. The abovementioned Share transfers were completed in July 2014. As Mr. ZOU Qiang and Ms. HUANG Ying left our Group in January 2015 and July 2018, respectively, and hence failed to satisfy the condition mentioned above, their Shares were bought back by Mr. KONG at nominal consideration of RMB1.00 in November 2018. Ms. YE Yi subsequently left our Group in December 2018 before satisfaction of the condition and her Shares were bought back by Mr. KONG in February 2021 as further discussed below. On the other hand, Mr. ZHOU Peng and Ms. KONG Xi fulfilled the conditions in July 2019 and continued to be our Shareholders as of the Latest Practicable Date.

## HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Subsequently, pursuant to the equity transfer agreements dated April 23, 2019 entered into between Shenzhen Qianhai Qilin and each of Mr. KONG, Ms. ZHONG Siyu (鍾思雨) and Ms. CHEN Qingyun (陳清雲) respectively, Shenzhen Qianhai Qilin transferred 19,650,000 Shares, 2,358,000 Shares and 1,572,000 Shares to Mr. KONG, Ms. ZHONG Siyu and Ms. CHEN Qingyun, for a consideration of RMB50.0 million, RMB6.0 million and RMB4.0 million, respectively, which in total equals to its initial subscription costs of RMB60.0 million. Each of Ms. ZHONG Siyu and Ms. CHEN Qingyun is an Independent Third Party. Upon completion of the said Share transfers, the shareholding structure of our Company was as follows:

Shareholders	Major position(s) in our Group upon completion of the Share transfers	Number of Shares	Approximate percentage of shareholding in our Company (%)
Mr. KONG	Director, general manager, chairman of our Board	52,100,000	66.30
Ms. ZHANG	Director, deputy general manager	19,250,000	24.50
Ms. JIANG	Deputy general manager, vice-chairlady of our Board	2,200,000	2.80
Ms. ZHONG Siyu	N/A	2,358,000	3.00
Ms. CHEN Qingyun	N/A	1,572,000	2.00
Ms. KONG Xi	Supervisor	550,000	0.70
Mr. ZHOU Peng	Director	300,000	0.38
Ms. YE Yi	N/A <sup>(Note)</sup>	250,000	0.32
<b>Total</b>		<b>78,580,000</b>	<b>100.00</b>

*Note:* Ms. YE Yi left our Group in December 2018, and she continued to be our Shareholder until February 2021 when her Shares were bought back by Mr. KONG as further discussed below.

On July 23, 2019, our Company, Mr. KONG and Ms. ZHANG entered into a capital increase agreement (the “**2019 Capital Increase Agreement**”) with (i) Beijing Yizhuang; and (ii) Beijing Science Sun, pursuant to which Beijing Yizhuang and Beijing Science Sun subscribed for 39,290,000 Shares and 9,822,500 Shares, respectively, at a consideration of RMB200.0 million and RMB50.0 million, respectively (the “**Series A Financing**”). The consideration was determined after arm’s length negotiations taking into account the prospects in the research and development of our product candidates, including that we obtained clinical trial approval from the NMPA to commence Phase I clinical trials of K193 (our antibody injection candidate) in China. The consideration payable by Beijing Science Sun was irrevocably settled and received by our Company as of August 15, 2019. On the other hand, pursuant to the terms of the 2019 Capital Increase Agreement, Beijing Yizhuang should settle its consideration payable in two installments of RMB100.0 million each. The first installment was settled by Beijing Yizhuang on August 1, 2019, whereas the second installment was settled by Beijing Yizhuang II and Beijing Science Sun on March 26, 2021 and March 4, 2021, respectively, following the transfer of Shares by Beijing Yizhuang to Beijing Yizhuang II and Beijing Science Sun in February 2021 as further discussed below. See “— [REDACTED] Investments” in this section for further details of the Series A Financing and the background of Beijing Yizhuang, Beijing Yizhuang II and Beijing Science Sun.

Investors	Number of Shares subscribed for	Approximate percentage of shareholding in our Company upon completion (%)	Consideration (RMB)
Beijing Yizhuang	39,290,000	30.77	200,000,000
Beijing Science Sun	9,822,500	7.69	50,000,000

## HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

The shareholding structure of our Company immediately following the subscriptions of Shares by Beijing Yizhuang and Beijing Science Sun was as follows:

Shareholders	Number of Shares	Approximate percentage of shareholding in our Company (%)
Mr. KONG	52,100,000	40.80
Ms. ZHANG	19,250,000	15.08
Beijing Yizhuang	39,290,000	30.77
Beijing Science Sun	9,822,500	7.69
Ms. ZHONG Siyu	2,358,000	1.85
Ms. JIANG	2,200,000	1.72
Ms. CHEN Qingyun	1,572,000	1.23
Ms. KONG Xi	550,000	0.43
Mr. ZHOU Peng	300,000	0.23
Ms. YE Yi	250,000	0.20
<b>Total</b>	<b>127,692,500</b>	<b>100.00</b>

On February 2, 2021, Hengqin Luzhu LP, our employee incentive platform, entered into an investment cooperation agreement with our Company, pursuant to which Hengqin Luzhu LP subscribed for 12,307,500 Shares at a par value of RMB1.00 per Share. The consideration of RMB12,307,500 was fully settled on March 30, 2021. See “— Employee Incentive Scheme” in this section for further details.

Pursuant to an equity transfer agreement dated February 7, 2021, Mr. KONG bought back 250,000 Shares from Ms. YE Yi at a consideration of approximately RMB0.6 million because the condition of the transfer of such Shares from Mr. KONG back in July 2014 had not been fulfilled as mentioned above. The said consideration was determined after negotiations between the parties taking into account the long-term tenure of Ms. YE Yi at our Company since February 2013, and had been fully settled on February 8, 2021. Ms. YE Yi ceased to be a Shareholder upon completion of such share transfer. Mr. KONG then further transferred such 250,000 Shares to Ms. ZHANG, his spouse, at nil consideration.

Separately, on February 7, 2021, Ms. ZHANG entered into equity transfer agreements with each of Ms. JIANG and Ms. HUANG Ying (who re-joined our Group in December 2020 as our deputy manager), pursuant to which Ms. ZHANG transferred 800,000 Shares and 1,100,000 Shares to Ms. JIANG and Ms. HUANG Ying, respectively, at a consideration of approximately RMB2.03 million and RMB2.79 million, respectively, with a settlement period of five years. As of the Latest Practicable Date, the consideration payable by Ms. JIANG was fully settled, whereas Ms. HUANG Ying had transferred all her 1,100,000 Shares back to Ms. ZHANG following her subsequent departure from our Group as further discussed below.

Pursuant to an equity transfer agreement dated February 16, 2021 entered into by (i) Mr. KONG, (ii) Ms. ZHANG, (iii) our Company, (iv) Beijing Science Sun, (v) Beijing Yizhuang and (vi) Beijing Yizhuang II, Beijing Yizhuang transferred 15,716,000 Shares and 3,929,000 Shares to Beijing Yizhuang II and Beijing Science Sun, respectively, at nil consideration. Pursuant to the terms of such equity transfer agreement, Beijing Yizhuang II and Beijing Science Sun should settle the second installment consideration of RMB100.0 million payable by Beijing Yizhuang to our Company under the 2019 Capital Increase Agreement, and upon completion of such Share transfers, Beijing Yizhuang II and Beijing Science Sun would enjoy the same shareholder’s rights as Beijing Yizhuang. Accordingly, the said transfer of 19,645,000 Shares by Beijing Yizhuang to Beijing Science Sun and Beijing Yizhuang II is considered as part of the Series A Financing. The corresponding capital contribution of Beijing Yizhuang II and Beijing Science Sun of RMB80.0 million and RMB20.0 million, respectively, were fully received

## HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

by our Company on March 26, 2021 and March 4, 2021, respectively. Upon completion of the said Share transfers, the shareholding structure of our Company was as follows:

Shareholders	Number of Shares	Approximate percentage of shareholding in our Company (%)
Mr. KONG	52,100,000	37.21
Ms. ZHANG	17,600,000	12.57
Beijing Yizhuang	19,645,000	14.03
Beijing Yizhuang II	15,716,000	11.23
Beijing Science Sun	13,751,500	9.82
Hengqin Luzhu LP	12,307,500	8.79
Ms. JIANG	3,000,000	2.14
Ms. ZHONG Siyu	2,358,000	1.68
Ms. CHEN Qingyun	1,572,000	1.12
Ms. HUANG Ying	1,100,000	0.79
Ms. KONG Xi	550,000	0.39
Mr. ZHOU Peng	300,000	0.21
<b>Total</b>	<b>140,000,000</b>	<b>100.00</b>

On August 30, 2021, our Company entered into an investment agreement (the “**Series B Financing**”) with (i) CCB International Capital Management (Tianjin) Ltd. (建銀國際資本管理(天津)有限公司) (“**CCB Capital**”); (ii) Jinjiang Zhenrui Equity Investment Partnership (Limited Partnership) (晉江禎睿股權投資合夥企業(有限合夥)) (“**Jinjiang Zhenrui**”); (iii) Zhuhai Livzon Pharmaceutical Equity Investment Management Co., Ltd. (珠海市麗珠醫藥股權投資管理有限公司) (“**Zhuhai Livzon**”); (iv) Hangzhou Taikun Equity Investment Fund Partnership (Limited Partnership) (杭州泰鯤股權投資基金合夥企業(有限合夥)) (“**Hangzhou Taikun**”); (v) Haikou Hengji Rongyu Investment Center (Limited Partnership) (海口恒基榮域投資中心(有限合夥)) (“**Hengji Rongyu**”) and (vi) Beijing Xinchuang Technology Phase I Venture Capital Center (Limited Partnership) (北京芯創科技一期創業投資中心(有限合夥)) (“**Xinchuang Technology**”) (collectively as the “**Series B Investors**”), pursuant to which the Series B Investors subscribed for an aggregate of 27,216,175 Shares at an aggregate consideration of RMB350.0 million. The funds were irrevocably settled and received by our Company as of September 10, 2021. The consideration was determined after arm’s length negotiations taking into account prospects in the research and development of our product candidates, including the submission of clinical trial application for LZ901 (our vaccine candidate and Core Product) with the NMPA, which result was still pending at the time when the consideration was determined in June 2021. See “— [REDACTED] Investments” in this section for further details of the Series B Financing.

Investors	Number of Shares subscribed for	Approximate percentage of shareholding in our Company upon completion (%)	Consideration (RMB)
CCB Capital	11,664,075	6.98	150,000,000
Jinjiang Zhenrui	7,776,050	4.65	100,000,000
Zhuhai Livzon	2,332,815	1.40	30,000,000
Hangzhou Taikun	2,332,815	1.40	30,000,000
Hengji Rongyu	2,332,815	1.40	30,000,000
Xinchuang Technology	777,605	0.47	10,000,000



## HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Upon completion of the Series B Financing, the shareholding structure of our Company was as follows:

Shareholders	Number of Shares	Approximate percentage of shareholding in our Company (%)
Mr. KONG	52,100,000	31.16
Ms. ZHANG	17,600,000	10.53
Hengqin Luzhu LP	12,307,500	7.36
Beijing Yizhuang	19,645,000	11.75
Beijing Yizhuang II	15,716,000	9.40
Beijing Science Sun	13,751,500	8.22
CCB Capital	11,664,075	6.98
Jinjiang Zhenrui	7,776,050	4.65
Ms. JIANG	3,000,000	1.79
Ms. ZHONG Siyu	2,358,000	1.41
Zhuhai Livzon	2,332,815	1.40
Hangzhou Taikun	2,332,815	1.40
Hengji Rongyu	2,332,815	1.40
Ms. CHEN Qingyun	1,572,000	0.94
Ms. HUANG Ying	1,100,000	0.66
Xinchuang Technology	777,605	0.47
Ms. KONG Xi	550,000	0.33
Mr. ZHOU Peng	300,000	0.18
<b>Total</b>	<b>167,216,175</b>	<b>100.00%</b>

Following Ms. HUANG Ying’s departure from our Group in September 2021, Ms. HUANG Ying and Ms. ZHANG entered into an equity transfer agreement dated December 20, 2021, pursuant to which Ms. HUANG Ying transferred all of her 1,100,000 Shares to Ms. ZHANG at nil consideration, and thereafter ceased to be a Shareholder. The reason for the nil consideration was because the consideration payable by Ms. HUANG Ying to Ms. ZHANG for the transfer of such 1,100,000 Shares in February 2021 had not been settled.

On December 31, 2021, our Company entered into an investment agreement (the “**Series B+ Financing**”) with (i) Hainan Zhaoan Private Equity Fund Management Partnership (Limited Partnership) (海南兆安私募基金管理合夥企業(有限合夥)) (“**Hainan Zhaoan**”); (ii) Hengji Rongyu; (iii) Gongqingcheng Zhenrui Equity Investment Partnership (Limited Partnership) (共青城臻銳股權投資合夥企業(有限合夥)) (“**Gongqingcheng Zhenrui**”); (iv) Jinjiang Xuanhong No.1 Equity Investment Partnership (Limited Partnership) (晉江軒弘壹號股權投資合夥企業(有限合夥)) (“**Jinjiang Xuanhong**”); and (v) Shaanxi Jinou Investment Fund Partnership (Limited Partnership) (陝西金甌投資基金合夥企業(有限合夥)) (“**Shaanxi Jinou**”) (collectively as the “**Series B+ Investors**”), pursuant to which the Series B+ Investors subscribed for 6,674,082 Shares at an aggregate consideration of RMB120.0 million. The funds were irrevocably settled and received by our Company as of January 28, 2022. The consideration was determined after arm’s length negotiations with reference to the investment price of the Series B Financing together with an upward adjustment primarily reflecting the grant of clinical trial approval for LZ901 by the NMPA. The subscriptions under the Series B+ Financing were registered with the relevant PRC regulatory authority on January 28, 2022. See “— [REDACTED] Investments” in this section for further details of the Series B+ Financing.

## HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Investors	Number of Shares subscribed for	Approximate percentage of shareholding in our Company upon completion  (%)	Consideration  (RMB)
Hainan Zhaoan	1,668,521	0.96	30,000,000
Gongqingcheng Zhenrui	556,173	0.32	10,000,000
Jinjiang Xuanhong	2,224,694	1.28	40,000,000
Shaanxi Jinou	556,173	0.32	10,000,000
Hengji Rongyu	1,668,521	2.30 <sup>(Note)</sup>	30,000,000

*Note:* Hengji Rongyu, being one of the Series B Investors, owned approximately 1.40% of the issued share capital of our Company immediately before completion of the Series B+ Financing. It then subscribed for an additional 1,668,521 Shares under the Series B+ Financing (representing approximately 0.98% of the post-subscription issued share capital of our Company), and therefore owned a total of approximately 2.30% of the issued share capital of our Company immediately upon completion of the Series B+ Financing.

Upon completion of the Series B+ Financing, the shareholding structure of our Company was as follows:

Shareholders	Number of Shares	Approximate percentage of shareholding in our Company  (%)
Mr. KONG	52,100,000	29.96
Ms. ZHANG	18,700,000	10.75
Hengqin Luzhu LP	12,307,500	7.08
Beijing Yizhuang	19,645,000	11.30
Beijing Yizhuang II	15,716,000	9.04
Beijing Science Sun	13,751,500	7.91
CCB Capital	11,664,075	6.71
Jinjiang Zhenrui	7,776,050	4.47
Hengji Rongyu	4,001,336	2.30
Ms. JIANG	3,000,000	1.73
Ms. ZHONG Siyu	2,358,000	1.36
Zhuhai Livzon	2,332,815	1.34
Hangzhou Taikun	2,332,815	1.34
Jinjiang Xuanhong	2,224,694	1.28
Hainan Zhaoan	1,668,521	0.96
Ms. CHEN Qingyun	1,572,000	0.90
Xinchuang Technology	777,605	0.45
Gongqingcheng Zhenrui	556,173	0.32
Shaanxi Jinou	556,173	0.32
Ms. KONG Xi	550,000	0.32
Mr. ZHOU Peng	300,000	0.17
<b>Total</b>	<b>173,890,257</b>	<b>100.00</b>

## HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Pursuant to the Series B Financing agreement, our Company, the then Shareholders and the then [REDACTED] Investors mutually agreed that, upon (i) our Company entering into a new round of [REDACTED] investment with a pre-money valuation of not less than RMB4.0 billion; or (ii) the commencement of the Phase II clinical trials for LZ901 in the PRC, our Company could issue 5% of the total issued share capital of our Company to our Promoters, namely Mr. KONG, Ms. ZHANG and Ms. JIANG at RMB1.00 per Share to incentivize them. Such arrangement was also acknowledged and confirmed in the Series B+ Financing agreement. We commenced Phase II clinical trials for LZ901 in April 2022. On May 13, 2022, we resolved to allot and issue to our promoters an aggregate of 8,694,513 Shares at par value, and the consideration had been fully settled as of the Latest Practicable Date.

Investors	Number of new Shares subscribed	Number of Shares after subscription	Approximate percentage of shareholding in our Company before subscription (%)	Approximate percentage of shareholding in our Company after subscription (%)
Mr. KONG	6,194,513	58,294,513	29.96	31.93
Ms. ZHANG	1,500,000	20,200,000	10.75	11.06
Ms. JIANG	1,000,000	4,000,000	1.73	2.19

On June 16, 2022, our Company entered into an investment agreement (the “**Series C Financing**”) with (i) Tianjin Huapu Biopharmaceutical Technology Partnership (Limited Partnership) (天津華普生物醫藥科技合夥企業(有限合夥)) (“**Tianjin Huapu**”); (ii) Beijing Xinyin Xinghong Equity Investment Partnership (Limited Partnership) (北京信銀興弘股權投資合夥企業(有限合夥)) (“**Xinyin Xinghong**”); (iii) Zibo Runxin Xinchuang Investment Partnership (Limited Partnership) (淄博潤信芯創投資合夥企業(有限合夥)) (“**Zibo Runxin**”); (iv) Zibo Runwen Kangju Equity Investment Partnership (Limited Partnership) (淄博潤文康聚股權投資合夥企業(有限合夥)) (“**Zibo Runwen**”); (v) Beijing Yizhuang II; and (vi) Hengji Rongyu (collectively as the “**Series C Investors**”), pursuant to which the Series C Investors subscribed for 9,478,262 Shares at an aggregate consideration of RMB218.0 million. The funds were irrevocably settled and received by our Company as of June 27, 2022. The consideration was determined after arm’s length negotiations with reference to, among others, the commencement of Phase II clinical trials for LZ901 in April 2022. The subscriptions under the Series C Financing were registered with the relevant PRC regulatory authority on June 17, 2022. See “— [REDACTED] Investments” in this section for further details of the Series C Financing.

Investors	Number of Shares subscribed for	Approximate percentage of shareholding in our Company upon completion (%)	Consideration (RMB)
Tianjin Huapu	3,043,478	1.58	70,000,000
Xinyin Xinghong	1,434,783	0.75	33,000,000
Zibo Runxin	652,174	0.34	15,000,000
Zibo Runwen	434,783	0.23	10,000,000
Beijing Yizhuang II	2,608,696	9.54 <sup>(1)</sup>	60,000,000
Hengji Rongyu	1,304,348	2.76 <sup>(2)</sup>	30,000,000

*Notes:*

- (1) Beijing Yizhuang II, being one of the investors under the Series A Financing, owned approximately 8.61% of the issued share capital of our Company immediately before completion of the Series C Financing. It then subscribed for an additional 2,608,696 Shares under the Series C Financing (representing approximately 1.36% of the post-subscription issued share capital of our Company), and therefore owned a total of approximately 9.54% of the issued share capital of our Company immediately upon completion of the Series C Financing.

## HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

- (2) Hengji Rongyu, being one of the Series B Investors and one of the Series B+ Investors, owned approximately 2.30% of the issued share capital of our Company immediately before completion of the Series C Financing. It then subscribed for an additional 1,304,348 Shares under the Series C Financing (representing approximately 0.68% of the post-subscription issued share capital of our Company), and therefore owned a total of approximately 2.76% of the issued share capital of our Company immediately upon completion of the Series C Financing.

Upon completion of the Series C Financing, the shareholding structure of our Company was as follows:

Shareholders	Number of Shares	Approximate percentage of shareholding in our Company (%)
Mr. KONG	58,294,513	30.35
Ms. ZHANG	20,200,000	10.52
Hengqin Luzhu LP	12,307,500	6.41
Beijing Yizhuang	19,645,000	10.23
Beijing Yizhuang II	18,324,696	9.54
Beijing Science Sun	13,751,500	7.16
CCB Capital	11,664,075	6.07
Jinjiang Zhenrui	7,776,050	4.05
Hengji Rongyu	5,305,684	2.76
Ms. JIANG	4,000,000	2.08
Tianjin Huapu	3,043,478	1.58
Ms. ZHONG Siyu	2,358,000	1.23
Zhuhai Livzon	2,332,815	1.21
Hangzhou Taikun	2,332,815	1.21
Jinjiang Xuanhong	2,224,694	1.16
Hainan Zhaoan	1,668,521	0.87
Ms. CHEN Qingyun	1,572,000	0.82
Xinyin Xinghong	1,434,783	0.75
Xinchuang Technology	777,605	0.40
Zibo Runxin	652,174	0.34
Gongqingcheng Zhenrui	556,173	0.29
Shaanxi Jinou	556,173	0.29
Ms. KONG Xi	550,000	0.29
Zibo Runwen	434,783	0.23
Mr. ZHOU Peng	300,000	0.16
<b>Total</b>	<b>192,063,032</b>	<b>100.00%</b>

### SUBSIDIARIES OF OUR COMPANY

As of the Latest Practicable Date, we had three wholly-owned subsidiaries and their details are set forth below:

#### Zhuhai Luzhu

Zhuhai Luzhu was established in the PRC with a registered capital of RMB100.0 million on November 29, 2018. On April 19, 2022, the registered capital of Zhuhai Luzhu was increased to RMB200.0 million. As of the Latest Practicable Date, the registered capital of Zhuhai Luzhu had been fully paid up. Zhuhai Luzhu principally engages in research, development and production of vaccines and therapeutic biologics in the PRC.

#### Hong Kong Luzhu

Hong Kong Luzhu was incorporated in Hong Kong on December 20, 2021 with limited liability. On the date of incorporation, 100,000 shares in Hong Kong Luzhu were allotted and issued to our Company at HK\$1.00 each. As of the Latest Practicable Date, Hong Kong Luzhu had not yet commenced any substantive business.

## HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

### Beijing Luzhu

Beijing Luzhu was established in the PRC with a registered capital of RMB150.0 million on March 31, 2022. As of the Latest Practicable Date, the registered capital of Beijing Luzhu had been fully paid up, and Beijing Luzhu had not yet commenced any substantive business.

### EMPLOYEE INCENTIVE SCHEME

In anticipation of the [REDACTED], we have adopted an employee incentive scheme on December 15, 2021 (the “**Employee Incentive Scheme**”) with a view to attract and retain talents for our Group, and foster shared interests between Shareholders and our management team. The Employee Incentive Scheme has replaced all outstanding share options granted to our employees historically under the previous employee incentive arrangements. Further, Hengqin Luzhu LP, Beijing Luzhu Kangrui Enterprise Management Partnership (Limited Partnership) (北京綠竹康瑞企業管理合夥企業(有限合夥)) (“**Beijing Luzhu Kangrui**”) and Zhuhai Luzhu Kangrui Enterprise Management Partnership (Limited Partnership) (珠海綠竹康瑞企業管理合夥企業(有限合夥)) (“**Zhuhai Luzhu Kangrui**”) have also been established in the PRC as our employee incentive platforms. Pursuant to our Employee Incentive Scheme, eligible participants will be granted interests in our employee incentive platform, and no share options will be granted under the Employee Incentive Scheme. For further details of the Employee Incentive Scheme, see “Statutory and General Information — B. Further Information about the Business of our Company — 3. Employee Incentive Scheme” in Appendix VII to this document.

### Hengqin Luzhu LP

Hengqin Luzhu LP was established in the PRC as a limited partnership on January 14, 2021. Mr. KONG, as the sole general partner of Hengqin Luzhu LP, is responsible for the management of Hengqin Luzhu LP and exercising the voting rights attaching to the Shares held by Hengqin Luzhu LP, in accordance with the partnership agreement entered into among the general and limited partners of Hengqin Luzhu LP. As of the Latest Practicable Date, Mr. KONG held approximately 0.97% interests in Hengqin Luzhu LP, with the remaining interests being held by five limited partners of Hengqin Luzhu LP, namely Beijing Luzhu Kangrui (holding approximately 40.67% interests), Zhuhai Luzhu Kangrui (holding approximately 19.87% interests), Ms. ZHANG, our executive Director (holding approximately 27.61% interests), and two Independent Third Parties, namely, Ms. DAN Xiaoning (淡肖寧) (“**Ms. DAN**”), our consultant (holding approximately 8.13% interests) and Ms. HUANG Ying, our former employee (holding approximately 2.76% interests).

Ms. DAN has years of experience in financial control and management, and has passed the qualification examinations of fund practitioner (基金從業員) under the Asset Management Association of China. She completed the Executive Master of Business Administration program of Cheung Kong Graduate School of Business in the PRC in 2021, and is currently pursuing the Cheung Kong Chief Executive Officer program of Cheung Kong Graduate School of Business in the PRC. Ms. DAN was first introduced to Mr. KONG by her acquaintance, Mr. ZHANG Zhiyong (張志勇), who is the deputy general manager of E-town Sun with years of experience in the investment industry, and an Independent Third Party. In early 2021, in light of Ms. DAN’s qualification and experience in financing and capital and financial management, Mr. KONG invited Ms. DAN to be a consultant of our Company to provide advice and necessary technical support on the financial aspects of our Group, including advising on our capital and financial management strategies, such as budgeting and internal financial arrangement related matters. The term of Ms. DAN’s engagement commenced in February 2021, and shall end in December 2024. In this connection, Ms. DAN has been transferred approximately 8.13% interests in Hengqin Luzhu LP as her remuneration, and she is also entitled to a sum of RMB4,000 per month as disbursement and subsidy.

As of the Latest Practicable Date, Hengqin Luzhu LP owned approximately 6.41% of the issued Shares.

### Beijing Luzhu Kangrui

Beijing Luzhu Kangrui was established in the PRC as a limited partnership on April 26, 2022. As of the Latest Practicable Date, Beijing Luzhu Kangrui had 32 limited partners, including one Director, two Supervisors and two other members of the senior management of our Group. The general partner of Beijing Luzhu Kangrui is Ms. PENG Ling (彭玲), our Supervisor.

## HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

As of the Latest Practicable Date, the partnership structure of Beijing Luzhu Kangrui was as follows:

<u>Name</u>	<u>Major positions in our Group</u>	<u>Capacity of partnership interests in Beijing Luzhu Kangrui</u>	<u>Approximate percentage of partnership interests (%)</u>
PENG Ling	Supervisor, chief technology officer	General partner	23.06
JIANG Xianmin	Executive Director, deputy general manager, chief medical officer, vice-chairlady of our Board	Limited partner	19.98
LIU Siyu	Joint company secretary of our Company, the secretary of our Board, one of our senior management members	Limited partner	9.99
ZHANG Hui	Chief finance officer, head of global capital markets, one of our senior management members	Limited partner	9.99
KONG Xi	Supervisor	Limited partner	5.00
CHEN Liang	Supervisor	Limited partner	2.60
27 other limited partners <sup>(1)</sup>	N/A	Limited partner	29.39
<b>Total</b>			<b>100.00%</b>

*Note:*

- (1) Such 27 other limited partners consist of 25 current employees and two consultants of our Group, namely (i) Mr. GAO Wenzhi (高文志) (holding approximately 2.00% interests); and (ii) Mr. LIU Zhaoyan (劉昭彥) (holding approximately 2.00% interests).

Mr. GAO Wenzhi is an experienced medical doctor and an acquaintance of Ms. JIANG Xianmin in the medical industry. He was invited by Ms. JIANG Xianmin to act as a consultant of our Group to provide advices in respect of our product research and development. The term of Mr. GAO Wenzhi’s engagement commenced in December 2021, and shall end in December 2024. In this connection, Mr. GAO Wenzhi is entitled to a sum of RMB4,000 per month as his remuneration and was granted approximately 2.00% interests in Beijing Luzhu Kangrui pursuant to the Employee Incentive Scheme.

Mr. LIU Zhaoyan was a college schoolmate of Mr. KONG. He is a PRC qualified lawyer and possesses years of experience in the legal profession. Mr. LIU Zhaoyan has been providing legal services to our Group for a number of years. The related legal fee paid by our Group is RMB300,000 per year and Mr. LIU Zhaoyan was granted approximately 2.00% interests in Beijing Luzhu Kangrui pursuant to the Employee Incentive Scheme.

## HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

### Zhuhai Luzhu Kangrui

Zhuhai Luzhu Kangrui was established in the PRC as a limited partnership on April 14, 2022. As of the Latest Practicable Date, Zhuhai Luzhu Kangrui had 33 limited partners, including three members of the senior management of our Group. The general partner of Zhuhai Luzhu Kangrui is Ms. ZHANG, our executive Director.

As of the Latest Practicable Date, the partnership structure of Zhuhai Luzhu Kangrui was as follows:

<u>Name</u>	<u>Major positions in our Group</u>	<u>Capacity of partnership interests in Zhuhai Luzhu Kangrui</u>	<u>Approximate percentage of partnership interests (%)</u>
ZHANG Yanping	Executive Director, deputy general manager	General partner	7.36
LU Lu	Deputy general manager of Zhuhai Luzhu, one of our senior management members	Limited partner	16.36
JIANG Lijuan	Deputy general manager of Zhuhai Luzhu, one of our senior management members	Limited partner	16.36
HAN Chaowei	Head of manufacturing and engineering, deputy general manager of Zhuhai Luzhu, one of our senior management members	Limited partner	16.36
30 other limited partners <sup>(1)</sup>	N/A	Limited partner	43.56
<b>Total</b>			<b>100.00%</b>

*Note:*

(1) Such 30 other limited partners of Zhuhai Luzhu Kangrui are current employees of our Group.

## HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

### [REDACTED] INVESTMENTS

#### Principal terms of the [REDACTED] Investments

We received four rounds of [REDACTED] Investments since our establishment. The following table sets forth a summary of the details of the [REDACTED] Investments:

	<u>Series A Financing</u>	<u>Series B Financing</u>	<u>Series B+ Financing</u>	<u>Series C Financing</u>
Number of Shares subscribed	49,112,500	27,216,175	6,674,082	9,478,262
Amount of consideration paid	RMB250,000,000	RMB350,000,000	RMB120,000,000	RMB218,000,000
Post-money valuation of our Company <sup>(1)</sup>	Approximately RMB650.0 million	Approximately RMB2.15 billion	Approximately RMB3.13 billion	Approximately RMB4.42 billion
Participants of the [REDACTED] Investments	Beijing Science Sun; Beijing Yizhuang; and Beijing Yizhuang II	CCB Capital; Jinjiang Zhenrui; Zhuhai Livzon; Hangzhou Taikun; Hengji Rongyu; and Xinchuang Technology	Hainan Zhaoan; Gongqingcheng Zhenrui; Jinjiang Xuanhong; Shaanxi Jinou; and Hengji Rongyu	Tianjin Huapu; Xinyin Xinghong; Zibo Runxin; Zibo Runwen; Beijing Yizhuang II; and Hengji Rongyu
Date of investment agreement(s)	July 23, 2019 <sup>(3)</sup> February 16, 2021 <sup>(4)</sup>	August 30, 2021	December 31, 2021	June 16, 2022
Date of payment of full consideration	March 26, 2021	September 10, 2021	January 28, 2022	June 27, 2022
Cost per Share paid under the [REDACTED] Investments	RMB5.09	RMB12.86	RMB17.98	RMB23.0
Discount to the [REDACTED] <sup>(2)</sup>	Approximately [REDACTED]	Approximately [REDACTED]	Approximately [REDACTED]	Approximately [REDACTED]
Use of proceeds from the [REDACTED] Investments	For the expenses of K193 clinical trial and development of various vaccines and therapeutic biologics such as recombinant herpes zoster vaccine	Working capital of our Company, such as development and production of pharmaceutical products, clinical trials, etc.	Working capital of our Company, such as development and production of pharmaceutical products, clinical trials, etc.	For research and development, capital expenditure and working capital requirements relating to the principal business of our Company
Lock-up arrangement	Subject to a lock-up period of 12 months following the [REDACTED] pursuant to the PRC Company Law.			
Strategic benefits to our Company	At the time of the [REDACTED] Investments, our Directors were of the view that our Company would benefit from the additional capital provided by the [REDACTED] Investors' investments in our Company for our research and development activities. Further, our Directors are also of the view that the investments by the [REDACTED] Investors demonstrated their confidence in our operations and served as an endorsement of our Company's performance and prospects. Further, our non-executive Directors represent certain of our [REDACTED] Investors and they complement our executive Directors to maintain good corporate governance.			



## HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

*Notes:*

- (1) The post-money valuation figures equal the total consideration paid by the [REDACTED] Investors in each round divided by the shareholding percentage held by them immediately following their respective round of investment. The increase in valuation from Series A Financing to Series B Financing was mainly due to the progress in the research and development of LZ901 where an application for clinical trial approval was accepted by the NMPA in May 2021. LZ901 is our Core Product and has a tetrameric molecular structure to prevent shingles caused by VZV for adults aged 50 years and older. The increase in valuation from Series B Financing to Series B+ Financing was mainly due to the grant of clinical trial approval for LZ901 by the NMPA, as the result of the clinical trial application for LZ901 was still pending at the time when the consideration for Series B Financing was determined in June 2021. The increase in valuation from Series B+ Financing to Series C Financing was mainly due to the commencement of the Phase II clinical trials of LZ901 in April 2022. Our anticipated market capitalization immediately upon completion of the [REDACTED] has primarily taken into account (a) the post-money valuation of the Series C Financing; (b) the expected capital raising during the [REDACTED]; (c) the actual and expected progress in the development of our product candidates since completion of the Series C Financing, including (i) LZ901, the Phase I clinical trial report of which was issued in February 2023 with head-to-head immunogenicity study comparing Shingrix<sup>®</sup> being disclosed. We expect to complete Phase II clinical trials for LZ901 in the second quarter of 2023, and initiate a multi-center, randomized, double-blind, placebo-controlled Phase III clinical trial comparing LZ901 against Shingrix<sup>®</sup> in the second quarter of 2023. In such connection, we completed clinical sample production of LZ901 for Phase III clinical trials at our first-phase Zhuhai manufacturing facility in February 2023. Outside of China, we received IND approval from the FDA in July 2022 for LZ901 and initiated a Phase I clinical trial in the U.S. in February 2023; and (ii) Recombinant Varicella Vaccine, which we filed its IND application to the NMPA in June 2022. Such development progresses, especially those achieved in relation to LZ901, our Core Product, have reduced the development risks in relation to the relevant products, which in turn indicate a higher success possibility thus bringing a higher valuation of our Company as compared to the Series C Financing; (d) the actual and expected development progress of the infrastructure of our Group since completion of the Series C Financing, which reflects our business development to prepare for the commercialization of our products. Our first-phase Zhuhai manufacturing facility commenced trial operation in October 2022 and obtained the Drug Production License (藥品生產許可證) issued by the Guangdong MPA (廣東省藥品監督管理局) for the production of therapeutic biologics (LZ901) in January 2023, whereas we expect to complete the construction of the second-phase Zhuhai manufacturing facility in the second quarter of 2023; (e) the difference in risks undertaken by our [REDACTED] Investors investing in a private company vis-à-vis investors investing in a public company; and (f) the Company's status as a listed company upon [REDACTED].
- (2) Calculated on the basis of the [REDACTED] of HK\$[REDACTED] per Share, being the mid-point of the indicative [REDACTED] range.
- (3) The date of the 2019 Capital Increase Agreement.
- (4) The date of the equity interest transfer agreement entered into by, among others, Beijing Yizhuang, Beijing Yizhuang II and Beijing Science Sun, pursuant to which Beijing Yizhuang transferred 15,716,000 Shares and 3,929,000 Shares to Beijing Yizhuang II and Beijing Science Sun, respectively.

As of the Latest Practicable Date, (i) approximately 12.7% of proceeds of the Series A Financing, amounting to approximately RMB31.8 million, remained unutilized. Such unutilized proceeds will be used to fund the clinical trial of K193 and the development of our various vaccines and therapeutic biologics; and (ii) approximately 52.6% of proceeds of Series B Financing, amounting to approximately RMB184.2 million, remained unutilized. Such unutilized proceeds will be used as our working capital to support our development and production of pharmaceutical products, clinical trials and other operations. On the other hand, the proceeds of the Series B+ Financing and the Series C Financing had yet been utilized as of the Latest Practicable Date. The proceeds of approximately RMB120.0 million from Series B+ Financing will be used as our working capital to support our development and production of pharmaceutical products, clinical trials and other operations, whereas the proceeds of approximately RMB218.0 million from Series C Financing will be used to fund our research and development, capital expenditure, and working capital requirements that relate to our principal business.

### Special Rights and Obligations under the [REDACTED] Investments Agreements

The [REDACTED] Investors were granted customary special rights, including but not limited to divestment right, pre-emptive right, information right and anti-dilution right. In this connection, the special rights of Series A Investors, Series B Investors, Series B+ Investors and Series C Investors are set out in the Series C Financing agreement, which was entered into among the Company, the Series C Investors and all the then Shareholders and unified the special rights granted in previous rounds of [REDACTED] Investments.

#### *Divestment right*

Each [REDACTED] investor is given the right to, upon the occurrence of specified divestment events, request Mr. KONG and Ms. ZHANG to repurchase the Shares each [REDACTED] Investor then holds at a specified purchase price.

## HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

If (i) our Company cannot achieve a [REDACTED] of the Shares on, among others, the Stock Exchange, with a minimum pre-[REDACTED] valuation of our Company of not less than RMB5.1 billion or not able to complete the Phase II clinical trial of LZ901 by December 31, 2023 (in either scenario); (ii) if our Company cannot achieve a [REDACTED] of the Shares on, among others, the Stock Exchange, with a minimum pre-[REDACTED] valuation of our Company of not less than RMB6.2 billion by December 31, 2025 or not able to complete the Phase III clinical trial of LZ901 by December 31, 2024 (whichever is earlier); (iii) Mr. KONG and Ms. ZHANG lose their actual control over our Company; (iv) our Company, Mr. KONG and Ms. ZHANG are subject to any administrative and/or criminal penalties which causes material harm to our Company; (v) our Company fails and/or Mr. KONG and Ms. ZHANG fail to procure our Company to use the relevant [REDACTED] Investment proceeds as agreed or there is a material breach of the terms of the Series C Financing agreement by our Company, Mr. KONG and/or Ms. ZHANG; or (vi) any other [REDACTED] Investors request to exercise their divestment rights, the [REDACTED] Investors shall have the right to request Mr. KONG and Ms. ZHANG or any third parties nominated by Mr. KONG and Ms. ZHANG to repurchase the relevant equity interests.

The divestment rights granted to the [REDACTED] Investors have been suspended immediately prior to the submission of our [REDACTED] application and will terminate upon [REDACTED]. The information rights granted to the [REDACTED] Investors will terminate upon the [REDACTED]. All other special rights under the [REDACTED] Investments had been terminated prior to the submission of our [REDACTED] application in accordance with Guidance Letter HKEX-GL43-12 issued by the Stock Exchange. Save as disclosed above, there are no other side agreements, understandings, arrangements or undertakings, verbal or in writing, between our Company (including any of our subsidiaries, their directors, supervisors, shareholders, senior management or any of their respective associates) and each of the [REDACTED] Investors (including their beneficial owners and directors), in relation to their investments in our Group, that are subsisting.

### Background of the [REDACTED] Investors

Our [REDACTED] Investors include major pharmaceutical companies and experienced investors such as seasoned healthcare funds and established funds with a focus on investments in the biopharmaceutical sector, the details of which are set out below:

#### 1. *Beijing Yizhuang, Beijing Yizhuang II and Beijing Science Sun*

Beijing Yizhuang is a limited liability partnership established in the PRC on November 16, 2015 and is an investment fund registered under the Asset Management Association of China with an aggregate amount of assets under management of approximately RMB800.0 million. Beijing Yizhuang primarily focuses on investment opportunities in next-generation biopharmaceutical companies, biomacromolecule technology, cell engineering technology and gene regulation. As of the Latest Practicable Date, Beijing Yizhuang had (i) one general partner and fund manager, namely E-town Sun, which held approximately 1.25% interest in Beijing Yizhuang; and (ii) seven limited partners, namely Beijing Science Sun (being the largest limited partner and holding approximately 26.25% interest in Beijing Yizhuang), Saide Ruibo (holding approximately 16.25% interest in Beijing Yizhuang), and five Independent Third Parties (together holding the remaining approximately 56.25% interest in Beijing Yizhuang). As of the Latest Practicable Date, E-town Sun was owned as to approximately 34.00%, 46.00% and 20.00% by Saiding Fangde, Saide Ruibo and Botai Fangde (Beijing) Capital Management Co., Ltd. (博泰方德(北京)資本管理有限公司) (“**Botai Fangde**”), respectively. Saiding Fangde and Saide Ruibo have confirmed that they are acting in concert in respect of their interests in E-town Sun. Further, E-town Sun is also regarded by Beijing Science Sun as having the same Actual Controller, i.e. Mr. MA Biao (馬彪), who is our non-executive Director. On the other hand, Botai Fangde is an Independent Third Party. As of the Latest Practicable Date, Botai Fangde was owned as to (i) approximately 69.39% by Beijing E-town International Industrial Investment Management Co., Ltd. (北京亦莊國際產業投資管理有限公司), which in turn was ultimately controlled by the Financial Audit Bureau of the Beijing Economic-Technological Development Area (北京經濟技術開發區財政審計局), an Independent Third Party; and (ii) approximately 30.61% by Beijing Yizhuang International Biomedical Investment Management Co. Ltd. (北京亦莊國際生物醫藥投資管理有限公司), which in turn was ultimately

## HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

controlled by the Management Committee of the Beijing Economic-Technological Development Area (北京經濟技術開發區管理委員會), an Independent Third Party. Except for the fact that (i) E-town Sun, being the general partner of Beijing Yizhuang, is our connected person, (ii) Beijing Science Sun and Saide Ruibo, being limited partners of Beijing Yizhuang, are our connected persons, and (iii) Beijing Yizhuang, together with Beijing Yizhuang II and Beijing Science Sun, are regarded as a group of substantial shareholders of our Company as discussed below, the limited partners of Beijing Yizhuang are all Independent Third Parties.

Beijing Yizhuang II is a limited liability partnership established in the PRC on December 27, 2019 and is an investment fund registered under the Asset Management Association of China with an aggregate amount of assets under management of approximately RMB1.0 billion. Beijing Yizhuang II primarily focuses on investment opportunities in next-generation biopharmaceutical companies, biomacromolecule technology, cell engineering technology and gene regulation. As of the Latest Practicable Date, Beijing Yizhuang II had (i) one general partner and fund manager, namely E-town Sun, which held approximately 1.00% interest in Beijing Yizhuang II; and (ii) five limited partners, namely Beijing Science Sun (being the largest limited partner and holding approximately 31.00% interest in Beijing Yizhuang II) and four Independent Third Parties (together holding the remaining approximately 68.00% interest in Beijing Yizhuang II). Except for the fact that (i) E-town Sun, being the general partner of Beijing Yizhuang II, is our connected person, (ii) Beijing Science Sun, being a limited partner of Beijing Yizhuang II, is our connected person, and (iii) Beijing Yizhuang II, together with Beijing Yizhuang and Beijing Science Sun, are regarded as a group of substantial shareholders of our Company as discussed below, the limited partners of Beijing Yizhuang II are all Independent Third Parties.

Beijing Science Sun is a limited liability company established in the PRC on May 20, 1999, and was converted into a joint stock limited company on July 28, 2011. Beijing Science Sun principally engaged in the research, manufacture and sales of biological and biochemical pharmaceuticals. It is a company listed on the Shenzhen Stock Exchange (stock code: 300485) since June 2015, with Mr. MA Biao as its Actual Controller, holding approximately 49.51% of the issued shares of Beijing Science Sun as of the Latest Practicable Date.

Beijing Yizhuang and Beijing Yizhuang II share the same general partner and fund manager, i.e. E-town Sun, which in turn is regarded as having the same Actual Controller as Beijing Science Sun (i.e. Mr. MA Biao). Accordingly, Beijing Yizhuang, Beijing Yizhuang II and Beijing Science Sun are regarded as a group of substantial shareholders of our Company.

### 2. CCB Capital

CCB Capital is a limited liability company established in the PRC on September 17, 2008, and is primarily engaged in investment management and consulting. It is a Sophisticated Investor having made meaningful investment in our Company during the Series B Financing, which is more than six months before the [REDACTED] for the purpose of Guidance Letter HKEX-GL92-18 issued by the Stock Exchange. As of December 31, 2022, CCB Capital had assets under management of approximately RMB6.0 billion. Other than our Company, the investment portfolio of CCB Capital and its associates in the biopharmaceutical sector also includes the following companies: (i) Novogene Co., Ltd. (北京諾禾致源科技股份有限公司), a genomic products and services provider listed on the Shanghai Stock Exchange (stock code: 688315); (ii) Kintor Pharmaceutical Limited (開拓藥業有限公司), a novel drug developer listed on the Stock Exchange (stock code: 9939), focusing on cancers and other androgen receptor-related diseases; (iii) Hinova Pharmaceuticals Inc. (海創藥業股份有限公司), a pharmaceutical listed on the Shanghai Stock Exchange (stock code: 688302), focusing on deuteration technology and PROTAC targeted protein degradation; and (iv) Beijing Kangle Weishi Biotechnology Co., Ltd. (北京康樂衛士生物技術股份有限公司), a biotech company quoted on the National Equities Exchange and Quotations (stock code: 833575), focusing on the research, development and industrialization of vaccines. CCB Capital is indirectly and wholly owned by CCB International (Holdings) Limited (建銀國際(控股)有限公司), which in turn is an investment services flagship indirectly and wholly-owned by China Construction Bank Corporation (中國建設銀行股份有限公司), a joint-stock company established in the PRC and dually listed on the Stock Exchange (stock code: 939) and the Shanghai Stock Exchange (stock code: 601939).

## HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

### 3. *Jinjiang Zhenrui and Jinjiang Xuanhong*

Jinjiang Zhenrui is a limited liability partnership established in the PRC on April 23, 2021 and is an investment fund registered under the Asset Management Association of China with an aggregate amount of assets under management of approximately RMB100.0 million. Jinjiang Zhenrui primarily focuses on investment opportunities in the medical, pharmaceutical and healthcare industries in the PRC. As of the Latest Practicable Date, (i) Jinjiang Zhenrui had nine limited partners, with the largest limited partner holding approximately 49.75% interests in Jinjiang Zhenrui; and (ii) the general partner and fund manager of Jinjiang Zhenrui was Herui Venture Capital Fund Management (Shenzhen) Co., Ltd. (和瑞創業投資基金管理(深圳)有限公司) (“**Herui VC**”), which was owned as to 40.00%, 40.00% and 20.00% by Mr. CHEN Ruolin (陳若霖), Mr. WANG Zhixian (王智顯) and Ms. LIN Bei (林貝), respectively. Both Mr. CHEN Ruolin and Ms. LIN Bei have years of experience in the finance industry and are currently responsible for the investment related matters of Herui VC. Mr. WANG Zhixian, on the other hand, works in the healthcare industry. Jinjiang Zhenrui and its general partner and limited partners are all Independent Third Parties.

Jinjiang Xuanhong is a limited liability partnership established in the PRC on May 13, 2021 and is an investment fund registered under the Asset Management Association of China with an aggregate amount of assets under management of approximately RMB40.0 million. Jinjiang Xuanhong primarily focuses on investment opportunities in the medical, pharmaceutical and healthcare industries in the PRC. As of the Latest Practicable Date, (i) Jinjiang Xuanhong had 14 limited partners, with the largest limited partner holding approximately 25.00% interests in Jinjiang Xuanhong; and (ii) the general partner and fund manager of Jinjiang Xuanhong was Herui VC. Jinjiang Xuanhong and its general partner and limited partners are all Independent Third Parties.

As Jinjiang Zhenrui and Jinjiang Xuanhong share the same general partner and fund manager, i.e. Herui VC, they are regarded as a group of Shareholders.

### 4. *Zhuhai Livzon*

Zhuhai Livzon is a limited liability company established in the PRC on May 17, 2019, and is primarily engaged in investments in the biomedical industry. Zhuhai Livzon is a wholly-owned subsidiary of Livzon Pharmaceutical Group Inc. (麗珠醫藥集團股份有限公司), a PRC-based pharmaceutical company dually listed on the Stock Exchange (stock code: 1513) and the Shenzhen Stock Exchange (stock code: 000513), which principally engaged in the research and development, production and sales of pharmaceutical products.

### 5. *Hangzhou Taikun*

Hangzhou Taikun is a limited liability partnership established in the PRC on August 10, 2021 and is an investment fund registered under the Asset Management Association of China with an aggregate amount of assets under management of approximately RMB1.0 billion. Hangzhou Taikun primarily focuses on investment opportunities in companies which engage in development of innovative medical devices and medicine, medical services, etc. As of the Latest Practicable Date, (i) Hangzhou Taikun had three limited partners, with the largest limited partner holding approximately 49.00% in Hangzhou Taikun; (ii) the general partner and fund manager of Hangzhou Taikun was Hangzhou Tailong Venture Capital Partnership (Limited Partnership) (杭州泰瓏創業投資合夥企業(有限合夥)) (“**Hangzhou Tailong**”). The general partner of Hangzhou Tailong is Zhaotai (Zibo) Venture Capital Management Partnership (Limited Partnership) (昭泰(淄博)創業投資管理合夥企業(有限合夥)), the general partner of which is Mr. LIU Chunguang (劉春光), holding approximately 99.00% partnership interest therein. Mr. LIU Chunguang is a private investor with interest and experience in the biopharmaceutical industry. As of the Latest Practicable Date, approximately 49.00% and 99.00% of the respective interest in Hangzhou Taikun and Hangzhou Tailong was held by their respective largest limited partner, Hangzhou Tigermed Equity Investment Partnership (Limited Partnership) (杭州泰格股權投資合夥企業(有限合夥)), which is a wholly-owned subsidiary of Tigermed Consulting Co., Ltd. (杭州泰格醫藥科技股份有限公司), a biopharmaceutical company dually listed on the Stock Exchange

## HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

(stock code: 3347) and the Shenzhen Stock Exchange (stock code: 300347). The remaining approximately 51.00% interests of Hangzhou Taikun was held by three partners, namely Hangzhou Tailong and two other Independent Third Parties. Hangzhou Taikun and its general partner and limited partners are all Independent Third Parties.

### 6. *Hengji Rongyu*

Hengji Rongyu is a limited liability partnership established in the PRC on June 11, 2021, primarily focuses on research and production of disposable biological consumables with an aggregate amount of assets under management of approximately RMB100.0 million. As of the Latest Practicable Date, (i) Hengji Rongyu had three limited partners, with the largest limited partner holding approximately 10.0% interest in Hengji Rongyu; and (ii) the general partner of Hengji Rongyu was Ms. WANG Li (王麗), who held approximately 85.20% interest in Hengji Rongyu. Ms. WANG Li is an entrepreneur. Apart from being the general partner of Hengji Rongyu, she is also the controlling shareholder, director and general manager of Beijing Kemanhua Technology and Trading Co., Ltd. (北京科曼華科貿有限公司) (“**Beijing Kemanhua**”), a trading company with registered capital of RMB19.0 million as of the Latest Practicable Date. Ms. WANG Li held approximately 97.00% of the equity interests in Beijing Kemanhua as of the Latest Practicable Date. Hengji Rongyu and its general partner and limited partners are all Independent Third Parties.

### 7. *Xinchuang Technology*

Xinchuang Technology is a limited liability partnership established in the PRC on February 20, 2021 and is an investment fund registered under the Asset Management Association of China with an aggregate amount of assets under management of approximately RMB680.0 million. Xinchuang Technology primarily focuses on investment opportunities in information technology application innovation industry, advanced manufacturing and biomedical industry. As of the Latest Practicable Date, (i) Xinchuang Technology had 13 limited partners, with the largest limited partner holding approximately 29.91% interest in Xinchuang Technology; and (ii) the general partners of Xinchuang Technology were (a) Beijing E-town International Technology Innovation Private Equity Fund Management Co., Ltd. (北京亦莊國際科技創新私募基金管理有限公司) (“**E-town Private Equity**”) (which was also the fund manager of Xinchuang Technology); and (b) Beijing E-town Huaray Investment Management Co., Ltd. (北京屹唐華睿投資管理有限公司) (“**E-town Huaray Investment**”), holding approximately 1.00% and 0.25% interest in Xinchuang Technology, respectively. As of the Latest Practicable Date, (i) E-town Private Equity was owned as to approximately 45.00% by Beijing Rongyue Changxiang Information Consulting Service Center (Limited Partnership) (北京榮躍暢享信息諮詢服務中心(有限合夥)) (“**Rongyue Changxiang**”), and approximately 20.00%, 15.00%, 10.00% and 10.00% by four other shareholders, respectively. The general partner of Rongyue Changxiang is Mr. ZHANG Peng (張鵬), holding approximately 10.00% interest in Rongyue Changxiang as of the Latest Practicable Date. Mr. ZHANG Peng has years of experience in the investment and finance industry and is a fund practitioner (基金從業員) registered under the Asset Management Association of China; and (ii) E-town Huaray Investment was owned as to approximately 37.50% by Beijing E-town International Industrial Investment and Management Co., Ltd (北京亦莊國際產業投資管理有限公司), which in turn was ultimately owned by the Financial Audit Bureau of the Beijing Economic-Technological Development Area (北京經濟技術開發區財政審計局), and approximately 31.25%, 18.75% and 12.50% by three other shareholders, respectively. Xinchuang Technology and its general partners and limited partners are all Independent Third Parties.

### 8. *Hainan Zhaoan*

Hainan Zhaoan is a limited liability partnership established in the PRC on June 11, 2021, and is an investment fund registered under the Asset Management Association of China with an aggregate amount of assets under management of approximately RMB200.0 million. Hainan Zhaoan primarily focuses on private equity investment. As of the Latest Practicable Date, (i) Hainan Zhaoan had seven limited partners, with the largest limited partner holding approximately 31.50% interest in Hainan Zhaoan; and (ii) the general partner and fund manager of Hainan Zhaoan was Tibet Ming Feng Capital Investment Management Co., Ltd. (西藏銘豐資本投資管理有限公司), which was owned as to approximately 33.50%, 30.00%, 15.00%, 15.00%, 3.50% and 3.00% by Mr. FEI Simin (費思敏), Mr. WANG Dapeng (王大鵬), Ms. ZHANG Lanying (張蘭英), Ms. WANG Xiongling (王熊玲), Mr. ZHANG Yong (張勇) and Mr. QIN Yong (秦勇), respectively. Each of Mr. FEI Simin, Mr. WANG Dapeng, Ms. ZHANG Lanying,

## HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Ms. WANG Xiongling, Mr. ZHANG Yong and Mr. QIN Yong is a private investor with years of investment experience, and their backgrounds are diversified: (i) Mr. FEI Simin, Mr. WANG Dapeng and Mr. QIN Yong had previously worked in the real estate development and/or investment industry; (ii) Ms. ZHANG Lanying had previously worked in the medical industry; (iii) Ms. WANG Xiongling had previously worked in the mining industry; and (iv) Mr. ZHANG Yong had previously worked in the engineering and construction industry. Hainan Zhaoan and its general partner and limited partners are all Independent Third Parties.

### 9. *Gongqingcheng Zhenrui*

Gongqingcheng Zhenrui is a limited liability partnership established in the PRC on October 14, 2021 and is an investment fund registered under the Asset Management Association of China with an aggregate amount of assets under management of approximately RMB10.0 million. Gongqingcheng Zhenrui primarily focuses on investment opportunities in biomedical industry. As of the Latest Practicable Date, (i) Gongqingcheng Zhenrui had seven limited partners, with the largest limited partner holding approximately 19.81% interests in Gongqingcheng Zhenrui; and (ii) the general partner and fund manager of Gongqingcheng Zhenrui was Shenzhen Mingsheng Private Equity Fund Management Co., Ltd. (深圳銘盛私募股權基金管理有限公司) (formerly known as Hainan Mingsheng Private Equity Fund Management Co., Ltd. (海南銘盛私募基金管理有限公司)), which was wholly owned by Ms. JI Lingzi (紀鈴子). Ms. JI Lingzi has years of experience in the banking and investment industry and is a fund practitioner (基金從業員) registered under the Asset Management Association of China. Gongqingcheng Zhenrui and its general partner and limited partners are all Independent Third Parties.

### 10. *Shaanxi Jinou*

Shaanxi Jinou is a limited liability partnership established in the PRC on July 30, 2021 and is an investment fund registered under the Asset Management Association of China with an aggregate amount of assets under management of approximately RMB25.0 million. Shaanxi Jinou primarily focuses on investment opportunities in biomedical industry. As of the Latest Practicable Date, (i) Shaanxi Jinou had two limited partners, with the largest limited partner holding approximately 12.00% interests in Shaanxi Jinou; and (ii) the general partner and fund manager of Shaanxi Jinou was Shaanxi New Age Capital Management Co., Ltd. (陝西新時代資本管理有限公司), which was ultimately owned by the Department of Finance of Shaanxi Province. Shaanxi Jinou and its general partner and limited partners are all Independent Third Parties.

### 11. *Tianjin Huapu*

Tianjin Huapu is a limited liability partnership established in the PRC on June 7, 2022, and primarily focuses on the investment opportunities in biomedical field, with an aggregate amount of assets under management of approximately RMB400.0 million. As of the Latest Practicable Date, the general partner of Tianjin Huapu was Mr. LV Maojie (呂茂傑). Mr. LV Maojie works in the biopharmaceutical industry and has years of industry experience. Mr. LV Maojie and the limited partner of Tianjin Huapu, Tianjin Huapu Haihe Biopharmaceutical Industry Fund Partnership (Limited Partnership) (天津華普海河生物醫藥產業基金合夥企業(有限合夥)) (“**Huapu Haihe**”) held approximately 0.1% and 99.9% interest in Tianjin Huapu, respectively. As of the Latest Practicable Date, Huapu Haihe was owned as to approximately 50.00%, 20.00%, 29.90% and 0.10% by Tianjin Haihe Industry Fund Partnership (Limited Partnership) (天津市海河產業基金合夥企業(有限合夥)) (“**Haihe Fund**”), Tianjin Ringpu Bio-Technology Co., Ltd. (天津瑞普生物技術股份有限公司) (a company listed on the Shenzhen Stock Exchange (stock code: 300119)), Shanghai Wantian Investment Management Co., Ltd. (上海萬天投資管理有限公司) and Tianjin Ruisheng Private Fund Management Co., Ltd. (天津瑞晟私募基金管理有限公司) (“**Tianjin Ruisheng**”). The general partner of Huapu Haihe is Tianjin Ruisheng, and the fund manager of Huapu Haihe is Ruijiu Venture Capital (天津瑞久創業投資管理有限公司). As of the Latest Practicable Date, Haihe Fund was owned as to approximately 99.8% by Tianjin Jinrong Investment Service Group Co., Ltd. (天津津融投資服務集團有限公司), which was owned as to approximately 77.62% by State-owned Assets Supervision and Administration Commission of Tianjin People’s Government (天津市人民政府國有資產監督管理委員會) (through itself and Tianjin Jincheng State-owned Capital Investment and Operations Co., Ltd. (天津津誠國有資本投資運營有限公司), its wholly owned company). Tianjin Huapu and its general partner and limited partner are all Independent Third Parties.

### 12. *Xinyin Xinghong*

Xinyin Xinghong is a limited liability partnership established in the PRC on February 14, 2019, with its investments amounting to approximately RMB33.0 million, and primarily focuses on investment

## HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

opportunities in emerging industries such as intelligent technology, high-end manufacturing, medical healthcare, next-generation information technology and new energy and materials. As of the Latest Practicable Date, (i) Xinyin Xinghong had only one limited partner, which held approximately 99.86% interest in Xinyin Xinghong; and (ii) the general partner of Xinyin Xinghong was Xinyin Zhenhua (Beijing) Equity Investment Fund Management Co., Ltd. (信銀振華(北京)股權投資基金管理有限公司) (“**Xinyin Zhenhua**”), which held approximately 0.14% interest in Xinyin Xinghong. Xinyin Zhenhua is a subsidiary of CNCB (Hong Kong) Investment Limited (信銀(香港)投資有限公司), which is in turn the overseas investment banking platform of China CITIC Bank Corporation Limited (中信銀行股份有限公司), and ultimately controlled by CITIC Group (中信集團), a PRC state-owned investment company and an Independent Third Party. Xinyin Xinghong and its general partner and limited partner are all Independent Third Parties.

### 13. *Zibo Runxin and Zibo Runwen*

Zibo Runxin is a limited liability partnership established in the PRC on August 12, 2021, and is an investment fund registered under the Asset Management Association of China with an aggregate amount of assets under management of approximately RMB15.0 million. Zibo Runxin primarily focuses on equity investments, covering the semi-conductor, high-end manufacturing and biomedical industries. As of the Latest Practicable Date, (i) Zibo Runxin had nine limited partners, with the largest limited partner holding approximately 30.67% interests in Zibo Runxin; and (ii) the general partner and fund manager of Zibo Runxin was Beijing Runsen Yixin Investment Management Co., Ltd. (北京潤森義信投資管理有限公司) (“**Runsen Yixin**”), which was owned as to approximately 85.00% and 15.00% by Mr. GAO Wei (高巍) and Mr. WANG Han (王涵), respectively. Mr. GAO Wei and Mr. WANG Han are the founders of Runsen Yixin and had previously worked in the investment banking industry. Zibo Runxin and its general partner and limited partners are all Independent Third Parties.

Zibo Runwen is a limited liability partnership established in the PRC on June 8, 2021 and is an investment fund registered under the Asset Management Association of China with an aggregate amount of assets under management of approximately RMB10.0 million. Zibo Runwen primarily focuses on equity investments, covering the semi-conductor, high-end manufacturing and biomedical industries. As of the Latest Practicable Date, (i) Zibo Runwen had three limited partners, with the largest limited partner holding approximately 49.51% interests in Zibo Runwen; and (ii) the general partner and fund manager of Zibo Runwen was Runsen Yixin. Zibo Runwen and its general partner and limited partners are all Independent Third Parties.

As Zibo Runxin and Zibo Runwen share the same general partner and fund manager, i.e. Runsen Yixin, they are regarded as a group of Shareholders.

Other than Beijing Yizhuang, Beijing Yizhuang II and Beijing Science Sun, and save as disclosed above all the other [REDACTED] Investors, their general partners and limited partners (where applicable), and their respective ultimate beneficial owners are Independent Third Parties.

### **Public Float**

Upon [REDACTED], (i) the Domestic Shares directly held by Mr. KONG and Xinyin Xinghong, and (ii) the H Shares directly held by Ms. ZHANG, Hengqin Luzhu LP, Beijing Yizhuang, Beijing Yizhuang II, Beijing Science Sun, Ms. JIANG and Ms. KONG Xi will not be counted towards the public float. Except as stated above, all the H Shares held by other Shareholders upon [REDACTED] will be counted towards the public float for the purpose of Rules 8.08 and 18A.07 of the Listing Rules.

Immediately upon completion of the [REDACTED], assuming (i) [REDACTED] H Shares are [REDACTED] and [REDACTED] to public Shareholders in the [REDACTED]; (ii) the conversion of [REDACTED] Domestic Shares into H Shares as applied in “Full Circulation” as shown in the table in “— Corporate Structure immediately after completion of the [REDACTED]” in this section below; and (iii) the [REDACTED] is not exercised, and based on an [REDACTED] of HK\$[REDACTED] per [REDACTED] (being the low-end of the indicative [REDACTED] range), the total number of H Shares of our Company held by the public represents approximately [REDACTED]% of the total number of issued Shares of our Company and our Company will have a [REDACTED] of at least HK\$[REDACTED] held by the public. Therefore, our Company will be able to meet the minimum public float requirement under Rules 8.08 and 18A.07 of the Listing Rules.

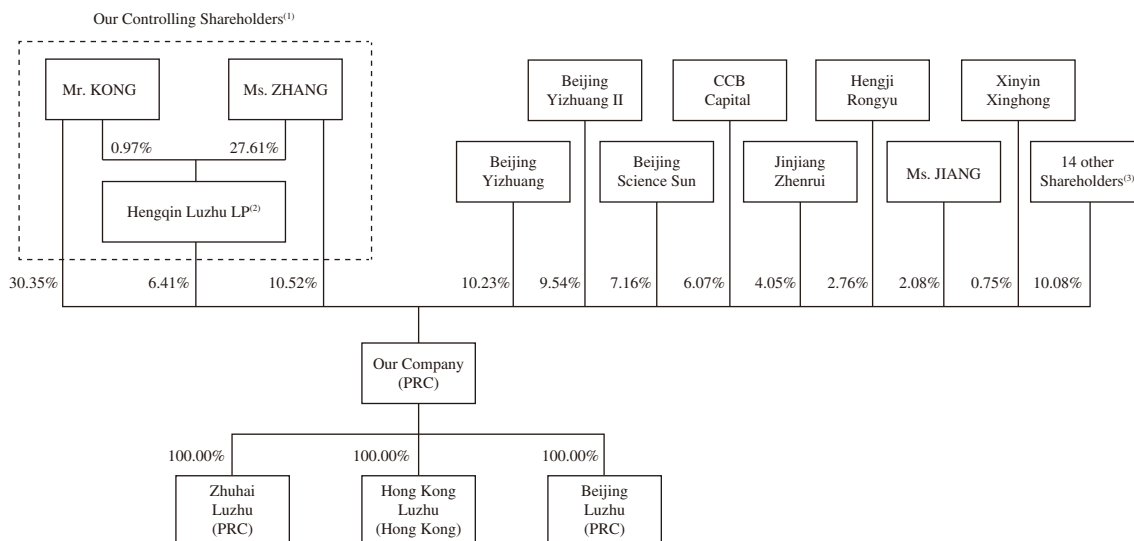
## HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

### Sole Sponsor’s Confirmation

On the basis that (i) the consideration for Series A Financing, Series B Financing and Series B+ Financing was settled more than 28 clear days before the date of first submission of the [REDACTED] application to the Stock Exchange; (ii) the consideration for Series C Financing was settled no less than 120 clear days before the [REDACTED]; and (iii) the special rights granted to the [REDACTED] Investors had been suspended or terminated prior to the submission of the application for the [REDACTED] and/or will be terminated upon completion of the [REDACTED], in compliance with Guidance Letter HKEX-GL43-12, the Sole Sponsor confirms that the [REDACTED] Investments are in compliance with Guidance Letter HKEX-GL29-12 issued by the Stock Exchange in January 2012 and updated in March 2017, Guidance Letter HKEX-GL43-12 issued by the Stock Exchange in October 2012 and updated in July 2013 and in March 2017 and Guidance Letter HKEX-GL44-12 issued by the Stock Exchange in October 2012 and updated in March 2017.

### CORPORATE STRUCTURE IMMEDIATELY PRIOR TO COMPLETION OF THE [REDACTED]

The following chart sets forth a simplified corporate structure of our Group immediately prior to completion of the [REDACTED]:



#### Notes:

- As (i) Ms. ZHANG is the spouse of Mr. KONG, and (ii) Mr. KONG is the sole general partner of Hengqin Luzhu LP and can exercise the voting rights attached to the Shares held by Hengqin Luzhu LP in accordance with the partnership agreement entered into among the general and limited partners of Hengqin Luzhu LP, Mr. KONG, Ms. ZHANG and Hengqin Luzhu LP are considered to be a group of Controlling Shareholders, who collectively held approximately 47.28% of our total issued Shares as of the Latest Practicable Date.
- The sole general partner of Hengqin Luzhu LP is Mr. KONG. As of the Latest Practicable Date, the remaining 71.42% interests of Hengqin Luzhu LP were held by Beijing Luzhu Kangrui (holding approximately 40.67%), Zhuhai Luzhu Kangrui (holding approximately 19.87%) and two Independent Third Parties, namely Ms. HUANG Ying (holding approximately 2.76%), and Ms. DAN (holding approximately 8.13%). The general partner of Beijing Luzhu Kangrui is Ms. PENG Ling, our Supervisor. As of the Latest Practicable Date, Beijing Luzhu Kangrui had 32 limited partners, including one Director, two Supervisors and two other members of the senior management of our Group. The general partner of Zhuhai Luzhu Kangrui is Ms. ZHANG, our executive Director. As of the Latest Practicable Date, Zhuhai Luzhu Kangrui had 33 limited partners, including three members of the senior management of our Group.
- Such 14 other Shareholders include Tianjin Huapu, Ms. ZHONG Siyu, Zhuhai Livzon, Hangzhou Taikun, Jinjiang Xuanhong, Hainan Zhaoan, Ms. CHEN Qingyun, Xinchuang Technology, Zibo Runxin, Gongqingcheng Zhenrui, Shaanxi Jinou, Ms. KONG Xi, Zibo Runwen and Mr. ZHOU Peng, respectively holding approximately 1.58%, 1.23%, 1.21%, 1.21%, 1.16%, 0.87%, 0.82%, 0.40%, 0.34%, 0.29%, 0.29%, 0.23% and 0.16% of our total issued Shares immediately prior to completion of the [REDACTED]. Tianjin Huapu, Zhuhai Livzon, Hangzhou Taikun, Jinjiang Xuanhong, Hainan Zhaoan, Xinchuang Technology, Zibo Runxin, Gongqingcheng Zhenrui, Shaanxi Jinou, and Zibo Runwen are our [REDACTED] Investors. Ms. KONG Xi is our Supervisor and also the niece of Mr. KONG and Ms. ZHANG. Mr. ZHOU Peng, Ms. ZHONG Siyu and Ms. CHEN Qingyun are Independent Third Parties.





## BUSINESS

### OVERVIEW

We are a biotechnology company committed to developing innovative human vaccines and therapeutic biologics to prevent and control infectious diseases and treat cancer and autoimmune diseases. Since our inception in 2001, we have focused on human medicine and established technology platforms with our understanding of immunology and protein engineering.

After two decades of research and development and introduction of technologies, we have established an innovative precision protein engineering platform empowering the full cycle of drug development, which provides a solid foundation for the development of our human vaccines candidates, monoclonal antibody product candidates and bispecific antibody product candidates.

Our innovative antigen presentation technology for vaccine development starts from the concept of enhancing the immunogenicity of a target antigen, then streamlines the design of a recombinant virus vaccine antigen while retaining the primary structure of the natural antigen to enhance immunogenicity, improve safety and patient vaccination experience. Our internally developed next-generation bispecific antibody development platform, Fabite<sup>®</sup>, of which we own intellectual property rights, has competitive advantages in the development of bispecific antibody products for the treatment of relapsed/refractory hematological malignancies. Fabite<sup>®</sup> has a fully controllable mechanism of action and mode of administration to ensure the safety of patients. It can be used in a variety of immunotherapies based on the activation of T cells to kill cancer cells. Fabite<sup>®</sup> optimizes the purification process of bispecific antibodies, achieving high purity of monomers. At the same time, we have developed several types of liquid formulations to address stability issues, resulting in bispecific antibody solutions that can be stable for more than three years in storage conditions of 2-8°C.

By employing our Fabite<sup>®</sup> technology platform and mammalian expression technology platform and leveraging our in-house biologics manufacturing infrastructure and capabilities, we established a diversified and advanced product pipeline covering human vaccine candidates, monoclonal antibody product candidates and bispecific antibody product candidates.

- **LZ901**, our independently developed recombinant herpes zoster vaccine candidate and Core Product, has a tetrameric molecular structure to prevent shingles caused by varicella-zoster virus (“**VZV**”) for adults aged 50 years and older. Its molecular structure has double the Fc regions for antigen presenting cells (“**APCs**”) to bind to compared to naturally occurring VZV antigen. LZ901 actively presents VZV antigens to immune cells to trigger an immune response. In addition, LZ901 has demonstrated high immunogenicity, efficacy and safety profile in pre-clinical studies, while inducing specific humoral and cellular immunity. We have initiated a Phase I clinical trial in January 2022 and completed the Phase I clinical trial and initiated a Phase II clinical trial for LZ901 in China in April 2022. We expect to complete the Phase II clinical trial for LZ901 in China in the second quarter of 2023, initiate a multi-center, randomized, double-blind, placebo-controlled Phase III clinical trial comparing LZ901 against Shingrix<sup>®</sup> in the second quarter of 2023, and file Biologics License Application (“**BLA**”) in the third quarter of 2024 for LZ901 to the NMPA. In addition, we have received IND approval from the United States Food and Drug Administration (“**FDA**”) in July 2022 for LZ901 and initiated a Phase I clinical trial in the U.S. in February 2023. We plan to complete the Phase I clinical trial and initiate a Phase II clinical trial in the first quarter of 2024. Furthermore, we expect to complete the Phase II clinical trial in the second quarter of 2025, initiate a Phase III clinical trial in the fourth quarter of 2025, and complete the Phase III clinical trial in the second quarter of 2027.

## BUSINESS

- K3**, our independently developed recombinant human anti-tumor necrosis factor (“TNF”)- $\alpha$  monoclonal antibody injection product candidate, is a biosimilar of Humira<sup>®</sup> (adalimumab) and mainly used for the treatment of various autoimmune diseases, such as rheumatoid arthritis, ankylosing spondylitis and psoriasis. We initiated our Phase I clinical trial in China in September 2018, in which K3 displayed pharmacokinetics consistent with adalimumab, and completed the Phase I clinical trial in December 2019. We plan to initiate a Phase III clinical trial for K3 in China in the second quarter of 2023, complete the Phase III clinical trial in the second quarter of 2024 and submit a BLA to the NMPA in the fourth quarter of 2024. We expect K3 to receive BLA approval from the NMPA in 2025. We expect K3 to expand the market in China for adalimumab biosimilars.
- K193**, our independently developed bispecific antibody injection (B-lymphocyte antigen CD19 (“CD19”)-cluster of differentiation 3 (“CD3”)) product candidate for the treatment of B cell leukemia and lymphoma, is the world’s first bispecific antibody against CD19/CD3 with an asymmetric structure. K193 has an innovative molecular structure that was developed based on our internally developed bispecific antibody development platform, Fabite<sup>®</sup>, and our mammalian expression technology platform, which makes it less prone to polymerization and decreased activity compared to other similar products in the market. In our pre-clinical studies, K193 displayed high *in vivo* and *in vitro* anti-tumor activity, and its optimized formulation is stable and convenient to use. K193’s unique mechanism of action endows it with a strong ability to treat various types of B cell leukemia and lymphoma. The safe and controllable administration of K193 also reduces the impact of patient stress caused by medication administration. In December 2019, we initiated a Phase I clinical trial of K193 in China and expect to complete the Phase I clinical trial in the second quarter of 2023. We plan to initiate a Phase II clinical trial for K193 in the first quarter of 2024 and complete the Phase II clinical trial of K193 in China in the fourth quarter of 2027.
- In addition, our diversified and advanced pipeline includes recombinant varicella vaccine, recombinant rabies vaccine, K333 bispecific antibody for the treatment of myeloid leukemia and K1932 bispecific antibody for the treatment of lymphoma.

The following diagram summarizes the status of our product pipeline as of the Latest Practicable Date:

PRODUCT TYPE	PRODUCT PIPELINE	MECHANISM/TARGET	INDICATIONS	PRE-CLINICAL	CLINICAL TRIALS			Expected Timetable
					Phase I	Phase II	Phase III	
Recombinant Vaccine	LZ901 <sup>(1)</sup>	VZV gE	Herpes zoster			China		Complete Phase II in Q2 2023 and expected to initiate Phase III in Q2 2023
			Herpes zoster	US				Complete Phase I in Q1 2024 and expected to initiate Phase II in Q1 2024
Monoclonal Antibody	K3 <sup>(2)</sup>	TNF- $\alpha$	Rheumatoid arthritis, ankylosing spondylitis, plaque psoriasis			China		Initiate Phase III in Q2 2023 and expected to submit a BLA in Q4 2024
Bispecific Antibody	K193	CD3/CD19	Relapsed/Refractory B-cell lymphoma/leukemia		China			Complete Phase I in Q2 2023 and expected to initiate Phase II in Q1 2024
Recombinant Vaccine	Recombinant Varicella Vaccine	VZV gE	Varicella	China				Initiate Phase I in Q3 2023 and expected to initiate Phase II in Q3 2024
Recombinant Vaccine	Recombinant Rabies Vaccine	RABV-G	Rabies	China				Request pre-IND meeting with the NMPA in Q4 2023
Bispecific Antibody	K333	CD33/CD3	Myeloid leukemia	China				Request pre-IND meeting with the NMPA in the second half of 2024
Bispecific Antibody	K1932	CD19/CD3	Relapsed/Refractory B-cell lymphoma	China				Request pre-IND meeting with the NMPA in the second half of 2024

*Notes:*

- Core Product.
- K3 is a biosimilar of adalimumab and therefore, is not required to conduct a Phase II clinical trial. For more details, please see “— Our Products and Product Candidates — Our Core Product and Clinical-Stage Product Candidates — 2. K3” in this section.

## BUSINESS

Our full industrialization capabilities encompass the entire lifecycle of protein drugs from drug discovery to clinical research and production. Our production is excellent in terms of protein expression, purification and stability as we have established a mature process development, amplification and quality control system. Our R&D and pilot manufacturing facility located in Beijing, China, supplies materials for our pre-clinical studies and early-stage clinical trials, and occupies approximately 27 acres of land with a total GFA of approximately 3,757 sq.m. in the R&D and production area.

We plan to commence construction of a new R&D and manufacturing facility in Beijing in the second quarter of 2023 and expect to complete construction of the new Beijing R&D and manufacturing facility in the first quarter of 2025. The new Beijing R&D and manufacturing facility is expected to have a total production capacity of eight million doses of Recombinant Varicella Vaccine a year and four million doses of Recombinant Rabies Vaccine a year.

In addition, we are building our manufacturing facilities in Zhuhai in two-phases to expand our production in preparation for the commercialization of our pipeline candidates. We commenced operations at our first-phase Zhuhai manufacturing facility and commenced construction of our second-phase Zhuhai manufacturing facility, which is expected to commence operations by the second quarter of 2023. Our second-phase Zhuhai manufacturing facilities, as planned and approved by Zhuhai Municipal Bureau of Natural Resources, occupy approximately 69,366 sq.m. of land with a total gross floor area (“GFA”) of approximately 120,000 sq.m. in the production area.

We assembled an experienced management team that manages our research and development, manufacturing and commercialization. Our experienced management team is led by a team of scientists who are deeply involved in the industry with a proven track record of obtaining strong endorsement from industry companies and financial institutions to accelerate our product development. Our founders have medical backgrounds, extensive experience in vaccine and antibody drug development and successfully developed the world’s first liquid formulation Meningococcal Group A and C Polysaccharide Conjugate Vaccine, the world’s first Meningococcal Group A and C and Haemophilus Influenzae Type b Conjugate Vaccine, China’s first Haemophilus Influenzae Type b Conjugate Vaccine with aluminum phosphate adjuvant, and China’s first Group ACYW<sub>135</sub> Meningococcal Polysaccharide Vaccine and a number of other blockbuster vaccines. In addition, our product development, clinical research, manufacturing, business development and capital operations are led by our experienced management team.

During the Track Record Period and up to the Latest Practicable Date, we did not generate any revenue as we had out-licensed most of our historically developed candidates before the Track Record Period, and by the Latest Practicable Date, we had not commercialized any of our product candidates. Since our inception in 2001 and prior to the Series A Financing in 2019, we primarily relied on (i) capital injections from our shareholders, primarily due to which our registered capital increased from RMB0.5 million in 2001 to RMB78.6 million in 2019, (ii) one-off or milestone payments of RMB34.8 million in total received from our historically developed products that had been transferred or out-licensed to third-parties prior to the Track Record Period, and (iii) revenue generated from the sales of the Immunoreagent Testing Kits to support our business operations, which amounted to RMB9.1 million from 2004 to 2018. For details of the revenue generated from the sales of the Immunoreagent Testing Kits, please see “Summary — Our Products and Product Candidates — Our Other Historically Developed Products” in this document. Our shareholders include well-known leading industry companies and financial institutions, such as Hangzhou Tigermed Consulting Co., Ltd., Livzon Pharmaceutical Group Inc., Beijing Science Sun, CCB Capital and CITIC Group, who provide us with financial support for clinical advancement and commercialization of our products. For details of the our registered capital and subsequent capital injections by our shareholders since our inception and prior to the Series A Financing, please see the section headed “History, Development and Corporate Structure” in this document.

## BUSINESS

### OUR COMPETITIVE STRENGTHS

We believe the following strengths have contributed to our success and differentiate us from our competitors.

**Innovative precision protein engineering platform, which empowers us to develop our recombinant vaccine and antibody product candidates with favorable efficiency, high purity and improved stability.**

Our founders have conducted more than 30 years of research in the field of human vaccines and immunology and are able to design improved human vaccines through the identification of protective antigens of pathogens. Our recombinant virus vaccines are developed based on our innovative antigen presentation technology and the concept of enhancing the immunogenicity of a target antigen, and designed to enhance immunogenicity while retaining the primary structure of the natural antigen. By using our innovative technology platforms, we are empowered to improve the efficiency, purity and stability of our recombinant vaccine and antibody product candidates. Leveraging the experience and technical know-how of our founders, we have internally developed five technology platforms:

- *Fabite<sup>®</sup> technology platform.* Fabite<sup>®</sup>, our next-generation bispecific antibody development technology platform of which we own intellectual property rights, has competitive advantages in the development of bispecific antibody products for the treatment of hematological malignancies. It can be used in a variety of immunotherapies based on the activation of T cells to kill cancer cells. Fabite<sup>®</sup> optimizes the purification process of bispecific antibodies, achieving high purity of monomers. At the same time, we have developed several types of liquid formulations for bispecific antibody solutions that can be stable for more than three years in storage conditions of 2-8°C.

We have developed three bispecific antibody injection product candidates, namely K193, K333 and K1932, using our Fabite<sup>®</sup> technology platform, the production process of which achieves consistent quality and high bispecific antibody yield and purity, featuring favorable safety profile and fewer side effects. In our research and development of K193, K333 and K1932, our Fabite<sup>®</sup> technology platform empowers us to develop bispecific antibodies with favorable efficiency, higher purity and strong affinity by recombinantly fusing a scFv molecule with a comparatively weak binding ability with a Fab fragment of a different specificity with strong binding ability, which ensures the tumor target protein is bound and then activates T cells to kill the malignant tumor cell.

- *Targeted recombinant antigen presentation technology platform.* Our targeted recombinant antigen presentation technology platform forms antigen expressing recombinant immune complexes (“**RICs**”), and directly presents viral membrane antigens to APCs. This technology platform greatly enhances the utilization efficiency of antigens and can induce high-titer specific antibodies and cellular immunity. Furthermore, the antigens expressed by our targeted recombinant antigen presentation technology platform contain multiple fragment crystallizable (“**Fc**”) regions, which is an improvement upon traditional fusion protein technology that only expresses antigens with a single Fc region.

## BUSINESS

---

We have developed three recombinant protein vaccine candidates, namely LZ901, Recombinant Varicella Vaccine and Recombinant Rabies Vaccines, using our targeted recombinant antigen presentation technology platform. In our research and development of these three recombinant protein vaccine candidates, our targeted recombinant antigen presentation technology platform empowers us to improve the utilization efficiency of antigens and induce high-titer specific antibodies and cellular immunity, by using a molecular design that includes a genetically engineered target viral membrane antigen containing multiple Fc regions that cross-link to Fc receptors connected to the cell surface of APCs.

- *Polysaccharide-protein conjugation technology platform.* Our polysaccharide-protein conjugation technology platform links bacteria polysaccharides to carrier proteins. This technology platform can be used to develop conjugate vaccines and antibody-drug conjugates. We utilized our polysaccharide-protein conjugation technology platform to develop three bacterial polysaccharide-protein conjugate vaccines, which have enhanced immunogenicity and stability, and are in easy to administer liquid dosage forms.

We have historically developed three commercialized vaccine products, namely (i) Haemophilus Influenzae Type b Conjugate Vaccine, (ii) Meningococcal Groups A and C and Haemophilus Influenzae Type b Conjugate Vaccine and (iii) Meningococcal Group A and C Polysaccharide Conjugate Vaccine, using our polysaccharide-protein conjugation technology platform. Our polysaccharide-protein conjugation technology platform empowered us to successfully develop three commercialized vaccine products with better solubility, stability, and targeting ability, through chemical conjugation of polysaccharide antigens to proteins.

- *Protein purification technology platform.* We have developed technology to purify complex recombinant proteins, such as humanized monoclonal antibodies and complex glycosylated proteins. We use a high-speed centrifugation or deep filtration workflow to isolate proteins in cell culture media, which is highly effective in removing cells and cellular debris from the soluble protein. In addition, we employ a series of chromatographic techniques during the protein purification process. First, we attach affinity protein tags to proteins of interest during the construct design and conduct affinity chromatography to purify and improve the solubility of the proteins of interest. Second, we perform an additional chromatographic step such as ion exchange chromatography or hydrophobic interaction chromatography to further increase purity. As a final polishing step, we perform size exclusion chromatography which results in high purity proteins of interest.

As proteins are highly heterogeneous and different techniques are used to purify different types of proteins, we have utilized our protein purification technology platform to increase the purity of LZ901, K3, K193 and K11 using various techniques. By using diverse techniques to purify different kinds of proteins, our protein purification technology platform empowers us to characterize the function, structure and interactions of recombinant proteins in our development of LZ901, K3, K193 and K11.

## BUSINESS

- *Protein stability technology platform.* We have developed a variety of highly stable liquid formulations for human monoclonal antibodies, bispecific antibodies and recombinant protein vaccines. Our in-solution protein-stabilizers offer longer stability by extending the shelf life of antibodies, antigens and other recombinant proteins at working strength concentrations. In addition, they offer retained activity of most monoclonal antibodies or bispecific antibodies in solution for up to five years. Our liquid protein stabilizers also offer a variety of options for immune-assay development. We offer multiple formulations with different stabilizing mechanisms to satisfy different antibody or antigen requirements. Our formulations are protein-free that are able to satisfy the background requirements for human drugs or specific assay systems and stabilize enzymes and control materials in immunoassays.

Our protein stability technology platform empowers us to improve the efficacy and stability of our human vaccine candidates, monoclonal antibody product candidates and bispecific antibody product candidates in various environmental conditions through in-solution protein-stabilizers developed by ourselves. All of our human vaccine candidates, monoclonal antibody product candidates and bispecific antibody product candidates utilize protein-stabilizers developed using our protein stability technology platform to enhance stability.

- *Mammalian expression technology platform.* We introduced the GS Xceed™ expression system from Lonza in 2012. The system covers a wide range of technologies and processes such as host cells, expression vectors, and optimized culture media, and provides high-quality, high-efficiency and high-capacity production services for a variety of biopharmaceuticals.

Our mammalian expression technology platform empowers us to optimize the protein expression in our development of bispecific antibody product candidates and recombinant vaccine product candidates by rapidly and reliably generating high-producing cell lines. We have increased the purity and expression levels of LZ901 and K193 using our mammalian expression technology platform.

### **LZ901, our Core Product, is a herpes zoster vaccine in China seeking global filing with improved immunogenicity, and high safety and stability due to its specific structure**

We are developing our recombinant herpes zoster vaccine candidate, LZ901, featuring a specific molecular structure and mechanism, improved immunogenicity, and high safety and stability profile. LZ901 has a tetrameric molecular structure to prevent shingles caused by VZV for adults aged 50 years and older. Its molecular structure has double the Fc regions for APCs to bind to compared to naturally occurring VZV antigen. LZ901 exhibits improved immunogenicity as demonstrated by the higher geometric mean titer ("GMT") level of antibodies compared against naturally occurring VZV antigen in pre-clinical studies, while inducing strong specific humoral and cellular immunity.

In a BALB/c mice study, LZ901 induced a stronger cellular immune response with higher expression of multiple types of immune cell activating biomarkers compared to Shingrix®, and the level of humoral immune response of LZ901 was non-inferior to that of Shingrix®. Compared to Shingrix®, mice immunized with LZ901 were observed to have significantly higher magnitude of expression of activation biomarkers and higher proportion of helper (CD4+) T cells and cytotoxic (CD8+) T cells expressing multiple biomarkers, which indicate LZ901 provides strong protection against shingles.

## BUSINESS

In the Phase I clinical trial for LZ901 in China, LZ901 was able to stimulate the rapid production of higher levels of anti-VZV antibodies after the first vaccination and no significant difference in the levels of anti-VZV antibodies after the full course of vaccination compared to Shingrix<sup>®</sup> based on humoral response data. In addition, LZ901 was able to stimulate helper (CD4+) T cells to express significantly higher levels of multiple types of immune cell activating biomarkers and cytotoxic (CD8+) T cells to express slightly higher levels of multiple types of immune cell activating biomarkers compared to Shingrix<sup>®</sup> based on cellular immune response data, indicating that the immunogenicity of LZ901 is not weaker than Shingrix<sup>®</sup> and LZ901 provides strong protection against shingles.

In addition, we developed a liquid formulation with improved stability to reduce the rate of degradation caused by storage in elevated temperatures. Our recombinant herpes zoster vaccine candidate, LZ901, adopts a highly stable liquid formulation, which allows for easy storage and transportation. It is stable for two weeks at 37°C, 12 weeks at 25°C and 24 months at 2-8°C. Furthermore, the side effects from the administration of LZ901 are minimal as the liquid formulation only contains an aluminum hydroxide adjuvant and is free of immune stimulants, which reduce the likelihood of serious adverse reactions at the injection site.

LZ901 is a herpes zoster vaccine in China seeking global filing, which demonstrates our outstanding R&D and product development capabilities. We have initiated a Phase I clinical trial in January 2022 and completed the Phase I clinical trial and initiated a Phase II clinical trial for LZ901 in China in April 2022. We expect to complete the Phase II clinical trial for LZ901 in China in the second quarter of 2023, initiate a multi-center, randomized, double-blind, placebo-controlled Phase III clinical trial comparing LZ901 against Shingrix<sup>®</sup> in the second quarter of 2023, and file the BLA in the third quarter of 2024 for LZ901 to the NMPA. In addition, we have received IND approval from the FDA in July 2022 for LZ901 and initiated a Phase I clinical trial in the U.S. in February 2023. We plan to complete the Phase I clinical trial and initiate a Phase II clinical trial in the first quarter of 2024. Furthermore, we expect to complete the Phase II clinical trial in the second quarter of 2025, initiate a Phase III clinical trial in the fourth quarter of 2025, and complete the Phase III clinical trial in the second quarter of 2027.

### **Strong pipeline of vaccine, autoimmune disease and hematological malignancy product candidates**

We have a strong pipeline of vaccine, autoimmune disease and hematological malignancy product candidates developed based on our Fabite<sup>®</sup> bispecific antibody development, targeted recombinant antigen presentation, polysaccharide-protein conjugation, protein purification, protein stability and mammalian expression technology platforms. As of the Latest Practicable Date, in addition to LZ901, we had another two product candidates under clinical development stage in China, including K3 and K193, and four pre-clinical stage product candidates, including Recombinant Varicella Vaccine, Recombinant Rabies Vaccine, K333 and K1932.

**K3**, our independently developed recombinant human anti-TNF- $\alpha$  monoclonal antibody injection product candidate, is a biosimilar of adalimumab and mainly used for the treatment of various autoimmune diseases, such as rheumatoid arthritis, ankylosing spondylitis and plaque psoriasis. The molecular design of K3 maximizes the safety of the antibody when used in the human body.

**K193**, our independently developed bispecific antibody injection (CD19-CD3) product candidate for the treatment of B cell leukemia and lymphoma, is a bispecific antibody that binds to human CD19 and CD3. K193 is a bispecific antibody against CD19/CD3 with an asymmetric structure. K193's



## BUSINESS

molecular structure has good thermal stability and is less susceptible to polymerization, which ensures the stability and binding ability of K193. In addition, K193 displayed high *in vivo* and *in vitro* anti-tumor activity in pre-clinical studies. The liquid preparation formulation and stable molecular structure of K193 provide a guarantee for convenient and safe clinical administration. K193 is indicated for the treatment of B cell leukemia and lymphoma.

**Recombinant Varicella Vaccine**, our independently developed recombinant varicella vaccine candidate, is an adjusted dosage of LZ901 for the prevention of chickenpox caused by VZV. Recombinant Varicella Vaccine prevents childhood chickenpox and has a wide range of applications. It is expected to partially replace live attenuated vaccines of the OKA strain of VZV as an alternative vaccination method, reduce the chance of children suffering from VZV infection, and reduce the risk of developing shingles in adults. Unlike other marketed live-attenuated vaccines that contain weakened forms of VZV which may lay dormant in the patient and reactivate causing shingles, Recombinant Varicella Vaccine does not contain VZV and does not carry the risk of developing into shingles.

**Recombinant Rabies Vaccine**, our proprietary recombinant rabies glycoprotein G (“RVG”) subunit vaccine candidate for the prevention of rabies in humans, is a prophylactic that provides protection against rabies prior to exposure and simplifies post-exposure treatment for rabies. In addition, Recombinant Rabies Vaccine has high purity and is suitable for immunizing both children and adults.

**K333**, our proprietary bispecific antibody injection (CD33-CD3) product candidate for the treatment of myeloid leukemia, is a bispecific antibody that binds to human CD33 and CD3.

**K1932**, our proprietary bispecific antibody injection (CD19-CD3) product candidate for the treatment of B cell lymphoma, is based on the molecular structure of K193. Compared with K193, K1932 has a much longer half-life in the human body. Patients administered K1932 following the first stage administration of K193 have lower risk of experiencing a cytokine storm, which allows for dose escalation. After the induction period of K193, K1932 can be administered on a weekly basis, which greatly improves the medication experience of B cell lymphoma patients.

### **Vaccine and antibody production facilities with commercial-scale manufacturing capacity and professional quality management system**

We have assembled a manufacturing team with extensive industry experience and initiated a two-phase construction plan to further expand our production capacity. We commenced operations at our first-phase manufacturing facility in Zhuhai. Currently, our existing Zhuhai manufacturing facility occupies a total GFA of approximately 8,000 sq.m. and is equipped with several 500L stainless steel bioreactors, purification equipment and a high-speed vial filling linkage line.

We commenced construction of the second-phase manufacturing facility in Zhuhai, which is expected to be completed and commence operations by the second quarter of 2023. Our second-phase Zhuhai manufacturing facility will occupy approximately 69,366 sq.m. of land with a total GFA of approximately 120,000 sq.m. in the production area and will be equipped with multiple 2.5-ton stainless steel bioreactors and two antibody biopharmaceutical production workshops. Our first-phase Zhuhai manufacturing facility and the second-phase Zhuhai facility will have in total, an annual capacity to manufacture 20 million doses of LZ901, three million doses of K193 and two million doses of K3. For details of the manufacturing capacity of each existing and planned manufacturing facility, please see “— Manufacturing” in this section.

## BUSINESS

The construction standards of the above-mentioned manufacturing facilities in Zhuhai are designed according to international standards and are expected to meet the GMP requirements of the NMPA, the EMA, the FDA and related ICH guidelines.

In addition, we have an experienced quality management team with professional quality management system. Ms. ZHANG Yanping, our co-founder and deputy general manager, has over 36 years of experience in the biopharmaceutical industry with extensive experience in quality control, quality assurance, and preclinical safety studies of biological products. All of our Zhuhai quality management team members have received professional trainings in regulations, GMP standards and quality control analysis methods. We have implemented quality management systems that conform to national regulations and industry guidelines, and adopted standard operating procedures.

### **Experienced scientific and management team backed by strong investor support**

We are led by an experienced scientific and management team with diverse backgrounds and skillsets.

Mr. KONG Jian, our co-founder, executive Director, general manager and chief scientist, has over 33 years of biopharmaceutical experience. Prior to starting our company and since 1988, he worked at National Vaccine and Serum Institute of the Ministry of Health. He worked as the deputy director of the Science and Technology Development Division (科技開發處副處長), and was later promoted as the director of the Science and Technology Development Division (科技開發處處長) and manager of the immunodiagnostic laboratory (免疫診斷研究室主任) of the National Vaccine and Serum Institute of the Ministry of Health in October 2000, and was primarily responsible for scientific research of biological products. Mr. KONG and his colleagues have developed five vaccines, including three types of bacterial polysaccharide conjugate vaccines and two multi-valent meningococcal polysaccharide vaccines. In addition, Mr. KONG has developed vaccines and monoclonal antibodies under clinical investigation, including a recombinant herpes zoster vaccine, two monoclonal antibodies, a bispecific antibody and an inactivated enterovirus 71 vaccine.

Ms. JIANG Xianmin, our co-founder, Chief Medical Officer and deputy general manager, has over 36 years of experience in biopharmaceutical research and development. Prior to starting our company and since 1984, she worked at National Vaccine and Serum Institute of the Ministry of Health. Ms. JIANG leads the development of our Meningococcal Group A and C Polysaccharide Conjugate Vaccine, Meningococcal Group A and C and Haemophilus Influenzae Type b Conjugate Vaccine, Group ACYW<sub>135</sub> Meningococcal Polysaccharide Vaccine, typhoid polysaccharide vaccine and tetanus toxoid vaccine.

Ms. ZHANG Yanping, our co-founder and deputy general manager, has over 36 years of experience in the biopharmaceutical industry. Prior to starting our company and since 1985, she previously worked at National Vaccine and Serum Institute. Ms. ZHANG has extensive experience in quality control, quality assurance, and preclinical safety studies of biological products. Ms. ZHANG led the team to obtain GMP certification for Meningococcal Group A and C Polysaccharide Conjugate Vaccine, and Group ACYW<sub>135</sub> Meningococcal Polysaccharide Vaccine.

Mr. ZHANG Hui, our Chief Financial Officer and head of global capital markets, has over 20 years of financial and investment experience, including at DBS Bank Ltd., BNP Paribas Capital (Asia Pacific) Limited, Lehman Brothers Securities Asia Limited, Deutsche Bank, Samsung Securities (Asia) Limited and Guosen Securities (HK) Capital Company Limited.

## BUSINESS

We have strong support from prominent shareholders, consisting of well-known industry companies and financial institutions, such as Hangzhou Tigermed Consulting Co., Ltd., Livzon Pharmaceutical Group Inc., Beijing Science Sun, CCB Capital and CITIC Group, endowing us with industry expertise and crucial connections to the biopharmaceutical industry.

### OUR STRATEGIES

Our goal is to utilize state-of-the-art technologies to develop and produce various biological products that meet clinical needs, and focus on the research and development of vaccines and therapeutic bispecific antibodies for human disease prevention, control and treatment. We plan to implement the following strategies to achieve this goal:

#### **Actively promote the clinical development of our pipeline candidates**

We intend to actively promote the clinical development of our pipeline candidates, namely LZ901, K3 and K193.

##### ***LZ901***

With the safety and efficacy results observed in pre-clinical studies to date of LZ901 for the prevention of herpes zoster, we intend to expedite clinical development of LZ901 in China and globally. We have initiated a Phase I clinical trial in January 2022 and completed the Phase I clinical trial and initiated a Phase II clinical trial for LZ901 in China in April 2022. We expect to complete the Phase II clinical trial for LZ901 in China in the second quarter of 2023, initiate a multi-center, randomized, double-blind, placebo-controlled Phase III clinical trial comparing LZ901 against Shingrix<sup>®</sup> in the second quarter of 2023, and file the BLA in the third quarter of 2024 for LZ901 to the NMPA. In addition, we have received IND approval from the FDA in July 2022 for LZ901 and initiated a Phase I clinical trial in the U.S. in February 2023. We plan to complete the Phase I clinical trial and initiate a Phase II clinical trial in the first quarter of 2024. Furthermore, we expect to complete the Phase II clinical trial in the second quarter of 2025, initiate a Phase III clinical trial in the fourth quarter of 2025, and complete the Phase III clinical trial in the second quarter of 2027.

##### ***K3***

We initiated our Phase I clinical trial in September 2018, and have completed our Phase I clinical trial in China for K3 in December 2019, a biosimilar of adalimumab, for the treatment of various autoimmune diseases, such as rheumatoid arthritis, ankylosing spondylitis and plaque psoriasis, which displayed pharmacokinetics consistent with adalimumab. We plan to initiate a Phase III clinical trial for K3 in China in the second quarter of 2023, complete the Phase III clinical trial in the second quarter of 2024 and submit a BLA to the NMPA in the fourth quarter of 2024. We expect K3 to receive BLA approval from the NMPA in 2025.

We are currently constructing and plan to complete setting up our production line for K3 in the second quarter of 2023, which will be used to produce K3 required for our Phase III clinical trial.

## BUSINESS

---

### **K193**

Our bispecific antibody injection (CD19-CD3) for the treatment of B cell leukemia and lymphoma, K193, displayed high *in vivo* and *in vitro* anti-tumor activity in pre-clinical studies. In December 2019, we initiated a Phase I clinical trial of K193 in China and expect to complete the Phase I clinical trial in the second quarter of 2023. We plan to initiate a Phase II clinical trial for K193 in the first quarter of 2024 and complete a Phase II clinical trial of K193 in China in the fourth quarter of 2027 due to difficulty finding suitable subjects, as K193 is a later-line therapy which requires enrolling patients who have failed other therapies, and difficulty enrolling subjects willing to commit to 28 consecutive days of hospitalization and treatment of K193. We plan to apply for a conditional BLA approval from the NMPA in 2027.

### **Rapidly advance the development of our other pre-clinical product candidates**

We intend to rapidly advance the development of our other pipeline candidates in the pre-clinical stage, namely Recombinant Varicella Vaccine, Recombinant Rabies Vaccine, K333 and K1932.

Currently, we have completed pre-clinical studies for Recombinant Varicella Vaccine, and submitted an IND application for Recombinant Varicella Vaccine to the NMPA in June 2022. For Recombinant Varicella Vaccine, we plan to initiate a Phase I clinical trial in the third quarter of 2023, and complete a Phase I clinical trial in the second quarter of 2024. We plan to initiate a Phase II clinical trial in the third quarter of 2024, complete the Phase II clinical trial in the third quarter of 2025, initiate a Phase III clinical trial in the fourth quarter of 2025 in China, and complete the Phase III clinical trial in the second quarter of 2027.

Recombinant Rabies Vaccine is also in the pre-clinical stage, and we expect to request a pre-IND meeting with the NMPA as early as in the fourth quarter of 2023. We initiated pre-clinical studies for Recombinant Rabies Vaccine in the second quarter of 2020, and we expect to complete the pre-clinical studies in the fourth quarter of 2023. For Recombinant Rabies Vaccine, we plan to initiate a Phase I clinical trial in the second quarter of 2024 and expect to complete the Phase I clinical trial in the third quarter of 2024 in China. We plan to initiate a Phase II clinical trial for Recombinant Rabies Vaccine in the third quarter of 2024, and complete the Phase II clinical trial in the first quarter of 2025. Furthermore, we expect to initiate the Phase III clinical trial in the first quarter of 2025 and complete the Phase III clinical trial in the second quarter of 2026 in China.

For each of K333 and K1932, we expect to request a pre-IND meeting with the NMPA in the second half of 2024.

### **Expand production capacity to meet growing market demand**

We plan to continue to advance our existing product development and production scale-up processes. In particular, we are continually optimizing our bioreactor production process to ensure robust manufacturing. In addition, we are exploring CMC development for different liquid formulations to improve patient experience and convenience when administering our drugs. We also plan to develop our culture expansion processes as we prepare to transfer and scale-up manufacturing at our new Zhuhai manufacturing facilities.

## BUSINESS

---

We plan to continue to promote the construction of our second-phase Zhuhai manufacturing facility to expand our production in preparation for the commercialization of our pipeline candidates. We commenced operations at our first-phase Zhuhai manufacturing facility and commenced construction of our second-phase manufacturing facility, which is expected to commence operations by the second quarter of 2023. Our second-phase Zhuhai manufacturing facilities, as planned and approved by the local government agency, occupy approximately 69,366 sq.m. of land with a total GFA of approximately 120,000 sq.m. in the production area.

### **Lay out strategic plans to promote commercialization at home and abroad**

We formulate targeted commercialization strategies for each of our product candidates in China. We will assemble an in-house sales team for the commercialization of K193 and collaborate with contract sales organizations (“CSOs”) for the commercialization of our other product candidates. In China, we plan to adopt a two-pronged approach for sales and marketing activities. Our commercialization team will cover Beijing, Chengdu, Guangzhou, Shanghai, Tianjin, Wuhan, Xi’an, Zhengzhou and other provincial capitals in China. We plan to engage CSOs to cover major provinces and municipalities in China, including the same cities as our commercialization team and neighboring second- and third-tier cities. We will select CSOs based on their industry experience and expertise, product sales experience, business channels, cold-chain transportation capabilities, financial condition, record of compliance with regulatory agencies and management capabilities. In addition, we will adopt commercialization strategies for LZ901 and K3, including favorable and competitive pricing in the short- to medium-term. LZ901 is expected to be priced at a retail price of approximately RMB500 to RMB800 an injection, with a total of two injections per treatment and does not require a third booster shot, which is more affordable compared to the retail price of the other commercially available herpes zoster vaccines in China, with Shingrix<sup>®</sup> priced at RMB1,600 an injection with a total of two injections per treatment. According to Frost & Sullivan, there is no booster shot requirement for other peer products of herpes zoster vaccine. K3 is expected to be priced at a retail price of approximately RMB400 to RMB500 a dose, which is more affordable compared to the retail price of the other commercially available biosimilars of adalimumab in China, which are priced at approximately RMB700 to RMB1,200 a dose.

For overseas markets, we will formulate international commercialization strategies according to market conditions to quickly promote our products to benefit patients worldwide. In particular, we plan to seek collaboration opportunities with global partners to leverage their established sales expertise. We will also focus on our layout strategy of the countries under China’s Belt and Road Initiative, with a focus on Southeast Asian countries including Singapore and Indonesia, and accelerate our products’ entry into relevant countries through seeking collaborations with local partners, which should have in-depth market expertise and are familiar with regulatory requirements of the relevant jurisdiction, after the successful commercialization of LZ901 in China and realize commercial opportunities with the support of government policies.

In order to increase adoption and acceptance of our product candidates by healthcare professionals and ensure end-patient compliance, we plan to promote awareness of our product candidates among patients, physicians, hospitals, CDCs and KOLs through academic promotion, including on-site trainings, academic conferences and events, and regular communications, visits and follow-ups on the safety and effectiveness of our product candidates.

## BUSINESS

### Expand our product pipeline with collaboration

We will actively explore collaboration opportunities in the development, manufacturing and sales of our products. Through the active deployment of our overseas business development capabilities, we plan to introduce a diversified and advanced product pipeline to meet major unmet medical needs. We will seek collaboration opportunities domestically and worldwide and selectively enter into strategic partnerships or licensing transactions to combine our deep research and development experience with global resources to advance our product development and facilitate the commercialization of our product candidates. We will select collaboration partners based on their research and development capability, vaccine and therapeutic biologics development experience, management and research team, business scale and reputation. We believe building a global collaboration network provides us with global endorsement and enhances our brand recognition. Our collaborations will also lead to better access to leading drugs and candidates and potentially offer an extra funding source to advance our product development and facilitate the commercialization of our product candidates.

### OUR PRODUCTS AND PRODUCT CANDIDATES

#### Overview

We are a biotechnology company committed to developing innovative human vaccines and therapeutic biologics for the prevention and control of infectious diseases and addressing the medical needs in the treatment of cancer and autoimmune diseases. We have built our product pipeline by employing our Fabite<sup>®</sup> technology platform, our mammalian expression technology platform and leveraging our in-house biologics manufacturing infrastructure and capabilities. As of the Latest Practicable Date, our product pipeline consisted of three clinical-stage product candidates, including our Core Product, LZ901, and four pre-clinical-stage product candidates.

The following table summarizes our product portfolio:

PRODUCT TYPE	PRODUCT PIPELINE	MECHANISM/TARGET	INDICATIONS	PRE-CLINICAL	CLINICAL TRIALS			Expected Timetable
					Phase I	Phase II	Phase III	
Recombinant Vaccine	LZ901 <sup>(1)</sup>	VZV gE	Herpes zoster			China		Complete Phase II in Q2 2023 and expected to initiate Phase III in Q2 2023
			Herpes zoster	US				Complete Phase I in Q1 2024 and expected to initiate Phase II in Q1 2024
Monoclonal Antibody	K3 <sup>(2)</sup>	TNF- $\alpha$	Rheumatoid arthritis, ankylosing spondylitis, plaque psoriasis			China		Initiate Phase III in Q2 2023 and expected to submit a BLA in Q4 2024
Bispecific Antibody	K193	CD3/CD19	Relapsed/Refractory B-cell lymphoma/leukemia			China		Complete Phase I in Q2 2023 and expected to initiate Phase II in Q1 2024
Recombinant Vaccine	Recombinant Varicella Vaccine	VZV gE	Varicella			China		Initiate Phase I in Q3 2023 and expected to initiate Phase II in Q3 2024
Recombinant Vaccine	Recombinant Rabies Vaccine	RABV-G	Rabies			China		Request pre-IND meeting with the NMPA in Q4 2023
Bispecific Antibody	K333	CD33/CD3	Myeloid leukemia			China		Request pre-IND meeting with the NMPA in the second half of 2024
Bispecific Antibody	K1932	CD19/CD3	Relapsed/Refractory B-cell lymphoma			China		Request pre-IND meeting with the NMPA in the second half of 2024

#### Notes:

- (1) Core Product.
- (2) K3 is a biosimilar of adalimumab and therefore, is not required to conduct a Phase II clinical trial. For more details, please see “Our Products and Product Candidates — Our Core Product and Clinical-Stage Product Candidates — 2. K3” in this section.

## BUSINESS

### Our Core Product and Clinical-Stage Product Candidates

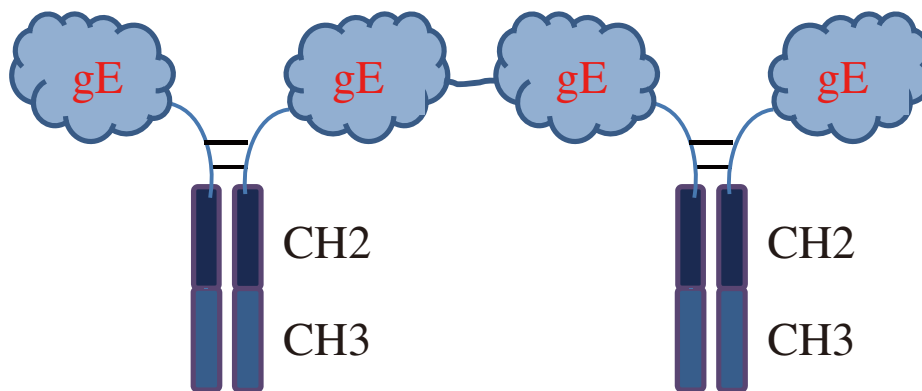
Our clinical-stage product candidates comprise one vaccine candidate, LZ901, our Core Product, and two antibody injection product candidates, including K3 and K193.

#### 1. LZ901

##### *Overview*

LZ901, our Core Product and independently developed recombinant herpes zoster vaccine candidate, has a tetrameric molecular structure to prevent shingles caused by VZV for adults aged 50 years and older. LZ901 prevents the occurrence of herpes zoster and related complications caused by herpes zoster, including PHN. LZ901 is designed on the basis of making full use of the mechanism of the human immune system for processing foreign antigens. Employing the mammalian expression technology platform, we developed LZ901 based on the VZV glycoprotein E (“gE”)-fragment crystallizable (“Fc”) region. VZV gE is an antigen that is abundantly expressed on the surface of VZV, and the Fc region is the tail region of immunoglobulin G (“IgG”), a human antibody, that interacts with cell surface receptors. LZ901 is a recombinant tetramer fusion protein consisting of VZV gEs expressed on CHO cells bound to two Fc fragment of IgG. The carboxyl end of the VZV gE extracellular domain is connected to the Fc fragment of IgG1, and based on the characteristic of VZV gE to form covalent dimers, a multi-step liquid chromatography process is used to obtain high-purity recombinant VZV gE tetramer-Fc fusion proteins containing two Fcs by purification from protein solutions with complex compositions.

The tetrameric molecular structure of LZ901 is illustrated below:



## BUSINESS

We commenced the development of LZ901 in March 2018. LZ901 has demonstrated high immunogenicity, efficacy and safety profile in pre-clinical studies, while inducing specific humoral and cellular immunity. An *in vitro* VZV plaque reduction neutralization test demonstrated the ability of the Oka strain to infect MRC-5 cells could be neutralized by the serum of mice, rats and cynomolgus monkeys immunized with the LZ901 aluminum adjuvant vaccine, which indicates that LZ901 can also stimulate the body’s immune system to produce neutralizing antibodies. Mouse anti-VZV gE monoclonal antibody 2G9 also fully demonstrated the ability to block the Oka strain virus from infecting MRC-5 cells. The result of 2G9 monoclonal antibody neutralizing the Oka strain virus indicates 2G9 monoclonal antibody alone could completely neutralize the ability of the Oka strain to infect MRC-5, and this blocking did not require the participation of complements. By using 2G9 monoclonal antibody and WHO standard serum (W1044, varicella-zoster immunoglobulin), the detection of neutralizing antibody levels in the serum of mice, rats and cynomolgus monkeys after immunization with LZ901 by ELISA showed high contents/titers of neutralizing antibodies of in the serum of immunized animals, demonstrating that LZ901 can stimulate the body’s immune system to produce anti-VZV neutralizing antibodies, and LZ901 can be used to prevent the onset of herpes zoster. We plan to observe whether LZ901 will prevent PHN in future clinical research.

We have initiated a Phase I clinical trial in January 2022 and completed the Phase I clinical trial and initiated a Phase II clinical trial for LZ901 in China in April 2022. We expect to complete the Phase II clinical trial for LZ901 in China in the second quarter of 2023, initiate a multi-center, randomized, double-blind, placebo-controlled Phase III clinical trial comparing LZ901 against Shingrix® in the second quarter of 2023, and file the BLA in the third quarter of 2024 for LZ901 to the NMPA. In addition, we have received IND approval from the FDA in July 2022 for LZ901 and initiated a Phase I clinical trial in the U.S. in February 2023. We plan to complete the Phase I clinical trial and initiate a Phase II clinical trial in the first quarter of 2024. Furthermore, we expect to complete the Phase II clinical trial in the second quarter of 2025, initiate a Phase III clinical trial in the fourth quarter of 2025, and complete the Phase III clinical trial in the second quarter of 2027.

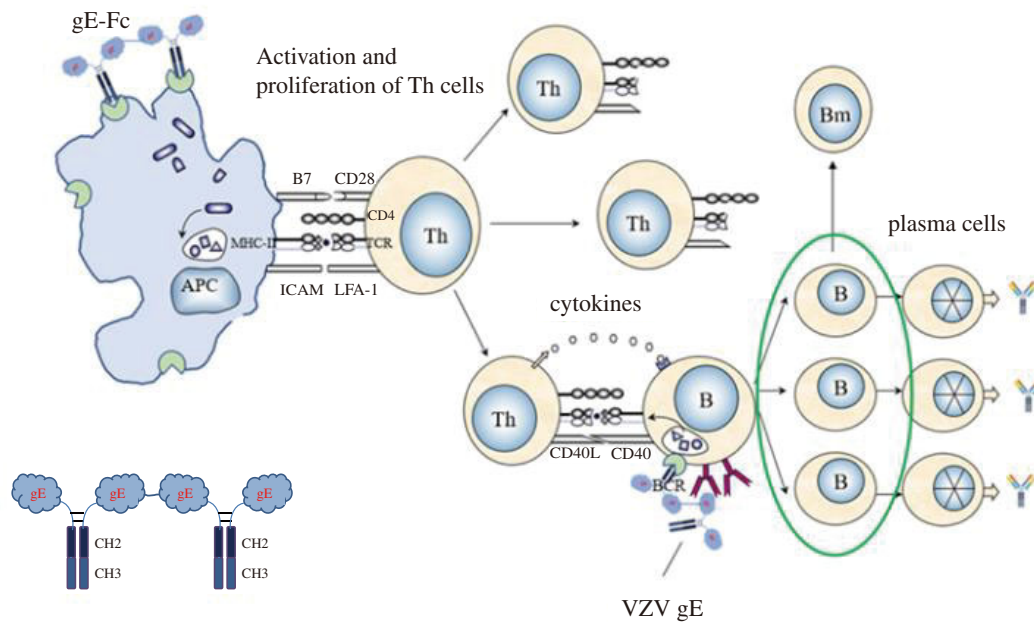
### *Mechanism of Action*

LZ901 is designed on the basis of making full use of the mechanism of using the human immune system to process foreign antigens. LZ901 is a recombinant tetramer fusion protein consisting of VZV gEs bound to two Fc to mimic the immune complex formed from the binding of VZV antigens to antibodies when VZV invades the body. Fc receptors on the surface of APCs bind to the two Fc regions of the LZ901 antigen, which is then internalized via either phagocytosis by macrophages and dendritic cells or receptor-mediated endocytosis by B cells, and degraded into peptide fragments. The APCs then display these peptide fragments co-presented with a class II major histocompatibility complex (“MHC”) molecule or cross-presented with a class I MHC molecule on the surface of their cell membranes. Helper (CD4+) T cells recognize and interact with the LZ901 antigen-class II MHC molecule complex or LZ901 antigen-class I MHC molecule complex on the membrane of the APC. Such interaction induces a Th2-based humoral immune response and activates cytotoxic (CD8+) T cells to kill cells infected with VZV through apoptosis. In addition to presenting LZ901 antigens to helper (CD4+) T cells, B cells also produce neutralizing antibodies to neutralize VZV and form memory responses to provide long-term protection against VZV.



## BUSINESS

The following diagram illustrates the mechanism of action of LZ901:



Although both LZ901 and Shingrix<sup>®</sup> utilize recombinant protein technologies, the mechanics of LZ901 is different compared to Shingrix<sup>®</sup> and both have different subdivision technology routes and methods of presenting antigens. Shingrix<sup>®</sup> uses an innovative adjuvant technology, while LZ901 has an innovative tetrameric molecular structure. Shingrix<sup>®</sup> has the same molecular structure as VZV gE which relies on the addition of adjuvants such as immune stimulant QS21 to enhance the immunogenicity of gE protein because the extracellular region of the gE protein relies on the addition of an adjuvant with a strong immune stimulant to stimulate the gE protein to produce stronger immunogenicity. LZ901 has a tetrameric molecular structure consisting of VZV gEs bound to two Fc to mimic the immune complex formed from the binding of VZV antigens to antibodies when VZV invades the body. As LZ901 exhibited improved immunogenicity compared to naturally occurring VZV gE in pre-clinical studies, LZ901 uses a safer liquid formulation that only contains an aluminum hydroxide adjuvant and is free of immune stimulants, which reduces the likelihood of serious adverse reactions at the injection site.

### *Market Opportunities and Competition*

Shingles is becoming more prevalent in China due to a growing aging population that is more susceptible to shingles. According to Frost & Sullivan, the number of new cases of herpes zoster in people aged 50 years old and above in China increased from 2.5 million in 2015 to 3.9 million in 2021 at a CAGR of 7.8%. It is expected to increase to 4.9 million in 2025 at a CAGR of 6.0% from 2021 to 2025, and further increase to 6.0 million in 2030 at a CAGR of 4.2% from 2025 to 2030. As the public awareness of herpes zoster continues to grow and the number of available herpes zoster vaccines increases, the herpes zoster vaccine market in China is expected to grow significantly. Among global markets, the herpes zoster vaccination rate in the U.S. is the highest due to the earlier availability of the vaccine in the U.S., favorable reimbursement policies, high awareness of herpes zoster. The herpes zoster vaccination rate in China is relatively low compared

## BUSINESS

to the rate of U.S. Given the large patient population in China, there is great potential for the herpes zoster vaccine market to grow in the future. The number of new cases of herpes zoster in people aged 50 years old and above in China increased from 2.5 million in 2015 to 3.9 million in 2021 at a CAGR of 7.8%. It is expected to increase to 4.9 million in 2025 at a CAGR of 6.0% from 2021 to 2025, and further increase to 6.0 million in 2030 at a CAGR of 4.2% from 2025 to 2030. The vaccination rate of herpes zoster vaccine among people aged 50 years and older is expected to reach 1.9% in 2025 and 12.6% in 2030 in China. For details of the key assumptions driving the forecasted growth in herpes zoster vaccination rate in China, please see “Industry Overview — Herpes Zoster Vaccine Market — Overview” in this document. In comparison, the number of new cases of herpes zoster in people aged 50 years old and above in the U.S. is expected to grow at a slower rate compared to China. The number of new cases of herpes zoster in the U.S. increased from 1.0 million in 2015 to 1.1 million in 2021 at a CAGR of 2.4%, and is expected to increase to 1.2 million in 2025 at a CAGR of 1.8% from 2021 to 2025, and further increase to 1.3 million in 2030 at a CAGR of 1.5% from 2025 to 2030.

According to Frost & Sullivan, the recurrence rate of shingles for unvaccinated patients is approximately 4% to 6%, with the recurrence rate of shingles increasing with age. After receiving herpes zoster vaccination, the risk of recurrence of shingles is reduced by approximately 50% in vaccinated patients. For Shingrix<sup>®</sup>, two doses are recommend, and for Zostavax<sup>®</sup>, one dose is recommended. Currently, no booster is recommended for either Shingrix<sup>®</sup> or Zostavax<sup>®</sup> by the CDC, other clinical guidelines or medical organizations. Due to the low effectiveness of Zostavax<sup>®</sup> as a herpes zoster prophylaxis and its weakened market competitiveness, it has discontinued production in the U.S. LZ901 does not face the same risks of discontinued commercialization as Zostavax<sup>®</sup> because LZ901 is a recombinant vaccine while Zostavax<sup>®</sup> is a live attenuated vaccine and the cellular immune response and humoral response data from the Phase I clinical trial of LZ901 indicate the immunogenicity of LZ901 is not weaker than Shingrix<sup>®</sup>.

In 2021, the vaccination rate of herpes zoster, among those aged 50 years and older, was 0.1% in China, 5.2% in the EU and 26.8% in the U.S., according to Frost & Sullivan. According to 2022 China Herpes Zoster Vaccine Expert Consensus (帶狀皰疹疫苗預防接種專家共識), herpes zoster vaccine is recommended in order to prevent herpes zoster.<sup>(1)</sup> PRC government guidelines on herpes zoster vaccination recommend that individuals aged 50 years and older (regardless of whether the individual has a history of varicella infection or varicella vaccination) receive herpes zoster vaccine. The complete immunization program consists of two doses, and the second dose is administered two to six months after the first dose of herpes zoster vaccination. Individuals who are or may have immunodeficiency or immunosuppression due to disease or treatment are recommended to receive the second dose within one to two months after the first dose.

The U.S. CDC recommends that adults aged 50 years and older receive herpes zoster vaccine as a prevention regimen for shingles. The U.S. CDC recommends Shingrix<sup>®</sup> as the primary vaccine for shingles, and immunocompetent adults aged 50 years and older should obtain two doses of

*Note:*

- (1) “2022 China Herpes Zoster Vaccine Expert Consensus”: Dermatology Branch of China Medical Care International Exchange Promotion Association, Senile Dermatology Research Center of Chinese Medical Association Dermatology Branch. Herpes Zoster Vaccine Expert Consensus. Medical Journal, 2022, 102(8): 538-543. DOI: 10.3760/cma.j.cn112137-20210828-01958.

## BUSINESS

Shingrix<sup>®</sup> two to six months apart. In the EU, Shingrix<sup>®</sup> is indicated for both shingles and PHN, a common complication of shingles. However, having PHN listed as an indication does not imply that Shingrix<sup>®</sup> has any advantages over peer products that do not list PHN as a separate indication, because any vaccine that prevents herpes zoster will by nature prevent PHN, regardless of whether PHN is listed as a separate indication or not. The Background Paper on Herpes Zoster Vaccine authored by SAGE Working Group of WHO mentions recommendations for herpes zoster vaccine administration in Europe and Asia, including Austria and Sweden for individuals aged 50 years and older, the U.S., Canada, Greece, Korea and Thailand for individuals aged 60 years and older, Australia for individuals aged between 60 to 79 years old and the U.K. for individuals aged between 70 to 79 years old.

The vaccination rate in people age 50 or above in China increased from 0.04% in 2020 to approximately 0.13% in 2022 according to Frost & Sullivan. According to Frost & Sullivan, in terms of sales revenue, the herpes zoster vaccine market in China increased from nil in 2015 to RMB0.6 billion in 2021, and is expected to grow to RMB10.8 billion in 2025 at a CAGR of 103.8% from 2021 to 2025, and further grow to RMB28.1 billion in 2030 at a CAGR of 21.1% from 2025 to 2030. In the U.S., the vaccination rate of herpes zoster vaccine of people aged 50 or above in 2021. was approximately 26.8%, compared to approximately 0.1% in China. By 2030, the cumulative vaccination rate of people aged 50 or above in the U.S. is expected to be approximately 70%. In terms of sales revenue, the herpes zoster vaccine market in the U.S. increased from US\$0.5 billion in 2016 to US\$1.7 billion in 2021 at a CAGR of 27.2% from 2016 to 2021, and is expected to remain stable at US\$1.7 billion in 2025 at a CAGR of 0.2% from 2021 to 2025, and decrease to US\$1.6 billion in 2030 at a CAGR of -1.4% from 2025 to 2030. From 2023 to 2030, the herpes zoster vaccine market in the U.S. is expected to remain stable due to (i) the U.S. is a relatively mature market for herpes zoster vaccine, the vaccination rate of herpes zoster vaccine among people aged 50 years and older in the U.S. was 26.8% in 2021; and (ii) the number of people aged 50 years and older in the U.S. was 119 million in 2021 and is expected to reach 130 million in 2030, and the population of people aged 50 years old and above in the U.S. is expected to grow at a slower pace with an average year-over-year growth rate between 0.8% to 1.0%. Currently, Shingrix<sup>®</sup> is the only commercialized herpes zoster vaccine in the U.S. In terms of medical coverage, Shingrix<sup>®</sup> is covered by Medicare Part D in the U.S., which greatly reduce the financial burden of patient to be vaccinated, and Medicaid covers Shingrix<sup>®</sup> for people aged 50 and older in approximately two-thirds of the states in the U.S. The price of Shingrix<sup>®</sup> has remained stable in the U.S. at approximately US\$120 per dose. The price of herpes zoster vaccines is expected to increase in the future as more herpes zoster vaccines featuring more advanced technology are approved and sold in the U.S.

In Southeast Asia, the number of people aged 50 and over grew from 134.7 million in 2016 to 144.5 million in 2021, with a CAGR of 1.4%. It is expected to continue to grow in the future, reaching 156.2 million in 2026, with a CAGR of 1.6% from 2021 to 2026. The number of new cases of herpes zoster in Southeast Asia increased from 1.57 million in 2016 to 1.79 million in 2021, with a CAGR of 2.7% over this period. With the increase in the population over 50 years old, the number of new cases in Southeast Asia will reach 1.99 million in 2026, with a CAGR of 2.2% from 2021 to 2026. The growing population of people aged over 50 coupled with increasing new cases of herpes zoster in Southeast Asia implies that there is a large potential market for shingles vaccine in Southeast Asia. Southeast Asia consists of 11 countries including Singapore, the Philippines, Malaysia, Indonesia, etc, and each country currently has different national medical insurance coverages. The herpes zoster vaccines have been marketed in some Southeast Asian countries such

## BUSINESS

as Singapore, Malaysia, and the Philippines, while the vaccines are not available in other Southeast Asian countries, such as Indonesia. The pricing of herpes zoster vaccines in different Southeast Asian countries vary which depends on the level of local medical development and the affordability of local people. For example, the price of Shingrix per dose is SGD430 in Singapore. In terms of medical insurance coverage, herpes zoster vaccines are generally not covered in the local vaccination schedule of Southeast Asian countries such as Singapore, Malaysia, and the Philippines. People have to pay it out-of-pocket when they want to get vaccinated. In addition, favorable government policies have promoted herpes zoster vaccines in Southeast Asia. For example, the Society of Infectious Disease (Singapore) Handbook (2020 edition) recommends herpes zoster vaccine for the prevention of shingles.

We also intend to conduct marketing activities raising the public awareness of shingles of the benefits and costs of receiving herpes zoster vaccines to further capitalize on the increased public awareness. According to Frost & Sullivan, LZ901, once approved, is not likely to be included in the National Immunization Program as it is mainly for adults aged 50 years or older and herpes zoster vaccines were not included in the NRDL as of the Latest Practicable Date. Accordingly, the public needs to purchase LZ901 at their own expense. Not being included under the National Immunization Program or the NRDL would not affect the pricing of LZ901 as we would price our product candidates at market price. However, if peer products are included under the NRDL, our peer products will gain market competitive advantage in market penetration, which would cause market pressure on our product candidates. As also confirmed by Frost & Sullivan, there are five antiviral drugs, including aciclovir, valaciclovir, famciclovir, brivudine and foscarnet for treatment of herpes zoster. Aciclovir is listed in Category A or Category B, depending on the dosage form, and valaciclovir, famciclovir, and foscarnet are listed in Category B of the NRDL. They are also four first-line treatment drugs for PHN, including pregabalin, gabapentin, amitriptyline and 5% lidocaine patch, all of which are listed in the Category B of the NRDL. According to the Interim Measures for the Administration of Use of Drugs Covered by the Basic Medical Insurance (《基本醫療保險用藥管理暫行辦法》), western drugs and Chinese drugs in the national Drug Catalog are divided into “drugs of Category A” and “drugs of Category B”. The expenses for “drugs of Category A” used by the insured shall be paid according to the payment standards and sharing measures stipulated for basic medical insurance, while those for “drugs of Category B” shall be first paid by the insured in a certain percentage, and then paid according to the sharing measures stipulated for basic medical insurance. The percentage of expenses paid by individuals for “drugs of Category B” is determined by the provincial or pooling region’s healthcare security administrative department. For details, please see “Regulatory Overview — Regulatory Provisions — Biosimilars Application and Approval — Drug Operation” in this document.

As of the Latest Practicable Date, there were two herpes zoster vaccines approved in China, namely GlaxoSmithKline plc’s Shingrix<sup>®</sup> which also captured almost 100% of the global market share in terms of sales revenue in 2021, and BCHT Biotechnology’s Gan Wei (感維), which was

## BUSINESS

recently approved in January 2023 and will commence to be sold in June 2023. The following table sets forth details of Shingrix<sup>®</sup> and BCHT Biotechnology’s Gan Wei (感維):

Company Name	GlaxoSmithKline	BCHT Biotechnology
<b>Product name</b>	Shingrix <sup>®</sup>	Gan Wei (感維)
<b>Indications</b>	Herpes zoster and PHN <sup>(1)</sup>	Herpes zoster
<b>Type of technology</b>	Recombinant	Live attenuated
<b>Targeted age/ gender group</b>	Immunocompetent male and female adults aged 50 years and older and immunodeficient male and female adults aged ≥ 19 years old	Males and females aged 40 years and older
<b>Effectiveness reducing herpes zoster</b>	50-59 years old: 96.6% 60-69 years old: 97.4% 70+: 91.3%	≥40 years old: 57.6% 40-49 years old: 37.4% 50-59 years old: 62.7% 60-69 years old: 64.4% ≥70 years old: 18.6%
<b>Effectiveness reducing post-herpetic neuralgia</b>	≥50 years old: 91.2% ≥70 years old: 88.8%	≥45 years old: 62.8% ≥65 years old: 62.9%
<b>Long-term vaccine effectiveness against herpes zoster</b>	50 years and older: 81.6% (the first 6-10 years following vaccination)	N/A
<b>Date of approval</b>	U.S.: October 20, 2017 Europe: March 28, 2018 China: May 22, 2019 <sup>(2)</sup>	China: January 29, 2023 (expected commencement of sales in June 2023)
<b>Price</b>	RMB1,600/dose in China, approximately US\$120/dose overseas	RMB1,369/dose
<b>Vaccine administration procedure</b>	Two doses, second dose administered 2-6 months after first dose	One dose

*Notes:*

- (1) Though indications of Shingrix<sup>®</sup> include PHN in EU, it doesn’t mean that Shingrix<sup>®</sup> has any advantages over peer products that do not list PHN as a separate indication, because any vaccine that prevents herpes zoster will by nature prevent PHN, regardless of whether PHN is listed as a separate indication or not.
- (2) GlaxoSmithKline plc did not conduct clinical trials for Shingrix<sup>®</sup> in mainland China but used overseas data to support the conditional approval for Shingrix<sup>®</sup> in China. After receiving conditional approval, GlaxoSmithKline plc had initiated a follow-up Phase III clinical trial for Shingrix<sup>®</sup> in mainland China in 2021, which is expected to be completed in 2023.

*Source: Frost & Sullivan Analysis*

As of the Latest Practicable Date, there was only one marketed herpes zoster vaccine, namely Shingrix<sup>®</sup>, and four herpes zoster vaccines under development in the U.S. In November 2020, Zostavax<sup>®</sup> was no longer available for use in the U.S., as it has discontinued production in the U.S. due to its low effectiveness of as a herpes zoster prophylaxis and its weakened market competitiveness. In 2021, sales of Shingrix<sup>®</sup> in the U.S. was US\$1,727.2 million. As of the Latest Practicable Date, there were no marketed herpes zoster vaccines and no clinical research information of herpes zoster vaccines under development in Indonesia. As of the Latest Practicable Date, there were two marketed herpes zoster vaccines, namely Shingrix<sup>®</sup> and Zostavax<sup>®</sup>, and no herpes zoster vaccines under development in Singapore. Vaccines approved in the U.S. require additional clinical trials and approval procedures in Southeast Asia. Each Southeast Asian country has different regulations on vaccine products. However, once a vaccine is approved by FDA, it will be highly recognized in Southeast Asia and the time required to conduct local clinical trials and approval procedures will be greatly reduced.

## BUSINESS

Besides our LZ901, there were three other herpes zoster vaccines under development in China, including one live attenuated herpes zoster vaccine and two recombinant herpes zoster vaccines, and six other herpes zoster vaccine candidates at the clinical stage in Australia, the Philippines and the U.S., according to Frost & Sullivan. Wantai Biopharma strategically abandoned development of its live attenuated shingles vaccine as the Phase II clinical trial results demonstrated that its protective efficacy was inferior to Shingrix<sup>®</sup>. LZ901 does not face the same risks of discontinued research and development as Wantai Biopharma’s shingles vaccine because LZ901 is a recombinant vaccine while Wantai Biopharma’s shingles vaccine is a live attenuated vaccine and the cellular immune response and humoral response data from the Phase I clinical trial of LZ901 indicate the immunogenicity of LZ901 is not weaker than Shingrix<sup>®</sup>. Live attenuated herpes zoster vaccines usually are manufactured at a lower cost and cause fewer side effects, but they could retain residual virulence and are not applicable for people with weakened immune systems. Recombinant herpes zoster vaccines, on the other hand, have the advantage of inducing a immune response while avoiding other components of the pathogen that cause adverse health effects, and are safe for people with weak immune systems. The following chart sets forth details of the herpes zoster vaccines under development in Australia, China, the Philippines and the U.S.:

Vaccine Name	Technology	Company	R&D Progress	Clinical Application Country	Date of IND Approval	Date of Phase I Clinical Trial <sup>(1)</sup>	Formulation	Ages/Gender Eligible for Clinical Trial
Live attenuated herpes zoster vaccine	Live attenuated	Shanghai Institute of Biological Products (上海生物製品研究所)	Phase II (completed)	China	August 21, 2017	November 20, 2018	Powder for concentrate for solution for infusion	Males and females aged 40 years and older
Recombinant Herpes Zoster Vaccine (CHO)	Recombinant	Luzhu Biotech (綠竹生物)	Phase II	China	August 4, 2021	January 15, 2022	Liquid	Males and females aged 50 years and older
			Phase I	U.S.	July 13, 2022	February 2023		
Recombinant Herpes Zoster Vaccine (CHO)	Recombinant	Curevo Inc.	Phase II	U.S.	N/A	January 2019	N/A	Males and females aged 50 years and older
Recombinant Herpes Zoster Vaccine (CHO)	Recombinant	Eyegene Inc.	Phase I (completed)	Australia	N/A	January 2020	N/A	Males and females aged 50 years to 70 years
Recombinant Herpes Zoster Vaccine (CHO)	Recombinant	Dynavax Technologies Corporation	Phase I	Australia	N/A	January 2022	N/A	Males and females aged 50 years to 69 years
Recombinant Herpes Zoster Vaccine (CHO)	Recombinant	Ab&B Bio-Tech (中慧元通)/ Easyway (上海怡道)	Phase I/II	China	May 6, 2020	December 13, 2021	Liquid	Males and females aged 40 years and older
Recombinant Herpes Zoster Vaccine (CHO)	Recombinant	MAXVAX Biotechnology (邁科康生物)	Phase I	China	January 4, 2022	October 21, 2022	N/A	Males and females aged 18 years and older
Recombinant Shingles Vaccine	Recombinant	Jiangsu Recbio Technology Co., Ltd. (瑞科生物)	Phase I	Philippines	December 19, 2022	N/A	N/A	N/A
RNA Herpes Zoster Vaccine JCXH-105	srRNA	Immorna (Hangzhou) Biotechnology Co., Ltd. (嘉晨西海)	FDA approved to initiate Phase I	U.S.	December 19, 2022	N/A	N/A	N/A
VZV modRNA	mRNA	Pfizer Inc. & BioNTech SE	Phase I/II	U.S.	N/A	January 25, 2023	Frozen or freeze dry powder	Males and females aged 50 years to 69 years

Source: Frost & Sullivan Analysis

Notes:

- (1) Date when the phase of clinical trial was first published.
- (2) The recombinant herpes zoster vaccine developed by MAXVAX Biotechnology has adopted cytosine phosphoguanosine oligodeoxynucleotide (“CpG ODN”) as an adjuvant, the safety of which is yet to be demonstrated. On the other hand, LZ901 has adopted aluminum adjuvant, which is widely used and safe for vaccine development, according to Frost & Sullivan.

Source: Center for Drug Evaluation of the NMPA (the “CDE”), public disclosure of listed companies, Frost & Sullivan Analysis

## BUSINESS

---

Curevo Inc. and Eyegene Inc. are unlikely to seek market approval for commercialization in China for their herpes zoster vaccines because Curevo Inc. and Eyegene Inc. are both South Korean companies and South Korean biopharmaceutical companies often expand their market by selling vaccines in Southeast Asia, but rarely in China. In addition, neither Curevo Inc. nor Eyegene Inc. has applied for CTA approval for their herpes zoster vaccines in China. As of the Latest Practicable Date, there were no approved vaccine in China manufactured by a South Korean company. Dynavax Technologies Corporation is also unlikely to seek market approval for commercialization in China for its Recombinant Herpes Zoster Vaccine (CHO). As of the Latest Practicable Date, Dynavax had no product sales in China and had not planned to initiate clinical trials in China. Jiangsu Recbio Technology Co., Ltd. and Immorna (Hangzhou) Biotechnology Co., Ltd. are Chinese companies and may be more motivated than international companies to seek to commercialize their respective product candidates in their own country in the future. However, even if they have such plans, their respective product candidates are unlikely to enter the Chinese market in a short term, because in order to commercialize the relevant product candidates in China, they are required to complete new clinical trials in China, while as of the Latest Practicable Date, none of them had registered for any clinical trials in China for the relevant product candidates.

To support our sales and marketing efforts for LZ901 in China, we plan to build our commercialization team for LZ901 in or around the third quarter of 2024 upon submitting the BLA for LZ901 to the NMPA. In addition, we plan to collaborate with CSOs according to the administrative regions to expand the sales volume and increase market penetration of LZ901. To improve the competitiveness of LZ901 in overseas markets, we will formulate corresponding sales strategies according to the market conditions. We may develop out-licensing or collaboration strategies. We plan to commercialize LZ901 in-house in China and collaborate with multinational pharmaceutical companies who have a robust sales and marketing network to rapidly commercialize LZ901 globally in overseas markets, including in the U.S. and Southeast Asian countries. Upon entering into collaborations with such multinational pharmaceutical companies, we plan to authorize such multinational pharmaceutical companies to produce and sell LZ901 in the markets and countries that are agreed upon. As of the Latest Practicable Date, we had explored collaboration opportunities with third parties to out-license LZ901 in markets outside of China but had not identified any collaboration partners, and may pursue such out-licensing opportunities after we complete the Phase II clinical trial for LZ901 in the U.S. in the second quarter of 2025. We may also build overseas production workshops and establish our own overseas sales team. For details, please see “Business — Commercialization” in this document. LZ901 may fail to achieve high market acceptance as Shingrix<sup>®</sup> has first-mover advantages and captured almost 100% of the global and Chinese market share in terms of sales revenue. For details, please see “Risk Factors — Risks Relating to Our Business and Industry — Risks Relating to Sales and Distribution of Our Product Candidates — We operate in a competitive environment, and we may not be able to compete effectively against current and future competitors.” and “Industry Overview — Herpes Zoster Vaccine Market — Competitive Landscape” in this document.

## BUSINESS

However, Shingrix<sup>®</sup> has a incidence rate of 23.3% of Grade III AEs, while LZ901 has a different antigen structure and a formulation that uses a different adjuvant compared to Shingrix<sup>®</sup>, which demonstrates a much lower incidence rate as no Grade III AEs were observed in subjects dosed with LZ901 based on the results of the Phase I clinical trial of LZ901. Besides, LZ901 is expected to be priced at a retail price of approximately RMB500 to RMB800 an injection, with a total of two injections per treatment and does not require a third booster shot, which is more affordable compared to the retail price of the other commercially available herpes zoster vaccines in China, with Shingrix<sup>®</sup> priced at RMB1,600 an injection with a total of two injections per treatment. As LZ901 is highly stable, easy to store and transport, and convenient to use, with low price, mild side effects and favorable safety profile, molecular structure advantages and strong protection, we expect that LZ901 will capture a large market share in the future. For more details of the competitive advantages of LZ901, please see “— Our Products and Product Candidates — Our Core Product and Clinical-Stage Product Candidates — 1. LZ901 — Competitive Advantages” in this section.

We believe there is significant market potential for our LZ901, considering the following factors.

- ***Favorable government policies for domestic vaccine manufacturers in China.*** In 2017, Opinions of the General Office of the State Council on Further Strengthening the Management of Vaccine Circulation and Vaccination (國務院辦公廳關於進一步加強疫苗流通和預防接種管理工作的意見) set out principles to promote domestic vaccine manufacturers to scale up production of vaccines, independent R&D and to improve the quality of vaccines to support R&D and industrialization of new vaccines. Therefore, we believe we will benefit from such favorable government policies and LZ901 will capture a large market share in the future.
- ***Government support and new initiatives to encourage developments for vaccination.*** According to China’s 14th Five-Year Plan, it proposes improving the health of the elderly as a key task during this period. In addition, the NHC recommends people aged 50 years and older to obtain herpes zoster vaccination to prevent shingles. According to 2022 China Herpes Zoster Vaccine Expert Consensus (帶狀皰疹疫苗預防接種專家共識), herpes zoster vaccine is recommended in order to prevent herpes zoster, and individuals aged 50 years and older (regardless of whether the individual has a history of varicella infection or varicella vaccination) are recommended to receive herpes zoster vaccine.
- ***Cost effectiveness of vaccination.*** Shingles is a viral infection that causes a painful rash that can negatively impact quality of life. Shingles can also reoccur, with the recurrence rate of shingles increasing with age. The recurrence rate of shingles for unvaccinated patients is approximately 4% to 6%. After receiving herpes zoster vaccination, the risk of recurrence of shingles is reduced by approximately 50% in vaccinated patients. Based on a research study, the average cost of treatment for shingles (including both patients that develop and do not develop complications) is approximately RMB840 per patient and the average cost of treatment for shingles for patients that develop complications is approximately RMB1,221 per patient in people aged 50 years old and above in China according to Disease Burden Due to Herpes Zoster among Population Aged ≥50 Years Old in China: A Community Based Retrospective Survey\*, while LZ901 is expected to be priced at a retail price of approximately RMB500 to RMB800 an injection, with a total of two injections per treatment and does not require a third booster shot.<sup>(1)</sup> The treatment for shingles mainly includes outpatient service, hospitalization and medical treatment, and the average cost of



## BUSINESS

treatment for shingles was calculated based on (i) outpatient expenses, (ii) hospitalization expenses, and (iii) other expenses which include the cost of over-the-counter medication, transportation costs from seeking medical service, productivity loss for caring for the patient, and other costs considered to be associated with shingles. According to Frost & Sullivan, taking into consideration the pain and negative impact to quality life caused by shingles, higher recurrence rate of shingles for unvaccinated patients which could lead to increasing costs to treat shingles and its complications, and the cost of LZ901 is fixed at two injections of RMB500 to RMB800 an injection, it is the most advisable choice to receive LZ901 vaccination for shingles.

- ***Non-inferior safety and indicative efficacy of LZ901 compared to Shingrix®.*** As demonstrated in the Phase I clinical trial for LZ901 in China, the overall number and incidence rate of Grade I AEs and Grade II AEs of subjects dosed with LZ901 were lower compared to subjects dosed with Shingrix®, and no Grade III AEs were observed in subjects dosed with LZ901 while one Grade III AE was observed in subjects dosed with Shingrix®, demonstrating the mild side effects and favorable safety profile of LZ901. In addition, both the low-dosed and high-dosed LZ901 groups reported an incidence rate of AEs of 55%, which is lower compared to the Shingrix® positive control group that reported an incidence rate of AEs of 100% and similar to the placebo group that reported an incidence rate of AEs of 50%.

LZ901 induces a cellular immune response that confers strong protection against shingles. Compared to Shingrix® in BALB/c mice, LZ901 induces a stronger cellular immune response with higher expression of multiple types of immune cell activating biomarkers. In addition, based on immunogenicity data collected from the Phase I clinical trial for LZ901 in China, it has been demonstrated that there is no significant difference in the levels of anti-VZV antibodies after the full course of vaccination compared of LZ901 to Shingrix®, indicating that the immunogenicity of LZ901 is not inferior to that of Shingrix®.

*Note:*

- \* Li Y, An Z, Yin D, Liu Y, Huang Z, Xu J, Ma Y, Tu Q, Li Q, Wang H. Disease Burden Due to Herpes Zoster among Population Aged ≥50 Years Old in China: A Community Based Retrospective Survey. PLoS One. 2016 Apr 7; 11(4):e0152660.

## BUSINESS

### *Competitive Advantages*

We believe LZ901 has the following advantages, low price and mild side effects in particular, when compared to the currently marketed herpes zoster vaccine in China:

#### *Low Price*

LZ901 is expected to be priced at a retail price of approximately RMB500 to RMB800 an injection, with a total of two injections per treatment and does not require a third booster shot, which is more affordable compared to the retail price of the other commercially available herpes zoster vaccines in China, with Shingrix<sup>®</sup> priced at RMB1,600 an injection with a total of two injections per treatment. As LZ901 is indicated for middle-aged and elderly adults aged 50 years and older, who are price sensitive and will likely choose a lower priced herpes zoster vaccine, we priced LZ901 at approximately RMB500 to RMB800 an injection. We believe that we are able to maintain a healthy profit margin and to increase acceptance of herpes zoster vaccines in the target population while gaining market share for LZ901 taking into consideration (i) the current competitive landscape of herpes zoster vaccines; (ii) the expected pricing of LZ901 and the pricing of other herpes zoster vaccines with Shingrix<sup>®</sup> priced at approximately RMB1,600/dose with a total of two doses per treatment and Gan Wei (感維) to be priced at approximately RMB1,369/dose with a total of one dose per treatment once it commences sales in June 2023; and (iii) our manufacturing capacity, which will enable us to lower production cost and improve the profitability for LZ901.

#### *Mild Side Effects and Favorable Safety Profile*

The side effects from the administration of LZ901 are minimal as its liquid formulation only contains an aluminum hydroxide adjuvant and is free of immune stimulants, which reduces the likelihood of serious adverse reactions at the injection site. As demonstrated in the Phase I clinical trial for LZ901 in China, the overall number and incidence rate of Grade I AEs and Grade II AEs of subjects dosed with LZ901 were lower compared to subjects dosed with Shingrix<sup>®</sup>, and no Grade III AEs were observed in subjects dosed with LZ901 while one Grade III AE was observed in subjects dosed with Shingrix<sup>®</sup>, demonstrating the mild side effects and favorable safety profile of LZ901. In addition, both the low-dosed and high-dosed LZ901 groups reported an incidence rate of AEs of 55%, which is lower compared to the Shingrix<sup>®</sup> positive control group that reported an incidence rate of AEs of 100% and similar to the placebo group that reported an incidence rate of AEs of 50%.

LZ901 is a recombinant herpes zoster virus vaccine. Unlike live attenuated virus vaccines, LZ901 induces an immune response while avoiding risks of residual virulence from vaccinating with weakened herpes zoster virus.

#### *Molecular Structure Advantages*

LZ901 has a tetrameric molecular structure containing two Fc regions that actively present VZV gE to cell membrane surface Fc receptors of APCs to trigger an immune response. The carboxyl end of the VZV gE extracellular domain is connected to the Fc fragment of IgG1, and based on the characteristic of VZV gE to form covalent dimers, a multi-step liquid chromatography process is used to obtain high-purity recombinant VZV gE tetramer-Fc fusion proteins containing two Fcs by purification from protein solutions with complex compositions. In pre-clinical studies, compared to the naturally occurring VZV gE, LZ901 exhibits improved immunogenicity and induces a higher level of neutralizing antibody titers.

**BUSINESS**

*Highly Stable, Easy to Store and Transport, and Convenient to Use*

LZ901 adopts a liquid formulation with high stability, which allows for easy storage and transportation. It is stable for two weeks at 37°C, 12 weeks at 25°C and 24 months at 2-8°C.

*Strong Protection*

LZ901 induces a cellular immune response that confers strong protection against shingles. Compared to Shingrix® in BALB/c mice, our LZ901 induces a stronger cellular immune response with higher expression of multiple types of immune cell activating biomarkers. In addition, based on immunogenicity data collected from the Phase I clinical trial for LZ901 in China, it has been demonstrated that there is no significant difference in the levels of anti-VZV antibodies after the full course of vaccination compared of LZ901 to Shingrix®, indicating that the immunogenicity of LZ901 is not inferior to that of Shingrix®.

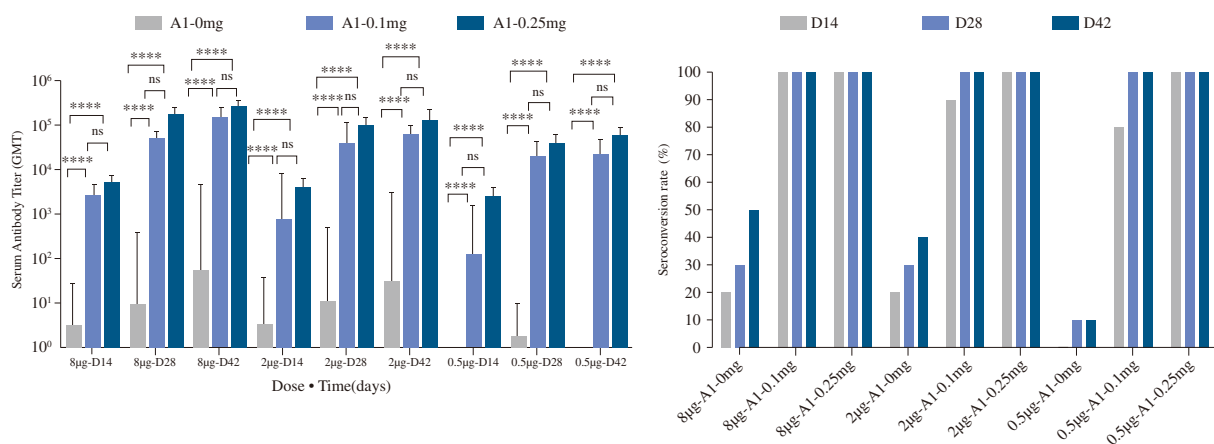
*Summary of Preclinical Studies*

We conducted a range of *in vitro*, *in vivo* and animal preclinical studies to characterize the immunogenicity, efficacy and safety of LZ901.

*Immunogenicity Study of LZ901 With Aluminum Hydroxide Adjuvant Formulations*

The addition of aluminum hydroxide adjuvant to the liquid formulation of LZ901 was confirmed to improve the immunogenicity of LZ901 as demonstrated in mice dosed with LZ901 with varying levels of aluminum hydroxide adjuvant. As shown in the graphs below, increasing the addition of aluminum hydroxide adjuvant from 0.1mg to 0.25mg significantly improved the immunogenicity of LZ901.

**Geometric Mean Titer (GMT) of Serum VZV gE Antibody after Immunization of Mice With Three Doses of LZ901 Vaccine With Different Aluminum Content**



Source: Company Data

**BUSINESS**

*Stability Study of LZ901 in Various Storage Conditions*

LZ901 has been confirmed to be stable for two weeks at 37°C, 12 weeks at 25°C and 24 months at 2-8°C. The pH value, protein content, and adsorption rate of LZ901 were examined under 2-8°C conditions after 24 months, and the relative *in vitro* efficacy of LZ901 was determined by double-antibody sandwich ELISA to investigate the biological activity. The verification test results meet the requirements of the specifications, and the 2-8°C stability testing is still in progress.

In addition, LZ901 stored at 37°C for two weeks was subjected to positive conversion analysis to investigate the *in vivo* efficacy. The stability test results of LZ901 stored at 37°C for two weeks and 25°C for 12 weeks meet the requirements of the specifications, indicating LZ901 is stable at storage conditions of both 37°C for two weeks and 25°C for 12 weeks.

*Head-to-Head Immunogenicity Study Comparing LZ901 and Shingrix®*

In a BALB/c mice study, our LZ901 induced a stronger cellular immune response with higher expression of multiple types of immune cell activating biomarkers compared to Shingrix®. We conducted a BALB/c mouse study to evaluate the effect of LZ901 and Shingrix® to activate helper (CD4+) T cells and cytotoxic (CD8+) T cells by detecting the expression of activation biomarkers, comprising interferon-γ (“IFN-γ”), interleukin 2 (“IL-2”), interleukin 4 (“IL-4”) and cluster of differentiation marker 40 ligand (“CD40L”). The purpose of this experiment was to compare BALB/c mice subcutaneously injected with LZ901 and Shingrix® twice, and to investigate the serum specific antibody titer of mice at different time points and the immunogenicity of cellular immune response two weeks after the last immunization.

gE-Specific Humoral Immune Response

The titers of VZV gE-specific antibodies in the serum of mice immunized with LZ901 and Shingrix® were measured to evaluate the humoral immune response of LZ901 and Shingrix®. There was no significant difference in the titers between mice immunized with Shingrix® and mice immunized with LZ901, which indicates the level of humoral immune response of LZ901 is non-inferior to that of Shingrix®. The following table summarize the VZV gE-specific antibody titers of serum of mice immunized with LZ901, mice immunized with Shingrix® and the mice control group three weeks after the first dose and two weeks after the second dose.

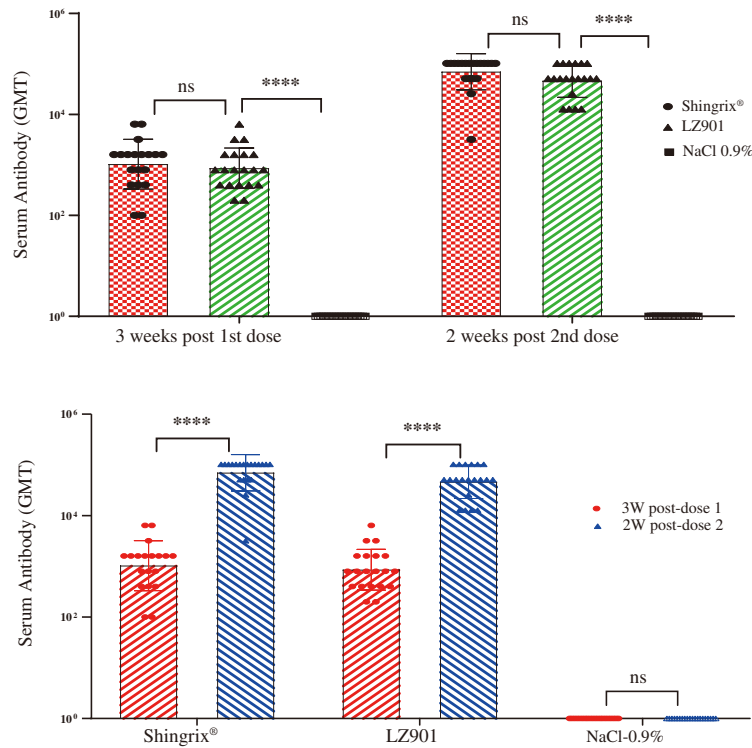
**Mouse Serum Titers and Antibody Positive Conversion Rates in Different Dose Groups**

<u>Group</u>	<u>Number of mice</u>	<u>Three weeks post 1st dose</u>		<u>Two weeks post 2nd dose</u>		<u>GMT Ratio (Two doses/ One dose)</u>
		<u>GMT</u>	<u>Positive rate (%)</u>	<u>GMT</u>	<u>Positive rate (%)</u>	
Shingrix®	20	1,033	95	69,941	100	67.7
LZ901	20	857	100	46,144	100	53.8
NaCl-0.9%	20	1	0	1	0	1

Source: Company Data

**BUSINESS**

**Serum Antibody Titers of BALB/c Mice in Different Dose Groups**



Note: No significant difference (“ns”) p≥0.05, \*\*\*\* p<0.0001

Source: Company Data

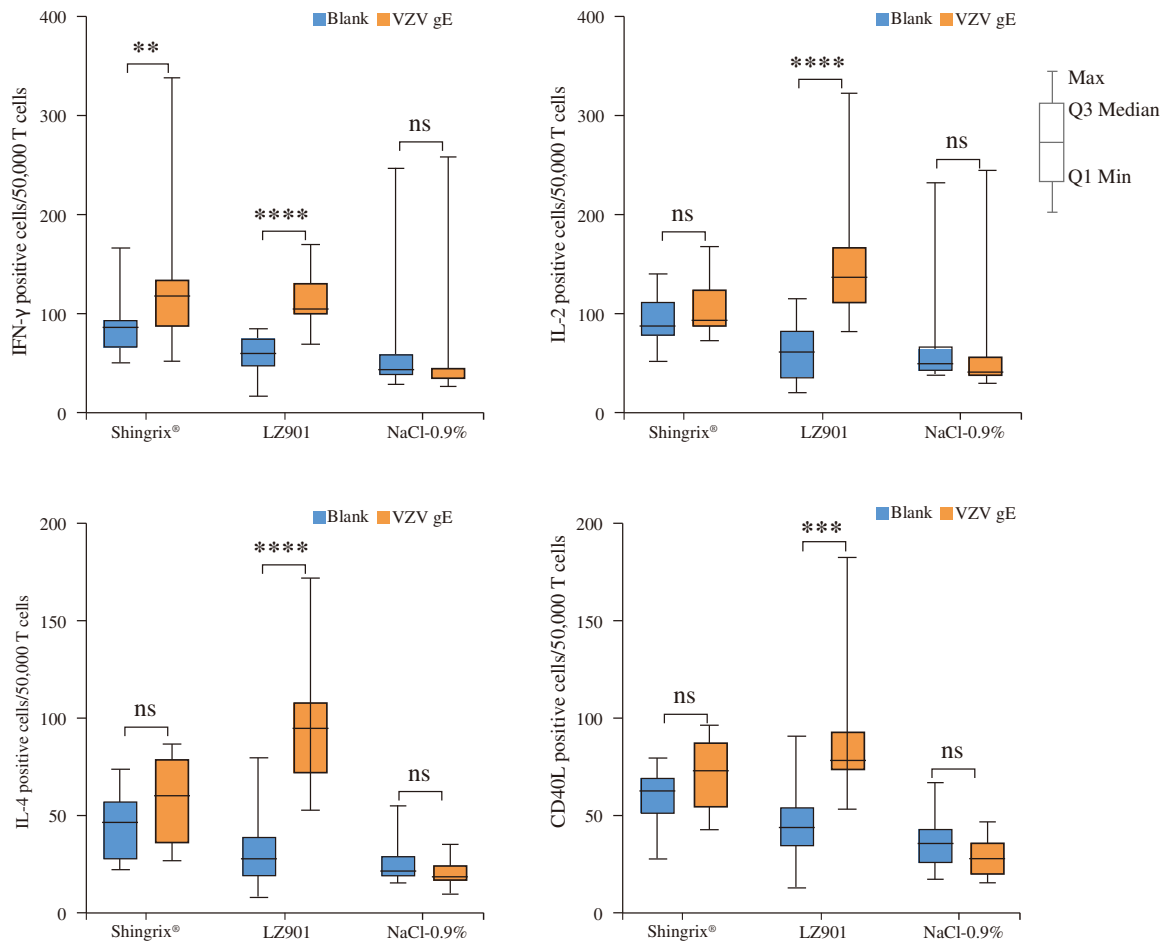
gE-Specific Cellular Immune Response

Shingrix® was used as a positive control to evaluate gE-specific cellular immune responses of LZ901 in the study. In order to evaluate the cellular immune response induced by LZ901, the spleen cells of BALB/c mice following the second inoculation were investigated to determine the number of helper (CD4+) T cells and cytotoxic (CD8+) T cells, and at least one of the detected markers (IFN-γ, IL-2, IL-4 and CD40L) in 50,000 T cells using intracellular cytokine staining.

After the administration of the second dose of LZ901, the number of helper (CD4+) T cells expressing VZV gE-specific IFN-γ, IL-2, IL-4, and CD40L in VZV gE stimulated mice increased significantly compared to baseline unstimulated mice. However, after the administration of the second dose of Shingrix®, only the number of helper (CD4+) T cells expressing VZV gE-specific IFN-γ in VZV gE stimulated mice increased significantly compared to baseline unstimulated mice. Compared to Shingrix®, mice immunized with LZ901 were observed to have significantly higher magnitude of expression of activation biomarkers and higher proportion of helper (CD4+) T cells and cytotoxic (CD8+) T cells expressing multiple biomarkers, which indicate LZ901 provides strong protection against shingles.

**BUSINESS**

**LZ901 and Shingrix® Activation of Helper (CD4+) T Cell Biomarker Expression**



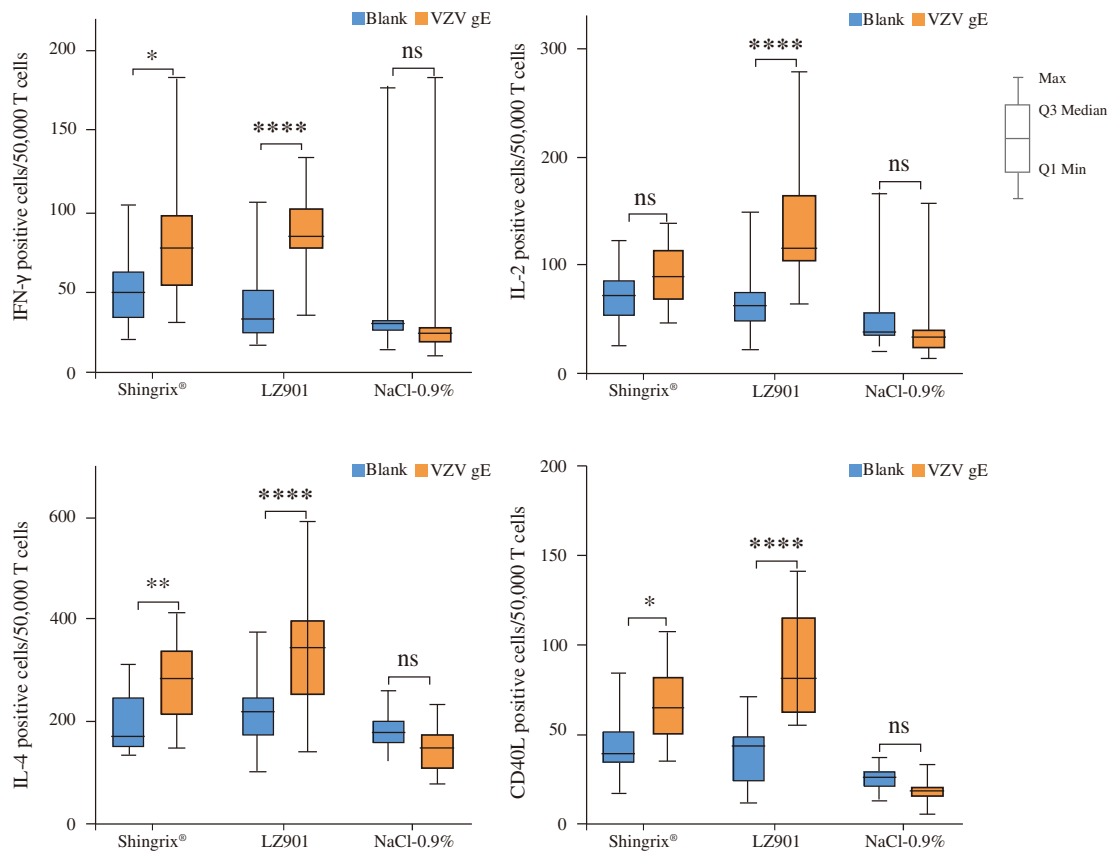
Note: ns p≥0.05, \*\* p<0.01, \*\*\* p<0.001, \*\*\*\* p<0.0001, error bars depict minimum and maximum values

Source: Company Data

10 to 14 days after the administration of the second dose of LZ901, the number of cytotoxic (CD8+) T cells expressing VZV gE-specific IFN-γ, IL-2, IL-4, and CD40L in VZV gE stimulated mice increased significantly compared to unstimulated mice. However, 10 to 14 days after the administration of the second dose of Shingrix®, only the number of cytotoxic (CD8+) T cells expressing VZV gE-specific IFN-γ, IL-4, and CD40L in VZV gE stimulated mice increased significantly compared to baseline unstimulated mice, but the level and magnitude of the increase were not as high as LZ901.

**BUSINESS**

**LZ901 and Shingrix® Activation of Cytotoxic (CD8+) T Cell Biomarker Expression**



Note: ns  $p \geq 0.05$ , \*\*  $p < 0.01$ , \*\*\*  $p < 0.001$ , \*\*\*\*  $p < 0.0001$ , error bars depict minimum and maximum values

Source: Company Data

The proportion of helper (CD4+) T cells in LZ901 dosed mice expressing a combination of two, three or four activation biomarkers were significantly higher than that of helper (CD4+) T cells in Shingrix® dosed mice. The proportion of cytotoxic (CD8+) T cells in LZ901 dosed mice expressing a combination of two, three or four activation biomarkers were significantly higher than that of cytotoxic (CD8+) T cells in Shingrix® dosed mice.

For the group immunized with LZ901, the proportion of mouse gE-specific helper (CD4+) T cells expressing at least two activation biomarkers was 100%, at least three activation biomarkers was 80% and four activation biomarkers was 60%. In addition, the proportion of mouse gE-specific cytotoxic (CD8+) T cells expressing at least two activation biomarkers was 90%, at least three activation biomarkers was 75% and four activation biomarkers was 60%. 90% of mouse gE-specific helper (CD4+) T cells expressed IFN- $\gamma$  and 85% of mouse gE-specific cytotoxic (CD8+) T cells expressed CD40L.





**BUSINESS**

***Summary of Phase I Clinical Trial Results***

*Trial design.* We conducted a randomized, blinded and active-controlled Phase I clinical trial to evaluate the safety and tolerability, and preliminarily explore the immunogenicity of LZ901 in healthy people aged between 50 to 70 years old. A total of 80 subjects were enrolled in the Phase I clinical trial for LZ901. The subjects were divided into four groups, including (i) low-dose group with 20 subjects receiving 50µg/0.5mL/vial of LZ901, (ii) high-dose group with 20 subjects receiving 100µg/0.5mL/vial of LZ901, (iii) 20 subjects receiving a 0.5mL/vial placebo control and (iv) 20 subjects receiving 50µg/0.5mL/vial of GlaxoSmithKline Biologicals SA’s Shingrix<sup>®</sup> positive control vaccine. Details of the trial groups are set out in the following table:

<b>Group</b>	<b>Number of Subjects</b>		
	<b>LZ901</b>	<b>Adjuvant</b>	<b>Shingrix<sup>®</sup></b>
Low-Dose	20	–	–
High-Dose	20	–	–
Placebo Control	–	20	–
Positive Control	–	–	20

The subjects in the low-dose LZ901 group, high-dose LZ901 group and placebo control group received an intramuscular injection on day 0 and one month, and the subjects in the Shingrix<sup>®</sup> positive control group received an intramuscular injection on day 0 and two months. Before each vaccine dose and the third day after vaccination, blood biochemistry, blood routine and urine routine tests were performed on all subjects, and abnormal laboratory indicators were observed. All 80 subjects completed the Phase I clinical trial.

The safety and tolerability primary endpoints were the occurrence of (i) adverse reaction (“**AEs**”) within 30 minutes, seven days (including solicited local AEs and systemic AEs) and 30 days (non-solicited AEs) after injection of the vaccination, and incidence of vaccine-related and unrelated AEs of varying severity; (ii) severe adverse events (“**SAEs**”) during the trial; and (iii) abnormal laboratory test indicators on the third day after each vaccination. The immunogenicity exploratory endpoints were (i) the content of anti-gE antibody and the GMT of anti-VZV antibody and positive conversion rate; (ii) cellular immune response 30 days after vaccination; and (iii) changes in anti-Fc antibody and anti-nuclear antibody levels 30 days after vaccination. The study to preliminarily explore the immunogenicity of LZ901 is voluntary, and the Phase II clinical trial has been initiated after completing the safety and tolerability primary endpoints.

*Trial status.* The Phase I clinical trial was initiated in January 2022. As confirmed by the competent regulatory authority, the Phase I clinical trial was completed. For details, see “—Material Communications with Competent Authorities” in this section.

## BUSINESS

---

*Safety and tolerability.* The results indicate that LZ901 is safe and well tolerated in healthy people aged between 50 to 70 years old. The frequency and severity of AEs observed in the low-dose and high-dose LZ901 groups were much lower compared to the Shingrix<sup>®</sup> positive control group. The overall number and incidence rate of AEs for the low-dose and high-dose LZ901 groups were much lower than the Shingrix<sup>®</sup> positive control group. The AEs observed in each group were mainly Grade I AEs, followed by Grade II AEs. The overall number and incidence rate of Grade I and Grade II AEs for the low-dose and high-dose LZ901 groups were much lower than the Shingrix<sup>®</sup> positive control group. One Grade III AE was observed in the Shingrix<sup>®</sup> positive control group. None of the subjects in the low-dose LZ901 group and high-dose LZ901 group experienced any Grade III AEs or any SAEs and none of the subjects withdrew from trial, indicating LZ901 is well tolerated. The incidence rate of AEs in the low-dose LZ901 group and high-dose LZ901 group were similar, and lower than the Shingrix<sup>®</sup> positive control group.

In the low-dose LZ901 group, 26 AEs occurred in 11 of the 20 subjects, with an incidence rate of 55.0%. The incidence rate of Grade I, Grade II and Grade III AEs in the low-dose LZ901 group was 35.0%, 10.0% and 0%, respectively. AEs observed in the low-dose group were pain at the vaccination site, swelling at the vaccination site, itching at the vaccination site, fatigue, headache, stomachache, hemorrhoid, muscle ache, pharyngitis, fungal infection and increased tearing.

In the high-dose LZ901 group, 29 AEs occurred in 11 of the 20 subjects, with an incidence rate of 55.0%. The incidence rate of Grade I, Grade II and Grade III AEs in the high-dose LZ901 group was 50.0%, 5.0% and 0%, respectively. AEs observed in the high-dose group were pain at the vaccination site, swelling at the vaccination site, itching at the vaccination site, spotted erythema at the vaccination site, fatigue, chills, headache, neuralgia, toothache, stomachache, tonsillitis, bronchitis, oropharyngeal discomfort, allergic rhinitis, ligament sprain, itchiness and Meniere's disease.

In the placebo control group, 17 AEs occurred in 10 of the 20 subjects, with an incidence rate of 50.0%. The incidence rate of Grade I, Grade II and Grade III AEs in the placebo group was 25.0%, 5.0% and 0%, respectively. AEs observed in the placebo control group were pain at the vaccination site, discomfort at the vaccination site, fatigue, headache, abnormal sensation, constipation, blood in stool, diarrhea, muscle ache, osteoarthritis and dry eye.

In the Shingrix<sup>®</sup> positive control group, 107 AEs occurred in 20 of the 20 subjects, with an incidence rate of 100%. The incidence rate of Grade I, Grade II and Grade III AEs in the Shingrix<sup>®</sup> positive control group was 95.0%, 45.0% and 10%, respectively. AEs observed in the Shingrix<sup>®</sup> positive control group were pain at the vaccination site, swelling at the vaccination site, itching at the vaccination site, spotted erythema at the vaccination site, vaccination site induration, fever, fatigue, dizziness, muscle ache and urinary tract infection.

Mainly Grade I AEs and Grade II AEs were observed. One Grade III AE (swelling at the vaccination site) was observed in the Shingrix<sup>®</sup> positive control group. Grade III AEs are severe or medically significant but not immediately life-threatening, hospitalization or prolongation of hospitalization indicated, disabling, and limiting self-care activities of daily living.

**BUSINESS**

The following table sets forth the AEs observed during the clinical trial.

	LZ901 High-Dose Group (N=20 subjects)			LZ901 Low-Dose Group (N=20 subjects)			Placebo Control Group (N=20 subjects)			Shingrix® Positive Control Group (N=20 subjects)						
	Number of AEs	Number of Subjects		Incidence (%)	Number of AEs	Number of Subjects		Incidence (%)	Number of AEs	Number of Subjects		Incidence (%)				
		with AEs				with AEs				with AEs			with AEs			
Adverse Events (AEs)	29	11		55	26	11		55	17	10		50	107	20		100
AEs associated with investigational vaccine	19	7		35	21	10		50	9	6		30	104	20		100
Grade I AEs	15	7		35	20	10		50	8	5		25	70	19		95
Grade II AEs	4	2		10	1	1		5	1	1		5	33	9		45
Grade III AEs	0	0		0	0	0		0	0	0		0	1	1		5
Solicited AEs	15	6		30	21	10		50	7	4		20	100	20		100
Local AEs	10	5		25	13	9		45	3	2		10	58	20		100
Systemic AEs	5	3		15	8	4		20	4	3		15	42	14		70
Unsolicited AEs	4	2		10	0	0		0	2	2		10	4	3		15
AEs not associated with investigational vaccine	10	7		35	5	3		15	8	6		30	3	2		10
AEs leading to shedding	0	0		0	0	0		0	0	0		0	0	0		0

## BUSINESS

*Immunogenicity.* Humoral immune response, cellular immune response, and anti-Fc antibody and anti-nuclear antibody data was obtained to preliminarily explore the immunogenicity of LZ901. LZ901 is able to stimulate the rapid production of higher levels of anti-VZV antibodies compared to Shingrix<sup>®</sup> 30 days after the first vaccination and there was no significant difference in the levels of anti-VZV antibodies of subjects dosed with LZ901 compared with subjects dosed with Shingrix<sup>®</sup> 30 days after the full course of vaccination based on humoral response data, and induce higher expression of multiple types of immune cell activating biomarkers compared to Shingrix<sup>®</sup> based on cellular immune response data, indicating that the immunogenicity of LZ901 is not weaker than Shingrix<sup>®</sup>.

Humoral immune response in terms of the GMT of anti-VZV antibody and positive conversion rate. 30 days after the first vaccination, the GMT of anti-VZV antibody of the high-dose LZ901 group was higher than the low-dose LZ901 group and the Shingrix<sup>®</sup> positive control group, but the difference was not statistically significant. 30 days after the first vaccination, the GMT of anti-VZV antibody for the low-dose LZ901, high-dose LZ901, placebo and Shingrix<sup>®</sup> positive control groups were 97.01 (95% CI: 46.64, 201.74), 207.94 (95% CI: 83.52, 517.67), 27.86 (95% CI: 17.28, 44.92) and 107.63 (95% CI: 45.51, 254.54), respectively, representing a 7.0 fold increase, 14.9 fold increase, 2.1 fold increase and 11.3 fold increase, respectively, compared to the GMT of anti-VZV antibody prior to the first vaccination. The positive conversion rate of anti-VZV antibody in the low-dose LZ901, high-dose LZ901, placebo and Shingrix<sup>®</sup> positive control groups 30 days after the first vaccination were 80.0%, 85.0%, 30.0% and 75.0%, respectively.

30 days after the full course of vaccination, the GMT of anti-VZV antibody of the high-dose LZ901 group was higher than the low-dose LZ901 group and the difference was statistically significant ( $p < 0.05$ ), and similar to the Shingrix<sup>®</sup> positive control group and the difference was not statistically significant ( $p=0.59$ ). There was no significant difference between the GMT of anti-VZV antibody of the high-dose LZ901 group and the Shingrix<sup>®</sup> positive control group (assuming the probability of occurrence of a class 1 error of  $\alpha=0.05$  referring to the probability of an error in this conclusion being less than 5% and the statistical probability that the two results would be consistent was not less than 95% and the degree of certainty of  $\beta=0.8$ ), indicating that the GMT values are consistent statistically and the immunogenicity of LZ901 is not weaker than that of Shingrix<sup>®</sup>. 30 days after the full course of vaccination, the GMT of anti-VZV antibody for the low-dose LZ901, high-dose LZ901, placebo and Shingrix<sup>®</sup> positive control groups were 194.01 (95% CI: 85.05, 442.59), 512.00 (95% CI: 290.48, 902.45), 36.76 (95% CI: 19.11, 70.69) and 652.58 (95% CI: 309.40, 1,376.36), respectively, representing a 13.9 fold increase, 36.8 fold increase, 2.7 fold increase and 68.6 fold increase, respectively, compared to the GMT of anti-VZV antibody prior to the first vaccination. The positive conversion rate of anti-VZV antibody in the low-dose LZ901, high-dose LZ901, placebo and Shingrix<sup>®</sup> positive control groups 30 days after the full course of vaccination were 90.0%, 100.0%, 55.0% and 95.0%, respectively.

## BUSINESS

Humoral immune response in terms of content of anti-gE antibody and positive conversion rate. Anti-gE antibodies are antibodies that are able to bind to recombinant gE protein, which include both functional and non-functional antibodies. Functional antibodies are neutralizing antibodies, while non-functional antibodies are non-neutralizing antibodies that have no virus killing effect. Therefore, the GMC values of anti-gE antibody do not determine the exact proportion of neutralizing antibodies compared to non-neutralizing antibodies, and cannot directly demonstrate immunogenicity. The geometric mean concentration ("GMC") of anti-gE antibody increased significantly in subjects in the low-dose LZ901, high-dose LZ901 and Shingrix<sup>®</sup> positive control groups 30 days after the first vaccination. 30 days after the first vaccination, the GMC of anti-gE antibody for the low-dose LZ901, high-dose LZ901, placebo and Shingrix<sup>®</sup> positive control groups were 14.81 IU/ml (95% CI: 7.91, 27.74), 18.95 IU/ml (95% CI: 10.83, 33.14), 1.26 IU/ml (95% CI: 0.81, 1.96) and 11.46 IU/ml (95% CI: 7.02, 18.69), respectively, representing a 20.3 fold increase, 13.5 fold increase, 1.1 fold increase and 19.1 fold increase, respectively, compared to the GMC of anti-gE antibody prior to the first vaccination. The positive conversion rate of anti-gE antibody in the low-dose LZ901, high-dose LZ901, placebo and Shingrix<sup>®</sup> positive control groups were 100.0%, 95.0%, 0.0% and 100.0%, respectively.

30 days after the full course of vaccination, the GMC of anti-gE antibody of the high-dose LZ901 group was slightly lower than the low-dose LZ901 group and the difference was not statistically significant ( $p=0.8637$ ), and the GMC of anti-gE antibody of the high-dose LZ901 group and the low-dose LZ901 group were both lower than the Shingrix<sup>®</sup> positive control group and the differences were statistically significant (both  $p$ -values were less than 0.0001). The GMC of anti-gE antibody increased significantly in subjects in the low-dose LZ901, high-dose LZ901 and Shingrix<sup>®</sup> positive control groups 30 days after the full course of vaccination. 30 days after the full course of vaccination, the GMC of anti-gE antibody for the low-dose LZ901, high-dose LZ901, placebo and Shingrix<sup>®</sup> positive control groups were 24.84 IU/ml (95% CI: 17.39, 35.49), 23.73 IU/ml (95% CI: 15.52, 36.29), 1.22 IU/ml (95% CI: 0.85, 1.75) and 71.86 IU/ml (95% CI: 54.28, 95.13), respectively, representing a 34.0 fold increase, 16.9 fold increase, 1.1 fold increase and 119.0 fold increase, respectively, compared to the GMC of anti-gE antibody prior to the first vaccination. The positive conversion rate of anti-gE antibody in the low-dose LZ901, high-dose LZ901, placebo and Shingrix<sup>®</sup> positive control groups were 100.0%, 100.0%, 0.0% and 100.0%, respectively.

With respect to the GMC of anti-gE antibody, antibodies that are able to bind to recombinant gE protein are measured, which include both functional and non-functional antibodies (neutralizing antibodies and non-neutralizing antibodies that have no virus killing effect). Therefore, the GMC values do not determine the exact proportion of neutralizing antibodies compared to non-neutralizing antibodies, and cannot directly demonstrate immunogenicity. Since anti-VZV antibody is the neutralizing antibody, the FAMA test that detects anti-VZV antibody is the gold standard and approved by the CDE. Therefore, as discussed above, as the GMT of anti-VZV antibody of the high-dose LZ901 group (GMT of 512.00) and Shingrix<sup>®</sup> positive control group (GMT of 652.58) 30 days after the full course vaccination have been demonstrated to be consistent statistically, it is indicated that the immunogenicity of LZ901 is not weaker than that of Shingrix<sup>®</sup>.

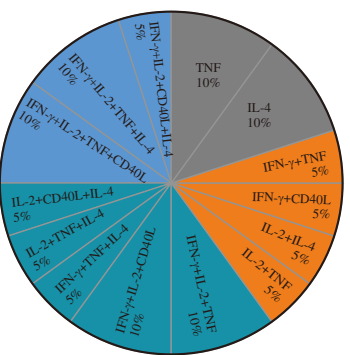
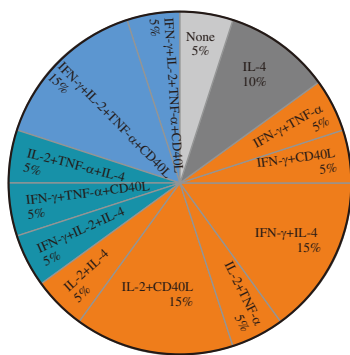
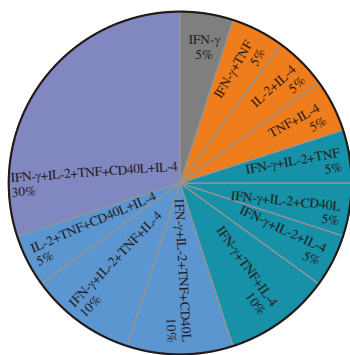
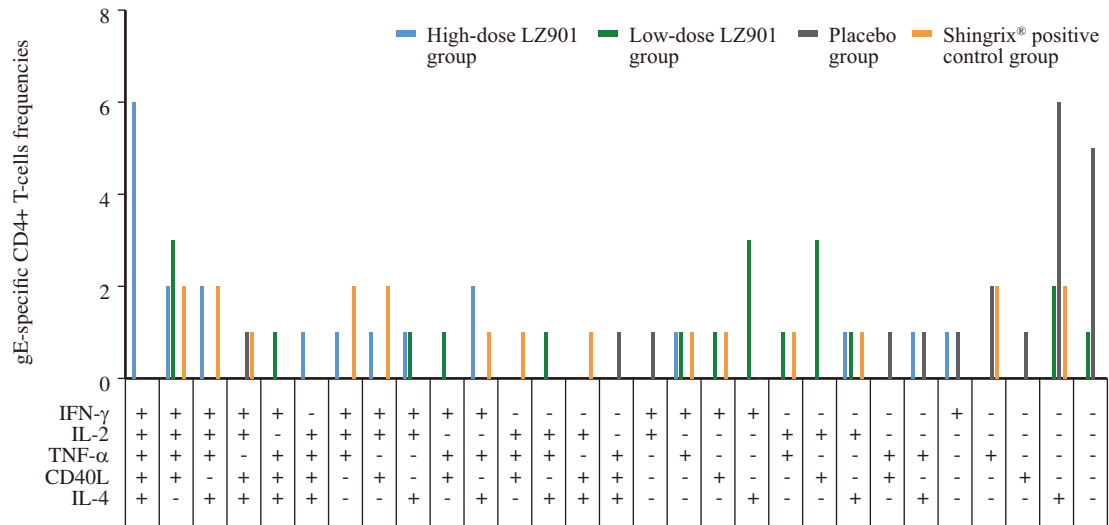
## BUSINESS

Cellular immune response in terms of activation of helper (CD4+) T cell expression of gE-specific biomarkers (IFN- $\gamma$ , TNF- $\alpha$ , IL-2, IL-4 and CD40L). For the low-dose LZ901 group, the number of subjects with helper (CD4+) T cells expressing at least two, at least three, at least four and five gE-specific activation biomarkers 30 days after the full course of vaccination was 17, seven, four and nil subjects, respectively, representing 85%, 35%, 20% and 0% of the subjects in the low-dose LZ901 group, respectively. For the high-dose LZ901 group, the number of subjects with helper (CD4+) T cells expressing at least two, at least three, at least four and five gE-specific activation biomarkers 30 days after the full course of vaccination was 19, 16, 11 and six subjects, respectively, representing 95%, 80%, 55% and 30% of the subjects in the high-dose LZ901 group, respectively. For the placebo group, the number of subjects with helper (CD4+) T cells expressing at least two, at least three, at least four and five gE-specific activation biomarkers 30 days after the full course of vaccination was five, two, one and nil subjects, respectively, representing 25%, 10%, 5% and 0% of the subjects in the placebo group, respectively. For the Shingrix<sup>®</sup> positive control group, the number of subjects with helper (CD4+) T cells expressing at least two, at least three, at least four and five gE-specific activation biomarkers 30 days after the full course of vaccination was 16, 12, five and nil subjects, respectively, representing 80%, 60%, 25% and 0% of the subjects in the Shingrix<sup>®</sup> positive control group, respectively.

The chi-square test for trend demonstrated that the ability of the high-dose LZ901 group to activate helper (CD4+) T cells to express gE-specific activation biomarkers 30 days after the full course of vaccination was significantly higher than that of the low-dose LZ901 group ( $p_{\text{high-dose LZ901 group vs. low-dose LZ901 group}} = 0.0026$ ) and the Shingrix<sup>®</sup> positive control group ( $p_{\text{high-dose LZ901 group vs. Shingrix}^{\text{®}} \text{ positive control group}} = 0.0158$ ). Compared to the Shingrix<sup>®</sup> positive control group, the low-dose LZ901 group had a similar ability to activate helper (CD4+) T cells to express gE-specific activation biomarkers 30 days after the full course of vaccination. There was no significant difference between the high-dose LZ901 group, low-dose LZ901 group and Shingrix<sup>®</sup> positive control group to activate helper (CD4+) T cells to express two or more gE-specific activation biomarkers 30 days after the full course of vaccination ( $p_{\text{high-dose LZ901 group vs. low-dose LZ901 group}} = 0.6050$ ;  $p_{\text{high-dose LZ901 group vs. Shingrix}^{\text{®}} \text{ positive control group}} = 0.3416$ ;  $p_{\text{low-dose LZ901 group vs. Shingrix}^{\text{®}} \text{ positive control group}} = 1.000$ ).

**BUSINESS**

**LZ901 and Shingrix® Activation of Helper (CD4+) T Cell Expression of Multiple VZV gE-Specific Biomarkers 30 Days After the Full Course of Vaccination**



High-dose LZ901 group

Low-dose LZ901 group

Shingrix® positive control group

Source: Company Data

## BUSINESS

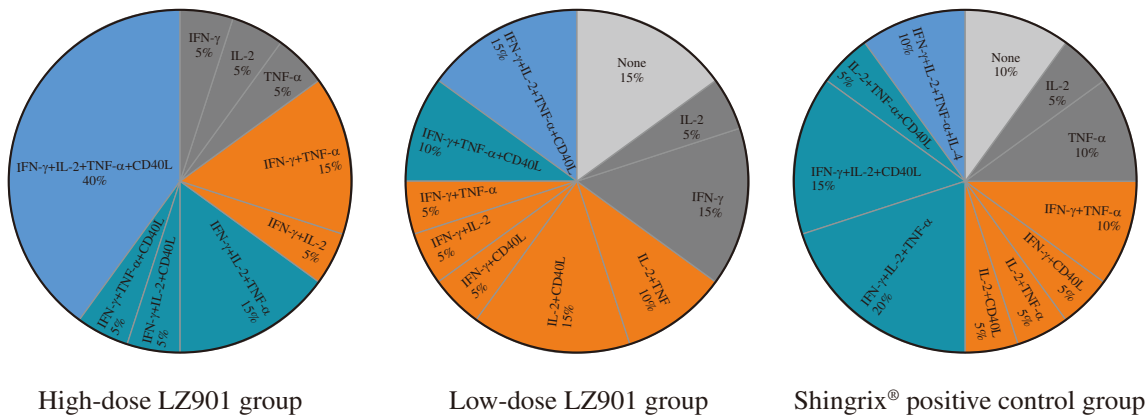
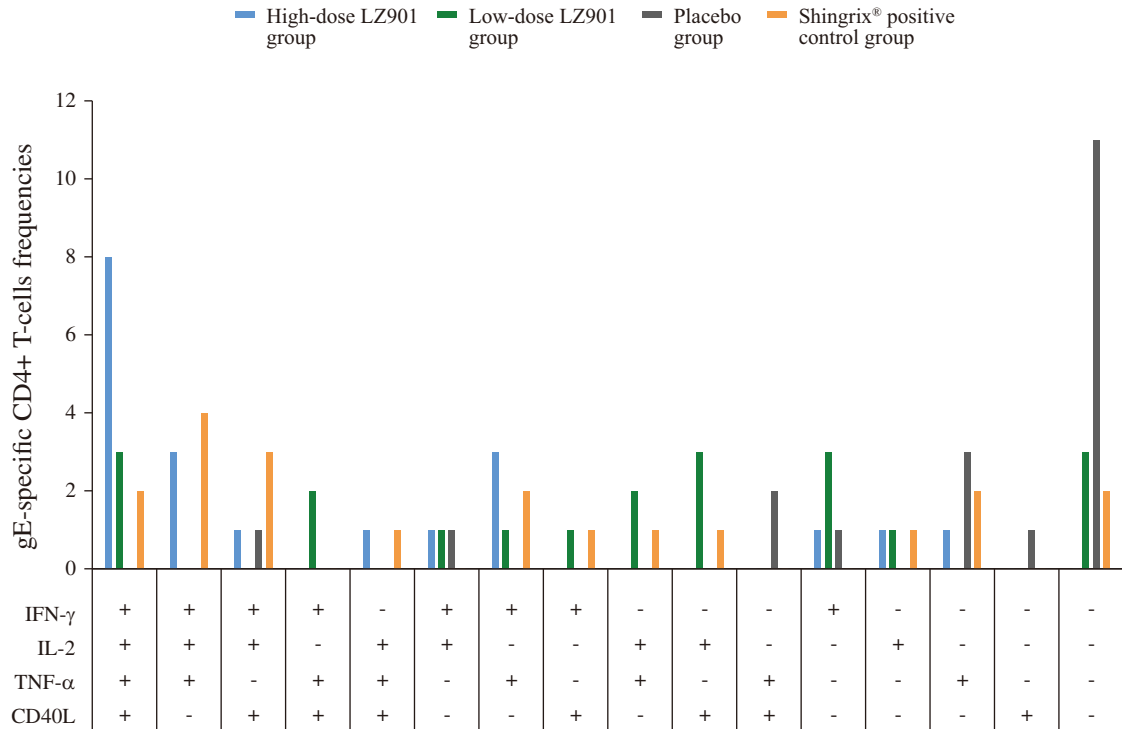
Cellular immune response in terms of activation of helper (CD4+) T cell expression of gE-specific biomarkers (IFN- $\gamma$ , TNF- $\alpha$ , IL-2 and CD40L). For the low-dose LZ901 group, the number of subjects with helper (CD4+) T cells expressing at least two, at least three and four gE-specific activation biomarkers 30 days after the full course of vaccination was 13, five and three subjects, respectively, representing 65%, 25% and 15% of the subjects in the low-dose LZ901 group, respectively. For the high-dose LZ901 group, the number of subjects with helper (CD4+) T cells expressing at least two, at least three and four gE-specific activation biomarkers 30 days after the full course of vaccination was 17, 13 and eight subjects, respectively, representing 85%, 65% and 40% of the subjects in the high-dose LZ901 group, respectively. For the placebo group, the number of subjects with helper (CD4+) T cells expressing at least two, at least three and four gE-specific activation biomarkers 30 days after the full course of vaccination was four, one and nil subjects, respectively, representing 20%, 5% and 0% of the subjects in the placebo group, respectively. For the Shingrix<sup>®</sup> positive control group, the number of subjects with helper (CD4+) T cells expressing at least two, at least three and four gE-specific activation biomarkers 30 days after the full course of vaccination was 15, 10 and two subjects, respectively, representing 75%, 50% and 10% of the subjects in the Shingrix<sup>®</sup> positive control group, respectively.

The chi-square test for trend demonstrated the ability of the high-dose LZ901 group to activate helper (CD4+) T cells to express four gE-specific activation biomarkers 30 days after the full course of vaccination was significantly higher than that of the low-dose LZ901 group ( $p_{\text{high-dose LZ901 group vs. low-dose LZ901 group}} = 0.0133$ ) and the Shingrix<sup>®</sup> positive control group ( $p_{\text{high-dose LZ901 group vs. Shingrix}^{\text{®}} \text{ positive control group}} = 0.0800$ ). Compared to the Shingrix<sup>®</sup> positive control group, the low-dose LZ901 group and the high-dose LZ901 group had a similar ability to activate helper (CD4+) T cells to express gE-specific activation biomarkers 30 days after the full course of vaccination ( $p_{\text{low-dose LZ901 group vs. Shingrix}^{\text{®}} \text{ positive control group}} = 0.3589$ ;  $p_{\text{high-dose LZ901 group vs. Shingrix}^{\text{®}} \text{ positive control group}} = 0.0800$ ). There was no significant difference between the high-dose LZ901 group, low-dose LZ901 group and Shingrix<sup>®</sup> positive control group to activate helper (CD4+) T cells to express two or more gE-specific activation biomarkers 30 days after the full course of vaccination ( $p_{\text{high-dose LZ901 group vs. low-dose LZ901 group}} = 0.1441$ ;  $p_{\text{high-dose LZ901 group vs. Shingrix}^{\text{®}} \text{ positive control group}} = 0.6948$ ;  $p_{\text{low-dose LZ901 group vs. Shingrix}^{\text{®}} \text{ positive control group}} = 0.4902$ ).



**BUSINESS**

**LZ901 and Shingrix® Activation of Helper (CD4+) T Cell Expression of Multiple VZV gE-Specific Biomarkers 30 Days After the Full Course of Vaccination**



Source: Company Data

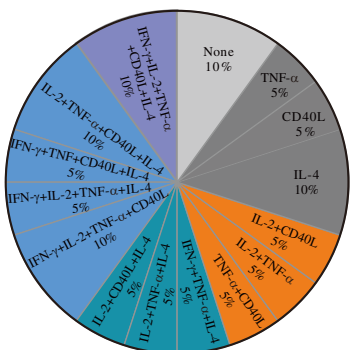
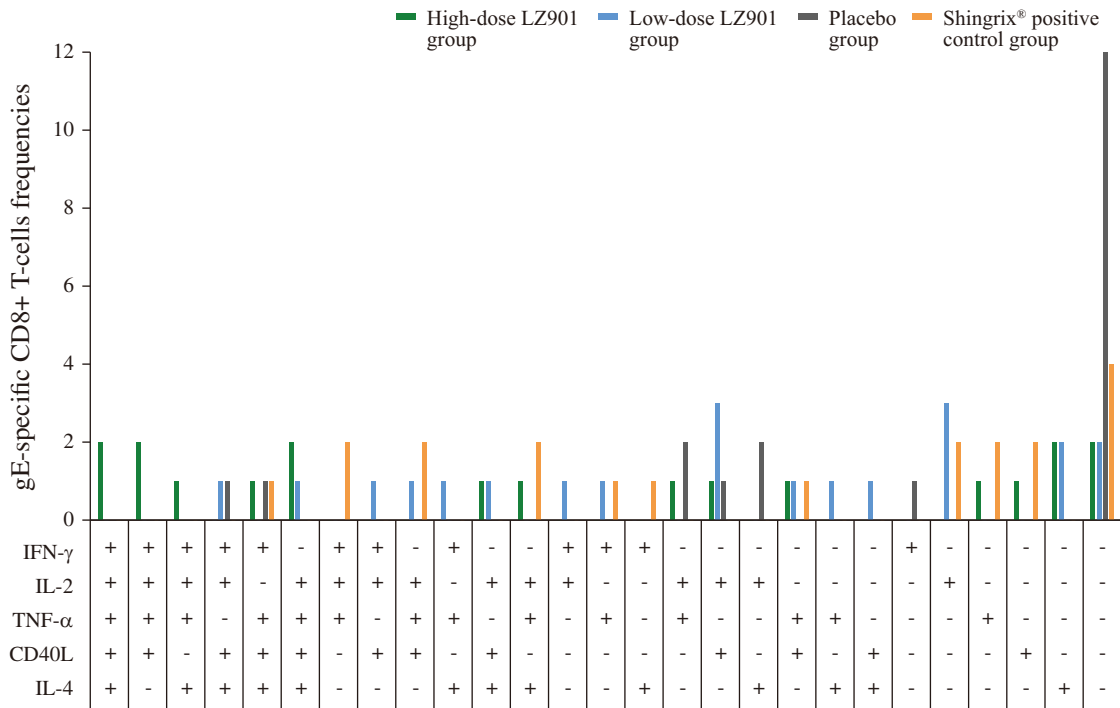
## BUSINESS

Cellular immune response in terms of activation of cytotoxic (CD8+) T cell expression of gE-specific biomarkers (IFN- $\gamma$ , TNF- $\alpha$ , IL-2, IL-4 and CD40L). For the low-dose LZ901 group, the number of subjects with cytotoxic (CD8+) T cells expressing at least two, at least three, at least four and five gE-specific activation biomarkers 30 days after the full course of vaccination was 13, five, two and nil subjects, respectively, representing 65%, 25%, 10% and 0%, respectively. For the high-dose LZ901 group, the number of subjects with cytotoxic (CD8+) T cells expressing at least two, at least three, at least four and five gE-specific activation biomarkers 30 days after the full course of vaccination was 14, 11, eight and two subjects, respectively, representing 70%, 55%, 40% and 10% of the subjects in the high-dose LZ901 group, respectively. For the placebo group, the number of subjects with cytotoxic (CD8+) T cells expressing at least two, at least three, at least four and five gE-specific activation biomarkers 30 days after the full course of vaccination was seven, two, two and nil subjects, respectively, representing 35%, 10%, 10% and 0% of the subjects in the placebo group, respectively. For the Shingrix<sup>®</sup> positive control group, the number of subjects with cytotoxic (CD8+) T cells expressing at least two, at least three, at least four and five gE-specific activation biomarkers 30 days after the full course of vaccination was 10, seven, one and nil subjects, respectively, representing 50%, 35%, 5% and 0% of the subjects in the Shingrix<sup>®</sup> positive control group, respectively.

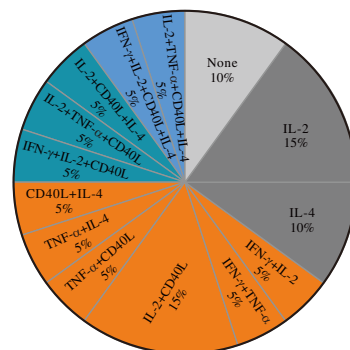
The chi-square test for trend demonstrated the ability of the high-dose LZ901 group to activate cytotoxic (CD8+) T cells to express gE-specific activation biomarkers was significantly higher than that of the Shingrix<sup>®</sup> positive control group ( $p_{\text{high-dose LZ901 group vs. Shingrix}^{\text{®}} \text{ positive control group}} = 0.0452$ ), and the ability of the low-dose LZ901 group to activate cytotoxic (CD8+) T cells to express gE-specific activation biomarkers was not significantly different from the high-dose LZ901 group ( $p_{\text{high-dose LZ901 group vs. low-dose LZ901 group}} = 0.0935$ ) and the Shingrix<sup>®</sup> positive control group ( $p_{\text{low-dose LZ901 group vs. Shingrix}^{\text{®}} \text{ positive control group}} = 0.5923$ ). There was no significant difference between the high-dose LZ901 group, low-dose LZ901 group and Shingrix<sup>®</sup> positive control group to activate cytotoxic (CD8+) T cells to express two or more gE-specific activation biomarkers 30 days after the full course of vaccination ( $p_{\text{high-dose LZ901 group vs. low-dose LZ901 group}} = 0.7537$ ;  $p_{\text{high-dose LZ901 group vs. Shingrix}^{\text{®}} \text{ positive control group}} = 0.1967$ ;  $p_{\text{low-dose LZ901 group vs. Shingrix}^{\text{®}} \text{ positive control group}} = 0.3373$ ).

**BUSINESS**

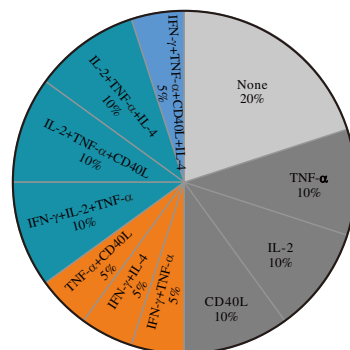
**LZ901 and Shingrix® Activation of Cytotoxic (CD8+) T Cell Expression of Multiple VZV gE-Specific Biomarkers 30 Days After the Full Course of Vaccination**



High-dose LZ901 group



Low-dose LZ901 group



Shingrix® positive control group

Source: Company Data

## BUSINESS

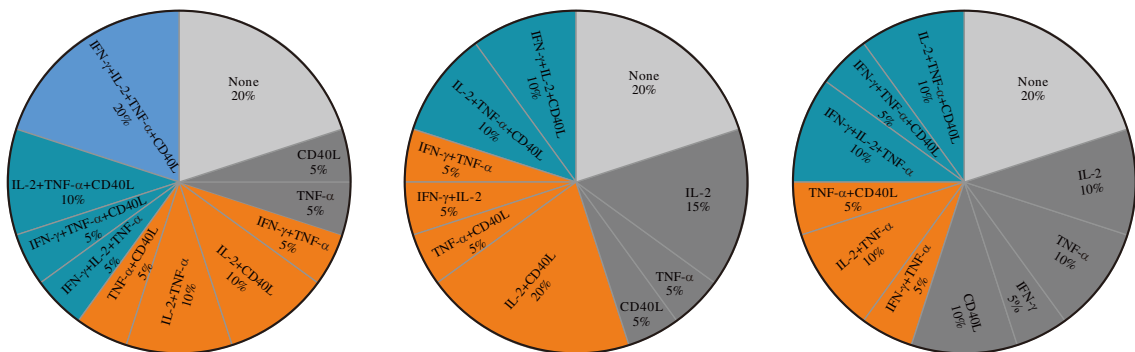
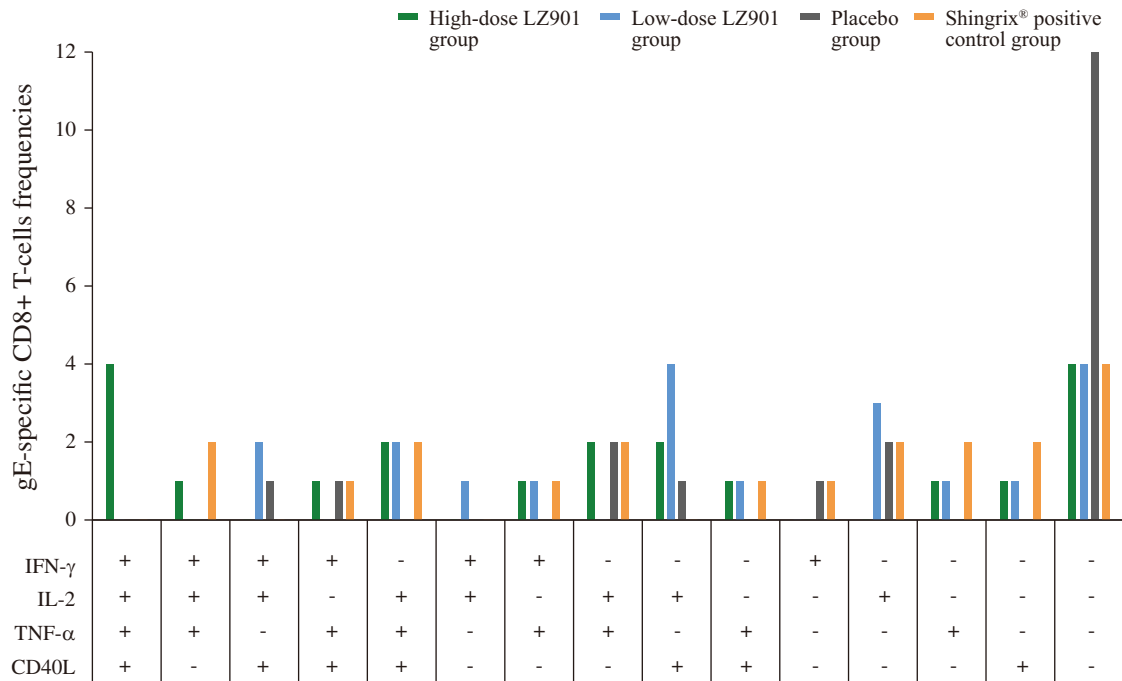
---

Cellular immune response in terms of activation of cytotoxic (CD8+) T cell expression of gE-specific biomarkers (IFN- $\gamma$ , TNF- $\alpha$ , IL-2 and CD40L). For the low-dose LZ901 group, the number of subjects with cytotoxic (CD8+) T cells expressing at least two, at least three and four gE-specific activation biomarkers 30 days after the full course of vaccination was 11, four and nil subjects, respectively, representing 55%, 20% and 0%, respectively. For the high-dose LZ901 group, the number of subjects with cytotoxic (CD8+) T cells expressing at least two, at least three and four gE-specific activation biomarkers 30 days after the full course of vaccination was 14, eight and four subjects, respectively, representing 70%, 40% and 20% of the subjects in the high-dose LZ901 group, respectively. For the placebo group, the number of subjects with cytotoxic (CD8+) T cells expressing at least two, at least three and four gE-specific activation biomarkers 30 days after the full course of vaccination was five, two and nil subjects, respectively, representing 25%, 10% and 0% of the subjects in the placebo group, respectively. For the Shingrix<sup>®</sup> positive control group, the number of subjects with cytotoxic (CD8+) T cells expressing at least two, at least three and four gE-specific activation biomarkers 30 days after the full course of vaccination was nine, five and nil subjects, respectively, representing 45%, 25% and 0% of the subjects in the Shingrix<sup>®</sup> positive control group, respectively.

The chi-square test for trend demonstrated there was no significant difference between the ability of the high-dose LZ901 group, low-dose LZ901 group and Shingrix<sup>®</sup> positive control group to express four gE-specific activation biomarkers ( $p_{\text{high-dose LZ901 group vs. low-dose LZ901 group}} = 0.1670$ ;  $P_{\text{high-dose LZ901 group vs. Shingrix}^{\text{®}} \text{ positive control group}} = 0.1398$ ;  $p_{\text{low-dose LZ901 group vs. Shingrix}^{\text{®}} \text{ positive control group}} = 0.8816$ ). There was no significant difference between the high-dose LZ901 group, low-dose LZ901 group and Shingrix<sup>®</sup> positive control group to activate cytotoxic (CD8+) T cells to express two or more gE-specific activation biomarkers 30 days after the full course of vaccination ( $p_{\text{high-dose LZ901 group vs. low-dose LZ901 group}} = 0.3272$ ;  $p_{\text{high-dose LZ901 group vs. Shingrix}^{\text{®}} \text{ positive control group}} = 0.1098$ ;  $P_{\text{low-dose LZ901 group vs. Shingrix}^{\text{®}} \text{ positive control group}} = 0.5271$ ).

**BUSINESS**

**LZ901 and Shingrix® Activation of Cytotoxic (CD8+) T Cell Expression of Multiple VZV gE-Specific Biomarkers 30 Days After the Full Course of Vaccination**



High-dose LZ901 group

Low-dose LZ901 group

Shingrix® positive control group

Source: Company Data

IL-4 is a gE-specific biomarker that induces an immune response by Th2 cells, while IFN- $\gamma$ , TNF- $\alpha$ , IL-2 and CD40L are gE-specific biomarkers that induce an immune response by Th1 cells. Th2 cells are helper (CD4+) T cells that transmit immune signals to B cells, stimulating B cells to differentiate into plasma cells to create antibodies to produce humoral immunity. Th1 cells are helper (CD4+) T cells that transmit processed immune signals to other effector cells, including cytotoxic (CD8+) T cells, activating effector cells to kill invading microorganisms. The immune response in terms of T cell expression of gE-specific biomarkers with IL-4 assesses Th1 and Th2 cell immune responses and without IL-4 assesses only Th1 cell immune responses. With the detection of more gE-specific biomarkers, the process of immune responses can be understood more objectively.

*Anti-Fc antibody and anti-nuclear antibody levels.* The anti-Fc antibody and anti-nuclear antibody levels of subjects in the low-dose LZ901, high-dose LZ901, placebo and Shingrix® positive control groups remained relatively unchanged 30 days after vaccination.

## BUSINESS

### *Ongoing Phase II Clinical Trial*

*Trial design and status.* We commenced a randomized, double-blinded and placebo-controlled Phase II clinical trial for LZ901 in Hubei province in April 2022. The primary objectives of this clinical trial are to evaluate the immunogenicity and safety of different doses of LZ901 in healthy people aged between 50 to 70 years old. The secondary objective of this clinical trial is to evaluate the immune persistence of different doses of LZ901 in healthy people aged between 50 to 70 years old. According to requirements of the approval notice of the NMPA for drug clinical trials of prophylactic biological products, only early studies with a positive control are required for prophylactic biological products. As LZ901 is classified as a prophylactic biological product, the active-controlled Phase I clinical trial for LZ901 satisfies this requirement and there is no further requirement to conduct a similar head-to-head study with Shingrix<sup>®</sup> for the Phase II clinical trial for LZ901, which we believe will not affect the future commercialization of LZ901.

A total of 450 subjects aged between 50 to 70 years old were enrolled in the Phase II clinical trial for LZ901. The subjects were divided into three groups, including (i) low-dose group with 150 subjects receiving 50µg/0.5mL/vial of LZ901, (ii) high-dose group with 150 subjects receiving 100µg/0.5mL/vial of LZ901 and (iii) placebo group with 150 subjects receiving a 0.5mL/vial placebo. Details of the trial groups are set out in the following table:

<b>Group</b>	<b>Sample Size</b>	<b>Vaccination Program</b>
Low-Dose	150 subjects	Day 0 and one month inoculate one dose in the deltoid muscle of the upper arm (injection in the deltoid muscle of the upper arm on the left and right sides in turn)
High-Dose	150 subjects	
Placebo	150 subjects	

The subjects in the low-dose LZ901 group, high-dose LZ901 group and placebo group received an intramuscular injection on day 0 and one month. During the treatment period, immunogenicity, safety and immune persistence will be evaluated. In order to evaluate the immunogenicity of LZ901, we conducted follow-up evaluations at 30 days following the administration of the second dose by collecting blood samples of subjects to test for the serum concentration of anti-gE antibody by ELISA and anti-VZV antibody titer by fluorescent antibody to membrane antigen (“FAMA”). In order to evaluate the safety of LZ901, we will conduct follow-up evaluations at six months following the administration of the second dose by recording the occurrence of AEs in subjects. In addition, we will conduct follow-up evaluations at six months, 12 months, 24 months and 36 months following the administration of the second dose to evaluate the long-term immune persistence of LZ901 by collecting blood samples of subjects to test for the serum concentration of anti-gE antibody by ELISA and anti-VZV antibody titer by FAMA.

The immunogenicity primary endpoints were (i) the GMC of anti-gE antibody and the GMT of anti-VZV antibody at 30 days following the administration of the second dose; and (ii) positive conversion rate of anti-gE antibody and anti-VZV antibody at 30 days following the administration of the second dose. The safety primary endpoints were the occurrence of (i) AEs within 30 minutes, seven days (including solicited AEs) and 30 days (non-solicited AEs) after administration of each

## BUSINESS

---

dose, and incidence of vaccine-related and unrelated AEs of varying severity; and (ii) SAEs after injection of the first dose to six months after administration of the second dose. The immune persistence secondary endpoint was the GMC and positive conversion rate of anti-gE antibody, and GMT and positive conversion rate of anti-VZV antibody at six months, 12 months, 24 months and 36 months following the administration of the second dose.

As of the Latest Practicable Date, we had (i) completed subject enrollment of all 450 trial subjects from April 2022 to May 2022, (ii) administered the first and second doses from May 2022 to July 2022, (iii) collected blood samples before the first dose, at 30 days following the administration of the first dose and 30 days following the administration of the second dose, and the number of samples has satisfied the criteria required for a valid study, and (iv) delivered such samples to the NIFDC for serum testing to evaluate the immunogenicity of LZ901 in August 2022, pending immunogenicity, safety or immune persistence data. In addition, we had completed six-month follow-ups with trial subjects following the administration of the second dose and collected blood samples from such trial subjects to evaluate the long-term immune persistence of LZ901. As of the Latest Practicable Date, the completion rate for the six-month follow-ups and blood sample collections reached 96.1%, which has already satisfied the criteria required for a valid study under the Phase II clinical trial study protocol for LZ901. We expect to complete the Phase II clinical trial in the second quarter of 2023. The incompleteness of follow-up evaluations at six months to 36 months following the administration of the second dose to evaluate the long-term immune persistence of LZ901 will not affect the further clinical development of LZ901, including the commencement of the Phase III clinical, primarily because (i) according to the clinical trial protocol of the Phase II clinical trial for LZ901, such follow-up evaluations are secondary (exploratory) endpoints to evaluate the long-term immune persistence of LZ901, while the primary immunogenicity endpoint only requires a 30-day follow-up and safety endpoint only requires a six-month follow-up as stated above, which the on-site work had been completed and only sample testing was pending as of the Latest Practicable Date; and (ii) based on the umbrella CTA approval we obtained for LZ901, we do not need to apply for additional CTAs before commencing the Phase III clinical trial, and according to Frost & Sullivan, the CDE generally would not have any objection for a vaccine developer that had obtained the umbrella CTA approval to proceed with the next-stage clinical trial. The BLA approval and future commercialization of LZ901 is subject to various factors such as the demonstration of LZ901’s safety and immunogenicity by clinical trial results and NMPA’s confirmation that the relevant requirements on production (including determination of quality standards, completion of the validation of commercial-scale production processes, etc.) are completely satisfied. Some of such factors are beyond our control. Although we believe that the incompleteness of the 36 months follow-ups would not materially affect the clinical development, BLA approval and future commercialization of LZ901, we could not assure you that there is no associated risk, given that the clinical development of LZ901, like any other drugs, is inherently unpredictable. Potential adverse events may occur and the clinical results may not be what we expect, which could halt our planned clinical plans and our commercialization efforts. For details, please see “Risk Factors — Risks Relating to Our Business and Industry — Risks Relating to the Research and Development of Our Product Candidates” in the document.

### *Phase III Clinical Trial Design*

The Phase III clinical trial protocol for LZ901 has not been finalized, however, we will hold a meeting with the CDE to communicate the results of the Phase II clinical trial for LZ901 and to determine whether any adjustments are required to finalize the Phase III clinical trial protocol

## BUSINESS

---

prior to initiating the Phase III clinical trial for LZ901. We plan to initiate a multi-center, randomized, double-blind, placebo-controlled Phase III clinical trial comparing LZ901 against Shingrix<sup>®</sup> for LZ901 in China in the second quarter of 2023.

The Phase III clinical trial for LZ901 will be divided into two studies, comprising the protective efficacy study, which we plan to enroll approximately 30,000 healthy subjects aged 40 years old and above and will divide the subjects in a 1:1 ratio into a LZ901 group and placebo group, to compare the protective efficacy, immunogenicity and immune persistence of LZ901 against placebo and the comparative study, which we plan to enroll approximately 300 healthy subjects aged 50 to 70 years old and will divide the subjects in a 1:1 ratio into a LZ901 group and Shingrix<sup>®</sup> group, to compare the immunogenicity of LZ901 against Shingrix<sup>®</sup>.

The primary objective of this clinical trial is to evaluate the protective efficacy of LZ901 compared to placebo in preventing herpes zoster in subjects aged 40 years old and above. The secondary objectives of this clinical trial are to evaluate (i) the immunogenicity and immune persistence of LZ901 compared to placebo in subjects aged 40 years old and above.

For the protective efficacy study, after the administration of all doses of LZ901 and the placebo have been completed and the number of herpes zoster cases required by the clinical trial protocol are accumulated, we plan to conduct a protective efficacy analysis and along with follow-up evaluations at 90 days after the cut-off date of the cases of herpes zoster are accumulated.

In order to evaluate the immunogenicity of LZ901, we plan to conduct follow-up evaluations at 30 days following the administration the final dose by collecting blood samples of subjects to test for the serum concentration of anti-gE antibody by ELISA.

In order to evaluate the long-term immune persistence of LZ901, we plan to conduct follow-up evaluations at 12 months, 24 months and 36 months following the administration of the final dose by collecting blood samples of subjects to test for the serum concentration of anti-gE antibody by ELISA.

For the comparative study against Shingrix<sup>®</sup>, we plan to collect cellular immune response, humoral response, and safety data to compare the immunogenicity and safety of LZ901 against Shingrix<sup>®</sup>.

After unblinding of the protective efficacy, immunogenicity and safety data, we plan to file the BLA to the NMPA in the third quarter of 2024, while continuing to observe and collect immune persistence data. All clinical trial data, excluding the immune persistence secondary endpoint data, will be used to file the BLA.

### ***Ongoing Phase I Clinical Trial in the U.S.***

*Trail design and status.* We commenced a randomized, double-blinded and placebo-controlled Phase I clinical trial for LZ901 in New Jersey, U.S. in February 2023. The primary objectives of this clinical trial are to evaluate the safety and tolerability of different doses of LZ901 in subjects aged between 50 to 70 years old. The exploratory objectives of this clinical trial are to preliminarily explore the immunogenicity of LZ901 in subjects aged between 50 to 70 years old and explore the safety of LZ901 by assessing the change of anti-Fc antibody in subjects aged 50 to 70 years old.



**BUSINESS**

A total of approximately 66 subjects aged between 50 to 70 years old are expected to be enrolled in the Phase I clinical trial for LZ901 in the U.S. The subjects will be divided into five groups, including (i) low-dose sentinel group with three subjects receiving 50µg/0.5mL/vial of LZ901, (ii) high-dose sentinel group with three subjects receiving 100µg/0.5mL/vial of LZ901, (iii) low-dose main group with 20 subjects receiving 50µg/0.5mL/vial of LZ901, (iv) high-dose main group with 20 subjects receiving 100µg/0.5mL/vial of LZ901 and (v) placebo group with 20 subjects receiving a 0.5mL/vial placebo. Details of the trial groups are set out in the following table:

Group	LZ901		Adjuvant
	50µg/0.5mL	100µg/0.5mL	
Low-Dose Sentinel Group	3 subjects	–	–
High-Dose Sentinel Group	–	3 subjects	–
Low-Dose Main Group	20 subjects	–	–
High-Dose Main Group	–	20 subjects	–
Placebo Group			20 subjects (10 subjects enrolled with each low-dose main LZ901 group and high-dose main LZ901 group)

The subjects in the low-dose sentinel group, high-dose sentinel group, low-dose main group, high-dose main group and placebo group will receive an intramuscular injection on day 0 and day 30. During the treatment period, safety, tolerability and immunogenicity will be evaluated. In order to evaluate the early safety signals of LZ901, two sentinel groups will be sequentially enrolled from low-dose (low-dose sentinel group) to high dose-dose (high-dose sentinel group) in open-label, prior to initiation of dosing in each dose level main group (low-dose main group and high-dose main group). Three subjects will be first enrolled in the low-dose sentinel group and administered two doses of LZ901 on Day 0 and Day 30, respectively. After reviewing the safety through seven days after the first dose of LZ901, if no safety signals occur, another three subjects will be enrolled into the high-dose sentinel group. Then if also no safety signals occur through seven days after the first dose of LZ901 in the high-dose sentinel group, 30 subjects will be randomized in a 2:1 ratio to receive two doses of LZ901 in the low-dose main group or placebo in the placebo group in a double-blind fashion. Subjects will be enrolled in the high-dose main group and placebo group also after the safety review through seven days after the first dose of LZ901 in the low-dose main group or placebo in the placebo group.

The safety and tolerability primary endpoints are (i) the incidence and severity of vaccine-related and unrelated AEs, including AEs occurred within 30 minutes after each study intervention, solicited local and systemic AEs from Day 0 through Day 6, unsolicited AEs from Day 0 through Day 29 after each study intervention, (ii) the incidence of AEs leading to withdrawal, (iii) the incidence of all SAEs and medically attended adverse events (“**MAAEs**”) from Day 0 through 6 months after the full course vaccination, and (iv) the incidence of abnormal laboratory tests results on Day 3 (+ 1 day) after each study intervention. The exploratory endpoint to preliminarily explore the immunogenicity of LZ901 are (i) the seropositivity rate (percentage of seropositive subjects) of anti-gE antibody and anti-VZV antibody on Day 30 after each study

## BUSINESS

---

intervention, (ii) GMC of anti-gE antibody and GMT of anti-VZV antibody on Day 30 after each study intervention, and (iii) the seroconversion rate (percentage of seroconversion subjects) of anti-gE antibody and anti-VZV antibody on Day 30 after each study intervention. The exploratory endpoint to explore the safety of LZ901 by assessing the change of anti-Fc antibody is the change of anti-Fc antibody on Day 30 after each study intervention compared with pre-immunization.

As of the Latest Practicable Date, we had initiated subject enrollment and plan to complete subject enrollment in the second quarter of 2023. We plan to complete the Phase I clinical trial for LZ901 in the U.S. in the first quarter of 2024.

### *Licenses, Rights and Obligations*

We have the global rights to develop and commercialize LZ901.

### *Material Communications with Competent Authorities*

We received an umbrella CTA approval for LZ901 from the NMPA in August 2021 and completed a Phase I clinical trial in China. Based on the umbrella CTA approval we obtained for LZ901 and the existing PRC laws and regulations, the umbrella CTA approval for LZ901 shall also apply to the Phase II and Phase III clinical trials and we do not need to apply for additional CTAs. For details of the PRC laws and regulations for umbrella approval, please see “Regulatory Overview — Regulatory Provisions — Laws and Regulations Related to Drugs — Clinical Trials Approval” in this document. Based on the interview with the CDE of the NMPA in June 2022, it confirmed that our Phase I clinical trial in China was completed and it has no objection for us to proceed to Phase II clinical trial in China. Our PRC Legal Adviser is of the view that the CDE is the competent authority to give the above confirmations.

We are currently conducting a Phase II clinical trial and expect to complete the Phase II clinical trial in the second quarter of 2023 in China as all on-site work and follow-up sampling for the Phase II clinical trial was completed in January 2023. We expect to complete serum testing, statistical analysis of data, and generation of the clinical trial report in the second quarter of 2023. The Phase III clinical trial protocol has not been finalized, however, we will hold a meeting with the CDE to communicate the results of the Phase II clinical trial for LZ901 and to determine whether any adjustments are required to finalize the Phase III clinical trial protocol prior to initiating the Phase III clinical trial. Currently, we have completed the production and verification of LZ901 clinical trial samples at our Zhuhai manufacturing facility, and the Phase III clinical trial can be initiated in the second quarter of 2023. We plan to initiate a multi-center, randomized, double-blind, placebo-controlled Phase III clinical trial comparing LZ901 against Shingrix<sup>®</sup> for LZ901 in China in the second quarter of 2023. Subject enrollment to unblinding of the clinical trial data is expected to be completed within approximately 10 months, which we expect to complete in the second quarter of 2024, while continuing to conduct follow-up evaluations to observe and collect immune persistence secondary endpoint data. After completing the primary endpoint and secondary endpoints, excluding the immune persistence secondary endpoint, of the Phase III clinical trial, we plan to complete production and testing of three batches of LZ901 for commercialization by the third quarter of 2024 and file the BLA in the third quarter of 2024 to the NMPA. In addition, we have received IND approval from the FDA in July 2022 for LZ901 and initiated a Phase I clinical trial in the U.S. in February 2023.

**WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET LZ901 SUCCESSFULLY.**

## BUSINESS

### 2. K3

#### *Overview*

K3, our independently developed recombinant human anti-TNF- $\alpha$  monoclonal antibody injection product candidate, is a biosimilar of adalimumab and mainly used for the treatment of various autoimmune diseases, such as rheumatoid arthritis, ankylosing spondylitis and plaque psoriasis. We developed K3 based on the antibody structure of adalimumab. Adalimumab is a blockbuster TNF- $\alpha$  inhibitor marketed by AbbVie Inc. under the brand name Humira<sup>®</sup>, with global sales of US\$20.7 billion in 2021. Since the initial FDA approval in December 2002, adalimumab has been approved for various indications worldwide, including rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn’s disease, ulcerative colitis, plaque psoriasis, hidradenitis suppurativa, juvenile idiopathic arthritis and non-infectious uveitis. K3 is expected to primarily compete with the Qletli<sup>®</sup> (格樂立), Sulinno<sup>®</sup> (蘇立信), Anjianning (安建寧), Handayuan (漢達遠), Taibowei (泰博維), Junmaikang (君邁康) and other adalimumab biosimilars that have been launched or currently under development in China.

The molecular design of K3 maximizes the safety of the antibody when used in the human body. We expect K3 to expand the market in China for adalimumab biosimilars.

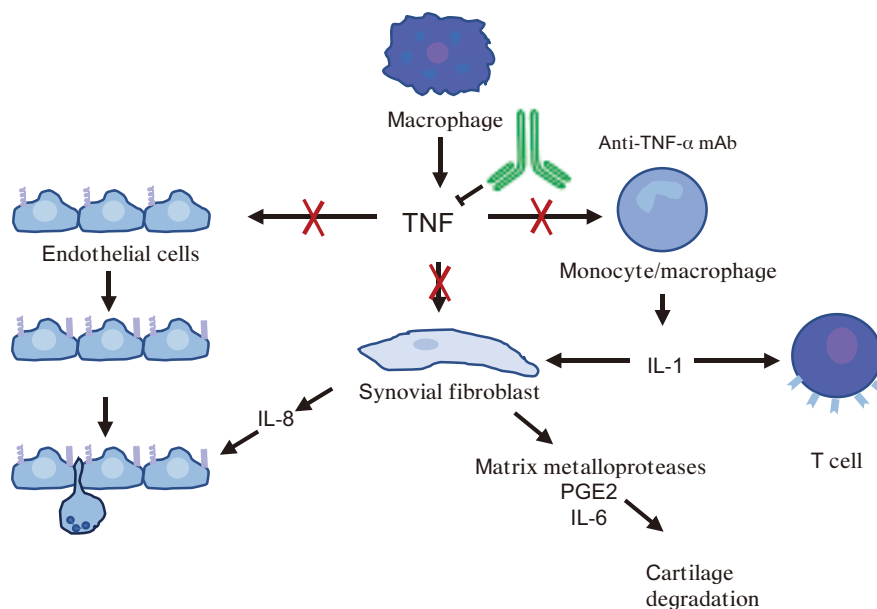
We commenced the development of K3 in 2010. Development of K3 is led by Mr. KONG Jian, our co-founder, executive Director, general manager and chief scientist, who has over 33 years of biopharmaceutical experience. Mr. KONG initiated the development of K3 in 2010 and led the development of K3 in gene synthesis, clone screening, establishing cell banks, production scale-up, purification method development and quality control testing. Mr. KONG contributed as the general director for the filing of the CTA application for K3 to the NMPA. In 2021, Mr. KONG guided the first-stage technology transfer at our Zhuhai manufacturing facilities to produce K3. Going forward, Mr. KONG will continue to guide the technology transfer to complete the large-scale commercial production of K3 at our first- and second-phase Zhuhai manufacturing facilities. We synthesized the genes that code for K3, developed the recombinant plasmid containing the K3 gene, transfected CHO K1 cells with the recombinant plasmid, cloned cell lines, screened clones for high-expression of K3 and established K3 cell banks. From 2010 to 2011, we developed the K3 cell bioreactor culture and antibody purification process parameters, and the K3 monoclonal antibody injection. In 2013, we engaged a CRO to conduct the preclinical safety research of K3. We produced the first pilot batch of K3 in 2016 and received an umbrella CTA approval for K3 from the NMPA in November 2017. In September 2018, we initiated a Phase I clinical trial for K3 in China for the treatment of various autoimmune diseases, and completed the Phase I clinical trial in December 2019. Since March 2021, we have optimized bioreactor culture conditions to improve our production capabilities, and monitored and improved K3 product stabilities. From the beginning of 2022 to October 2022, we increased the production yield of K3 by approximately 300%. In order to produce sufficient K3 antibodies to support our Phase III clinical trial for K3, we plan to conduct production testing for K3 on a large-scale bioreactor after we complete setting up our production line for K3. We plan to initiate a Phase III clinical trial for K3 in China in the second quarter of 2023, complete the Phase III clinical trial in the second quarter of 2024 and submit a BLA to the NMPA in the fourth quarter of 2024. We expect K3 to receive BLA approval from the NMPA in 2025.

#### *Mechanism of Action*

TNF- $\alpha$  is a key regulator of innate immunity and plays an important role in the regulation of Th1 immune responses against intracellular bacteria and certain viral infections. However, the natural occurring cytokines that TNF contribute to cause numerous pathological related inflammatory and immune responses and immune-mediated inflammatory diseases (“IMIDs”), including rheumatoid arthritis, Crohn’s disease, psoriatic arthritis, ankylosing spondylitis, ulcerative colitis and severe chronic plaque psoriasis.

**BUSINESS**

Anti-TNF- $\alpha$  monoclonal antibody (“mAb”) is a next generation therapy for treating IMIDs with high effectiveness, safety and convenient administration methods. K3, our recombinant human anti-TNF- $\alpha$  monoclonal antibody injection product candidate, binds specifically to TNF- $\alpha$  to inactivate TNF- $\alpha$  and promote the production of regulatory T cells, which reduces pain and swelling due to inflammation. TNF- $\alpha$  is a proinflammatory cytokine mainly produced by activated macrophages, natural killer cells and T cells, which is involved in inflammatory and immune responses. Anti-TNF- $\alpha$  mAb can restrict TNF- $\alpha$ ’s ability to activate T cells, effectively neutralizing TNF- $\alpha$  bioactivity and inducing the apoptosis of TNF-expressing cells. Anti-TNF- $\alpha$  mAb can bind to human TNF- $\alpha$  monomer or trimer, block TNF- $\alpha$  binding to the cellular surface receptor, p55 and p75, and neutralize the cytotoxic effect of TNF- $\alpha$ , thereby inhibiting the release of TNF- $\alpha$  mediated inflammatory factors and cytokines, the adhesion and infiltration of inflammatory cells, the proliferation of fibroblasts and the activation of osteoclasts.



Source: Frost & Sullivan Analysis

Note: Mechanism of action is applicable to chimeric, humanized and fully human anti-TNF- $\alpha$  monoclonal antibodies.

**Market Opportunities and Competition**

Adalimumab is a blockbuster TNF- $\alpha$  inhibitor marketed by AbbVie Inc. under the brand name Humira<sup>®</sup>. Humira<sup>®</sup> was approved by the NMPA in 2010 and included in the Category B of the National Reimbursement Drug List (“NRDL”). Patients purchasing medicines included in Category B of the NRDL are required to pay a certain percentage of the purchase price, generally ranging from 10% to 40%, depending on the policies of local government, and the remainder of the purchase price shall be reimbursed in accordance with the regulations in respect of basic medical insurance. Accordingly, K3, once approved, is also likely to be included in the NRDL and will enjoy similar reimbursement as well. Its average selling price was originally RMB7,729 per unit in 2015, and decreased from RMB5,572 in 2019 to RMB1,258 in 2020, directly contributing to a 440% increase in sales in 2020 compared to 2019.

Due to the wide range of indications for adalimumab, large market demand and continuous availability of new biosimilar products, the adalimumab market size is growing rapidly in China. In terms of sales revenue, the adalimumab market in China increased from RMB0.2 billion in 2015

## BUSINESS

to RMB1.6 billion in 2021 at a CAGR of 41.3%, and is expected to grow to RMB6.8 billion in 2025 at a CAGR of 42.7% from 2021 to 2025, and further grow to RMB11.7 billion in 2030 at a CAGR of 11.3% from 2025 to 2030.

In China, K3 is expected to primarily compete with biosimilars of adalimumab that have been launched or currently under development. Although K3 faces fierce competition from adalimumab and its biosimilars, the market demand and the number of eligible patients for adalimumab and its biosimilars are large. K3 is indicated for the treatment of various autoimmune diseases, such as rheumatoid arthritis, ankylosing spondylitis and plaque psoriasis, of which the total combined prevalence of these three types of indications in China exceeded 16 million in 2021 according to Frost & Sullivan. Rheumatoid arthritis, ankylosing spondylitis and plaque psoriasis are chronic diseases that require long-term medication of two doses of adalimumab a month with a total of 24 doses of adalimumab a year. Although adalimumab is included in Category B of the NRDL, patients are still required to pay in the range of the 10% to 40% of the purchase price of adalimumab and its biosimilars, which can range from RMB100 to RMB400 per dose and RMB2,400 to RMB9,600 per year based on a price of approximately RMB1,000 per dose of adalimumab and its biosimilars. Due to the high cost of adalimumab and its biosimilars, we plan to price K3 at a retail price of approximately RMB400 to RMB500 a dose, which will significantly reduce the out-of-pocket expense of patients and provide a competitive pricing advantage for K3 as K3 faces fierce competition from adalimumab and its biosimilars. In addition, the second-phase Zhuhai manufacturing facility will be able to produce two million doses of K3 a year, which will support the required yearly doses of K3 for approximately 83,000 patients. As of the Latest Practicable Date, there were six biosimilars of adalimumab approved in China, namely Qletli® (格樂立), Sulinno® (蘇立信), Anjianning (安建寧), Handayuan (漢達遠), Taibowei (泰博維) and Junmaikang (君邁康), and 10 biosimilars of adalimumab in development in China, according to Frost & Sullivan. The following tables set forth details of approved drugs and product candidates that may compete with K3 in China:

### Approved Products in China

Company Name	Product	NMPA Approval Date	Indications	Price
Bio-Thera Solutions, Ltd. (百奧泰)	QLETLI® / 格樂立	November 6, 2019	Rheumatoid arthritis, ankylosing spondylitis, psoriasis, Crohn's disease, uveitis, childhood plaque psoriasis, polyarticular juvenile idiopathic arthritis, Crohn's disease in children	RMB1,080/40mg RMB676/20mg
Hisun Pharmaceutical (海正藥業)	安建寧	December 6, 2019	Rheumatoid arthritis, ankylosing spondylitis, psoriasis, Crohn's disease, non-infectious uveitis, polyarticular juvenile idiopathic arthritis, childhood plaque psoriasis	RMB1,090/40mg
Innovent Bio (信達生物)	SULINNO® / 蘇立信	September 2, 2020	Rheumatoid arthritis, ankylosing spondylitis, psoriasis, polyarticular juvenile idiopathic arthritis, childhood plaque psoriasis, non-infectious uveitis	RMB1,088/40mg
Henlius Biotech (復宏漢霖)	漢達遠	December 2, 2020	Rheumatoid arthritis, ankylosing spondylitis, psoriasis, uveitis	RMB899/40mg
Chia Tai Tianqing (正大天晴)	泰博維	January 18, 2022	Rheumatoid arthritis, ankylosing spondylitis, psoriasis	RMB799/40mg
Junshi Biosciences (君實生物) / Mabwell (邁威生物)	君邁康	March 1, 2022	Rheumatoid arthritis, ankylosing spondylitis, psoriasis	RMB998/40mg

Source: CDE, public disclosure of listed companies, Frost & Sullivan Analysis

## BUSINESS

### Products Under Development in China

Company Name	Products	R&D Progress	Indication	Date of Phase I Clinical Trial*
SinoCellTech (神州細胞)	SCT630	Phase III completed, pending approval	Moderate-to-severe plaque psoriasis	January 29, 2019
Wuhan Institute of Biological Products (武漢生物製品研究所)	Recombinant fully human anti-human TNF- $\alpha$ monoclonal antibody injection	Phase III	Moderate-to-severe plaque psoriasis	May 24, 2019
Shandong Danhong Pharmaceutical Co., Ltd (山東丹紅)	BC002	Phase III	Ankylosing spondylitis	April 25, 2019
Huaota Biopharm (華奧泰生物)	HOT-3010	Phase III	Moderate-to-severe plaque psoriasis	September 21, 2018
Hualan Bio (華蘭生物)	HL01	Phase III	Rheumatoid arthritis, ankylosing spondylitis, psoriasis	May 21, 2018
Tonghua Dongbao Pharmaceutical (通化東寶)	DB101	Phase III	Moderate-to-severe plaque psoriasis	August 18, 2017
Luzhu Biotech (綠竹生物)	K3	Phase I (completed)	Rheumatoid arthritis, ankylosing spondylitis, psoriasis	November 13, 2018
Eastern Biotech (北京東方百泰生物/ 北京精益泰翔)	JY026	Phase I (completed)	Rheumatoid arthritis, ankylosing spondylitis	October 29, 2019
Anhui Weiming Damu Biomedicine Co., Ltd. (安徽未名達木生物醫藥有限公司)	Recombinant anti-TNF- $\alpha$ fully human monoclonal antibody injection	Phase I	Rheumatoid arthritis, ankylosing spondylitis	July 5, 2021
North China Pharmaceutical Company Ltd. (華北製藥)	Recombinant human antihuman tumour necrosis factor (TNF- $\alpha$ ) monoclonal antibody injection	Phase I	Rheumatoid arthritis, ankylosing spondylitis, psoriasis	January 15, 2020

*Note:*

\* Date when the Phase I clinical trial was first published by the CDE.

*Source:* CDE, public disclosure of listed companies, Frost & Sullivan Analysis

There may be further price adjustment for K3 in the next round of National Drug Price Negotiation (國家醫藥談判). The price control along with the fierce competition in the market may significantly impact the profitability of K3. For details, please see “Risk Factors — Risks Relating to Our Business and Industry — Risks Relating to Sales and Distribution of Our Product Candidates — Because some of our vaccine candidates are intended to prevent diseases of major public health concerns, we are at risk of governmental actions detrimental to our business, such as price controls or waivers on vaccine patent.” and “Risk Factors — Risks Relating to Our Business and Industry — Risks Relating to Sales and Distribution of Our Product Candidates — We operate in a competitive environment, and we may not be able to compete effectively against current and future competitors” in this document.

#### **Competitive Advantages**

The molecular design of K3 maximizes the safety of the antibody when used in the human body. The pharmacokinetic, safety and immunogenicity evaluations of K3 have shown that it is

## BUSINESS

highly similar to adalimumab, with no clinically meaningful difference between K3 and adalimumab, indicating K3’s potential to treat autoimmune diseases, such as rheumatoid arthritis, ankylosing spondylitis and plaque psoriasis. Our second-phase Zhuhai manufacturing facility will be able to produce two million doses of K3 a year, which will enable us to lower production cost and improve the profitability and competitive strength of K3. K3 is expected to be priced at a retail price of approximately RMB400 to RMB500 a dose, which will be a major competitive strength of K3. Taking into consideration the strong manufacturing capabilities of our second-phase Zhuhai manufacturing facility and our competitive pricing strategies for K3, we expect K3 to capture and further expand the market in China for adalimumab biosimilars. Please see “—Commercialization” in this section for more details about our commercialization plans for K3.

### *Non-human Primates Study (Cynomolgus Monkeys)*

*Study design.* In the development of K3, we conducted animal studies in cynomolgus monkeys to evaluate the immunogenicity, pharmacokinetics and safety of K3 compared to adalimumab. 50 cynomolgus monkeys were randomly assigned to five groups, including one 2mg/kg dose group, one 10mg/kg dose group and one 50mg/kg dose group of K3, and one 10mg/kg dose control group of adalimumab and one negative control group, with 10 monkeys in each group. Each group of monkeys were injected subcutaneously with their respective dose and one dose a week for a period of four weeks, with a total of five doses.

*Immunogenicity.* The neutralizing antibody titers observed in monkeys in the 10mg/kg dose groups of K3 and adalimumab were similar. 28 days after the initial injection, neutralizing antibodies were detected in five of the ten monkeys in the 10mg/kg dose group of K3 with the highest antibody titer of 1:6,400, and four of the ten monkeys in the 10mg/kg dose group of adalimumab with the highest antibody titer of 1:1,600. In addition, the absolute and differential counts of white blood cells, the levels of immunoglobulins and albumin/globulin (“A/G”) ratios, the distribution of lymphocyte subsets, cytokines and gross anatomical observations of lymphoid organs and tissues, and weight/coefficient of the thymus and spleen in the 10mg/kg dose groups of K3 and adalimumab were similar. The above results of the 10mg/kg dose groups of K3 and adalimumab indicate K3 indicate the immunogenicity of K3 and adalimumab are similar in monkeys.

*Pharmacokinetics profile.* The bioequivalence statistics for monkeys in the 10mg/kg dose groups of K3 and adalimumab for  $T_{max}$ ,  $C_{max}$ ,  $AUC_{last}$  and  $AUC_{\infty}$  indicate the pharmacokinetics of K3 and adalimumab are similar. The following table sets forth the bioequivalence analysis of pharmacokinetic parameters of K3 and adalimumab we observed during the preclinical study.

<u>Day</u>	<u>Group</u>	<u><math>T_{max}</math> h (hours)</u>	<u><math>C_{max}</math> <math>\mu</math>g/mL</u>	<u><math>AUC_{last}</math> h•mg/mL</u>	<u><math>AUC_{\infty}</math> h•mg/mL</u>
Day 1 to Day 8	10 mg/kg dose K3	38±25.16	145.78±20.63	19.46±2.61	49.77±12.32
	10 mg/kg dose adalimumab	52.80±10.12	130.19±19.73	17.53±2.57	54.40±29.45
Day 22 to Day 29	10 mg/kg dose K3	52.80±24.79	188.04±143.26	21.99±20.07	37.00±49.83
	10 mg/kg dose adalimumab	26.40±7.59	194.18±130.07	22.65±19.07	56.31±73.88

*Safety.* No noticeable toxic reactions were observed, indicating no acute toxicity in monkey subjects. The no observable effect level dose of K3 in monkeys was 50mg/kg, which is approximately 75 times higher than the designed clinical dose for humans of 0.67mg/kg.

*Conclusion.* Our preclinical study of K3 demonstrated the immunogenicity and pharmacokinetics of K3 are similar to adalimumab, and K3 is safe in cynomolgus monkeys.

**BUSINESS**

**Summary of Phase I Clinical Trial Results**

*Trial design.* We conducted a single-center, randomized, blind, single dose, parallel-controlled Phase I clinical trial to study the pharmacokinetics, safety and immunogenicity of our K3 in relation to Vetter Pharma-Fertigung GmbH & Co KG’s Humira® (adalimumab). During the trial, 647 subjects were screened and a total of 160 healthy Chinese male subjects aged between 18 to 45 years old were enrolled in the Phase I clinical trial for K3. Only male subjects were recruited due to uncertainty in the research of the effects of adalimumab on women, as there is currently no preclinical data on the postnatal toxicity of adalimumab and no clinical data on the effects of adalimumab on pregnant or lactating women. In addition, in a blinded study, it is necessary to ensure the uniformity of body weight and gender to a certain extent. If both male and female subjects were recruited, it cannot be guaranteed that the gender of the subjects will be maintained at a one-to-one ratio as men overall have higher body mass index figures and lower body fat compared to women. The Chinese male subjects were divided into two cohorts, 80 subjects per cohort: a K3 test group (K3, 40 mg) and a Humira® positive control group (adalimumab, 40 mg). Each subject in the K3 test cohort received a single dose of K3, and each subject in the Humira® positive control group received a single dose of Humira®. After subcutaneous administration, blood samples were collected at preset time points, and serum concentrations were tested by enzyme-linked immunosorbent assay (“ELISA”) for immunogenicity testing. The pharmacokinetics and immunogenicity of the K3 test group and the Humira® positive control group were observed after 71 days of administration. Except for one subject in the K3 test group who requested to withdraw from the trial, all the remaining subjects completed the trial. The subject voluntarily withdrew from the trial because he had an accident that resulted in a bone fracture and was unable to return to the clinical trial site.

*Trial status.* The Phase I clinical trial was initiated in September 2018 and was completed in December 2019.

*Pharmacokinetic profile.* A total of 155 subjects who completed the collection of pharmacokinetic samples were included in the calculation of pharmacokinetic parameters. The bioequivalence statistics for  $C_{max}$ ,  $AUC_{0-t}$  and  $AUC_{0-\infty}$  of K3 and Humira® indicate the pharmacokinetics of K3 and Humira® are similar, as all results were within the bioequivalence margins of 80.00%-125.00%. The geometric mean ratios of  $C_{max}$ ,  $AUC_{0-t}$  and  $AUC_{0-\infty}$  between K3 and Humira® were 115.14% (90% confidence interval (“CI”), 106.87-124.05), 96.97% (90% CI, 87.88-107.00) and 97.16% (90% CI, 87.71-107.64), which fall within the acceptance range of 80.00%-125.00%. The following table sets forth the bioequivalence analysis of pharmacokinetic parameters of our K3 we observed during the clinical trial.

Pharmacokinetic Parameters	N	Geometric Mean and Ratio			90% Confidence Interval	Degree of Certainty
		Test (K3)	Reference (Humira®)	Test/Reference Ratio		
(Unit)				(%)		(%)
$C_{max}$ (ng/mL)	155	3,675.2	3,191.9	115.14	106.87-124.05	56.8
$AUC_{0-t}$ (h*ng/mL)	155	2,032,726.1	2,096,237.4	96.97	87.88-107.00	93.8
$AUC_{0-\infty}$ (h*ng/mL)	154	2,156,640.6	2,219,567.7	97.16	87.71-107.64	92.3



**BUSINESS**

Furthermore, in the pharmacokinetic per protocol set (“PK-PPS”) analysis, the pharmacokinetic parameters for the K3 test group and the Humira® positive control group were highly similar. The following table sets forth the PK-PPS analysis of the pharmacokinetic parameters for the K3 test group and the Humira® positive control group.

Pharmacokinetic Parameters (Unit)	Mean ± SD	
	K3 Test Group (N=76 subjects)	Humira® Positive Control Group (N=79 subjects)
T <sub>max</sub> (h), median (minimum, maximum)	168.0 (72, 336)	168.0 (72, 336)
C <sub>max</sub> (ng/mL)	3,861.2 ± 1,236.80	3,281.0 ± 776.18
AUC <sub>0-t</sub> (h*ng/mL)	2,191,973.639 ± 782,397.7956	2,200,422.897 ± 679418.1397
AUC <sub>0-∞</sub> (h*ng/mL)	2,330,328.379 ± 862,469.6772	2,353,257.742 ± 814,920.8609
t <sub>1/2</sub> (h)	269.929 ± 134.5155	310.459 ± 149.1313
λ <sub>z</sub> (1/h)	0.004 ± 0.0054	0.003 ± 0.0016
%AUC <sub>ex</sub>	4.359 ± 3.3283	5.454 ± 4.3464
CL (mL/h)	20.476 ± 11.0975	19.121 ± 6.7677
V <sub>z</sub> (mL)	6,724.191 ± 2,191.5720	7,519.906 ± 2,333.0958

*Note:* T<sub>max</sub> = time to maximum observed concentration; C<sub>max</sub> = maximum observed concentration; AUC<sub>0-∞</sub> = area under the concentration curve from time zero to infinity; AUC<sub>0-t</sub> = area under the concentration curve from time zero to the last quantifiable concentration; t<sub>1/2</sub> = elimination half-life; λ<sub>z</sub> = terminal phase elimination constant; %AUC<sub>ex</sub> = percentage of area under the concentration curve extrapolated from time 0 to infinity; CL = clearance; V<sub>z</sub> = apparent volume of distribution.

*Safety data.* The results indicate that K3 is safe and well tolerated. There were no statistical differences in terms of AEs between the K3 test group and the Humira® positive control group. During the Phase I clinical trial, 45 subjects in the K3 test group experienced 87 AEs with an incidence rate of 56.25%, and 49 subjects in the Humira® positive control group experienced 93 AEs with an incidence rate of 61.25%. The incidence of AEs for K3 and Humira® were similar, with 56.25% for K3 and 61.25% for Humira®. The most frequent AEs in the K3 test group were bacterial infection, and elevated triglyceride, uric acid and glucose levels in blood, and the most frequent AEs in the Humira® positive control group were bacterial infection, elevated bilirubin, triglyceride, and aminotransferase levels in blood, and presence of red blood cells in urine. For drug-related AEs, 34 subjects in the K3 test group experienced 64 AEs with an incidence rate of 42.50%, and 44 subjects in the Humira® positive control group experienced 77 AEs with an incidence rate of 55.00%. One SAE was observed in a subject in the Humira® positive control group, which resulted in right axillary lymph node enlargement and right axillary abscess. In addition, two incidences of AEs were moderate, which resulted in right foot swelling and elevated triacylglycerol level. All other observed incidences of AEs for K3 and Humira® were mild, and no AEs led to subject withdrawal from the Phase I clinical trial.

**BUSINESS**

The following table sets forth the AEs observed during the clinical trial.

	<b>K3 Test Group (N=80 subjects)</b>		<b>Humira® Positive Control Group (N=80 subjects)</b>	
	<b>Number of AEs</b>	<b>Vaccine-related or unrelated</b>	<b>Number of AEs</b>	<b>Vaccine-related or unrelated</b>
<b>Adverse Events (AEs)</b>				
Low white blood cell count	1	Very likely related	–	–
High white blood cell count	1	Very likely related	–	–
Increased white blood cell count	1	Very likely related	3	2 May be related; 1 Very likely related
Decreased white blood cell count	1	Very likely related	4	2 Very likely related; 2 May be related
Inflammation of the tonsils	–	–	1	May be related
Constipation	4	May be related	2	May be related
Elevated alanine aminotransferase	3	2 Very likely related; 1 May be related	4	3 Very likely related; 1 May be related
Elevated bacteria count	–	–	1	May not be related
Blood in stool	1	May be related	–	–
Protein positive	–	–	1	May be related
Nausea	–	–	1	May be related
Abdominal pain	2	May be related	–	–
Bloating	–	–	1	May not be related
Cold	1	May be related	1	May be related
Cough	–	–	1	May be related
High creatine kinase	1	Very likely related	–	–
Elevated creatine kinase	1	May be related	1	Very likely related
Elevated urine leukocyte count	–	–	1	May be related
High urine white leukocyte count	–	–	1	May be related
Elevated urine bacteria count	3	May not be related	6	May be not related
Urine protein 1+	–	–	1	May be related
Urine protein positive	–	–	1	May be related
High urine red blood cell count	–	–	1	May be related
Elevated urinary red blood cell count	–	–	3	May be related
Urine abnormalities: positive for ketone bodies	1	May not be related	–	–
Urinary red blood cells	1	May be related	–	–
Elevated urinary erythrocytes	–	–	1	May be related
Urine glucose positive	1	May be related	1	May be related
High uric acid	3	May be related	1	May be related
High urine pH	1	May not be related	–	–
Elevated uric acid	2	May be related	–	–
High urine bacteria	1	May not be related	3	May not be related

**BUSINESS**

	<b>K3 Test Group (N=80 subjects)</b>		<b>Humira® Positive Control Group (N=80 subjects)</b>	
	<b>Number of AEs</b>	<b>Vaccine-related or unrelated</b>	<b>Number of AEs</b>	<b>Vaccine-related or unrelated</b>
Elevated urine bacteria	12	12 May not be related	3	May not be related
Urine bacterial abnormalities	1	May be not related	–	–
Urine occult blood 2+	–	–	1	May be related
Elevated urine occult blood	1	May be related	–	–
Positive urine occult blood test	–	–	1	May be related
Positive urine occult blood test	–	–	1	May be related
Skin rash	3	May be related	2	May be related
Anemia	–	–	1	May be related
Parotid gland pain	–	–	1	May be related
Parotid gland enlargement	–	–	1	May be related
High triglycerides	3	May be related	2	May be related
High triacylglycerol	–	–	1	May be related
Elevated triacylglycerol	3	May be related	2	May be related
Upper respiratory tract infection	–	–	1	May be related
Upper respiratory infection	–	–	1	May be related
Rash on both lower extremities	1	May be related	–	–
Elevated aspartate aminotransferase	–	–	1	Very likely related
Headache	2	May be related	–	–
Leg pain	1	May be related	–	–
Abnormal ECG (first degree atrioventricular block)	–	–	1	May be related
Abnormal ECG (sinus bradycardia)	–	–	1	May be related
Abnormal ECG (abnormal Q wave II, III, aVF)	–	–	1	May be related
Blood: Increased absolute number of neutrophils	–	–	1	May be related
Reduced hemoglobin	1	May be related	–	–
Increased blood creatine kinase	–	–	1	May be related
High blood potassium	1	May not be related	–	–
Elevated blood glucose	1	May be related	–	–
Low blood sugar	1	May be related	–	–
High blood sugar	1	May be related	1	May be related
Hyperglycemia	1	May be related	–	–
Elevated blood sugar	2	May be related	–	–
Elevated platelet count	2	May not be related	–	–
Direct blood bilirubin elevation	1	May be related	–	–
Elevated total bilirubin in blood	1	May be related	–	–
Toothache	1	May be related	–	–
Sore throat	1	May be related	–	–

**BUSINESS**

	K3 Test Group (N=80 subjects)		Humira® Positive Control Group (N=80 subjects)	
	Number of AEs	Vaccine-related or unrelated	Number of AEs	Vaccine-related or unrelated
Occult blood positive	–	–	1	May be related
Swollen inside right nose	–	–	1	May be related
Inner right knee pain	–	–	1	May not be related
Right foot pain	2	May be related	–	–
Red and swollen right eye corner	3	May be related	–	–
Swollen right eye corner	1	May be related	–	–
Lump in the right armpit	–	–	1	May be related
Direct bilirubin elevation	–	–	3	2 Very likely related; 1 May be related
Low absolute number of neutrophils	1	Very likely related	–	–
Decreased absolute number of neutrophils	1	May be related	4	3 Very likely related; 1 May be related
Increased absolute number of neutrophils	2	Very likely related	2	May be related
Absolute number of neutrophils decreased	1	Very likely related	–	–
Swelling at the injection site	–	–	1	Very likely related
Itchy skin at the injection site	1	Very likely related	–	–
Consciously fever	1	May not be related	–	–
High total bilirubin	1	Very likely related	2	Very likely related
Increased total bilirubin	2	Very likely related	6	2 Very likely related; 4 May be related
Right axillary lymph node enlargement, right axillary abscess	–	–	1	May be related
Left earache	–	–	1	May not be related
Left cheek infection	–	–	1	May be related
ALT high	–	–	1	May be related
AST increased	–	–	1	May be related
<b>Total</b>	<b>87</b>		<b>93</b>	

*Immunogenicity data.* A total of 159 subjects were included in the calculation and statistical analysis of immunogenicity data. K3 was observed to have similar positive rate of anti-drug antibody (“ADA”) and neutralizing anti-drug antibody (“NADA”), and antibody titer to Humira®. At day 22, the positive rate of ADA in the K3 test group and Humira® positive control group was 32.89% and 35.06%, respectively. At day 71, the positive rate of ADA in the K3 test group and Humira® positive control group was 58.44% and 61.04%, respectively. At day 22, the positive rate of NADA in the K3 test group and Humira® positive control group was 2.60% and 3.75%, respectively. At day 71, the positive rate of NADA in the K3 test group and Humira® positive

## BUSINESS

control group was 56.41% and 58.75%, respectively. At day 22, the K3 test group and Humira® positive control group had an average antibody titer of 18.36±24.01 and 16.00±14.35, respectively. At day 71, the K3 test group and Humira® positive control group had an average antibody titer of 20.27±20.69 and 25.43±32.81, respectively. The following table sets forth the positive rate of ADA and NADA of K3 and Humira® we observed during the clinical trial.

	Day	K3 Test Group			Humira® Positive Control Group		
		Number of Subjects	Number of Subjects Who Were Negative Before Receiving Dose	Number of Subjects Who Turned Positive After Receiving Dose (%)	Number of Subjects	Number of Subjects Who Were Negative Before Receiving Dose	Number of Subjects Who Turned Positive After Receiving Dose (%)
Anti-drug antibody (ADA)	22	77	76	25 (32.89%)	80	77	27 (35.06%)
	71	78	77	45 (58.44%)	80	77	47 (61.04%)
Neutralizing anti-drug antibody (NADA)	22	77	77	2 (2.60%)	80	80	3 (3.75%)
	71	78	78	44 (56.41%)	80	80	47 (58.75%)

*Conclusion.* The pharmacokinetic profile, safety data and immunogenicity data of K3 is highly similar to Humira®.

### *Clinical Development Plan*

We plan to initiate a Phase III clinical trial for K3 in China in the second quarter of 2023 as we are currently constructing our second-phase Zhuhai manufacturing facilities in order to meet the production capacity requirement to produce K3 used for conducting the Phase III clinical trial. After the completion of our first- and second-phase Zhuhai manufacturing facilities, our Zhuhai manufacturing facilities will support the clinical trial needs of K3 and early commercialization needs after product launch. The clinical development of K3, like any other drugs, is inherently unpredictable. Potential adverse events may occur and the clinical results may not be what we expect, which could halt our planned clinical plans and our commercialization efforts. For details, please see “Risk Factors — Risks Relating to Our Business and Industry — Risks Relating to the Research and Development of Our Product Candidates” in the document.

## BUSINESS

### *Licenses, Rights and Obligations*

In July 2019, we entered into a technology transfer agreement with Beijing Science Sun, a Shenzhen Stock Exchange-listed biopharmaceutical company focused on research, manufacture and sales of injectable products, (the “**Beijing Science Sun License Agreement**”), with respect to the assets and intellectual property rights in and to K3 and K11 in China. Pursuant to the Beijing Science Sun License Agreement, we originally agreed to assign Beijing Science Sun the intellectual property rights in and to our K3 and K11 product candidates and transfer all test results and research data in relation to pre-clinical studies of K3 and K11, testing and proprietary technology related to K3 and K11, as well as pilot-scale manufacturing and testing, related testing technologies, clinical research approval documents and Phase I clinical research results and materials of K3 to Beijing Science Sun. In exchange Beijing Science Sun agreed to pay us (i) a one-time payment of RMB8.35 million to compensate us for the related expenses paid and to be paid for the completion of the Phase I clinical study of K3 and (ii) a certain percentage of net sales or net profits of selling K3 and K11 as royalty payments for ten years after the commercial launch of K3 or K11. Prior to signing the Beijing Science Sun License Agreement, we had entered into a contract with a CRO to provide services for the Phase I clinical trial for K3. At the time when the Beijing Science Sun License Agreement was signed, the CRO had already begun providing services. Therefore, we had to pay a final payment of RMB8.35 million to the CRO after the completion of the Phase I clinical trial for K3. The purpose of the one-time payment of RMB8.35 million by Beijing Science Sun was to compensate us for the final payment of RMB8.35 million owed to the CRO subsequent to the transfer of K3 to Beijing Science Sun. As we did not have any similar payment arrangement with third parties in relation to the development of K11, there was nil upfront payment for K11. According to Frost & Sullivan, it is industry norm for the amount of upfront payments and proportion of royalty fee to be decided by the contracting parties through negotiation, and the nil upfront payment for K11 but a one-time payment of RMB8.35 million to compensate the expenses for the Phase I clinical trial for K3 under the Beijing Science Sun License Agreement is commercially rational. We did not receive any payment pursuant to the Beijing Science Sun License Agreement during the Track Record Period. The follow-up improvement of the technical secrets in relation to K3 and K11 transferred to Beijing Science Sun shall be jointly completed by Beijing Science Sun and us, and the follow-up improvement results belong to Beijing Science Sun. Unless Beijing Science Sun obtains written permission from us in advance, Beijing Science Sun may only use the follow-up improvement technology for the development K3 and K11. The confidentiality period of the trade secrets in relation to K3 and K11 to be transferred to Beijing Science Sun is a period of 10 years from the signing date of the Beijing Science Sun License Agreement.

At the time of entering into the Beijing Science Sun License Agreement, our Beijing R&D and pilot manufacturing facility only had limited production capacity to support pre-clinical studies and early-stage clinical trials, and we did not have a manufacturing facility with high-quality mass production capacity to produce the required doses of K3 to conduct the Phase III clinical trial and support early commercialization needs after product launch. In order to produce at least two million doses of K3 a year at a commercially reasonable price point (at a production cost per dose of K3 that is more favorable to the production cost of approximately RMB80 per dose of other marketed adalimumab biosimilars in China according to Frost & Sullivan) to support a Phase III clinical trial and commercialization, the manufacturing facility would need to meet various requirements, including (i) production area of approximately 1,500 sq.m. to 2,500 sq.m. to be designated exclusively for K3 to place two to four 2,000L to 3,500L stainless steel bioreactors

## BUSINESS

---

of at least two tons, and supporting facilities area of approximately 500 sq.m. to 800 sq.m. for HVAC, systems for clean air, compressed air systems, pharmaceutical grade water purification systems, etc., (ii) inner factory height of approximately 6 meters, and (iii) load bearing of more than 700 kg/m<sup>2</sup>, which our Beijing R&D and pilot manufacturing facility could not support. Therefore, we had to either build new manufacturing facilities or cooperate with business partners to further develop K3. We did not engage a CDMO to produce K3 to support the Phase III clinical trial for K3 because it would be commercially advisable to use the same CDMO for the commercial production of K3 as using different facilities would incur substantial additional cost for technology transfer, and we did not want to rely on a CDMO for production of K3, which would subject us to the risk of a CDMO controlling the cost of production of K3. When we were considering the further plans of K3, Beijing Science Sun approached us and proposed a collaboration opportunity with respect to K3. When considering the collaboration opportunity with Beijing Science Sun to further develop K3, we believed that Beijing Science Sun had the capability to further advance the development of K3 because Beijing Science Sun had (i) extensive experience in the research, manufacturing and sales of biological and biochemical pharmaceuticals, (ii) an existing manufacturing facility in Beijing, (iii) extensive commercialization capabilities and (iv) strong capital resources as a listed company. Although Beijing Science Sun had an existing manufacturing facility in Beijing, the existing manufacturing facility was not designed to manufacture K3 and Beijing Science Sun had to upgrade its existing manufacturing facility to carry out a Phase III clinical trial for K3, which we reasonably believed Beijing Science Sun would be able to accomplish due to its strong capital resources as a listed company.

After signing the Beijing Science Sun License Agreement, however, as (i) Beijing Science Sun considered K11 to be more in line with its pipeline development strategy compared to K3 as several of its product candidates were developed for the treatment of cancers, (ii) Beijing Science Sun did not establish necessary facilities to manufacture K3 antibodies or identify a suitable CDMO in China with high-quality mass-production capacity to meet the production capacity requirement for conducting the Phase III clinical trial for K3 and producing K3 at a commercially reasonable price point due to intense competition from other commercialized biosimilars of adalimumab in China and (iii) Beijing Science Sun, being one of our [REDACTED] Investors, had the knowledge that we were constructing our Zhuhai manufacturing facilities which would expand our production capacity, reduce production costs and increase the profit margin for K3, the transaction was not consummated as a result.

As K3 is expected to primarily compete with biosimilars of adalimumab that have been launched or currently under development in China, it is important to have sufficient production capacity to lower production cost and improve the profitability and competitive strength of K3. According to Frost & Sullivan, as of the Latest Practicable Date, there were six biosimilars of adalimumab approved in China and 10 biosimilars of adalimumab in development in China, and the average selling price of Humira<sup>®</sup> (under which the brand name adalimumab is marketed by AbbVie Inc) per unit in China decreased from RMB5,572 in 2019 to RMB1,258 in 2020 after being included in NRDL, and further decreased to RMB1,241 in 2021. The average selling price per unit of biosimilars of adalimumab in China ranged from RMB799 to RMB1,150 in 2020 to 2021. Considering the intense competition from other commercialized biosimilars of adalimumab in China which requires mass production capacity to produce K3 at a commercially reasonable price point, after signing the Beijing Science Sun License Agreement, Beijing Science Sun did not perform substantive research and development for K3 because (i) Beijing Science Sun did not establish the necessary manufacturing facilities with sufficient production capacity, which would

## BUSINESS

require substantial investment to build, or identify a suitable CDMO in China with high-quality mass-production capacity, and (ii) Beijing Science Sun had been informed in January 2021 that we were constructing our Zhuhai manufacturing facilities which would expand our production capacity, reduce production costs and increase the profit margin for K3. As advised by Beijing Science Sun, Beijing Science Sun did not incur research and development expenses for K3 after signing the Beijing Science Sun License Agreement. After signing the Beijing Science Sun License Agreement, we continued to supervise CROs and SMOs to complete the data analysis of the Phase I clinical trial of K3 and close out their engagements, and completed the Phase I clinical trial in December 2019. Given we have not transferred any K3 products after signing the Beijing Science Sun License Agreement due to Beijing Science Sun lacking the necessary manufacturing facilities to produce K3, we continued to monitor and improve the product stabilities, which is a part of our R&D efforts.

In January 2021, Beijing Science Sun and us had begun to discuss to rescind the Beijing Science Sun Licensing Agreement, shortly after we won the bid for purchasing manufacturing land in Zhuhai on December 29, 2020 and obtained a construction permit to build our Zhuhai manufacturing facilities on January 18, 2021. In April 2021, we obtained the state-owned land use right certificate to build the Zhuhai manufacturing facilities. Furthermore, in November 2021, we reached a consensus with Beijing Science Sun that we would be better positioned to accelerate the development and commercialization of K3 and lower the cost of manufacturing K3 to strengthen market competitiveness because of our increased R&D efficiency and expanded production capacity due to the construction of our first- and second-phase Zhuhai manufacturing facilities, and accordingly we and Beijing Science Sun entered into a supplemental technology transfer agreement (the “**Supplemental Beijing Science Sun License Agreement**”), which rescinded the previous technology transfer in respect to K3. After signing the Supplemental Beijing Science Sun License Agreement and as of the Latest Practicable Date, we had continued to optimize bioreactor culture conditions to improve our production capabilities for mass production of K3 antibodies required to support our Phase III clinical trial for K3. From August 2022 to October 2022, we increased the production yield of K3 by approximately 300%. Our R&D efforts for K3 include (i) conducting bridging experiments and production process tests for the Zhuhai manufacturing facilities, (ii) verifying the adaptability of small-scale production process systems and standardizing production process operations through small-scale multi-batch experiments to simulate pilot-scale and scale-up production processes for cell culture and purification of K3, (iii) investigating and evaluating the influence of cell culture media of other manufacturers on the cell culture process for K3, and (iv) preparing for the K3 technology transfer to the Zhuhai manufacturing facilities and process validation by training employees to become familiar with key process parameters and production processes of cell culture and fermentation of K3.

The Supplemental Beijing Science Sun License Agreement did not involve the re-assignment to us of any intellectual property rights related to our K3 product candidate. In addition, we agreed to repay and have paid Beijing Science Sun the one-time payment of RMB8.35 million Beijing Science Sun paid us under the Beijing Science Sun License Agreement.

We have entered into non-disclosure and confidentiality agreements with parties who have access to confidential aspects of our research and development output of K3, such as our employees, corporate collaborators, and other third parties. For details, please see “Risk Factors — Risks Relating to Our Business and Industry — Risks Relating to Our Intellectual Property Rights — If we are unable to obtain and maintain adequate patent and other intellectual property



## BUSINESS

---

protection for our product candidates throughout the world, or if the scope of such intellectual property rights obtained is not sufficiently broad, third parties could compete directly against us and our ability to successfully develop and commercialize any of our product candidates would be materially and adversely affected” in this document. In November 2021, we entered into a perpetual non-disclosure agreement with Beijing Science Sun to keep confidential all test results and research data in relation to pre-clinical studies of K3, testing and proprietary technology related to K3, as well as pilot-scale manufacturing and testing, related testing technologies, clinical research approval documents and Phase I clinical research results and materials of K3 that were transferred to Beijing Science Sun after the signing of the Beijing Science Sun License Agreement and returned back to us after the signing of the Supplemental Beijing Science Sun License Agreement.

As advised by Hiways Law Firm, our legal adviser as to intellectual property law (the “**IP Legal Adviser**”), from the beginning of the research and development of K3, we took appropriate and reasonable confidentiality measures, including but not limited to (i) signing confidentiality agreements with research and development participants, (ii) establishing confidentiality regulations within the company and providing trainings to employees, (iii) grading management of technical secrets, (iv) setting the guard, installing access control, and installing camera, among others, to restrict the activity areas of employees and visitors, and (v) employees who participate in K3 research and development, including but not limited to preparation processes, purification processes and quality verification processes, can only participate in their responsible part and only have access to the technical information of their responsible part. In addition, we entered into a non-disclosure agreement with Beijing Science Sun, pursuant to which the confidentiality obligation of Beijing Science Sun in relation to K3 related technical information shall maintain for an indefinite term. According to the non-disclosure agreement, if Beijing Science Sun breaches the confidentiality obligation, we have the right to hold it liable for breach of contract and compensating the economic loss. The preparation, purification and identification processes of K3 meet the constitutive requirements of trade secrets. Meanwhile, we filed a patent application for the preparation process relating to the low mannose level of K3 antibody. Our IP Legal Adviser has conducted freedom-to-operate searches and analyses for K3, the result of which indicates that there is no material infringement risk for us following the scheduled development and commercialization process of K3. Accordingly, the IP Legal Adviser is of the view that the intellectual property rights of K3 are well protected through the combination of patent, trade secret and know-how and there is no material risk that future development and commercialization of K3 will be interfered or challenged by any relevant third parties known to the Company. Based on the view of our IP Legal Adviser, our Directors are of the view that all the intellectual property rights (including patents, trade secrets and know-hows) in relation to K3 are well protected against infringement by Beijing Science Sun and/or other relevant third parties, and there is no material risk that future development and commercialization of K3 will be interfered or challenged by any relevant third parties. Having taken into account the factors above, the independent due diligence work conducted by the Sole Sponsor and the view of the IP Legal Adviser, the Sole Sponsor concurs with the Directors’ view above.

## BUSINESS

We have primarily engaged in and are responsible for the R&D of K3, including the Phase I clinical trial, and we have the global rights to develop and commercialize K3. Based on our unaudited management accounts, prior to signing the Beijing Science Sun License Agreement, our research and development expenses for K3 amounted to RMB48.2 million, which primarily consisted of staff costs, third-party contracting costs, costs of raw materials and depreciation and amortization, mainly in relation to pre-clinical studies and the Phase I clinical study of K3. Our research and development expenses for K3 after signing the Beijing Science Sun License Agreement and up to December 31, 2019, and in 2020 amounted to RMB2.2 million and RMB2.9 million respectively, which primarily consisted of staff costs, third-party contracting costs and costs of raw materials, mainly in relation to the Phase I clinical study and stability tests of K3. In 2021, our research and development expenses for K3 amounted to RMB4.1 million, which primarily consisted of staff costs, costs of raw materials and depreciation and amortization, mainly in relation to stability tests and the first-stage technology transfer at our Zhuhai manufacturing facilities to produce K3. In 2022 and from January 1, 2023 and up to the Latest Practicable Date, our research and development expenses for K3 amounted to RMB3.4 million and RMB0.3 million, respectively, which primarily consisted of staff costs, costs of raw materials and depreciation and amortization, mainly in relation to optimization of bioreactor culture conditions and improvement of the antibody purification.

As of the Latest Practicable Date, we did not have any disputes with Beijing Science Sun in association with the Beijing Science Sun Licensing Agreement and/or the Supplemental Beijing Science Sun License Agreement, and we expect to maintain a close and stable relationship with Beijing Science Sun.

### *Material Communications with Competent Authorities*

We received an umbrella CTA approval for K3 from the NMPA in November 2017. We initiated and sponsored our Phase I clinical trial in September 2018, and completed our Phase I clinical trial for K3 in China in December 2019 for the treatment of various autoimmune diseases, such as rheumatoid arthritis, ankylosing spondylitis and plaque psoriasis, which displayed pharmacokinetics consistent with adalimumab. Based on the interview with the CDE of the NMPA in June 2022, it confirmed that our Phase I clinical trial in China was completed in December 2019 and it has no objection for us to proceed to Phase III clinical trial in China directly. Our PRC Legal Adviser is of the view that the CDE is the competent authority to give the above confirmations. Accordingly, we did not conduct any Phase II clinical trials for K3 in China. For details, please see “Regulatory Overview — Regulatory Provisions — Biosimilars Application and Approval” in this document. We submitted the Phase I clinical trial report to the CDE in March 2021 and plan to initiate communication with the CDE in April 2023 with respect to the clinical trial design of the Phase III clinical trial for K3 prior to initiating the Phase III clinical trial. We plan to initiate a Phase III clinical trial for K3 in China in the second quarter of 2023, complete the Phase III clinical trial in the second quarter of 2024 and submit a BLA to the NMPA in the fourth quarter of 2024. We expect K3 to receive BLA approval from the NMPA in 2025. Upon obtaining BLA approval for K3, we are expected to be the market authorization holder (“MAH”) of K3.

**WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET K3 SUCCESSFULLY.**

**BUSINESS**

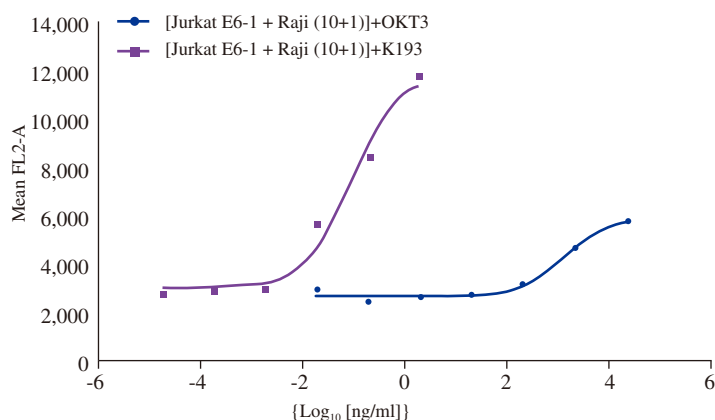
**3. K193**

*Overview*

K193, our independently developed bispecific antibody injection (CD19-CD3) product candidate for the treatment of B cell leukemia and lymphoma, is a bispecific antibody against CD19/CD3 with an asymmetric structure. Employing our proprietary Fabite® technology platform and our mammalian expression technology platform, we developed K193 with a fragment antigen-binding (“Fab”)-single-chain variable fragment (“scFv”) molecular structure, where the Fab region of humanized anti-CD19 monoclonal antibody that binds to antigens is linked to anti-CD3 epsilon (“CD3ε”) scFv, a fusion protein of the variable regions of heavy and light chain immunoglobulins. K193 binds to CD19 on the surface of human B cells and CD3ε on the surface of T cells, which activates the T cells to kill B cells and tumor cells derived from B cells associated with leukemia and lymphoma. K193 has a short half-life and is expected to be a lastline treatment option for patients with rapidly progressing relapsed or refractory B cell leukemia and lymphoma. K193 is recommended for patients with relapsed or refractory B cell leukemia and lymphoma, who have received at least two failed chemotherapy and/or at least one failed combination therapy with CD20 monoclonal antibody, or for patients who are ready to receive CAR-T treatment, which may significantly limit the market potential of K193.

K193 displayed high *in vivo* and *in vitro* anti-tumor activity in pre-clinical studies. As shown below, K193’s ability to activate T cells to kill B cells and tumor cells derived from B cells associated with leukemia and lymphoma is 10,000 times higher than OKT3 monoclonal antibody commonly used in CAR-T therapy.

**Dose Response Curve of Comparison of K193 and OKT3 Activated T Cells**



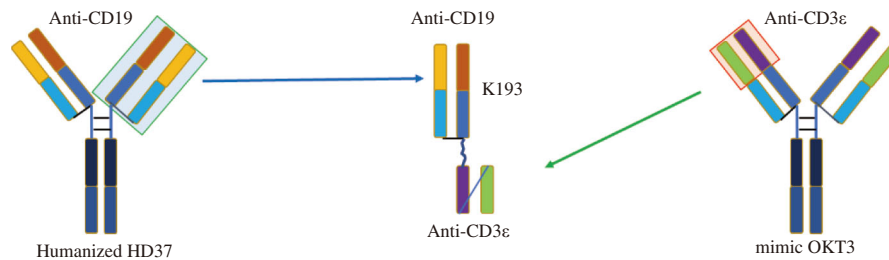
Source: Company Data

We initiated a Phase I clinical trial for K193 in China in December 2019 and we expect to complete the Phase I clinical trial in the second quarter of 2023. We plan to initiate a Phase II clinical trial for K193 in the first quarter of 2024 and complete the Phase II clinical trial of K193 in China in the fourth quarter of 2027. After receiving conditional approval, we plan to launch K193 in the second half of 2028.

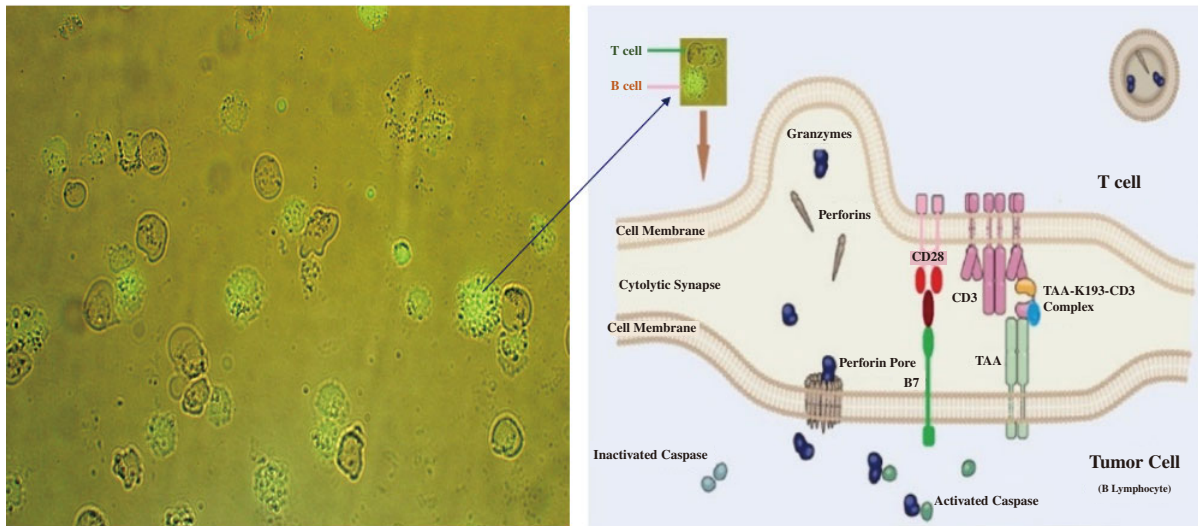
## BUSINESS

### *Mechanism of Action*

K193 is a bispecific antibody with an asymmetric structure consisting of Fab linked to scFv developed by employing our Fabite<sup>®</sup> technology platform and our mammalian expression technology platform. A bispecific antibody is developed by utilizing protein engineering techniques to link two antigen binding domains (such as Fab or scFv), allowing a single antibody to simultaneously bind two different antigens. Thus, bispecific antibodies may be engineered to exhibit novel functions, which do not exist in mixtures of the two parental antibodies. The following diagram illustrates the structure of K193:



K193 has two specific binding sites, where the Fab region binds to CD19, which is an antigen on the surface of human B cells, and the scFv structure weakly binds to CD3, which is a protein complex and T cell co-receptor that is involved in activating both helper (CD4+) T cells and cytotoxic (CD8+) T cells. As K193 has a higher affinity to CD19-positive B cells compared to CD3-positive T cells, this allow K193 to preferentially bind to B cells and then to T cells. Only after K193 binds to CD3-positive T cells, K193 activates the T cell signaling pathway to initiate the process of killing CD19-positive B cells and tumor cells derived from B cells associated with leukemia and lymphoma. The following diagram illustrates the mechanism of action of K193:



400-fold fluorescence microscopy: K193 links to T cells and B cells and causes B cell death. The green fluorescence is observed in dead B lymphoma cells and the B cell membranes have been destroyed. The smaller unstained cells are T cells.

- K193 binds to CD19 first and then to CD3, which is conducive to synaptic interaction on the cell surface between T cells and B cells.
- B7:CD28 costimulatory molecules bind to each other to activate T cells.
- T cells activate, release perforins and granzymes, break the anchored B cell membrane and cause B cells to dissolve.

**BUSINESS**

***Market Opportunities and Competition***

As of the Latest Practicable Date, there was only one bispecific antibody injection (CD19-CD3) approved in China, namely Amgen Inc.’s Blincyto®. Besides our K193, there were four other bispecific antibody injections (CD19-CD3), namely iExcyte’s YK012, Generon Biomed’s A-319, Curon Biopharma’s CN201 and Shandong Xinshidai Pharmaceutical Co., Ltd’s LNF1904, and one trispecific antibody injection (CD19-CD20-CD3), namely CMG1A46 of BioRay Pharmaceutical and Chimagen Biosciences, under clinical development registered with the CDE in China, according to Frost & Sullivan. Although the patient number is not large, the treatment cost is relatively high, and there remain great unmet medical needs from patients.

Name of Drug	Company Name	Indication	Target	Clinical Progress	Date of Clinical Publication <sup>(1)</sup>
Blincyto <sup>(2)</sup>	Amgen	Relapsed or refractory diffuse large B cell lymphoma	CD19×CD3	Listed	2014 FDA 2020 NMPA
A-319	Generon Biomed <sup>(3)</sup>	Refractory or relapsed B cell lymphoma	CD19×CD3	Phase I	April 8, 2019
K193	Luzhu Biotech	Refractory/relapsed B cell non-Hodgkin's lymphoma	CD19×CD3	Phase I	November 18, 2019
CN201	Curon Biopharma	rr-B-NHL	CD19×CD3	Phase I	January 11, 2021
LNF1904	Shandong Xinshidai Pharmaceutical Co., Ltd	Refractory/relapsed B cell malignant tumor	CD19 × CD3	Phase I	September 15, 2022
CMG1A46	BioRay Pharmaceutical Chimagen Biosciences	B cell NHL	CD19 × CD20 × CD3	Phase I	April 27, 2022
YK012	iEcyte	r/r-B-NHL	CD19 × CD3	Phase I	February 1, 2023

*Notes:*

- (1) Date of clinical publication is defined as the date of first publication of information based on clinical progress.
- (2) Blincyto® is a non-IgG-type antibody and has adopted the form of powder for concentration for solution for infusion.
- (3) Generon Biomed has changed its name to Evive Biotech.

Source: CDE, Frost & Sullivan Analysis

## BUSINESS

K193 is a bispecific antibody injection for the treatment of B cell leukemia and lymphoma, and according to Frost & Sullivan, its main competitors, such as Blincyto<sup>®</sup>, Yescarta<sup>®</sup> and Carteyva<sup>®</sup>, were not included in the latest NRDL as of the Latest Practicable Date. For the treatment of NHL/ALL, fludarabine, rituximab and imatinib were included in the Category B of the NRDL as of the Latest Practicable Date according to Frost & Sullivan, and patients generally pay 10% to 40% of the purchase price, depending on the policies of local government. Broad-spectrum anti-tumor drugs including cisplatin, carboplatin and doxorubicin were included in the Category A of the NRDL and were fully reimbursed as of the Latest Practicable Date according to Frost & Sullivan. Not being included under the National Immunization Program or the NRDL would not affect the pricing of K193 as we would price our product candidates at market price. However, if peer products are included under the NRDL, our peer products will gain market competitive advantage in mark penetration, which would cause market pressure on our product candidates.

### *Competitive Advantages*

We believe K193 has the following advantages when compared to currently marketed antibody injections for the treatment of B cell leukemia and lymphoma globally:

#### *Low Price*

K193 is expected to be priced at a retail price of approximately RMB200,000 for the first two treatments, RMB200,000 for the third treatment, and no cost for unlimited treatments after the third treatment, for a maximum total cost of RMB400,000 per patient, which is more affordable compared to the retail price of approximately RMB360,000 for a treatment of Blincyto<sup>®</sup> and approximately RMB1.5 million a year per patient for treatment of Blincyto<sup>®</sup>. We provide K193 at no cost after the third treatment in order to reduce the financial burden of patients. In addition, the production cost per treatment of K193 is low compared to the treatment cost and providing K193 at no cost for unlimited treatments after the third treatment will not have a large impact on our financial performance. As confirmed by Frost & Sullivan, patients usually have three to four rounds of treatment for B cell leukemia and lymphoma. If a patient does not respond to treatment, the patient will consider other treatment modalities, including hematopoietic stem cell transplantation. Therefore, patients will likely only elect to receive three to four rounds of K193 treatment before considering other treatment options if there is no response to K193.

#### *Liquid Formulation is Convenient and Easy to Administer*

K193 has an optimized liquid formulation which remains stable for more than 36 months when stored in 2-8°C conditions. The liquid formulation also makes it convenient to administer compared with counterparts in the dosage form of powder for concentrate for solution for infusion. K193 can be readily administered without preparation steps, while the dosage form of powder for concentrate for solution for infusion requires preparation steps such as reconstitution with diluent before administration.

## BUSINESS

---

### *Strong Affinity to B Cells and Ability to Kill B Cells*

K193 has strong binding affinity to CD19 on the surface of B cells, with a KD value of  $2.6 \times 10^{-9}$  mole/L. It adopts a humanized Fab antibody, which has a stronger affinity to CD19 than murine ScFv antibody. In comparison, its binding affinity to CD3 on the surface of T cells is weaker by the order of two magnitudes by adopting a ScFv structure with a KD value of  $1.0 \times 10^{-7}$  mole/L. The strong affinity to B cells facilitates K193 to first bind to B cells, then to T cells afterwards. The effect of K193's order of binding is strongly amplified by the participation of B7 molecules present on the surface of B cells, which interacts with cluster of differentiation 28 (“CD28”) co-stimulatory molecules on the surface of T cells to release perforin and Granzyme B to efficiently and accurately kill B cells and tumor cells derived from B cells associated with leukemia and lymphoma.

### *Easy to Control Side Effects*

The side effects of K193 are controllable with a low incidence. K193 is administered slowly at a constant rate. Administration of K193 can be stopped at any time to promptly avoid any adverse side effects. In addition, K193 can be metabolized with a short half-life after being injected and eliciting an immune response in the body to kill B cells and tumor cells derived from B cells associated with leukemia and lymphoma. Compared to competing CAR-T therapies, K193 does not have any risks of retroviral infection.

### *Ongoing Phase I Clinical Trial*

*Trial design and status.* We commenced a Phase I, multicenter, open-label, single-arm, dose-escalating clinical trial (“3+3” design) for K193 in December 2019. The primary objectives of this clinical trial are to evaluate the safety and tolerability of our K193 for the treatment of relapsed/refractory B cell non-Hodgkin's lymphoma. The secondary objectives of this clinical trial are to assess the pharmacokinetics of K193, explore the recommended Phase II dose of K193, assess the cytokine levels of K193 for the treatment of relapsed/refractory B cell non-Hodgkin's lymphoma, assess the immunogenicity of K193 and preliminarily explore the anti-tumor efficacy of K193.

The clinical trial plans to enroll 26 to 33 subjects aged between 18 to 75 years old. The clinical trial comprises six dose cohorts, namely 0.2, 0.4, 0.6, 0.8, 1.4 and 2.0 µg/kg/d. Each dose cohort is administered a 0.05 µg/kg dose of K193 once daily over the first four consecutive days (Day 1-4), followed by a 0.1 µg/kg dose of K193 once daily over seven consecutive days (Day 5-11), and further followed by the cohort's respective 0.2, 0.4, 0.6, 0.8, 1.4 or 2.0 µg/kg dose of K193 once daily over 17 days (Day 12-28). The outbreak of COVID-19 reduced the number and availability of patients with relapsed/refractory B cell non-Hodgkin's lymphoma who could commit to the 28 consecutive days of hospitalization and treatment of K193 for the Phase I clinical trial, which caused a temporary delay in subject enrollment. In addition, subject enrollment was further delayed due to difficulty finding suitable subjects, as K193 is a later-line therapy which requires enrolling patients who have failed other therapies. As of the Latest Practicable Date, we had enrolled 17 subjects and were in the dose escalation stage for this trial, but no safety or tolerability data is currently available. We expect to complete the Phase I clinical trial in the second quarter of 2023.

## BUSINESS

---

### *Clinical Development Plan*

We plan to initiate a multi-center Phase II clinical trial to evaluate the safety and efficacy of K193 for the treatment of relapsed or refractory acute lymphoblastic leukemia (“ALL”) in the first quarter of 2024, and have produced a bulk solution of sufficient K193 antibodies in November 2022 to support the Phase II clinical trial for K193. In the first half of 2024, we plan to commence enrollment of 150 subjects with ALL, who will receive two to five treatments cycles of K193 after enrollment. We expect to complete subject enrollment in 2025, complete treatment procedures for all subjects in the second half of 2026 and complete the Phase II clinical trial of K193 in China in the fourth quarter of 2027. In the fourth quarter of 2027, the Phase II clinical trial report is expected to be ready, based on which we plan to apply for conditional BLA approval from the NMPA. After receiving conditional approval, we plan to launch K193 in the second half of 2028.

### *Licenses, Rights and Obligations*

We have the global rights to develop and commercialize K193.

### *Material Communications with Competent Authorities*

Our bispecific antibody injection (CD19-CD3) for the treatment of B cell leukemia and lymphoma, K193, displayed high *in vivo* and *in vitro* anti-tumor activity in pre-clinical studies. We received CTA approval for K193 from the NMPA in April 2019. In December 2019, we initiated a Phase I clinical trial of K193 in China and expect to complete the Phase I clinical trial in the second quarter of 2023. We plan to initiate a Phase II clinical trial for K193 in the first quarter of 2024 and complete the Phase II clinical trial of K193 in China in the fourth quarter of 2027. We plan to apply for a conditional BLA approval from the NMPA prior to conducting a Phase III clinical trial for K193. For details, please see “Regulatory Overview — Regulatory Provisions — Laws and Regulations Related to Drugs — New Drug Application and Approval” in this document. Upon obtaining conditional BLA approval, the NMPA may require us to conduct Phase III clinical trials or confirmatory studies to verify the predicted clinical benefit and additional safety studies for K193.

In accordance with Drug Registration Regulation, conditional BLA approval can only be obtained for (i) biologics used for treatment of diseases that seriously endanger life and have no effective measure of treatment, and the data of clinical trials can prove the efficacy and forecast the clinical value of the biologic; (ii) biologics urgently needed for public health, and the data of clinical trials can prove the efficacy and forecast the clinical value of the biologics; or (iii) vaccines urgently needed to deal with major public health emergencies or other vaccines which the NHC deems to be urgently needed, and it is assessed that the benefits thereof outweigh the risks therein. BLA approval is usually obtained after the completion of a Phase III clinical trial, while conditional BLA can be obtained prior to completion of a Phase III clinical trial. For details of conditional BLA approval in China, see “Regulatory Overview — Regulatory Provisions — Laws and Regulations Related to Drugs — New Drug Application and Approval” in this document.

As K193 is indicated for the treatment of B cell leukemia and lymphoma, which are serious life-threatening diseases for which there are no effective treatment, our PRC Legal Adviser is of the view that there is a high possibility that K193 may obtain conditional approval and then conduct the Phase III clinical trial afterwards, which would accelerate the development and



## BUSINESS

commercialization of K193, so long as the data from the Phase I and Phase II clinical trials can prove the efficacy and forecast the clinical value of K193, and the NMPA confirms that the requirements for conditional approval of K193 are completely satisfied.

**WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET K193 SUCCESSFULLY.**

### **Our Pre-clinical-Stage Product Candidates**

Our pre-clinical-stage product candidates comprise two vaccine candidates, including Recombinant Varicella Vaccine and Recombinant Rabies Vaccine, and two antibody injection product candidates, including K333 and K1932.

#### **1. Recombinant Varicella Vaccine**

##### *Overview*

Recombinant Varicella Vaccine, our independently developed recombinant varicella vaccine candidate, is an adjusted dosage of LZ901 for the prevention of chickenpox caused by VZV. We developed Recombinant Varicella Vaccine based on LZ901. Recombinant Varicella Vaccine is expected to partially replace live attenuated vaccines of the OKA strain of VZV as an alternative vaccination method, reduce the chance of children suffering from VZV infection, and reduce the risk of developing shingles in adults. Unlike other marketed live-attenuated vaccines that contain weakened forms of VZV which may lay dormant in the patient and reactivate causing shingles, Recombinant Varicella Vaccine does not contain VZV and does not carry the risk of developing into shingles. We submitted an IND application for Recombinant Varicella Vaccine to the NMPA in June 2022. We expect to initiate a Phase I clinical trial for Recombinant Varicella Vaccine in the third quarter of 2023, and complete the Phase I clinical trial in the second quarter of 2024. We plan to initiate a Phase II clinical trial in the third quarter of 2024, complete the Phase II clinical trial in the third quarter of 2025, and initiate a Phase III clinical trial in the fourth quarter of 2025 in China, and complete the Phase III clinical trial in the second quarter of 2027.

##### *Mechanism of Action*

Recombinant Varicella Vaccine is designed on the basis of making full use of the mechanism of the human immune system for processing foreign antigens. The carboxyl end of the VZV gE extracellular domain is connected to the Fc fragment of human IgG1, and based on the characteristic of VZV gE to form covalent dimers. A multi-step liquid chromatography process is used to obtain high-purity recombinant VZV gE tetramer-Fc fusion proteins containing two Fcs by purification from protein solutions with complex compositions. The VZV gE recombinant protein containing two Fcs mimics the mechanism of action of the VZV-antibody complex in the human body. The two Fc fragments bind to Fc-gamma receptors (“FcγRs”) that are extensively present on the surface of APCs, including dendritic cells, macrophages and monocytes. As a result, VZV gE is actively engulfed into the cell by FcγR-mediated endocytosis, then degraded into polypeptides by

## BUSINESS

intracellular proteases, and eventually presented on the surface of the cell membrane together with MHC-II molecules or presented on the surface of the cell membrane together with MHC-I molecules through antigen cross-presentation. Then the processed antigen is presented to CD4+ or CD8+ T cells to induce an immune response dominated by Th1 and Th2, and the activated T cells and B cells will produce cytokines and specific antibodies including neutralizing antibodies.

### *Market Opportunities and Competition*

As of the Latest Practicable Date, there were five commercialized varicella vaccines marketed in China. According to Frost & Sullivan, although several economically developed cities in China, such as Beijing, Tianjin and Shanghai, have implemented policies to provide free varicella vaccination for children, varicella vaccine is less likely to be included in the National Immunization Program in the next three to five years since the costs will be very high to provide free varicella vaccination and varicella vaccines were not included in the latest NRDL as of the Latest Practicable Date. As also confirmed by Frost & Sullivan, oral antiviral drugs, including acyclovir, valaciclovir and famciclovir can be used to treat varicella. Acyclovir was listed in Category A or Category B, depending on the dosage form, valaciclovir and famciclovir were listed in Category B of the latest NRDL as of the Latest Practicable Date. Not being included under the National Immunization Program or the NRDL would not affect the pricing of Recombinant Varicella Vaccine as we would price our product candidates at market price. However, if peer products are included under the NRDL, our peer products will gain market competitive advantage in market penetration, which would cause market pressure on our product candidates. The following tables set forth details of the approved varicella vaccines in China:

### Commercialized Varicella Vaccines in China

Company	Technology	Vaccine Administration Procedure	Approval Date	Price, per Dose, 2021	Sales Revenue, 2021 (RMB million)	Market Share, 2021
Changchun Keygen Biological Products	Live attenuated	One dose administered for 12 month and older	March 30, 2007	RMB145.5-160.5	1,078.2	33.2%
BCHT Biotechnology	Live attenuated	One dose administered for 1-12 years of age; 2 dose administered for 13 years and older	February 4, 2008	RMB90-160.5	1,020.3	31.4%
Shanghai Institute Of Biological Products	Live attenuated	One dose administered for 12 month – 12 years old	November 7, 2006	RMB90-160.5	674.7	20.8%
RongSheng Biotech	Live attenuated	One dose administered for 12 months – 12 years old	October 25, 2016	RMB136-157	270.6	8.3%
Sinovac	Live attenuated	12 months – 12 years of age: One dose One booster dose can be administered when deemed necessary	December 18, 2019	RMB90	202.0	6.3%

Source: Public disclosure of listed companies, NMPA, Frost & Sullivan Analysis

## BUSINESS

### *Competitive Advantages*

Recombinant Varicella Vaccine prevents childhood chickenpox and has a wide range of applications. It is expected to partially replace live attenuated vaccines of the OKA strain of VZV as an alternative vaccination method, reduce the chance of children suffering from VZV infection, and reduce the risk of developing shingles in adults.

The currently marketed varicella vaccines in China are live-attenuated vaccines of the OKA strain. Unlike other marketed live-attenuated vaccines that contain weakened forms of VZV which may lay dormant in the patient and reactivate causing shingles, Recombinant Varicella Vaccine does not contain VZV and does not carry the risk of developing into shingles. Live-attenuated vaccines of the OKA strain of VZV have been administered for more than 30 years. After inoculation with a live-attenuated vaccine, VZV will lurk in the ganglia of the human body. After the age of 40, the immune system diminishes in competence and latent viruses are activated to produce herpes zoster. Recombinant varicella vaccine is a high-purity protein vaccine manufactured by genetic engineering technology. It does not have the ability to reproduce and replicate, but it can make the vaccinated person produce specific antibodies and cellular immunity against VZV.

### *Licenses, Rights and Obligations*

We have the global rights to develop and commercialize Recombinant Varicella Vaccine.

**WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET RECOMBINANT VARICELLA VACCINE SUCCESSFULLY.**

## **2. Recombinant Rabies Vaccine**

### *Overview*

We are currently developing Recombinant Rabies Vaccine, our recombinant RVG subunit vaccine candidate, for the prevention of rabies in humans. We developed Recombinant Rabies Vaccine based on the genetically engineered expression of rabies virus glycoprotein G in CHO cells.

Recombinant Rabies Vaccine is currently undergoing pre-clinical studies. We plan to request a pre-IND meeting for Recombinant Rabies Vaccine with the NMPA as early as the fourth quarter of 2023. We initiated pre-clinical studies for Recombinant Rabies Vaccine in the second quarter of 2020, and we expect to complete the pre-clinical studies in the fourth quarter of 2023. In September 2022, we screened CHO cell for high-yield clones to increase the expression level of Recombinant Rabies Vaccine and identified clones with a production yield of Recombinant Rabies Vaccine of more than 100 times higher compared to traditional tissue culture methods. We expect to initiate a Phase I clinical trial for Recombinant Rabies Vaccine in the second quarter of 2024 and complete the Phase I clinical trial in the third quarter of 2024 in China. We expect to initiate a Phase II clinical trial for Recombinant Rabies Vaccine in the third quarter of 2024, and complete the Phase II clinical trial in the first quarter of 2025. Furthermore, we expect to initiate the Phase III clinical trial in the first quarter of 2025 and complete the Phase III clinical trial in the second quarter of 2026 in China.

## BUSINESS

---

### *Mechanism of Action*

The major immune effector against rabies is the production of virus neutralizing antibodies (“VNA”) elicited by RVG protein. The capacity to trigger the production of VNA depends largely on the integrity of RVG protein “spikes” on the encapsulating viral envelope, which are comprised of trimers of RVG. RVG protein is the major viral antigen responsible for the induction of VNA and protective immunity against rabies. The RVG protein is responsible for cell attachment and membrane fusion in rabies virus and additionally is the main target for the host immune system.

### *Market Opportunities and Competition*

Rabies is a vaccine-preventable viral disease often transmitted through the bite of a rabidly infected animal. Rabies is caused by the *Rabies lyssavirus*, which includes the rabies virus and the Australian bat rabies virus. The rabies virus infects the central nervous system of mammals, eventually leading to brain disease and death. Rabies is a contagious disease with a very high mortality rate, which is why countries around the world are dedicated to eliminating rabies. The disease, which is nearly always fatal, is preventable by vaccines given either before and/or after exposure to a rabid animal. Numerous factors including the high cost of vaccines, the relative complexity of post-exposure vaccination protocols requiring multiple doses of vaccine, and insufficient surveillance contribute to the estimated 59,000 human deaths caused by rabies each year, according to the World Health Organization (“WHO”). According to the Center for Disease Control and Prevention (“CDC”) in China, the number of new human rabies cases in China was 2,048 cases in 2010 and decreased to 157 cases in 2021. A high post-exposure vaccination rate has led to the rapid decline in the number of cases in China.

Approved rabies vaccines for human use are based on inactivated purified rabies virus grown either in tissue culture or in embryonated duck or chicken eggs. A vaccine for post-exposure prophylaxis (“PEP”) needs to induce virus neutralizing antibodies (“VNAs”) as fast as possible to prevent rabies virus from spreading into the central nervous system. A pre-exposure prophylaxis (“PrEP”) vaccine on the other hand should induce sustained VNA titers and robust memory B and CD4+ T helper cell responses that allow for rapid VNAs recall after a boost.

Currently, most human rabies vaccines marketed in China are for PEP. Although this type of vaccine can also be given prior to exposure, most people still receive rabies vaccines after being bitten or scratched by animals such as cats and dogs. In addition, human rabies vaccination is used for PrEP for populations at high risk of rabies virus exposure, including sub-populations in highly endemic settings with limited access to timely and adequate PEP, individuals at occupational risk, and travelers who may be at risk of exposure. People who are at an occupational risk of rabies virus exposure account for a small portion of the total vaccine recipients, including Centers for Disease Control and Prevention staff, veterinary clinic staff and dog trainers. In the future, the market for human rabies vaccines as a PrEP can be expanded to other groups of people with a potential risk of rabies virus exposure, including courier and food delivery staff and other potential target groups.

The pre-exposure human rabies vaccine market in China increased from RMB4.2 million in 2015 to RMB10.7 million in 2021 at a CAGR of 16.8% from 2015 to 2021, and is expected to increase to RMB2,960.2 million in 2035 at a CAGR of 49.4% from 2021 to 2035.

## BUSINESS

As of the Latest Practicable Date, there were 13 commercialized human rabies vaccines marketed in China, which can be injected in both adults and children. According to Frost & Sullivan, human rabies vaccines aim to help protect people at risk of being exposed to rabies, regardless of their age, and therefore, it is unlikely that human rabies vaccines will be included in the National Immunization Program in China, which aims to protect children. However, human rabies vaccines were included in the Category B of the NRDL for work-injury insurance as of the Latest Practicable Date according to Frost & Sullivan. Not being included under the National Immunization Program or the NRDL would not affect the pricing of Recombinant Rabies Vaccine as we would price our product candidates at market price. However, if peer products are included under the NRDL, our peer products will gain market competitive advantage in market penetration, which would cause market pressure on our product candidates. The following table sets forth details of the commercialized human rabies vaccines in China:

### Commercialized Human Rabies Vaccines in China

Manufacturer	Cell Line	Administration	Approval Date	Price, 2021
Hualan Bio	PVCV	Pre-exposure: Three doses Post-exposure: Four doses (2-1-1) or five doses	January 29, 2023	/
Shandong Yidu Biotechnology		Pre-exposure: Three doses Post-exposure: Four doses (2-1-1) or five doses	July 12, 2021	/
Changchun Institute of Biological Products		Four-dose or five dose	April 30, 2021	/
Changchun Zhuoyi Biological		Pre-exposure: Three doses Post-exposure: Five doses	November 23, 2016	RMB65-93
Dalian Aleph Biomedical		Pre-exposure: Three doses Post-exposure: Five doses	September 28, 2016	RMB58.5-91.0
Liaoning Chengda		Pre-exposure: Three doses Post-exposure: Four doses (2-1-1) or five doses	March 6, 2007	Frozen-dried: RMB60-258.5 Non-frozen-dried: RMB42.09-104
Rongan Biological		Pre-exposure: Three doses Post-exposure: Five doses	September 30, 2007	RMB53.85-87
Promise Biological		Pre-exposure: Three doses Post-exposure: Five doses	May 8, 2008	RMB53
Jilin Maifeng Biopharmaceutical		Pre-exposure: Three doses Post-exposure: Five doses	January 9, 2008	/
Liaoning Yisheng Biopharma		Pre-exposure: Three doses Post-exposure: Five doses	November 6, 2006	RMB68.5-243.5
Henan Grand Biopharmaceutical	Hamster Kidney Cell	Pre-exposure: Three doses Post-exposure: Five doses	June 12, 2007	RMB46.2-89.5
Zhongke Biopharm		Pre-exposure: Three doses Post-exposure: Five doses	May 28, 2007	RMB58.8-95
Chengdu Kanghua Biological Products	HDCV	Pre-exposure: Three doses Post-exposure: Five doses	April 28, 2012	RMB275-320

Note:

\* Excluding human rabies vaccines in China that did not have any batches issued by the NMPA in the last five years.

Source: Public disclosure of listed companies, DataYes Inc., NMPA, Frost & Sullivan Analysis

## BUSINESS

### *Competitive Advantages*

Recombinant Rabies Vaccine is a prophylactic that provides protection against rabies prior to exposure and simplifies post-exposure treatment for rabies. In addition, Recombinant Rabies Vaccine has high purity and is suitable for immunizing both children and adults.

### *Licenses, Rights and Obligations*

We have the global rights to develop and commercialize Recombinant Rabies Vaccine.

**WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET RECOMBINANT RABIES VACCINE SUCCESSFULLY.**

### **3. K333**

#### *Overview*

We are currently developing K333, our bispecific antibody injection (CD33-CD3) product candidate, for the treatment of myeloid leukemia. K333 is a bispecific antibody that binds to human CD33 and CD3. We developed K333 with a IgG molecular structure from an anti-CD33 monoclonal antibody (mAb) and an anti-CD3ε scFv. K333 has a molecular structure that contains two Fabs that bind to CD33 on the surface of human myeloid cells and two Fabs that bind to CD3ε on the surface of T cells linked to the C-terminus of the consistent region of kappa chain through a hydrophilic peptide-linker, which activates the T cells to kill myeloid cells and tumor cells derived from myeloid cells associated with leukemia. Currently, drugs for treatment of myeloid leukemia, such as azacitidine, imatinib, and dasatinib, are included in the Category B of the NRDL, and patients generally need to self-finance 10% to 40% of the purchase prices, depending on the policies of local government, according to Frost & Sullivan.

K333 is currently undergoing pre-clinical studies. K333 exhibited statistically significant antitumor activity *in vivo* in established disseminated and subcutaneous mouse models of human acute myeloid leukemia (“AML”). From February 2022 to October 2022, we optimized cell culture media and bioreactor culture conditions to improve our production capabilities, increasing the yield of K333 by approximately 400%. We plan to request a pre-IND meeting for K333 with the NMPA in the second half of 2024.

#### *Mechanism of Action*

AML is a genetically heterogeneous disease characterized by clonal expansion of leukemic cells. Despite an increased understanding of the underlying disease biology in AML, the standard treatment with cytotoxic chemotherapy has remained largely unchanged over the last decades, and the overall five-year survival remains poor at under 30%. Thus, there is a pressing need for novel therapies with increased efficacy and decreased toxicity.

CD33 is a 67 kD single-pass transmembrane glycoprotein and is a member of the sialic acid-binding immunoglobulin-like lectins family. Expression of CD33 is restricted to the hematopoietic lineage with low levels present in myeloid progenitors, neutrophils, and macrophages and high levels detected in circulating monocytes and dendritic cells. Importantly, CD33 is absent on normal hematopoietic stem cells but is expressed on blasts and leukemic stem cells of 85% to 90% of patients presenting with AML. These findings suggest that CD33 is a suitable target for an antibody-based therapy in AML.

## BUSINESS

K333 is capable of binding to CD33 and to CD3, and induces T cell recruitment and tumor cell cytotoxicity. K333 is composed of a human IgG which specifically recognizes a cell membrane antigen CD33 and a single-chain antibody which recognizes a CD3 molecule linked to the C-terminus of the consistent region of kappa chain through a hydrophilic linker peptide-linker. K333 specifically binds to CD33-expressing target cells and induces cytotoxicity of CD33+ AML cell lines *in vitro* along with T cell activation.

### *Licenses, Rights and Obligations*

We have the global rights to develop and commercialize K333.

**WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET K333 SUCCESSFULLY.**

#### **4. K1932**

##### *Overview*

We are currently developing K1932, our bispecific antibody injection (CD19-CD3) product candidate, for the treatment of B cell lymphoma. K1932 is a bispecific antibody that binds to human CD19 and CD3. K1932 is recommended for patients with relapsed or refractory B cell leukemia and lymphoma, who have received at least two failed chemotherapy and/or at least one failed combination therapy with CD20 monoclonal antibody, or for patients who are ready to receive CAR-T treatment, which may significantly limit the market potential of K1932. We developed K1932 based on the molecular structure of K193, with the same binding sites for CD19 and CD3 $\epsilon$  to K193. The bispecific antibody is composed of a human IgG which specifically recognizes a cell membrane antigen CD19 and a single-chain antibody which recognizes a CD3 molecule linked to the C-terminus of the consistent region of kappa chain through a hydrophilic peptide-linker.

K1932 is expected to be administered in combination with K193 for the treatment of relapsed or refractory B cell lymphoma, and is not expected to compete with K193 for the treatment of B cell leukemia as K1932 is not indicated for leukemia. Lymphoma patients administered K1932 following the first stage administration of K193 have lower risk of experiencing a cytokine storm, which allows for dose escalation. In addition, K1932 has a longer half-life in the human body compared to K193. Due to K193's short half-life, the continuous use of syringe pump infusion is required for the treatment of K193, which requires patients to be hospitalized. K1932 improves the medication experience of patients as it is administered via injection on a weekly basis and does not require hospitalization. Patients will only need to return to the hospital on a weekly basis to receive K1932 injections. Patients with relapsed or refractory B cell lymphoma have the option to choose whether to receive K193 treatment only, which requires hospitalization throughout the treatment process, or treatment of K193 for a period of seven to 10 days followed by weekly injections of K1932, which allows patients to have more freedom to leave the hospital after the seven to 10 day induction period of K193.

For a patient with relapsed or refractory B cell lymphoma who chooses to receive a combination treatment of K193 and K1932, the patient is administered K193 for a period of seven to 10 days and is hospitalized during the K193 treatment process due to the required continuous use of syringe pump infusion. Following the induction period of K193, the patient is administered K1932 on a weekly basis and allowed to leave the hospital. However, K1932 cannot be administered prior to K193, which can be potentially harmful to the patient due to the long half-life

## BUSINESS

of K1932. During the induction period, K193 slowly kills the B cells associated with lymphoma in the human blood circulatory system. At the end of the induction period, there are essentially no B cells in the blood circulatory system and K1932 can be administered on a weekly basis. Therefore, large doses of K1932 with long half-life will not cause massive lysis of B cells, and cytokine storms are less likely to occur, which greatly improves the medication experience of B cell lymphoma patients.

K1932 is currently undergoing pre-clinical studies. From March 2022 to October 2022, we optimized cell culture media and bioreactor culture conditions to improve our production capabilities, increasing the yield of K1932 by approximately 600%. We plan to request a pre-IND meeting for K1932 with the NMPA in the second half of 2024.

### *Competitive Advantages*

The half-life of K1932 is expected to be longer than that of K193. Patients administered K1932 following the first stage administration of K193 have lower risk of experiencing a cytokine storm, which allows for dose escalation. Large doses of K1932 with long half-life will not cause massive lysis of B cells, and cytokine storms are less likely to occur, which greatly improves the medication experience of B cell lymphoma patients. In addition, K1932 is administered via injection and does not require hospitalization. As K1932 is complementary to K193 and the combination of K193 and K1932 provide patients with more treatment options, once K1932 is successfully developed and commercialized, K1932 is expected to mutually benefit K193 and not cannibalize the sales of K193.

### *Licenses, Rights and Obligations*

We have the global rights to develop and commercialize K1932.

**WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET K1932 SUCCESSFULLY.**

### **Our Other Historically Developed Products**

#### **1. Inactivated Enterovirus 71 ("EV71") Vaccine**

Inactivated EV71 Vaccine, a vaccine candidate we independently developed, is an inactivated Vero cell-based vaccine for the prevention of hand-foot-and-mouth disease. Inactivated EV71 Vaccine is produced by inoculating EV71 H9 strain into Vero cells. After culturing the EV71 H9 in media, the virus is harvested, inactivated and purified. Aluminum hydroxide adjuvant is added to enhance immunogenicity.

We commenced the development of Inactivated EV71 Vaccine in July 2007 and isolated EV71 H9 strain. From March to May in 2008, we established an Inactivated EV71 Vaccine seed bank. After three years of development, we finalized the production process for Inactivated EV71 Vaccine in August 2010. We continued to improve the purification process and produced an Inactivated EV71 Vaccine stock solution with high specific activity in September 2010. In February 2011, we prepared a batch of Inactivated EV71 Vaccine and conducted animal studies, including acute toxicity tests of BALB/c mice, repeated dose toxicity tests of cynomolgus monkeys, systemic active allergy tests of guinea pigs and injection irritation tests of rabbits. No abnormal adverse events were reported in the animals studies. In July 2011, we produced three batches of Inactivated EV71 Vaccines to perform further animals studies. We performed accelerated stability tests which indicated the three batches to be of good stability and stable quality.



## BUSINESS

In July 2011, we entered into a technology transfer agreement with Beijing Zhifei Luzhu Biopharmaceutical Co., Ltd. (“**Zhifei Biopharma**”), a wholly owned subsidiary of Chongqing Zhifei Biological Products Co., Ltd., a Shenzhen Stock Exchange-listed biotech company focused on researching, manufacturing, and selling vaccines and biological products (“**2011 Zhifei License Agreement**”) with respect to the assets and intellectual property rights in and to Inactivated EV71 Vaccine in China. We entered into the 2011 Zhifei License Agreement in order to leverage Zhifei Biopharma’s production and strong sales capacity to ensure the successful commercialization of Inactivated EV71 Vaccine. When we entered into the 2011 Zhifei License Agreement, Inactivated EV71 Vaccine was in the preclinical stage. Pursuant to the 2011 Zhifei License Agreement, we agreed to transfer Zhifei Biopharma all test results in relation to pre-clinical studies of Inactivated EV71 Vaccine, proprietary technology related to Inactivated EV71 Vaccine pilot-scale manufacturing and testing and relevant testing technologies that are not disclosed in the invention patent of Inactivated EV71 Vaccine to Zhifei Biopharma. We co-own with Zhifei Biopharma the invention patent of Inactivated EV71 Vaccine. Zhifei Biopharma solely owns all rights, titles, and interests in and to all innovations or improvement for Inactivated EV71 Vaccine by Zhifei Biopharma or us regardless of inventorship, authorship, or other origination. We agreed to provide guidance to the personnel of Zhifei Biopharma to fully master the technologies in relation to Inactivated EV71 Vaccine upon request by Zhifei Biopharma. The follow-up improvement of the technical secrets in relation to Inactivated EV71 Vaccine transferred to Zhifei Biopharma shall be jointly completed by Zhifei Biopharma and us, and the follow-up improvement results belong to Zhifei Biopharma. Unless Zhifei Biopharma obtains written permission from us in advance, Zhifei Biopharma may only use the follow-up improvement technology for the development Inactivated EV71 Vaccine. In addition, we agreed not to disclose the technologies in relation to Inactivated EV71 Vaccine to any third parties. The confidentiality period of the trade secrets in relation to Inactivated EV71 Vaccine to be transferred to Zhifei Biopharma is a period of 10 years from the signing date of the 2011 Zhifei License Agreement. Zhifei Biopharma agreed to pay us RMB19.0 million in milestone payments, comprising RMB5.0 million in October 2011, RMB5.0 million within 30 days of the acceptance of CTA, RMB5.0 million within 30 days of receiving CTA approval and RMB4.0 million within 30 days of receiving approval to commercialize Inactivated EV71 Vaccine, and royalty payments of 3% sales commission from sales of Inactivated EV71 Vaccine for a period of five years after receiving approval to commercialize Inactivated EV71 Vaccine. Zhifei Biopharma is an independent third party.

We transferred all assets of Inactivated EV71 Vaccine to Zhifei Biopharma, and co-own all intellectual property rights in and to Inactivated EV71 Vaccine with Zhifei Biopharma. After entering into the 2011 Zhifei License Agreement, we did not incur any expenses in relation to Inactivated EV71 Vaccine nor are we obligated to pay for any expenses in relation to Inactivated EV71 Vaccine after it was transferred to Zhifei Biopharma. As of the Latest Practicable Date, Zhifei Biopharma had paid us a total of RMB15.0 million under the 2011 Zhifei License Agreement. Zhifei Biopharma will further pay us a milestone payment of RMB4.0 million within 30 days after receiving approval to commercialize Inactivated EV71 Vaccine and royalty payments of low single-digit percentage of sales for a period of five years after the commercialization of Inactivated EV71 Vaccine according to the 2011 Zhifei License Agreement. We did not receive any payment pursuant to the 2011 Zhifei License Agreement during the Track Record Period. Except for China, we have the global rights to develop and commercialize Inactivated EV71 Vaccine. We currently have no global commercialization plan for Inactivated EV71 Vaccine because we do not own any patents in other countries in relation to Inactivated EV71 Vaccine.

In December 2018, CTA approval was granted for Inactivated EV71 Vaccine from the NMPA. Zhifei Biopharma initiated a single-center, randomized, double-blind, different-dosed and placebo-controlled Phase I clinical trial for Inactivated EV71 Vaccine in China in September 2020 and

## BUSINESS

received a clinical trial statistics report for the Phase I clinical trial for Inactivated EV71 Vaccine in October 2021. In October 2021, Zhifei Biopharma initiated a single-center, randomized, blinded, different-dosed and positive-controlled Phase II clinical trial for Inactivated EV71 Vaccine in China, which is currently ongoing. We and Zhifei Biopharma co-sponsored the Phase I clinical trial and Phase II clinical trial for Inactivated EV71 Vaccine in China. Upon obtaining NDA approval for Inactivated EV71 Vaccine, Zhifei Biopharma is expected to be the MAH of Inactivated EV71 Vaccine.

### 2. K11

K11, a humanized anti-VEGF monoclonal antibody injection product candidate we independently developed, is a biosimilar of bevacizumab and mainly used for the treatment of colorectal cancer, lung cancer and other cancers. K11 is expressed by Chinese hamster ovary ("CHO")-K1 cells grown in chemically-defined cell culture media containing no animal or plant-derived proteins. K11 binds to human vascular endothelial growth factor ("VEGF") to prevent VEGF from binding to two VEGF receptors (FMS-like receptor tyrosine kinase 1 ("FLT-1") and kinase insert domain receptor ("KDR")) on the surface of endothelial cells. This prevents the formation and growth of new blood vessels, hinders the blood supply in tumor tissue, and leads to unsustainable tumor growth. Combined with cytotoxic synthetic drugs, K11 can significantly inhibit the growth of tumors and inhibit the volume of existing malignant tumors.

Mr. KONG initiated the development of K11 in June 2012 and led the development of K11 in gene synthesis, clone screening, establishing cell banks, production scale-up, purification method development and quality control testing. Mr. KONG contributed as the general director for the filing of the CTA application for K11 to the NMPA and obtained CTA approval from the NMPA in April 2017. We commenced the development of K11 based on the antibody structure of bevacizumab in June 2012. In 2013, we created cell banks, performed purification method development and explored product formulas for K11. We also produced three batches of K11 in 2013. We stored the three batches of K11 in 2-8°C and -20°C conditions for 18 months and conducted stability tests with results that indicated the three batches of K11 were highly consistent with bevacizumab. In 2014, we produced an additional three batches of K11 and conducted preclinical evaluations of K11, including animal safety evaluations and pharmacodynamic research. We stored the three additional batches of K11 in 2-8°C conditions for 14 months and conducted stability tests with results that indicated the three additional batches of K11 were stable. In 2015, we began clinical sample production of K11 and completed preclinical studies in September 2015. In order to leverage Beijing Science Sun's R&D capabilities in developing anti-cancer drugs and its commercialization team that is mainly engaged in the sales of anti-cancer drugs to accelerate the R&D and commercialization of K11, we entered into the Beijing Science Sun Licensing Agreement in July 2019 and transferred all assets and intellectual property rights in and to K11 to Beijing Science Sun. Beijing Science Sun solely owns all rights, titles, and interests in and to all innovations or improvement for K11 by Beijing Science Sun or us regardless of inventorship, authorship, or other origination. Beijing Science Sun agreed to pay us royalty payments of 8% of net profits from sales of K11, or 50% of net profits from sales of K11 if the net profit margin is less than 15% for a period of ten years after receiving approval to commercialize K11. As we did not have other payment arrangements with third-parties in relation to the development of K11, there was nil upfront payment for K11 before and during the Track Record Period. As advised by Frost & Sullivan, it is industry norm for the amount of upfront payments and proportion of royalty fee to be decided by the contracting parties through negotiation, and the nil upfront payment for K11 under the Beijing Science License Agreement is commercially rational. When we entered into the Beijing Science Sun License Agreement, K11 was in the clinical stage. After entering into the Beijing Science Sun Licensing Agreement, we did not incur any expenses in relation to K11 nor are we obligated to pay for any expenses in relation to K11 after it was

## BUSINESS

transferred to Beijing Science Sun. Except for China, we have the global rights to develop and commercialize K11. We currently have no global commercialization plan for K11 because we do not own any patents in other countries in relation to K11. For further details regarding the terms of the Beijing Science Sun License Agreement with Beijing Science Sun, please see “— Our Products and Product Candidates — Our Core Product and Clinical-Stage Product Candidates — 2. K3 — Licenses, Rights and Obligations” in this section.

We received an CTA approval for K11 from the NMPA in April 2017. After receiving CTA approval, we engaged a CRO to commence a single-center, randomized, double-blinded, single dose, parallel-controlled Phase I clinical trial to study the pharmacokinetics, safety and immunogenicity of our K11 in relation to F. Hoffmann-La Roche AG’s Avastin® (bevacizumab) in healthy males aged 18 to 45 years old in China at Tianjin Cancer Hospital, and initiated subject enrollment in January 2018. We sponsored the Phase I clinical trial for K11 in China. However, the Phase I clinical trial for K11 was suspended because we were only able to recruit 58 subjects and unable to complete enrollment of the planned number of 96 subjects, which is not within our control and is not related to the product quality of K11. According to Frost & Sullivan, subject enrollment criteria for clinical trials of oncology drugs in China often have high barriers of entry for subjects according to industry practice and patients may be unwilling to enroll due to their own personal reasons or other objective reasons unrelated to the quality of the drug, which may lead to low subject enrollment and suspension of the clinical trial due to failure in subject recruitment. In July 2019, we transferred all assets and intellectual property rights in and to K11 to Beijing Science Sun. From January 2020 to June 2020, Beijing Science Sun screened for CROs and prepared for a Phase I clinical trial for K11. Beijing Science Sun obtained approval for the clinical trial protocol from the ethics committee of a clinical trial institution in April 2020. In September 2021, Beijing Science Sun engaged a CDMO to produce K11. Beijing Science Sun plans to resume the Phase I clinical trial of K11 in China. Beijing Science Sun plans to initiate and sponsor a Phase III clinical trial of K11 in China, to complete the Phase III clinical trial in the fourth quarter of 2024 and file the BLA to the NMPA in the first quarter of 2026. Upon obtaining BLA approval for K11, Beijing Science Sun is expected to be the MAH of K11.

### 3. Immunoreagent Testing Kits

We have independently developed five immunoreagent testing kits (for research purposes only), including: Group A Meningococcal Polysaccharide IgG Antibody Detection Kit, Group C Meningococcal Polysaccharide IgG Antibody Detection Kit, Group Y Meningococcal Polysaccharide IgG Antibody Detection Kit, Group W<sub>135</sub> Meningococcal Polysaccharide IgG Antibody Detection Kit and Haemophilus Influenzae Type b Polysaccharide IgG Antibody Detection Kit (“**Immunoreagent Testing Kits**”). Our Immunoreagent Kits are immunoreagent enzyme-linked kits and indirect enzyme-linked immunoassays used to detect the amount of Group A Meningococcal Polysaccharide Antibody (IgG), Group C Meningococcal Polysaccharide Antibody (IgG), Group Y Meningococcal Polysaccharide Antibody (IgG), Group W<sub>135</sub> Meningococcal Polysaccharide Antibody (IgG) and Hib Polysaccharide Antibody (IgG) in human serum or plasma. We commenced the development of our Immunoreagent Testing Kits in 2003. During the development of Meningococcal Group A and C Polysaccharide Conjugate Vaccine, we first developed Group C Meningococcal Polysaccharide IgG Antibody Detection Kit to test serum samples. In 2004, we purchased meningococcal polysaccharide antibody reference standard from The National Institute for Biological Standards and Control, the reference standard provider of the World Health Organization, to develop a reference substance based on the meningococcal polysaccharide antibody reference standard for our Immunoreagent Testing Kits. In addition, we also began to provide our Immunoreagent Testing Kits to CDCs in China to determine the prevalence of meningococcal meningitis in different regions of China in 2004. Our Group A Meningococcal Polysaccharide IgG Antibody

## BUSINESS

Detection Kit, Group C Meningococcal Polysaccharide IgG Antibody Detection Kit, Group Y Meningococcal Polysaccharide IgG Antibody Detection Kit, Group W<sub>135</sub> Meningococcal Polysaccharide IgG Antibody Detection Kit are the first domestically produced kits for the quantitative detection of meningococcal polysaccharide antibodies.

We had generated income of RMB4.7 million from sales of our immunoreagent testing kits (for research purposes only) to pharmaceutical companies during the Track Record Period.

### Our Commercialized Vaccine Products

We have historically developed five commercialized vaccine products, namely (i) Haemophilus Influenzae Type b Conjugate Vaccine, (ii) Group ACYW<sub>135</sub> Meningococcal Polysaccharide Vaccine, (iii) Meningococcal Groups A and C and Haemophilus Influenzae Type b Conjugate Vaccine, (iv) Group A and C Meningococcal Polysaccharide Vaccine and (v) Meningococcal Group A and C Polysaccharide Conjugate Vaccine (the "**Bacteria Vaccines**").

*Haemophilus Influenzae Type b Conjugate Vaccine.* Zhifei Biopharma and we commenced the co-development of Haemophilus Influenzae Type b Conjugate Vaccine for the prevention of *Haemophilus influenzae* type b ("**Hib**") disease in infants and young children in January 2002 and completed preclinical studies in December 2006. Zhifei Biopharma and we received CTA approval for Haemophilus Influenzae Type b Conjugate Vaccine in July 2008. Zhifei Biopharma completed a Phase I clinical trial in November 2008 and a Phase III clinical trial in August 2009. Zhifei Biopharma sponsored the Phase I clinical trial and Phase III clinical trial for Haemophilus Influenzae Type b Conjugate Vaccine in China.

*Group ACYW<sub>135</sub> Meningococcal Polysaccharide Vaccine.* Zhifei Biopharma and we commenced the co-development of Group ACYW<sub>135</sub> Meningococcal Polysaccharide Vaccine for the prevention of Groups A, C, Y and W<sub>135</sub> meningococcal disease in people over two years of age in March 2002 and completed preclinical studies in May 2004. Zhifei Biopharma and we received CTA approval for Group ACYW<sub>135</sub> Meningococcal Polysaccharide Vaccine in March 2005, and completed a Phase I clinical trial in May 2005 and a Phase III clinical trial in December 2005. We and Zhifei Biopharma co-sponsored the Phase I clinical trial and Phase III clinical trial for Group ACYW<sub>135</sub> Meningococcal Polysaccharide Vaccine in China. We received NDA approval for Group ACYW<sub>135</sub> Meningococcal Polysaccharide Vaccine from the NMPA in November 2007.

*Meningococcal Groups A and C and Haemophilus Influenzae Type b Conjugate Vaccine.* Zhifei Biopharma and we commenced the co-development of Meningococcal Groups A and C and Haemophilus Influenzae Type b Conjugate Vaccine for the prevention of Groups A and C meningococcal disease and Hib disease in infants in January 2002 and completed preclinical studies in December 2005. Zhifei Biopharma and we received CTA approval for Meningococcal Groups A and C and Haemophilus Influenzae Type b Conjugate Vaccine in February 2007, and completed a Phase I clinical trial in April 2007 and a Phase II clinical trial in January 2008. Zhifei Biopharma completed a Phase III clinical trial in April 2011. We and Zhifei Biopharma co-sponsored the Phase I clinical trial and Phase II clinical trial, and Zhifei Biopharma sponsored the Phase III clinical trial for Meningococcal Groups A and C and Haemophilus Influenzae Type b Conjugate Vaccine in China.

## BUSINESS

*Group A and C Meningococcal Polysaccharide Vaccine.* Zhifei Biopharma and we commenced the co-development of Group A and C Meningococcal Polysaccharide Vaccine for the prevention of Groups A and C meningococcal disease in people over two years of age in January 2002 and completed preclinical studies in February 2006. Zhifei Biopharma and we received CTA approval for Group A and C Meningococcal Polysaccharide Vaccine in July 2007, completed a Phase I clinical trial in September 2007 and completed a Phase III clinical trial in April 2008. We and Zhifei Biopharma co-sponsored the Phase I clinical trial and Phase III clinical trial for Group A and C Meningococcal Polysaccharide Vaccine in China.

*Meningococcal Group A and C Polysaccharide Conjugate Vaccine.* We commenced the independent development of Meningococcal Group A and C Polysaccharide Conjugate Vaccine for the prevention of Groups A and C meningococcal disease in infants and young children in March 2002 and completed preclinical studies in February 2003. We received CTA approval for Meningococcal Group A and C Polysaccharide Conjugate Vaccine in November 2003, completed a Phase I clinical trial in December 2003 and completed a Phase III clinical trial in September 2004. We sponsored the Phase I clinical trial and Phase III clinical trial for Meningococcal Group A and C Polysaccharide Conjugate Vaccine in China. We received NDA approval for Meningococcal Group A and C Polysaccharide Conjugate Vaccine from the NMPA in May 2006.

In October 2008, we entered into a technology transfer agreement with Zhifei Biopharma ("**2008 Zhifei License Agreement**") in order to leverage Zhifei Biopharma's production capacity to accelerate the commercialization of the Bacteria Vaccines. Pursuant to the 2008 Zhifei License Agreement, we assigned Zhifei Biopharma the intellectual property rights in and to the Bacteria Vaccines and transferred technical data and materials to produce the Bacteria Vaccines to Zhifei Biopharma for a total of RMB19.8 million, which was a one-off payment. We did not receive any payment pursuant to the 2008 Zhifei License Agreement during the Track Record Period and we do not expect to receive any further payments pursuant to the 2008 Zhifei License Agreement in the future. We agreed to provide guidance to the personnel of Zhifei Biopharma to carry out production operations according to the transferred technical data in relation to the Bacteria Vaccines. Zhifei Biopharma solely owns all rights, titles, and interests in and to all innovations or improvement for the Bacteria Vaccines by Zhifei Biopharma or us regardless of inventorship, authorship, or other origination. The confidentiality period of the trade secrets in relation to the Bacteria Vaccines that were transferred to Zhifei Biopharma was a period of 10 years from the signing date of the 2008 Zhifei License Agreement. When we entered into the 2008 Zhifei License Agreement, Haemophilus Influenzae Type b Conjugate Vaccine, Meningococcal Groups A and C and Haemophilus Influenzae Type b Conjugate Vaccine and Group A and C Meningococcal Polysaccharide Vaccine were in the clinical stage, and Group ACYW<sub>135</sub> Meningococcal Polysaccharide Vaccine and Meningococcal Group A and C Polysaccharide Conjugate Vaccine were already commercialized. Currently, all of the Bacteria Vaccines have been commercialized. After entering into the 2008 Zhifei License Agreement, we did not incur any expenses in relation to the Bacteria Vaccines nor are we obligated to pay for any expenses in relation to the Bacteria Vaccines after they were transferred to Zhifei Biopharma. Zhifei Biopharma is the MAH of the Bacteria Vaccines. Except for China, we have the global rights to develop and commercialize the Bacteria Vaccines. We currently have no global commercialization plan for the Bacteria Vaccines because we do not own any patents in other countries in relation to the Bacteria Vaccines. Furthermore, the global market for the Bacteria Vaccines is highly saturated with many similar products, and therefore, we have no plan to pursue global commercialization for the Bacteria Vaccines. Zhifei Biopharma is an independent third party.

## BUSINESS

---

### RELATIONSHIP WITH ZHIFEI BIOPHARMA

Zhifei Biopharma, formerly known as Beijing Luzhu Biopharmaceutical Co., Ltd., is a biotech company based in Beijing that is focused on researching, manufacturing, and selling vaccines and biological products, and a wholly owned subsidiary of Chongqing Zhifei Biological Products Co., Ltd., a Shenzhen Stock Exchange-listed biotech company. As of the Latest Practicable Date, Zhifei Biopharma and Chongqing Zhifei Biological Products Co., Ltd. were Independent Third Parties.

During the first few years of operation since 2001, we focused on R&D instead of commercialization and did not establish our own commercial manufacturing facilities. We built the Beijing R&D and Pilot Manufacturing Facility, which only has limited production capacity because the industrial steam supplied to the Beijing R&D and Pilot Manufacturing Facility does not support the commercial production of vaccine products. In order to accelerate the commercialization of the Bacterial Vaccines of the Company, in October 2003, we, Mr. KONG Jian, and one other Independent Third Party jointly established Zhifei Biopharma to engage in the manufacturing of Meningococcal Group A and C Polysaccharide Conjugate Vaccine, Group ACYW<sub>135</sub> Meningococcal Polysaccharide Vaccine, and other vaccines, with an initial registered capital of RMB2.0 million. As of the date of establishment, Zhifei Biopharma was a subsidiary of us and was owned as to 80.0% by us, 5.0% by Mr. KONG and 15.0% by the other Independent Third Party, respectively. Zhifei Biopharma completed the construction of manufacturing facilities in 2005. Zhifei Biopharma obtained a series of capital increases from Chongqing Zhifei Biological Products Co., Ltd. to build the manufacturing facilities and Chongqing Zhifei Biological Products Co., Ltd. thereby became a shareholder of Zhifei Biopharma.

As our co-founders decided to pursue an R&D focused business strategy, and Chongqing Zhifei Biological Products Co., Ltd. decided to pursue a manufacturing and commercialization focused business strategy, in August 2008, shareholders of Zhifei Biopharma reached an agreement that Chongqing Zhifei Biological Products Co., Ltd. would purchase all other shares of Zhifei Biopharma from us, Mr. KONG, Ms. ZHANG Yanping, and Ms. JIANG Xianmin, who are our co-founders and Zhifei Biopharma’s shareholders at the time of the proposal, in order to facilitate the development of the manufacturing and commercialization capabilities of Zhifei Biopharma and Chongqing Zhifei Biological Products Co., Ltd., and provide us with capital to support the R&D of our product candidates. In September 2008, Chongqing Zhifei Biological Products Co., Ltd. acquired Zhifei Biopharma and Zhifei Biopharma became a wholly-owned subsidiary of Chongqing Zhifei Biological Products Co., Ltd. After Chongqing Zhifei Biological Products Co., Ltd. acquired Zhifei Biopharma and up to the Latest Practicable Date, we, the Directors, Mr. KONG, Ms. ZHANG, and Ms. JIANG no longer held any shares in Zhifei Biopharma. In October 2008, we entered into the 2008 Zhifei License Agreement in order to leverage Zhifei Biopharma’s production capacity to accelerate the commercialization of the Bacteria Vaccines. In July 2011, we entered into the 2011 Zhifei License Agreement in order to leverage Zhifei Biopharma’s production and strong sales capacity to ensure the successful commercialization of Inactivated EV71 Vaccine. In 2013, Zhifei Biopharma was renamed as Beijing Zhifei Luzhu Biopharmaceutical Co., Ltd.

## BUSINESS

---

### RESEARCH AND DEVELOPMENT

#### In-house Research and Development

Our in-house R&D team is involved in all stages of novel vaccine and biologic therapeutic candidates development, from pre-clinical studies, laboratory research, to clinical trials, regulatory filings and manufacturing process development. We have established a full range of in-house product discovery capabilities, including recombinant protein design and optimization, amplification, cultivation and harvesting. Leveraging our Fabite® technology platform, our mammalian expression technology platform and our deep understanding of recombinant protein engineering, we are focused on building out a diversified and advanced discovery pipeline of novel vaccines and biologic therapies targeting a broad spectrum of infectious diseases, cancer, autoimmune diseases and biologic targets. See also “— Our Research and Development Platforms” in this section for more information.

Led by our management team and supported by our in-house R&D team, we have adopted an efficient approach to identify proven targets, such as antigens, that have produced effects during treatment to optimize, transform and develop into product candidates that enhance our portfolio for the treatment of cancer and autoimmune diseases. Furthermore, we take into consideration unmet medical needs, scientific rationale, commercial potential, synergies with our existing product portfolio, competition, manufacturing capacity, commercialization capability, timelines and costs to evaluate whether to move forward with development. For each product candidate, we carefully design a detailed development plan in order to utilize our resources effectively and to efficiently complete the development process. During the preclinical stage, we conduct extensive early-stage investigation in relation to efficacy and safety of our product candidates. Prior to beginning clinical development, we evaluate the preclinical data of our product candidates to assess whether regulatory requirements are met and the likelihood of regulatory approval, and conduct a market evaluation weighing factors including competition, research results and market forecast through a risk-benefit assessment to avoid unnecessary costs, efforts, delays and market failures.

We are committed to developing innovative human vaccines and therapeutic biologics and have demonstrated strong R&D capabilities with a robust product pipeline of innovative vaccines and therapeutic biologics as well as extensive R&D experience and an innovative precision protein engineering platform.

We have established a diversified and advanced product pipeline of innovative human vaccines and therapeutic biologics. We have independently developed our Core Product, LZ901, an innovative human vaccine and recombinant vaccine product candidate featuring a specific molecular structure and mechanism, improved immunogenicity, and high safety and stability profile. LZ901 has a tetrameric molecular structure to prevent shingles caused by VZV for adults aged 50 years and older. We successfully completed pre-clinical studies and a Phase I clinical trial for LZ901, and expect to file the BLA for LZ901 to the NMPA in the third quarter of 2024. In addition, we are seeking global filing for LZ901 and received IND approval from the FDA in July 2022 for LZ901, which demonstrates our outstanding R&D and product development capabilities as one of the few vaccine companies in China to receive an IND approval from the FDA, as confirmed by Frost & Sullivan.

## BUSINESS

---

Our other innovative human vaccines in our product pipeline include two independently developed recombinant vaccine product candidates in the pre-clinical stage, namely Recombinant Varicella Vaccine and Recombinant Rabies Vaccine. Currently, there are no clinical stage or commercialized varicella vaccines or rabies vaccines in China based on recombinant protein technology. Recombinant vaccines induce a human immune response while avoiding other components of pathogens that cause adverse effects on the human body, and are safe for people with weak immune systems, which make recombinant vaccines suitable for immunizing both children and adults. Recombinant Varicella Vaccine is an adjusted dosage of LZ901 for the prevention of chickenpox caused by VZV and is expected to partially replace live attenuated vaccines of the OKA strain of VZV as an alternative vaccination method, reduce the chance of children suffering from VZV infection, and reduce the risk of developing shingles in adults. Unlike other marketed live-attenuated vaccines that contain weakened forms of VZV which may lay dormant in the patient and reactivate causing shingles, Recombinant Varicella Vaccine does not contain VZV and does not carry the risk of developing into shingles. Recombinant Rabies Vaccine is a recombinant rabies glycoprotein G subunit vaccine for the prevention of rabies in humans and is a prophylactic that provides protection against rabies prior to exposure and simplifies post-exposure treatment for rabies. Recombinant Rabies Vaccine has high purity and is suitable for immunizing both children and adults.

Our innovative therapeutic biologics in our product pipeline include one independently developed bispecific antibody product candidate in the clinical stage, namely K193, and two independently developed bispecific antibody product candidates in the pre-clinical stage, namely K333 and K1932. Bispecific antibodies recognize and specifically bind to two antigens or epitopes and simultaneously block the biological functions mediated by both antigens/epitopes or draws the cells of both antigens closer together and enhances the interaction. K193 is a bispecific antibody that binds to human CD19 and CD3 and is indicated for the treatment of B cell leukemia and lymphoma. K193's molecular structure has good thermal stability and is less susceptible to polymerization, which ensures the stability and binding ability of K193. K333 is a bispecific antibody that binds to human CD33 and CD3 and is indicated for the treatment of myeloid leukemia. K1932 is a bispecific antibody that binds to human CD19 and CD3 and is indicated for the treatment of B cell lymphoma. Compared with K193, K1932 has a much longer half-life in the human body. Patients administered K1932 following the first stage administration of K193 have lower risk of experiencing a cytokine storm, which allows for dose escalation. After the induction period of K193, K1932 can be administered on a weekly basis, which greatly improves the medication experience of B cell lymphoma patients.

With respect to our R&D experience, we have historically developed a broad range of human vaccines and therapeutic biologics, including bacteria vaccines, inactivated vaccines and monoclonal antibodies. We have made various breakthroughs in the R&D of bacteria vaccines, including completing pre-clinical studies and clinical trials and obtaining NDA approvals. Our leading R&D personnel, who have extensive biopharmaceutical experience, developed the world's first liquid formulation Meningococcal Group A and C Polysaccharide Conjugate Vaccine, the world's first Meningococcal Group A and C and Haemophilus Influenzae Type b Conjugate Vaccine, China's first Haemophilus Influenzae Type b Conjugate Vaccine with aluminum phosphate adjuvant, and China's first Group ACYW<sub>135</sub> Meningococcal Polysaccharide Vaccine. We independently developed the Bacteria Vaccines, and when we transferred the Bacteria Vaccines to Zhifei Biopharma in October 2008, the Bacteria Vaccines were mostly in the late clinical stage or commercialized. In addition, we independently developed K11, a humanized anti-VEGF monoclonal antibody injection product candidate and a biosimilar of bevacizumab. K11 is mainly used for the treatment of colorectal cancer, lung cancer and other cancers. We initiated the development of K11 in June 2012, completed pre-clinical studies for K11 in September 2015 and received CTA approval for K11 from the NMPA in April 2017 before transferring K11 to Beijing Science Sun in July 2019.



## BUSINESS

The R&D of technology platforms is time- and resource-consuming and requires strong R&D capabilities. We internally developed an innovative precision protein engineering platform comprising five technology platforms (including Fabite<sup>®</sup> technology platform, targeted recombinant antigen presentation technology platform, polysaccharide-protein conjugation technology platform, protein purification technology platform and protein stability technology platform). These technology platforms empower the full cycle of drug development to improve product efficiency, purity and stability, which provide a solid foundation for the development of human vaccine, monoclonal antibody, and bispecific antibody product candidates. From 2001 to 2008, we had established and refined our polysaccharide-protein conjugation technology platform to develop the Bacteria Vaccines. From 2009 to the Latest Practicable Date, we had established and refined our Fabite<sup>®</sup> technology platform, targeted recombinant antigen presentation technology platform, polysaccharide-protein conjugation technology platform, protein purification technology platform and protein stability technology platform to develop seven product candidates, including three product candidates in the clinical stage and four product candidates in the pre-clinical stage.

As of the Latest Practicable Date, our research and development team consisted of 71 personnel in China, most of whom hold bachelor's or higher degrees, mainly majoring in bioengineering, biology, organic chemistry, pharmaceutical engineering and pharmaceutical sciences. Nearly a third of our researchers have more than ten years of industry experience, and almost half of our researchers have at least five years of industry experience. The team is led by Mr. KONG Jian, our co-founder, executive Director, general manager and chief scientist, who has over 33 years of biopharmaceutical experience. For details of the background of Mr. KONG, please see “Directors, Supervisors and Senior Management” in this document. We plan to expand our research and development team to approximately 80 to 120 personnel in the next one to two years based on development and launch plans of our product candidates. As of the Latest Practicable Date, we do not have research and development personnel in the U.S., but we currently have one administrative personnel in the U.S., who is mainly responsible for our business development overseas and will supervise the Phase I clinical trial of LZ901 in the U.S. In addition, we have engaged a CRO to support the research and development of LZ901 in the U.S. since November 2022.

Our research and development expenses primarily consisted of staff costs, including salaries, welfare and share-based payment to our research and development personnel, third-party contracting costs, costs of raw materials and depreciation and amortization. Our research and development expenses increased from RMB43.0 million in 2021 to RMB91.4 million in 2022, largely due to (i) an increase of share-based payments of RMB15.7 million primarily arising from the share options and awards we granted to our research and development personnel and (ii) an increase of sub-contracting costs of RMB12.5 million mainly arising from our Phase I clinical trial and Phase II clinical trial for LZ901. The research and development expenses incurred for our Core Product, excluding share-based payments, amounted to RMB6.2 million and RMB38.2 million in 2021 and 2022, respectively. As our research and development expenses incurred for our Core Product (excluding share-based payments) increased by RMB32.0 million from 2021 to 2022, primarily relating to our initiations of the Phase I clinical trial and the Phase II clinical trial for LZ901 in China in 2022, the proportion of the research and development expenses incurred for our Core Product (excluding share-based payments) in our total research and development expenses (excluding share-based payments) increased from 38.3% in 2021 to 78.1% in 2022, and the proportion of our total research and development expenses in our total operating expenses\* increased from 41.7% in 2021 to 51.6% in 2022. The proportion of our total research and development costs (excluding share-based payments) in our total cash operating costs increased from 80.0% in 2021 to 82.6% in 2022.

*Note:*

\* Operating expenses consist of research and development expenses and administrative expenses.

## BUSINESS

---

### **Our Research and Development Platforms**

#### ***Fabite<sup>®</sup> Technology Platform***

Our internally developed next-generation Fab-scFv bispecific antibody development platform, Fabite<sup>®</sup>, of which we own intellectual property rights, has competitive advantages in the development of bispecific antibody products for the treatment of relapsed/refractory hematological malignancies. It uses humanized Fab fragments to bind to target antigens on the surface of malignant tumor cell membranes and scFv to bind to T cells, which activates the T cells to kill the malignant tumor cells. The humanized Fab fragments strongly bind to the tumor target protein, while the scFvs weakly bind to T cells, which ensures that the tumor target protein is bound. The bispecific antibodies developed by our Fabite<sup>®</sup> technology platform are capable of binding to two targets and have a molecular design that not only ensures the targeting of the bispecific antibodies but also does not over activate T cells. Our Fabite<sup>®</sup> technology platform has a fully controllable mechanism of action and mode of administration to ensure the safety of patients. It can be used in a variety of immunotherapies based on the activation of T cells to kill malignant tumor cells. Our Fabite<sup>®</sup> technology platform optimizes the purification process of bispecific antibodies, achieving high purity of monomers.

We have developed three bispecific antibody injection product candidates, namely K193, K333 and K1932, using our Fabite<sup>®</sup> technology platform, the production process of which achieves consistent quality and high bispecific antibody yield and purity, featuring favorable safety profile and fewer side effects.

#### ***Targeted Recombinant Antigen Presentation Technology Platform***

Our targeted recombinant antigen presentation technology platform forms antigen expressing RICs, and directly presents viral membrane antigens to APCs, which simulates the natural human immune system response to invading microorganisms. The recombinant protein vaccine candidates developed by our targeted recombinant antigen presentation technology platform have a molecular design that include a genetically engineered target viral membrane antigen containing multiple Fc regions that bind to APCs. Once bound to the APC, the APC engulf the antigen and then presents the antigen to other immune cells, which elicits an immune response to target viruses. Our targeted recombinant antigen presentation technology platform greatly enhances the utilization efficiency of antigens and can induce high-titer specific antibodies and cellular immunity. Furthermore, the antigens expressed by our targeted recombinant antigen presentation technology platform contain multiple Fc regions, which is an improvement upon traditional fusion protein technology that only expresses antigens with a single Fc region.

We have developed three recombinant protein vaccine candidates, namely LZ901, Recombinant Varicella Vaccine and Recombinant Rabies Vaccines, using our targeted recombinant antigen presentation technology platform.

#### ***Polysaccharide-Protein Conjugation Technology Platform***

Our polysaccharide-protein conjugation technology platform links bacteria polysaccharides to carrier proteins. This technology platform can be used to develop conjugate vaccines and antibody-drug conjugates. We utilized our polysaccharide-protein conjugation technology platform to develop three bacterial polysaccharide-protein conjugate vaccines, which have enhanced immunogenicity and stability, and are in easy to administer liquid dosage forms.

## BUSINESS

---

We have historically developed three commercialized vaccine products, namely (i) Haemophilus Influenzae Type b Conjugate Vaccine, (ii) Meningococcal Groups A and C and Haemophilus Influenzae Type b Conjugate Vaccine and (iii) Meningococcal Group A and C Polysaccharide Conjugate Vaccine, using our polysaccharide-protein conjugation technology platform.

### ***Protein Purification Technology Platform***

We have developed technology to purify complex recombinant proteins, such as humanized monoclonal antibodies and complex glycosylated proteins. We use a high-speed centrifugation or deep filtration workflow to isolate proteins in cell culture media, which is highly effective in removing cells and cellular debris from the soluble protein. In addition, we employ a series of chromatographic techniques during the protein purification process. First, we attach affinity protein tags to proteins of interest during the construct design and conduct affinity chromatography to purify and improve the solubility of the proteins of interest. Second, we perform an additional chromatographic step such as ion exchange chromatography or hydrophobic interaction chromatography to further increase purity. As a final polishing step, we perform size exclusion chromatography which results in high purity proteins of interest.

As proteins are highly heterogeneous and different techniques are used to purify different types of proteins, we have utilized our protein purification technology platform to increase the purity of LZ901, K3, K193 and K11 using various techniques.

### ***Protein Stability Technology Platform***

We have developed a variety of highly stable liquid formulations for human monoclonal antibodies, bispecific antibodies and recombinant protein vaccines. Our in-solution protein-stabilizers offer longer stability by extending the shelf life of antibodies, antigens and other recombinant proteins at working strength concentrations. In addition, they offer retained activity of most monoclonal antibodies or bispecific antibodies in solution for up to five years. Our liquid protein stabilizers also offer a variety of options for immune-assay development. We offer multiple formulations with different stabilizing mechanisms to satisfy different antibody or antigen requirements. Our formulations are protein-free that are able to satisfy the background requirements for human drugs or specific assay systems and stabilize enzymes and control materials in immunoassays.

All of our human vaccines candidates, monoclonal antibody product candidates and bispecific antibody product candidates utilize protein-stabilizers developed using our protein stability technology platform to enhance stability.

### ***Mammalian Expression Technology Platform***

We have used the GS Xceed<sup>TM</sup> expression system from Lonza in combination with our internally developed recombinant protein purification process to increase the purity of protein expression to a leading level. The system covers a wide range of technologies and processes such as host cell lines, a range of vectors, and access to optimize culture media and feeds and detailed system know-how, and provides high-quality, high-efficiency and high-capacity production services for a variety of biopharmaceuticals.

We have increased the purity and expression levels of LZ901 and K193 using our mammalian expression technology platform.

## BUSINESS

---

### Clinical Development Team

As of the Latest Practicable Date, our medical affairs and clinical operations team consisted of ten members. Our medical affairs and clinical operations team is led by our co-founder, Chief Medical Officer and deputy general manager, Ms. JIANG Xianmin, who has over 37 years of experience in biopharmaceutical research and development.

The clinical development team manages all stages of clinical trials, including clinical trial design, implementation, drug supply, and the collection and analysis of trial data. Each of our clinical development programs is led by a program leader who (i) formulates a clinical development plan, (ii) designs the trial protocol and (iii) oversees the trial execution, all with support from relevant team members. We employ an adaptive clinical trial design strategy to achieve efficiency in product development processes and potentially accelerate approvals for our product candidates. Our clinical development unit is also responsible for the selection of trial sites. To maximize trial efficiency, we strategically select trial sites based on their location in proximity to major metropolitan cities, number of addressable patients, and principal investigators in order to optimize trial speed, cost effectiveness, and cultural compatibility. We plan to enter into agreements with hospitals and principal investigators located worldwide that can support our various stages of clinical trials and indications.

### Relationships with Third Parties in Research and Development

In line with industry norms, we outsource certain pre-clinical studies and clinical trial-related activities to CROs and SMOs that are independent from our Group. We select CROs and SMOs based on various factors, including their quality, reputation and research experience in the vaccine field. The services provided by CROs include helping us select and work with clinical trial institutions, to implement the trial protocols and execute the clinical trials, and to prepare materials for NDA filings. We closely monitor and manage the activities of these CROs to ensure their progress and quality, including (i) requiring CROs to conduct clinical trials in accordance with the agreed-upon protocols and GCP requirements; (ii) conducting periodic review of progress of clinical trials; and (iii) requiring CROs to offer assistance to audit clinical trials. We also outsource certain pre-clinical studies activities to CROs. Such activities primarily include safety and immunogenicity evaluation. Key terms of these agreements with CROs are summarized as follows:

- *Services.* With respect to pre-clinical studies, the CROs mainly help us conduct safety and immunogenicity evaluation by conducting tests on animals. With respect to clinical trials, the CROs are responsible for assisting in preparing clinical trial protocols and trial plans, clinical monitoring and inspection, clinical research coordination, data management, and medical monitoring.
- *Term.* For pre-clinical studies, contract term is typically one year or the duration of the study. The agreements for clinical trials typically do not have a fixed term, and agreements generally expire after the completion of the relevant clinical trials and passing of NMPA inspection.
- *Payments.* We are typically required to make payments to CROs by installments according to milestones of respective services during the trials and clinical studies.
- *Intellectual property rights.* All intellectual property rights arising from the pre-clinical studies and clinical trials conducted by CROs are owned by us.

**BUSINESS**

During the Track Record Period, we also engaged an SMO to assist researchers to complete certain supporting duties in relation to our ongoing Phase I clinical trial of K193, including collecting source data and providing progress reports, among others.

In 2021 and 2022, we engaged 18 CROs and one SMO to manage, conduct and support our clinical trials and pre-clinical studies, and the aggregate service fees paid by us to such CROs and SMO were RMB2.0 million and RMB8.9 million, respectively. We determine the service fee for such CROs and SMO based on the expected or actual work performed by the CRO or SMO as well as the estimated or actual cost incurred on an hourly, monthly or by project basis. The following table sets forth the detailed information of the key CROs and SMO engaged by us during the Track Record Period:

<b>Identity</b>	<b>Background</b>	<b>Primary Involvement</b>	<b>Service fees paid by us during the Track Record Period</b>
			<i>RMB'000</i>
CRO A	A company that provides CRO services, including large sample, multi-center clinical trial operations, data management and statistical analysis	Provision of project management, clinical supervision and medical affairs services for the Phase I clinical trial for LZ901	4,050.1
CRO B	A company that provides CRO services, including clinical trial operations, medical writing and translation, medical registration services, statistical analysis, independent audits and pharmacovigilance	Provision of pre-clinical pharmacology research, pre-clinical safety evaluation and subject sample detection in Phase I clinical trials for LZ901 and K193	2,274.7
Hangzhou Tigermed Consulting Co., Ltd.*	A company that provides services for new drug research and development and other supporting services to global and Chinese pharmaceutical and biotechnology companies	Provision of U.S. filing clinical registration services for the development of LZ901	1,696.2
CRO C	A company that provides CRO services, including clinical trial data management and statistical analysis	Provision of data management and statistical analysis services for the Phase I clinical trial for LZ901	794.0
CRO D/SMO A	A company that provides CRO and SMO services including project evaluation, research and development, registration management, clinical trials and post-marketing studies, and clinical trial site management	Provision of clinical trial project management, inspection and verification services, and clinical trial site management services in the development of K193	75.8

*Note:*

\* Provided CRO services during the Track Record Period.

## BUSINESS

During the Track Record Period, none of our CROs and SMO, other than Hangzhou Tigermed Consulting Co., Ltd., (being one of our [REDACTED] Investors) including their directors, shareholders and senior management, had any past or present relationship with us or our subsidiaries, shareholders, directors or senior management, or any of their respective associates. For further details of Hangzhou Tigermed Consulting Co., Ltd., see “History, Development and Corporate Structure — [REDACTED] Investments — Background of the [REDACTED] Investors — 5. Hangzhou Taikun” in this document.

### MANUFACTURING

#### Manufacturing Team

Our manufacturing team is led by our deputy general manager and head of manufacturing and engineering, Mr. HAN Chaowei, who has 21 years of experience in the biopharmaceutical industry. As of the Latest Practicable Date, we had 29 manufacturing personnel. 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.

#### Beijing R&D and Pilot Manufacturing Facility

We have a self-owned R&D and pilot manufacturing facility located in Beijing, China to supply materials for our pre-clinical studies and early-stage clinical trials of every product candidate, which occupies approximately 27 acres of land with a total GFA of approximately 3,757 sq.m. in the R&D and production area. The material refers to the bulk solution that can be used to prepare samples for pre-clinical and clinical research of our product candidates after fermentation and culture in a bioreactor and a series of chromatographic purification. Our Beijing R&D and pilot manufacturing facility has 5L, 10L, 15L, 40L, 50L, 75L and 500L stainless steel bioreactor capacity as well as a pilot-scale drug product (DP) filling line. Utilizing our Beijing R&D and pilot manufacturing facility, we have supplied materials for pre-clinical studies and early-stage clinical trials for our product candidates, including LZ901, K3, K193, Recombinant Varicella Vaccine, Recombinant Rabies Vaccine, K333 and K1932. As of the Latest Practicable Date, we owned all the equipment and machinery used in our manufacturing process. During the Track Record Period, we did not outsource any manufacturing activities of our product candidates to CDMOs.

The following table sets forth our manufacturing capacity, manufacturing volume and utilization rate of our Beijing R&D and Pilot Manufacturing Facility for the periods indicated.

	<b>For the year ended December 31.</b>	
	<b>2021</b>	<b>2022</b>
Manufacturing capacity ( <i>batch</i> ) <sup>(1)</sup>	40	40
Actual manufacturing volume ( <i>batch</i> )	24	30
Utilization rate (%) <sup>(2)</sup>	60.0	75.0

*Note:*

- (1) The production of one batch means one fermentation in the selected bioreactors. Our Beijing R&D and pilot manufacturing facility is only used to support pre-clinical studies and early-stage clinical trials and phase I and phase II clinical research. It has a small volume of production capacity with 5L, 10L, 15L, 40L, 50L, 75L and 500L stainless steel bioreactors. During the pilot production, we select the bioreactors with appropriate scale according to the development stage of our product candidate for pilot production.
- (2) Utilization rate is calculated based on the actual manufacturing volume of the relevant period divided by the manufacturing capacity for the relevant period, multiplied by 100%.

## BUSINESS

---

### **Beijing R&D and Commercial Manufacturing Facility**

We plan to commence construction of a new R&D and manufacturing facility in Beijing in the second quarter of 2023 and expect to complete construction of the new Beijing R&D and manufacturing facility in the first quarter of 2025. The new Beijing R&D and manufacturing facility is expected to have a total production capacity of eight million doses of Recombinant Varicella Vaccine a year and four million doses of Recombinant Rabies Vaccine a year. The utilization rate of the new Beijing R&D and manufacturing facility is expected to increase from less than 5% from 2024 to 2026, to 60%-90% after 2027 given the commercialization of Recombinant Varicella Vaccine and Recombinant Rabies Vaccine. We will adjust our actual capacity based on our marketing plan and the market conditions.

### **Zhuhai Commercial Manufacturing Facilities**

In January 2018, we began to explore various sites in China for constructing a manufacturing facility, but did not locate a suitable plot of land to build our manufacturing facility until December 2020, when the plot of land to build our first- and second-phase Zhuhai manufacturing facilities became available. After we bought the land in April 2021, we began construction of our first- and second-phase Zhuhai manufacturing facilities. We commenced operations at our first-phase Zhuhai manufacturing facility and are constructing our second-phase Zhuhai manufacturing facility to expand our production in preparation for commercialization of our pipeline candidates. Currently, our existing Zhuhai manufacturing facility occupies a total GFA of approximately 8,000 sq.m. and is equipped with several 500L stainless steel bioreactors, purification equipment and a high-speed vial filling linkage line.

We commenced construction of our second-phase manufacturing facility in April 2022, and expect to complete the construction of the second-phase Zhuhai manufacturing facility in the second quarter of 2023, which is expected to commence operations by the second quarter of 2023. Our first- and second-phase Zhuhai manufacturing facilities, as planned and approved by the local government agency, occupy approximately 69,366 sq.m. of land with a total GFA of approximately 120,000 sq.m. in the production area. The second-phase Zhuhai manufacturing facility will be equipped with multiple 2.5-ton stainless steel bioreactors and two antibody biopharmaceutical production workshops. In total, the first-phase Zhuhai manufacturing facility and the second-phase Zhuhai facility will have an annual capacity to manufacture 20 million doses of LZ901, three million doses of K193 and two million doses of K3.

The construction standards of the above-mentioned manufacturing facilities in Zhuhai are designed according to international standards and are expected to meet the GMP requirements of the NMPA, the EMA, the FDA and related ICH guidelines. We will equip our workshops with appropriate facilities, equipment and instruments to enhance the quality management systems in chemistry, manufacturing and controls of large-scale production.

## BUSINESS

The following table sets forth the timeframe of the commencement and completion of the construction and (expected) manufacturing capacity and utilization rate of each existing and planned manufacturing facility by each product type. For the development status and commercialization plans of relevant product candidates, please see “— Our Products and Product Candidates — Our Core Product and Clinical-Stage Product Candidates” and “— Commercialization” in this section.

Manufacturing Facility		Commencement of the Construction	Completion of the Construction	Capacity <sup>(1)</sup>	Expected Average Utilization Rate <sup>(5)</sup>	
					2025-2027	2028-2030
Zhuhai manufacturing Facility	First-phase	July 2021	April 2022	LZ901: 20 million doses a year <sup>(2)</sup>	~42%-47%	~89%
	Second-phase	April 2022	2023Q2	K193: 3 million doses a year <sup>(3)</sup> K3: 2 million doses a year <sup>(4)</sup>		

*Notes:*

- (1) The capacity represents the total capacity to produce end products of the first-phase Zhuhai manufacturing facility and second-phase Zhuhai facility. The production capacities of our product candidates were estimated based on (i) the number of working hours needed for a production worker to manufacture or package and storage one unit of stock solution of our product candidates; (ii) the number of production workers designated by us for the manufacturing of our product candidates during the respective year; (iii) each of our production workers works eight hours per day and 250 days per year; and (iv) our production lines operated on a one-shift per day basis.
- (2) The production process of LZ901 includes the production of stock solution, sub-packaging, packaging and storage. In relation to the manufacturing capacity of LZ901, the first-phase Zhuhai manufacturing facility only has a capacity of stock solution manufacturing of 14 million doses for LZ901 a year, to support the Phase III clinical trial and the initial stage of commercialization of LZ901 as the first-phase Zhuhai facility has limited production area and equipment. The second-phase Zhuhai manufacturing facility has the capacity of sub-packaging, packaging and storage of 20 million doses for LZ901 a year. The second-phase Zhuhai manufacturing facility will reserve a production line for stock solution manufacturing with capacity of 6 million doses a year, to support the further commercialization in domestic and overseas markets of LZ901.
- (3) In relation to the manufacturing capacity of K193, the first-stage Zhuhai manufacturing facility has a capacity to produce 1 million doses end products of K193 a year, to support clinical trials of K193. The second-phase Zhuhai manufacturing facility has a capacity to produce 2 million doses end products of K193 a year to support the BLA submission and commercialization of K193.
- (4) The second-phase Zhuhai manufacturing facility has a capacity to produce 2 million doses end products of K3 a year to support clinical trials and commercialization of K3.
- (5) Utilization rate is calculated based on the average manufacturing volume divided by the manufacturing capacity for the relevant period, multiplied by 100%.
- (6) The abovementioned manufacturing volume and utilization rate is based on our marketing plan and the market conditions, and may be different from actual circumstances in the relevant period.



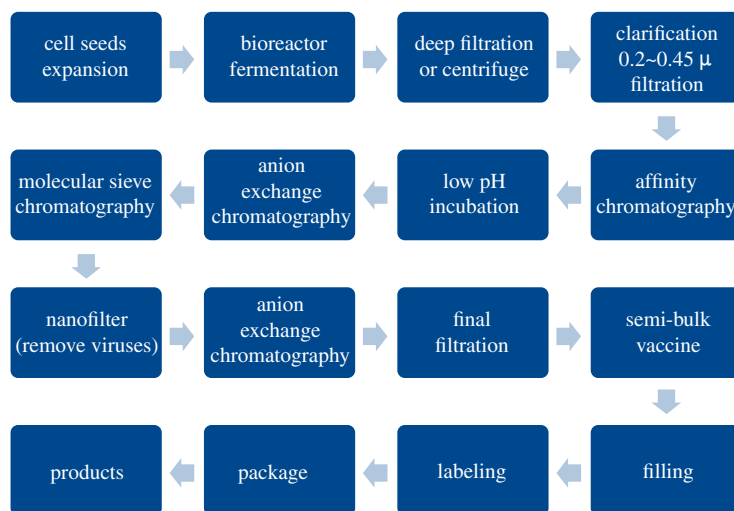
## BUSINESS

### Manufacturing Process

Our ability to manufacture different vaccines in large scale is demonstrated by the unique production processes and techniques used for each of our vaccine products. Below are the manufacturing process charts that highlight the key steps in producing our vaccine and therapeutic biologics product candidates.

#### *Vaccine Manufacturing Process:*

Our vaccine manufacturing process includes the following steps: cell seed expansion, fermentation culture, depth filtration, clarification and harvest, affinity chromatography, inactivation, anion exchange chromatography, molecular sieve chromatography, virus removal by nanofiltration, diethylaminoethyl (“DEAE”) anion exchange chromatography (or ultrafiltration) exchange buffer, sterilization and virus removal filtration, stock solution storage, adjuvant preparation, semi-finished products preparation, formulation filling, packaging and labeling, boxing and palletizing, finished product storage. Below is the manufacturing process chart that highlights the key steps in producing our vaccine product candidates.

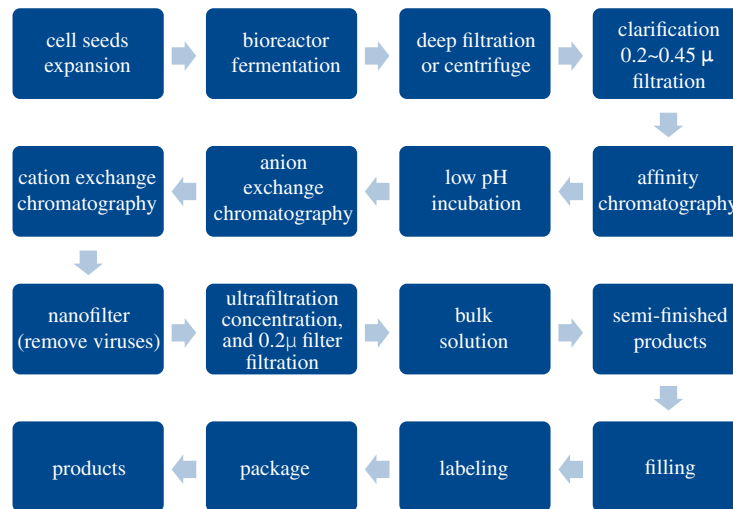


#### *Antibody Manufacturing Process:*

Our antibody drug manufacturing process includes the following steps: cell seed expansion, fermentation culture, deep filtration (or high speed centrifugation), clarification, affinity layer analysis, low pH incubation and pH adjustment, anion exchange chromatography, cation exchange chromatography, virus removal by nanofiltration, ultrafiltration concentration shrinkage, adding antibody protection solution, stock solution storage, semi-finished product preparation, preparation

## BUSINESS

filling, boxing and testing, finished product storage. Below is the manufacturing process chart that highlights the key steps in producing our antibody drug product candidates.



## QUALITY CONTROL AND ASSURANCE

The quality and safety of our vaccine and therapeutic biologics products are crucial to our continued success. We endeavor to ensure the quality of our operations through a comprehensive quality management system. Our quality management system was designed to adhere to applicable national standards, including the GMP standards, covering substantially every aspect of our operations including product design, raw materials and manufacturing, among others.

### Our Quality Control System

We have an experienced quality management team, consisting of 27 personnel as of the Latest Practicable Date. All of our Zhuhai quality management team members have received professional training in regulations, GMP standards and quality control analysis methods. After the commercialization of K3, we plans to employ 10 more personnel to enlarge the quality management team and further enhance the quality management systems. We have implemented quality management systems that conform to national regulations and industry guidelines and adopted standard operating procedures. All of our manufacturing facilities are designed and maintained, and we implement quality standards, in conformity with GMP standards adopted by NMPA, the EMA, the FDA and related ICH guidelines. GMP is the basic principle of pharmaceutical manufacturing and quality management for ensuring that products are consistently produced while achieving the required quality.

### Quality Control of Raw Materials

We have established detailed internal rules governing the selection of raw material suppliers and raw material quality control. We purchase raw materials only from suppliers of which we have verified business qualifications and product quality. We select suppliers based on a variety of factors including qualifications, business reputation, production scale, technological strengths, quality management capabilities, after-sales services and price. After initial screening by our procurement department, we typically request product samples from a supplier, which is examined by our quality management team. The examination result provides an important basis for our supplier selection decisions. In addition, we

## BUSINESS

---

would conduct on-site quality audit at the supplier's manufacturing facilities, and we require the supplier to execute a quality guarantee agreement with us. Our purchased supplies are inspected, and for supplies that do not pass our inspection, they will be transferred to our warehouse, categorized as unqualified supplies, pursuant to our protocols regarding non-conforming products.

### Quality Control of Manufacturing

Our quality management team is responsible for ensuring that our manufacturing processes consistently conform to applicable standards through regular on-site inspections. We perform cleaning and maintenance procedures in accordance with the regulations. Each batch of our products is subject to internal inspection before lot release to ensure the product has met the quality requirements. We conduct sample testing on certain work in progress at particular stages of production. Our quality assurance department also inspects the documentation relating to product quality, including the laboratory control records and production process records. Products that do not meet our quality standards will be destroyed or otherwise disposed of in accordance with the relevant disposal requirements.

### COMMERCIALIZATION

According to Frost & Sullivan, our vaccine candidates, once approved, are not likely to be included in the National Immunization Program, which primarily aims to protect children in China. When determining the types of vaccines to be included in the National Immunization Program, the government would consider various factors, such as the prevalence of infectious diseases, disease burden, effectiveness and safety of the vaccine, the supply capacity of vaccine manufacturers, adequate government funds and social benefits. LZ901 is mainly for adults aged 50 years and older, therefore, it is unlikely to be included in the National Immunization Program in China or similar programs in the U.S. in the foreseeable future. Human rabies vaccine aims to help protect people at risk of being exposed to rabies, regardless of their age, and therefore, it is unlikely that recombinant human rabies vaccine will be included in the National Immunization Program in China. For varicella vaccine, although several economically developed cities in China, such as Beijing, Tianjin and Shanghai, have implemented policies to provide free varicella vaccination for children, it is less likely to be included in the National Immunization Program in the next three to five years since the costs will be very high for the nation to provide free varicella vaccination. The U.S. CDC recommends that adults aged 50 years and older to get two doses of Shingrix<sup>®</sup> to prevent shingles and the complications from the disease. In the 2018 Chinese Expert Consensus on Herpes Zoster\*, it was mentioned that herpes zoster vaccine can significantly reduce the disease burden of herpes zoster. K3, a biosimilar of adalimumab, is likely to be included in the NRDL as adalimumab under the brand name Humira<sup>®</sup> has been included in the NRDL. However, herpes zoster vaccine, varicella and rabies vaccines are prophylactic vaccines which are not included in the NRDL. K193, K333, K1932 are Class A innovative biological products. There are no similar products in

*Note:*

\* The 2018 Chinese Expert Consensus on Herpes Zoster is written by Chinese Dermatologist Association (CDA) under CMDA, which is registered and approved by the State Ministry of Health and the Ministry of Civil Affairs; and CDA is a national, professional, non-profit academic group voluntarily formed by practicing physicians. Experts evaluated and analyzed literature published domestically and internationally to conduct a comprehensive analysis for the expert teams to discuss and revise repeatedly to reach a consensus that will guide the clinical standardized diagnosis and treatment of herpes zoster, and provide patients with an economic and efficient diagnosis and treatment plan. Therefore, the authority and relevance of this consensus is well-recognized. There is no mandated frequency to update this consensus. Referring to expert guidance, which is another similar format for diagnosis and treatment of diseases, the recommended frequency is two to five years.

## BUSINESS

---

this category covered by NRDL. Therefore, our vaccine product candidates, K193, K333 and K1932 are unlikely to be included in the NRDL. Not being included under the National Immunization Program, regional equivalent immunization programs or NRDL would not affect the pricing of our product candidates as we would price our product candidates at market price. However, if peer products are included under the National Immunization Program or regional equivalent immunization programs, our peer products will gain market competitive advantage in market penetration, which would cause market pressure on our product candidates. For details, please see “Risk Factors”, “Regulatory Overview” and “Industry Overview” in this document. As some of our product candidates are unlikely to be included in the NRDL, we plan to seek opportunities to collaborate with insurance companies to include such product candidates into their coverage. According to Frost & Sullivan, some of private insurance companies in China are able to provide insurance coverage for vaccines that are not covered in the NRDL. For example, certain high-end medical insurances of Taikang Insurance Group Inc. and Axa Tianping Property & Casualty Insurance Co., Ltd. provide insurance coverage for vaccines. We expect that some of the private insurance companies in China will be able to include LZ901 into their coverage in the future. Furthermore, Shingrix<sup>®</sup> is covered by commercial insurance in the United States, and thus, we expect that we will be able to collaborate with insurance companies to include LZ901 into their coverage in the U.S. as well.

As of the Latest Practicable Date, we did not have a commercialization team. Our director of overseas business development has over 17 years of experience in the biopharmaceutical industry. We are in the process of executing our launch readiness plan and formulating our sales and marketing plans in anticipation of multiple potential product launches within the next few years. The focus will be on product readiness, market readiness, and organizational readiness. As we expect our major customers to be local CDCs, hospitals and/or other medical institutions, we will focus on improving the recognition of our vaccine products among local CDCs, hospitals and physicians. In addition, since whether local CDCs, hospitals and/or other medical institutions will purchase our products ultimately depends on the vaccination willingness of individuals, we will also conduct marketing activities raising the public awareness of the relevant diseases, and the benefits and costs of receiving our vaccine products.

We plan to begin building our commercialization team ahead of the launch of our product candidates. We intend to build our commercialization capabilities through a combination of efficient and specialized internal sales and marketing teams and external marketing and distribution partnerships with CSOs, with the goal of achieving broad product access across the globe to benefit patients worldwide. We plan to set up our commercialization team in China after the filing of the BLA of LZ901. We expect to build a commercialization team with about 300 people, consisting of four departments, including sales department, marketing department, medical department, storage and transportation department.

In China, we plan to adopt a two-pronged approach for sales and marketing activities. Our commercialization team will cover Beijing, Chengdu, Guangzhou, Shanghai, Tianjin, Wuhan, Xi’an, Zhengzhou and other provincial capitals in China. We plan to engage CSOs to cover major provinces and municipalities in China, including the same cities as our commercialization team and neighboring second- and third-tier cities. We will select CSOs based on their industry experience and expertise, product sales experience, business channels, local promotion capabilities, logistics and distribution capabilities, cold-chain transportation capabilities, financial condition, record of compliance with regulatory agencies and management capabilities and other important indicators, to further improve clients’ experience.

## BUSINESS

---

Our commercialization team will formulate the criteria for screening CSOs, determine the cooperation conditions, select CSOs, assess the performance of CSOs, participate in the discussion of CSO sales strategies, and carry out national promotion of our product candidates, while do not participate in terminal sales. CSOs will mainly be responsible for regional promotion of our product candidates, establishment of sales channels and provision of logistics services, and will regularly report market demands and other feedbacks to our commercialization team. We do not have any plan to out-license our Core Product and product candidates in China.

We intend to formulate targeted commercialization strategies for each of our product candidates in China.

- *LZ901*. To support our sales and marketing efforts for LZ901, we plan to build our commercialization team for LZ901 in or around the third quarter of 2024 upon submitting the BLA for LZ901 to the NMPA. In addition, we plan to collaborate with CSOs to increase market penetration of LZ901. Our sales and marketing strategy to jointly promote LZ901 includes selecting various CSOs, along with our commercialization team for LZ901, to cover four regions, namely Northern China, Yangtze River Delta, Greater Bay Area and Midwestern China, and providing sales goals for such CSOs based on population density, consumption level, morbidity associated with shingles, and other factors of the regions covered. Such CSOs will be responsible for sales of LZ901 in the cities and provinces of the regions that they are selected to cover. Our sales department and CSOs will look into the needs of doctors in community hospitals or grass-roots hospitals, discover the cognitive weaknesses of relevant doctors on the applicable groups of herpes zoster vaccine, the advantages and disadvantages of different herpes zoster vaccines and other key information, summarize the doctors' preference for cases, literature or other vaccine promotion methods, and provide feedback to our marketing department. We plan to adopt favorable and competitive pricing for our LZ901. LZ901 is expected to be priced at a retail price of approximately RMB500 to RMB800 an injection, with a total of two injections per treatment and does not require a third booster shot, which is more affordable compared to the retail price of the other commercially available herpes zoster vaccine in China, with Shingrix<sup>®</sup> priced at RMB1,600 an injection with a total of two injections per treatment. In addition, we also plan to provide incentives for our CSOs to further motivate our CSOs to increase sales.

Furthermore, we plan to continuously educate and guide the market by conducting academic promotion and publishing scientific papers to introduce the advantages of LZ901. We will highlight the advantages of LZ901 compared with Shingrix<sup>®</sup>. Our commercialization team will be responsible for national promotion of LZ901, including educating the market of the advantages of LZ901 and promoting LZ901 through national media advertisements, and will collaborate with our CSOs to promote and increase market awareness of LZ901 in their respective regions, including holding academic conferences and events. Our marketing department will cooperate with not-for-profit organizations and local CDCs to organize seminars and participate in industry conferences to introduce the importance of vaccination of the herpes zoster vaccine and the competitiveness of LZ901 both to relevant doctors and the public. We will customize the forms of doctor education, including but not limited to academic lectures and seminars, to deepen doctors' understanding of the various advantages of LZ901. At the same time, our marketing department will carry out targeted marketing for the middle-aged and elderly groups and their children respectively, and create a brand image

## BUSINESS

---

with high quality, low price and good vaccination experience through professional education regarding the importance of vaccination of the herpes zoster vaccine and the advantages of LZ901.

Our medical department will be responsible for the collection of adverse reaction information and the treatment of adverse reactions. In order to protect the privacy of patients, we are not responsible for and the associated costs of gathering, maintaining and storing vaccination information for patients who will be administered LZ901, which is the responsibility of local CDCs and hospitals. Our storage and transportation department is responsible for the storage of LZ901 and cold chain transportation management.

- *K3*. To support our sales and marketing efforts for K3, we plan to build our commercialization team for K3 in or around the fourth quarter of 2024 upon submitting the BLA for K3 to the NMPA. Our sales and marketing strategy to jointly promote K3 includes our commercialization team for K3 and CSOs both covering four regions, namely Northern China, Yangtze River Delta, Greater Bay Area and Midwestern China. Such CSOs will be responsible for sales of K3 in the cities and provinces of the regions that they are selected to cover. Our commercialization team will be responsible for national promotion of K3, including educating the market of the advantages of K3 and promoting K3 through national media advertisements, and will collaborate with our CSOs to promote and increase market awareness of K3 in their respective regions, including holding academic conferences and events. We plan to adopt favorable and competitive pricing for our K3. K3 is expected to be priced at a retail price of approximately RMB400 to RMB500 a dose, which is more affordable compared to the retail price of the other commercially available biosimilars of adalimumab in China, which are priced at approximately RMB700 to RMB1,200 a dose.
- *K193*. To support our sales and marketing efforts for K3, we plan to build our commercialization team for K193 in 2027 after completing the Phase II clinical trial for K193.

For overseas markets, we plan to formulate international commercialization strategies according to market conditions to promote our products. In particular, we plan to seek collaboration opportunities with global partners to leverage their established sales expertise. We currently have one administrative personnel in the U.S., who is mainly responsible for our business development overseas, and we have no plan to expand commercialization team for the overseas market for the next three years. For LZ901, we plan to collaborate with multinational pharmaceutical companies who have a robust sales and marketing network to rapidly commercialize LZ901 globally, including in the U.S. and Southeast Asian countries. Upon entering into collaborations with such multinational pharmaceutical companies, we plan to authorize such multinational pharmaceutical companies to produce and sell LZ901 in the markets and countries that are agreed upon. We may develop corresponding out-licensing or collaboration strategies. Our domestic commercialization team will be responsible for the out-licensing of LZ901. As of the Latest Practicable Date, we had explored collaboration opportunities with third parties to out-license LZ901 in markets outside of China but had not identified any collaboration partners, and may pursue such out-licensing opportunities after we complete the Phase II clinical trial for LZ901 in the U.S. in the second quarter of 2025. Before deciding whether to out-license a product candidate, we identify collaboration partners who may be better positioned to accelerate or further research and development or successful commercialization of the product candidate. We evaluate and select collaboration partners based on their research and development and commercialization capabilities and experience, management and research team, business scale and reputation. For each collaboration partner, we will enter into an agreement setting out the transfer of right to intellectual property, technology and assets to

## BUSINESS

---

develop or market within a particular geographical area, license fees, milestones and duration of the license. For other products, we do not have plans or intention for out-licensing. We may also build overseas production workshops and establish our own overseas sales team. In addition, we will focus on our layout strategy of the countries under China's Belt and Road Initiative, with a focus on Southeast Asian countries including Singapore and Indonesia, and accelerate our products' entry into relevant countries through seeking collaborations with local partners, which should have in-depth market expertise and are familiar with regulatory requirements of the relevant jurisdiction, after the successful commercialization of LZ901 in China and realize commercial opportunities with the support of government policies. According to Frost & Sullivan, herpes zoster vaccine is not included in the reimbursement coverage of Southeast Asian countries including Singapore and Indonesia, and we or our local partner may seek opportunities to collaborate with insurance companies to include LZ901 into their coverage in the future. We will authorize local partners to complete the commercialization of LZ901 in the countries under China's Belt and Road Initiative, and we will only obtain milestone payments and royalty payments. The pricing of LZ901 in the relevant countries will be determined jointly by the local partners and us after discussion or by the local partners themselves. We and our local partner will obtain relevant licenses and comply with relevant requirements during the process of commercialization of LZ901 in the future. We currently do not have concrete overseas commercialization plans for our other product candidates. With the advancement of the research and development and commercialization of other product candidates, we will make relevant commercialization strategies for them accordingly.

In order to increase adoption and acceptance of our product candidates by healthcare professionals and ensure end-patient compliance, we plan to promote awareness of our product candidates among patients, physicians, hospitals, CDCs and KOLs through academic promotion, including on-site trainings, academic conferences and events, and regular communications, visits and follow-ups on the safety and effectiveness of our product candidates.

### SUPPLIERS

During the Track Record Period, our major suppliers primarily consisted of (i) suppliers of raw materials and consumables for our vaccine and therapeutic biologics development, (ii) construction service providers, (iii) property leasing providers and (iv) CROs, who provide third-party contracting services for research and development.

We procure raw materials from numerous suppliers around the world according to our product development plans. Our raw materials for our product candidates primarily include biological and chemical materials. Most of our raw materials are widely available. We have established stable collaboration relationships with qualified suppliers for raw materials, which we believe have sufficient capacity to meet our demands. Nevertheless, we believe that adequate alternative sources for such supplies exist. Based on our management account and as measure by purchase price, in 2021 and 2022, the raw materials from overseas suppliers accounted for approximately 50.6% and 42.1% of our total raw materials, respectively. The price of raw material sourced from overseas and their delivery time increased due to the outbreak of COVID-19. However, we have not experienced any shortage or delays in the supply of raw materials during the Track Record Period, and the increasing price of raw materials sourced from overseas has little impact on our costs as (i) the amount of raw materials used in the research and development stage is small, and (ii) our overseas suppliers, most of which are domestic agents, have cooperated with us for many years, with stable supply of goods and reasonable prices, and (iii) there are more alternative raw materials with the same quality available in China, which reduces the proportion of raw materials sourced from overseas to a certain extent. We currently do not expect our supply chain to be materially and negatively impacted by the COVID-19. Our major domestic suppliers maintained normal operations during the Track Record Period and up to the Latest Practicable Date. We have not experienced any material difficulties in procuring our major raw materials and have not experienced significant fluctuations in the prices of our supplies. We expect the situation to continue to be improved with the

## BUSINESS

sustained implementation of containment policies in response to the COVID-19 outbreak, and we may adjust our current clinical development plan covering multiple jurisdictions to the extent necessary depending on the status of the COVID-19 outbreak worldwide. Currently, we do not expect the COVID-19 outbreak to have any material long-term impact on data quality of our clinical trials or our overall clinical development plans.

We select our suppliers by considering their qualifications, compliance with relevant regulations and industry standards, manufacturing facilities, production quality, prices, business scale, market share, reputation, and after-sales service quality. During the Track Record Period, we did not experience any material disputes with suppliers, difficulties during the procurement of raw materials, interruptions in our operations due to a shortage or delay of raw materials, or significant fluctuations in raw material prices.

Our purchases from our five largest suppliers in each year during the Track Record Period amounted to RMB86.7 million and RMB152.2 million, respectively, representing 66.3% and 80.3% of our total purchases for the same periods, respectively. Our purchases from our largest supplier in each year during the Track Record Period amounted to RMB26.4 million and RMB127.1 million, respectively, representing 20.2% and 67.1% of our total purchases for the same periods, respectively.

We generally settle with our suppliers by wire transfer. Credit terms granted to us are determined on a case-by-case basis based on milestone payments contemplated under the supply agreements. The following table sets forth details of our five largest suppliers during the Track Record Period.

Five Largest Suppliers for the year ended December 31, 2021	Supplier Background	Products/ Services Purchased	Length of Business Relationship	Credit Term Granted and Settlement Information	Purchase Amount	Percentage of Total Purchase
					<i>RMB'000</i>	<i>%</i>
Supplier A	Local land bureau in Guangdong province	Land use rights	Since 2021	Net 30 days by wire transfer	26,364	20.2
Supplier B	Property management company based in Guangdong province	Property leasing	Since 2020	Net 30 days by wire transfer	23,546	18.0
Supplier C	Construction service provider based in Hebei province	Construction services	Since 2021	Net 30 days by wire transfer	16,789	12.8
Supplier D	Bioengineering product and service provider based in Shanghai	Bioreactors and manufacturing equipment	Since 2021	Net 10 days by wire transfer	13,404	10.3
Supplier E	Construction service provider based in Guangdong province	Construction services	Since 2021	Net 30 days by wire transfer	6,556	5.0
<b>Total</b>					<b>86,659</b>	<b>66.3</b>



## BUSINESS

Five Largest Suppliers for the year ended December 31, 2022	Supplier Background	Products/ Services Purchased	Length of Business Relationship	Credit Term Granted and Settlement Information	Purchase Amount <i>RMB'000</i>	Percentage of Total Purchase %
Supplier F	Construction service provider based in Wuhan	Construction services	Since 2022	Net 30 days by wire transfer	127,125	67.1
Supplier D	Bioengineering product and service provider based in Shanghai	Bioreactors and manufacturing equipment	Since 2021	Net 10 days by wire transfer	8,614	4.5
Supplier G	Local public health department in Hubei province	Clinical trial services	Since 2021	Net 10 days by wire transfer	7,705	4.1
Supplier H	Purification products and equipment provider based in Shanghai	Chromatography columns	Since 2021	Net 7 days by wire transfer	5,142	2.7
Supplier I	Biopharmaceutical integrated solutions provider based in Switzerland	Patented expression technology	Since 2012	Net 360 days by wire transfer	3,653	1.9
<b>Total</b>					<b>152,239</b>	<b>80.3</b>

During the Track Record Period, we engaged 18 CROs and one SMO based on the needs of our pre-clinical and clinical studies. Our procurement of CRO and SMO services will continue to depend on the cadence of our clinical and pre-clinical studies. We also had suppliers of equipment and construction of production lines as we built our Zhuhai manufacturing facilities and equipped our R&D facilities.

During the Track Record Period, all of our five largest suppliers were Independent Third Parties. None of our Directors, Supervisors, their respective associates nor any shareholder who, to the knowledge of our Directors, owned more than 5% of our issued share capital as of the Latest Practicable Date, has any interest in any of our five largest suppliers during the Track Record Period. In addition, we believe that adequate alternative sources for such supplies exist, and we have developed alternative sourcing strategies to decrease our reliance on existing suppliers. We will establish necessary relationships with alternative sources based on our assessment on the risk of supply continuity.

## INVENTORY

Our inventory primarily consists of raw materials and consumables used for vaccine and therapeutic biologics development and immunoreagent testing kits. We regularly monitor our inventories and endeavor to keep an optimal inventory level in line with the expected usages in the near term. We have established an inventory management system to monitor each stage of the warehousing process. Warehouse personnel are responsible for the inspection, storage and distribution of raw materials. Raw materials are separately stored in different areas of the warehouse according to their storage condition requirement, usage and batch number.

## BUSINESS

---

### COMPETITION

We face competition in several different forms. Product candidates engineered using our Fabite® technology platform and our other protein engineering platforms face actual or potential competition from various companies. Our Fabite® technology platform and our other protein engineering platforms also face actual or potential competition from other technology platforms.

The pharmaceutical and biotechnology industries are characterized by rapidly advancing technologies, competition, and a strong emphasis on proprietary products. While our Fabite® technology platform, our other protein engineering platforms, well-established management team, and robust pipeline of clinical and pre-clinical stage product candidates will provide us with competitive advantages, we face actual or potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions, and public and private research institutions. Any product candidates that we successfully develop and commercialize will compete with existing products and new products that may become available in the future.

We operate in the segments of the pharmaceutical, biotechnology, and other related markets that develop vaccines, oncology, or autoimmune disorders. There are other companies working to develop similar vaccines or therapies in these fields. These companies include divisions of large pharmaceutical companies and biotechnology companies of various sizes. Many of these companies and institutions, either alone or together with their partners, have substantially greater financial resources and larger research and development divisions than we have. In addition, many of these competitors, either alone or together with their partners, have substantially greater experience than us in developing pharmaceutical products, undertaking pre-clinical testing and clinical trials, obtaining the relevant regulatory approvals of such products and the manufacturing and commercialization of such products. Accordingly, our competitors may succeed in obtaining patent protection, relevant marketing approval, and commercializing products more rapidly than us.

We face competition from companies developing or testing product candidates for the same or similar targets we are pursuing with our own pipeline. Please see “— Our Products and Product Candidates” and “Industry Overview” for further details of our major competitors. In addition, there may be additional competitors working on the targets of our critical programs of whom we are currently unaware.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are more potent and effective, are safer and have fewer side effects, are more convenient, or are less expensive than any drugs that we may develop. Our competitors also may obtain the relevant regulatory approvals for their drugs or vaccines earlier than we obtain approval for ours, which could result in our competitors establishing a strong market position before we or our collaborators are able to enter the market. The key competitive factors affecting the success of our product candidates, if approved, are likely to be their efficacy, safety, convenience and price, the effectiveness of companion diagnostics in guiding the use of related therapeutics, the level of generic competition, and the availability of reimbursement from government and other third-party payers.

## BUSINESS

### INTELLECTUAL PROPERTY RIGHTS

Our continued success depends on our ability to obtain and maintain proprietary or intellectual property protection for our vaccine products, vaccine and therapeutic biologics candidates and our core technologies and other know-how. We also have internal protocols in place to ensure that we operate without infringing, misappropriating or otherwise violating the proprietary rights of others, and to prevent others from infringing, misappropriating or otherwise violating our proprietary or intellectual property rights. We protect our proprietary and intellectual property position by, among other methods, licensing or filing patent applications related to our proprietary technology, inventions and improvements. We also rely on trade secrets, know-how and continuing technological innovation to develop and maintain our proprietary and intellectual property position, which we generally seek to protect through contractual obligations with third parties.

According to Hiways Law Firm, our legal advisor as to intellectual property law (“**IP Legal Adviser**”), who has taken a thorough review of the specifications and claims of our filed patent applications, the technical subject matters of the patents for our Core Product, LZ901, cover the expression gene of biomacromolecule, and vaccine formulation containing the biomacromolecule. Meanwhile, the technical characteristics of independent and dependent claims of the patent cover the key characteristics of LZ901 hierarchically and therefore, LZ901 has been well protected hierarchically from different aspects through the patents. Furthermore, our IP Legal Adviser conducted the FTO analysis on LZ901 from three technical subject matters, including biomacromolecule itself, the pharmaceutical formulation thereof, and the pharmaceutical use of the biomacromolecule. Regarding the patent protection, the above three technical subjects cover the routine and main aspects of a biomacromolecule medicine, and therefore, the risk of our Core Product infringing on the intellectual property rights of third parties is low.

As of the Latest Practicable Date, we had three invention patents granted and eight registered trademarks in the PRC, one invention patent granted in Russia and one registered trademark in Hong Kong. As of the same date, we had filed eight patent applications worldwide. The following table sets forth the material patents and patent applications we owned as of the Latest Practicable Date.

Number	Patent Number	Patent Name	Product	Jurisdiction	Patent Type	Patent Filing Date	Patent Status	Patent Expiration	Protection
1.	ZL201010127032.X*	A hand-foot-and-mouth disease virus vaccine (一種手足口病病毒疫苗)	Inactivated EV71 Vaccine	PRC	Invention	March 18, 2010 (Filing Date) July 25, 2012 (Grant Date)	Effective	March 18, 2030	Protecting the vaccine used in the Company's product of EV71, the use of the vaccine in the preparation of EV71, and the virus strain for preparing the vaccine in EV71
2.	ZL201711131955.0	A bispecific antibody binding to human CD19 and CD3 (一種結合人CD19和CD3的雙特異性抗體)	K193	PRC	Invention	November 15, 2017 (Filing Date) January 29, 2021 (Grant Date)	Effective	November 15, 2037	Protecting the bispecific antibody used in the Company's product of K193, the preparation method of the bispecific antibody used in K193, the use of the bispecific antibody in K193 and the pharmaceutical composition of K193
3.	CN112870344B	A recombinant varicella-zoster virus vaccine (一種重組水痘帶狀疱疹病毒疫苗)	LZ901	PRC	Invention	November 29, 2019 (Filing Date) July 19, 2022 (Grant Date)	Effective	November 29, 2039	Protecting the vaccine formulation of LZ901 and the recombinant gene for the fusion protein used in LZ901

**BUSINESS**

Number	Patent Number	Patent Name	Product	Jurisdiction	Patent Type	Patent Filing Date	Patent Status	Patent Expiration	Protection
4.	2021120973	A recombinant varicella-zoster virus vaccine (一種重組水痘帶狀疱疹病毒疫苗)	LZ901	Russia	Invention	May 14, 2020 (Filing Date) May 26, 2022 (Grant Date)	Effective	May 14, 2040	
5.	17422835	A recombinant varicella-zoster virus vaccine (一種重組水痘帶狀疱疹病毒疫苗)	LZ901	US	Invention	May 14, 2020	Pending	–	Protecting the vaccine formulation of LZ901 and the recombinant gene for the fusion protein used in LZ901
6.	3,125,908	A recombinant varicella-zoster virus vaccine (一種重組水痘帶狀疱疹病毒疫苗)	LZ901	Canada	Invention	May 14, 2020	Pending	–	
7.	20891532.2	A recombinant varicella-zoster virus vaccine (一種重組水痘帶狀疱疹病毒疫苗)	LZ901	EU	Invention	May 14, 2020	Pending	–	Protecting the vaccine formulation of LZ901 and the recombinant gene for the fusion protein used in LZ901
8.	2108457.9	A recombinant varicella-zoster virus vaccine (一種重組水痘帶狀疱疹病毒疫苗)	LZ901	UK	Invention	May 14, 2020	Pending	–	
9.	2020391074	A recombinant varicella-zoster virus vaccine (一種重組水痘帶狀疱疹病毒疫苗)	LZ901	Australia	Invention	May 14, 2020	Pending	–	
10.	10-2021-7021384	A recombinant varicella-zoster virus vaccine (一種重組水痘帶狀疱疹病毒疫苗)	LZ901	Korea	Invention	May 14, 2020	Pending	–	
11.	2021537120	A recombinant varicella-zoster virus vaccine (一種重組水痘帶狀疱疹病毒疫苗)	LZ901	Japan	Invention	May 14, 2020	Pending	–	
12.	202210919694.3	A low mannose human anti-tumor necrosis factor- $\alpha$ monoclonal antibody and use thereof (一種低甘露糖型抗人腫瘤壞死因子- $\alpha$ 單抗及其用途)	K3	PRC	Invention	August 2, 2022	Pending	–	Protecting the low mannose type antibody used in K3 and the preparation method thereof

*Note:*

\* Patent co-owned with Zhifei Biopharma.

For details of our other intellectual property rights, see Appendix VII to this document.

According to our IP Legal Adviser, there is no substantive legal impediment for each of our filed patent applications in relation to LZ901 and K193 of being granted, because each has a high possibility to satisfy the patentability requirements for novelty and inventive step of their respective jurisdictions and to be granted after substantive examination. Furthermore, there is no substantive legal impediment for our filed patent application in relation to K3 of being granted, because it possesses the essential content that may be authorized, and it is possible to obtain authorization as long as the protection scope of the claims are determined to be appropriate in the examination procedure.

In the event that these pending patent applications are ultimately rejected, this would simply mean that the technology intended to be covered by such patent applications is not protected by patent rights. For more details, please see “Risk Factors — Risks Relating to Our Business and Industry — Risks Relating to Our Intellectual Property Rights — If we are unable to obtain and maintain adequate patent

## BUSINESS

---

and other intellectual property protection for our product candidates throughout the world, or if the scope of such intellectual property rights obtained is not sufficiently broad, third parties could compete directly against us and our ability to successfully develop and commercialize any of our product candidates would be materially and adversely affected” in this document. Practically, however, the loss of patent protection will not hinder us from developing and commercializing our product candidates by using such technology. In the absence of patent protection, we may also have extensive know-how in developing product candidates which enable us to maintain a competitive advantage in the market.

The term of an individual patent may vary based on the countries/regions in which it is granted. The actual protection afforded by a patent varies on a claim-by-claim and country-by-country 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 country/region and the validity and enforceability of the patent. We cannot provide any assurance that patents will issue with respect to any of our owned or licensed 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, licensed or issued patents or any such patents that may be issued in the future will be commercially useful in protecting our product candidates and methods of manufacturing the same.

In February 2023, our IP Legal Adviser conducted freedom-to-operate (“FTO”) searches and analyses in target country(s) and/or region(s) in relation to our Core Product, namely LZ901, as well as K3 and K193, and did not identify any substantial risk of infringement by all of the current key technologies and features of our Core Product, K3 and K193 against active patents in such country(s) and/or region(s).

We rely, in some circumstances, on trade secrets and/or confidential information to protect aspects of our technology. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality arrangements with our core research and development team members and CROs. We have entered into confidentiality and non-compete agreements with our key employees and employees involved in research and development, pursuant to which intellectual property conceived and developed during their employment belongs to us and they waive all relevant rights or claims to such intellectual property. We also have established an internal policy governing the confidentiality of all company information. Despite the measures we have taken to protect our intellectual property, our proprietary information may be obtained by unauthorized parties. For details, see “Risk Factors — Risks Relating to Our Business and Industry — Risks Relating to Our Intellectual Property Rights — We may fail to protect the confidentiality of our trade secrets, as we may be subject to claims that our employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of their former employers, or that asserting ownership of what we regard as our own intellectual property” in this document.

These agreements may not provide sufficient protection of our trade secrets and/or confidential information. These agreements may also be breached, resulting in the misappropriation of our trade secrets and/or confidential information, and we may not have an adequate remedy for any such breach. In addition, our trade secrets and/or confidential information may become known or be independently developed by a third party, or misused by any collaborator or third party 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 to 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.

## BUSINESS

---

We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises 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.

We also own a number of registered trademarks and pending trademark applications. As of the Latest Practicable Date, we had registered eight trademarks in China and one trademark in Hong Kong for our Company, and are seeking trademark protection for our Company and our corporate logo.

As of the Latest Practicable Date, we were not involved in any material proceedings in respect of, and we had not received written notice of any material claims of infringement of any intellectual property rights, in which we may be a claimant or a respondent. However, there are risks if we fail to protect our intellectual property rights in the future. For details, see “Risk Factors — Risks Relating to Our Business and Industry — Risks Relating to Our Intellectual Property Rights” in this document for a description of risks related to our intellectual property.

## HEALTH, SAFETY, SOCIAL AND ENVIRONMENTAL MATTERS

We strive to operate our facilities in a manner that protects the environment and the health and safety of our employees, patients, and communities. We have implemented company-wide environmental, health and safety (“EHS”) manuals, policies, and standard operating procedures in relation to wastewater treatment, biological solid waste management, and emergency response and practices. We periodically provide EHS trainings to our employees.

Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials, and may also produce hazardous waste products. To further ensure our compliance with applicable environmental protection and health and safety laws and regulations, we (i) have established various guidelines governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes to ensure such guidelines are strictly enforced for the disposal of laboratory materials and wastes; (ii) inspect our equipment and facilities regularly to identify and eliminate safety hazards; (iii) provide regular safety awareness training to our employees; (iv) keep health records for all employees and conduct health examinations before, during and after their time at the Company, especially for employees engaged in work involving occupational hazards; and (v) conduct regular fire safety inspections, maintenance of fire-fighting equipment and regular emergency drills.

Our EHS coordinator is responsible for implementing and enforcing the compliance of our operations with environment, health and safety laws and regulations. This responsibility is executed through supervision and inspection of environmental protection work and participate in incident investigation. We have not had any significant workplace accidents in the history of our Company.

We believe we have maintained good relationships with the communities surrounding our manufacturing facilities. During the Track Record Period and up to the Latest Practicable Date, we complied with the relevant environmental and occupational health and safety laws and regulations in all material aspects, and we did not have any incidents or complaints which had a material and adverse effect on our business, financial condition or impact on the operations of our business during the period. For the years ended December 31, 2021 and 2022, our expenses in relation to environmental protection amounted to approximately RMB3,000 and RMB13,000, respectively. We expect our costs of complying with current and future environmental protection laws to increase in the future, as we further our research and development efforts and commence commercial manufacturing of our products after regulatory approval.

## BUSINESS

---

### Governance of Environmental and Social Matters

We incorporate a sustainable development approach in our daily business operation decisions. Our EHS department is responsible for establishing, adopting and reviewing our environmental, social, and governance (“ESG”) policies, vision and goals to evaluate, determine and address our ESG-related risks once a year.

We are subject to environmental-related and social related risks. See “Risk Factors — Risks Relating to Our Business and Industry — Risks Relating to Our General Operations — If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could materially and adversely affect the success of our business” in this document. We may adopt more ESG policies relating to social responsibility and internal governance as our EHS department deems fit. Our EHS department takes full responsibility to our ESG strategy and reporting. Our EHS department may assess or engage independent third-party advisory companies to evaluate the ESG risks and review our existing strategy, target and internal controls. Necessary improvements will then be implemented to mitigate the risks. At the same time, we are committed to the sustainable growth and long-term development of the Company.

### Environmental Matters

We are concerned about the impact of our business on climate and environment. We strive to take measures to protect the ecological environment during our business operation, so as to minimize adverse environmental impact. The projects under our management are subject to PRC environmental laws and regulations as well as environmental regulations promulgated by local governments including, but not limited to the PRC Environmental Protection Law (《中華人民共和國環境保護法》), the PRC Environmental Impact Appraisal Law (《中華人民共和國環境影響評價法》), the Administration Rules on Environmental Protection of Construction Projects (《建設項目環境保護管理條例》), and the Regulation on Pollutant Discharge Permit Administration (《排污許可管理條例》).

Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials, and may also produce hazardous waste products. We have implemented company-wide EHS manuals, policies and standard operation procedures and periodically provide EHS trainings to our employees to ensure the compliance with applicable environmental protection and health and safety laws and regulations. See “— Health, Safety, Social and Environmental Matters” in this section. Specifically, in January 2022, we established a hazardous waste management system, under which we set up a leading group to supervise and coordinate our environmental protection work. This leading group is headed by Mr. KONG and consists of seven members. We have also engaged third-party waste management company to assist in the preparation of hazardous waste management plan and provide consulting services on the problems arising from the process of hazardous waste treatment since January 2022. During the Track Record Period, we actively monitored our resource consumption for our manufacturing function. For the years ended December 31, 2021 and 2022, our consumption of water amounted to approximately 5,096 tons and 18,843 tons, respectively, and electricity amounted to 462.3 thousand kWh and 1,485.0 thousand kWh, respectively. In addition, the gas generated from our operations and discharged into the air is mainly oxygen and a small amount of nitrogen, which will not cause pollution of the air, and we are not subject to any climate-related issues.

## BUSINESS

---

While there is no virus used in the manufacturing process of our vaccine-related products, the manufacturing process of our potential commercialized products may involve the use of non-biodegradable raw materials, mainly include mixing plastic bag, and may produce hazardous waste products. Under our ESG policies, we have established stringent guidelines in relation to the manufacturing procedures and the handling, use, storage, treatment and disposal of hazardous materials. We provide periodic training on these guidelines and procedures to our employees as part of our employee-training program to ensure such procedures are strictly enforced. In addition, we monitor the implementation of our ESG policies through our EHS department for each stage of the manufacturing process. Our Directors (who are responsible for monitoring the corporate governance of our Group), with help from our legal advisors, will also periodically review our compliance status with ESG policies after the [REDACTED]. We will continue to use quantitative metrics to evaluate, assess and manage our pollutants emission and resource consumption after the commercialization of our product candidates. We may engage an external consultant or establish an internal committee to further assess the Company’s ESG approach after the [REDACTED].

We pay close attention to the global trend and China’s national strategy of addressing climate change and ecological environment protection, and will actively enhance our ability to address climate change and cope with China’s initiatives and action plans regarding future carbon dioxide emission. In terms of major climate change-related initiatives or action plans that may affect us, we plan to formulate policies after the [REDACTED] to systematically identify, assess and manage climate change-related risks, and formulate relevant response strategies.

### Social Matters

We endeavor to provide safe products to the society through a comprehensive quality management system. We have an experienced quality management team, consisting of 27 personnel as of the Latest Practicable Date. Ms. ZHANG Yanping, our co-founder and deputy general manager, has extensive experience in quality control, quality assurance, and preclinical safety studies of biological products. All of our Zhuhai quality management team members have received professional training in regulations, GMP standards and quality control analysis methods. All of our manufacturing facilities are designed and maintained, and we implement quality standards, in conformity with GMP standards adopted by NMPA, the EMA, the FDA and related ICH guidelines.

In addition, we also have an effective supply chain management as we have established detailed internal rules governing the selection of raw material suppliers and raw material quality control. We purchase raw materials only from suppliers of which we have verified business qualifications and product quality. We select suppliers based on a variety of factors including qualifications, business reputation, production scale, technological strengths, quality management capabilities, after-sales services and price. After initial screening by our procurement department, we typically request product samples from a supplier, which is examined by our quality management team. The examination result provides an important basis for our supplier selection decisions. In addition, we would conduct on-site quality audit at the supplier’s manufacturing facilities, and we require the supplier to execute a quality guarantee agreement with us. Our purchased supplies are inspected, and for supplies that do not pass our inspection, they will be transferred to our warehouse, categorized as unqualified supplies, pursuant to our protocols regarding non-conforming products. Therefore, we believe that we have the ability to ensure that our product candidates are consistently produced while achieving the required quality and safety.

We plan to increase the public accessibility and improve the affordability of herpes zoster vaccines and treatment for autoimmune diseases through adopting commercialization strategies, including



## BUSINESS

---

favorable and competitive pricing in the short- to medium-term for LZ901 and K3. Our pricing policy aims to provide affordable products for the public. LZ901 is expected to be priced at a retail price of approximately RMB500 to RMB800 an injection, with a total of two injections per treatment and does not require a third booster shot, which is more affordable compared to the retail price of the other commercially available herpes zoster vaccines in China. K3 is expected to be priced at a retail price of approximately RMB400 to RMB500 a dose, which is more affordable compared to the retail price of the other commercially available biosimilars of adalimumab in China, which are priced at approximately RMB700 to RMB1,200 a dose. We also plan to seek opportunities to collaborate with insurance companies to include the product candidates which are not included in the NRDL into their coverage, which will make treatments of relevant diseases more accessible to the public. Furthermore, we endeavor to achieve broad product access to benefit patients and improve their access to healthcare through building our commercialization capabilities. For examples, our marketing department of our commercialization team will cooperate with not-for-profit organizations and local CDCs to organize seminars and participate in industry conferences to introduce the importance of vaccination of the herpes zoster vaccine and the competitiveness of LZ901 both to relevant doctors and the public, which will improve the public awareness of herpes zoster. For details, please see “— Commercialization” in this section.

Regarding the data security and privacy protection, we have taken measures to maintain the confidentiality of the medical records and personal data of subjects enrolled in our clinical trials we collected, including setting internal rules requiring our employees and business partners to maintain the confidentiality of our subjects’ medical record. In addition, the CROs and SMOs that we select have professional data management with complete privacy protection policies. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and electronic security of our information technology systems. Therefore, we believe we have implemented effective measures for data security and privacy protection. We also have relevant procedures and controls to monitor compliance with applicable anti-corruption laws during the collaboration with CROs and SMOs and we require all of our employees, especially those involved in business development activities, to abide by our anti-bribery and anti-corruption compliance requirements and applicable laws and regulations to eliminate bribery and corruption risks.

We have policies on compensation and dismissal, equal opportunities and anti-discrimination. If our employees encounter any unequal discrimination, they should seek immediate assistance from either their department head, human resources department or our management team. We will immediately follow up, investigate, and, if necessary, report to the law enforcement authorities. Our Directors confirmed that during the Track Record Period and up to the Latest Practicable Date, there had been no violation of any applicable social laws, rules and regulations and no claim or penalty imposed upon us as a result of such laws, rules and regulations.

We have adopted and maintained a series of rules, standard operating procedures and measures to maintain a healthy and safe environment for our employees. We ensure safe storage and handling of flammable and corrosive materials used in our manufacturing process. We also have safety equipment and instruments in place, and we periodically inspect our utility equipment and fire services to ensure the safety of our employees. Additionally, we have established an EHS department in charge of safety and emergency issues consisting of four employees mainly responsible for identifying and mitigating safety risks, improving the safety production policies and procedures, supervising the implementation of such policies and procedures, making emergency plans and providing trainings in respect of production safety to our employees. In addition, we provide our employees with training in various areas to improve their knowledge and skills.

## BUSINESS

### EMPLOYEES

As of the Latest Practicable Date, we employed 131 full-time employees. The following table sets forth the number of our full-time employees by function as of the Latest Practicable Date.

<b>Function</b>	<b>Number of full-time employees</b>	<b>Percentage</b>
Management and General Administrative (including Financial Department)	39	29.8%
Research and Development (including Manufacturing Department and Quality Management Department)	71	54.2%
Medical Affairs and Clinical Operations	10	7.6%
Engineering	11	8.4%
<b>Total</b>	<b>131</b>	<b>100.0%</b>

The total staff costs of our Group, which consist of (i) salaries and other allowances, (ii) retirement benefits and (iii) equity-settled share-based payment expenses, for the years ended December 31, 2021 and 2022 were approximately RMB87.9 million and RMB134.1 million, respectively.

We recruit our employees based on a number of factors, including work experience, educational background and the requirements of a relevant vacancy. We invest in continuing education and training programs for our management staff and other employees to upgrade their skills and knowledge continuously. We also provide training and development programs to our employees from time to time to ensure their awareness and compliance with our various policies and procedures. We provide our employees with regular feedback as well as internal and external training in various areas, such as product knowledge, project development and team building. We also assess our employees based on their performance to determine their salary, promotion and career development.

We require all of our employees, especially those involved in business development activities, to abide by our anti-bribery and anti-corruption compliance requirements and applicable laws and regulations to eliminate bribery and corruption risks. We closely monitor our employees’ compliance with anti-bribery and anti-corruption policies.

In compliance with the relevant PRC labor laws, we enter into individual employment contracts with our employees covering matters such as terms, wages, bonuses, confidentiality obligations and grounds for termination. In addition, we are required under PRC law to make contributions to statutory employee benefit plans (including pension plans, medical insurance, work-related injury insurance, unemployment insurance, maternity insurance and housing funds) at a certain percentage of our employees’ salaries, including bonus and allowances, up to a maximum amount specified by the local government. As of the Latest Practicable Date, we did not have any non-compliance with statutory social security insurance fund and housing fund obligations applicable to us under applicable laws in all material respects.

We are also subject to safety laws and regulations of the PRC. We have implemented various internal occupational health and safety procedures to maintain a safe work environment, including adopting protective measures at our testing and manufacturing facilities, inspecting our equipment and facilities regularly to identify and address safety hazards, and providing regular training to our employees on safety awareness.

## BUSINESS

As of the Latest Practicable Date, one of our employees was represented by a labor union. All labor disputes are handled in accordance with all applicable laws, rules and regulations. We believe that we have maintained good working relationships with our employees. During the Track Record Period and up to the Latest Practicable Date, we were not subject to any material claims, lawsuits, penalties or administrative actions relating to non-compliance with occupational health and safety laws or regulations, and had not experienced any strikes, labor disputes or industrial actions which have had a material effect on our business.

### PROPERTIES

We are headquartered in Beijing, China, where we conduct our R&D and manufacturing operations. As of the Latest Practicable Date, we owned three properties in Beijing and Zhuhai with a total site area of approximately 107,973 sq.m. We have obtained the land use right certificates for all three parcels of land. As of the Latest Practicable Date, we had also obtained the building ownership right certificate for one building in Beijing, with a total GFA of approximately 3,757 sq.m. We use this building primarily for the R&D of our products. The following table sets forth a summary of our owned properties.

No.	Address	Usage	Owned Area <i>(Approximate sq.m.)</i>
1.	Xiangtian Road East, Anwan Road South, Sanzao Town, Jinwan District, Zhuhai City, Guangdong Province	Manufacturing	69,366
2.	No. 3, Guangtong Street, Tongzhou Industrial Development Zone, Tongzhou District, Beijing	Offices, Laboratories and Pilot Manufacturing Facility	17,422
3.	Block X29F2, No. X29, Beijing Economic-Technological Development Area, Beijing	Offices, Laboratories and Manufacturing Facility	21,185

As of the Latest Practicable Date, we also leased properties in Zhuhai and Beijing mainly for offices, manufacturing and/or research and development. The following table sets forth a summary of leased properties.

No	Address	Usage	Leased Area <i>(Approximate sq.m.)</i>	Term
1	Floor 1-3, Building 8, Zhuhai International Health Port, No. 628 Airport West Road, Sanzao Town, Jinwan District, Zhuhai City, Guangdong Province	Manufacturing, Research and Development, Testing, Laboratories and Offices	8,061	10 years
2	Room 302-303, Building A, Zhuhai International Health Port, No. 628 Airport West Road, Sanzao Town, Jinwan District, Zhuhai City, Guangdong Province	Testing, Laboratories and Offices	499	3 years

## BUSINESS

No	Address	Usage	Leased Area <i>(Approximate sq.m.)</i>	Term
3	Room C535, 5th floor, Building C, No. 18 Xihuan South Road, Beijing Economic Technological Development Area, Daxing District, Beijing	Offices	31	1 year

According to Chapter 5 of the Listing Rules and section 6(2) of the Companies (Exemption of Companies and Prospectuses from Compliance with Provisions) Notice (Chapter 32L of the Laws of Hong Kong), we need to comply with the requirements of section 38(1) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance in relation to paragraph 34(2) of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance which requires a valuation report with respect to all of our Group’s interests in land or buildings, as we have property interest with a carrying amount of 15% or more of our consolidated total assets. Accordingly, we have prepared a property valuation report with respect to our Group’s owned properties pursuant to Chapter 5 of the Listing Rules. For more details, please see “Appendix III — Property Valuation Report” to this document.

## INSURANCE

We maintain property insurance covering our manufacturing facilities and equipment that we believe are sufficient in accordance with customary industry practice, as well as social welfare insurance in accordance with the relevant laws and regulations in China. In line with industry practice in the PRC, we have elected not to maintain certain types of insurances, such as business interruption insurance or product liability insurance. We are responsible for any adverse events or deaths caused by the vaccination of LZ901 due to product defects. We maintain clinical trial insurance and plan to obtain liability insurance for LZ901 to cover product liability claims in accordance with the relevant laws and regulations after we obtain approval for LZ901 in China and overseas. See “Risk Factors — Risks Relating to Our Business and Industry — Risks Relating to Our General Operations — We have limited insurance coverage, and any claims beyond our insurance coverage may result in our incurring substantial costs and a diversion of resources”, “Risk Factors — Risks Relating to Our Business and Industry — Risks Relating to the Research and Development of Our Product Candidates — Our product candidates may cause AEs or undesirable side effects, which could interrupt, delay or halt clinical trials, delay or prevent regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following any regulatory approval” and “Risk Factors — Risks Relating to Our Business and Industry — Risks Relating to the Research and Development of Our Product Candidates — In conducting research and development, we face potential liabilities, in particular, product liability claims or lawsuits that could cause us to incur substantial liabilities” in this document for further details of risks relating to our current insurance coverage. Our Directors are of the view that our current insurance coverage is in line with industry practice and is adequate for our operations.

## BUSINESS

### LICENSES, PERMITS AND APPROVALS

As we are primarily engaged in the R&D of vaccine and therapeutic biologics products in China, we are required to obtain necessary licenses, permits and certificates for our business. Our PRC Legal Adviser has advised us that, as of the Latest Practicable Date, we had obtained all requisite and material licenses, approvals and permits required by PRC laws and regulations for our operations. The table below sets forth the relevant details of the material licenses we hold for our operations.

<u>Entity</u>	<u>Name of the License, Approval or Permit</u>	<u>Expiry Date</u>	<u>Description of the License</u>
Guangdong MPA (廣東省藥品監督管理局)	Drug Production License (藥品生產許可證)	January 12, 2028	Production of therapeutic biologics (LZ901)
Tongzhou Branch of Beijing Public Security Bureau (北京市公安局通州區分局)	The record certificate of the business unit of explosive hazardous chemicals (易製爆危險化學品從業單位備案證明)	December 25, 2023	Use of hazardous chemicals, including potassium permanganate, hexamethylenetetramine, silver nitrate, lead nitrate, nitric acid, potassium dichromate, hydrogen peroxide solution (>8%)
Beijing Tongzhou District Emergency Management Bureau (北京市通州區應急管理局)	Safety Production Standardization Certificate (Beijing AQBHQ) (安全生產標準化證書(京AQBHQ))	November 30, 2023	Safety production standardization three-level enterprise
Beijing Tongzhou District Water Affairs Bureau (北京市通州區水務局)	Urban sewage discharge into the drainage network permit (城鎮污水排入排水管網許可證)	April 7, 2024	Sewage discharge permit
Zhongguancun High-Tech Certificate (中關村高新技術證書)	Zhongguancun Science and Technology Park Management Committee (中關村科技園區管理委員會)	August 16, 2023	High-tech certificate
Certificate of Beijing-level Enterprise Science and Technology Research and Development Organization (北京市級企業科技研究開發機構證書)	Beijing Municipal Commission of Science and Technology (北京市科學技術委員會)	–	Science and technology research and development certificate

## BUSINESS

### AWARDS AND RECOGNITION

We received various awards, honors, and recognitions, including:

<u>Prize</u>	<u>Year</u>	<u>Awarding Organization</u>
Top 50 Innovative Biotechnology Companies in Guangdong-Hong Kong-Macao Greater Bay Area Award 2022	2022	ZDVC Research; Guangdong Medical Valley
Beijing’s “specialized and new” small and medium-sized enterprises	2022	Beijing Municipal Bureau of Economy and Information Technology
Second Prize — Beijing Science and Technology Award	2017	The People’s Government of Beijing Municipality
Patent Pilot Certificate	2014	Beijing Municipal Intellectual Property Office

### LEGAL PROCEEDINGS AND REGULATORY COMPLIANCE

As of the Latest Practicable Date, we had not been a party to any actual or threatened material legal or administrative proceedings, and our Directors had not been involved in any such proceedings. We are committed to maintaining the highest standards of compliance with the laws and regulations applicable to our business. However, we may from time to time be subject to various legal or administrative claims and proceedings arising in the ordinary course of business.

### RISK MANAGEMENT AND INTERNAL CONTROL

#### Risk Management

We recognize that risk management is critical to our long-term development and success. Key operational risks faced by us include changes in the general market conditions and the regulatory environment of the PRC and global biopharmaceutical markets, our ability to develop, manufacture and commercialize our drug and vaccine candidates, and our ability to compete with other vaccines, immuno-oncology and biotechnology companies. See “Risk Factors” in this document for a more detailed discussion on various risks we may subject to.

We have adopted a consolidated 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 ongoing basis. Our senior management, and ultimately our Directors, supervise the implementation of our risk management policies. Risks identified by management will be analyzed on the basis of likelihood and impact, and will be properly followed up and mitigated and rectified by our Group and reported to our Directors.

## BUSINESS

---

The following key principles outline our Group’s approach to risk management and internal control we plan to implement:

- Our senior management oversees and manages 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) monitoring the most significant risks associated with our business operations and our management’s handling of such risks; and (iii) ensuring the appropriate application of our risk management framework across our Group;
- Our executive Director, general manager and chief scientist, Mr. KONG Jian, is responsible for (i) formulating and updating our risk management policy; (ii) reviewing and approving major risk management issues of our company; (iii) promulgating risk management measures; (iv) providing guidance on our risk management approach to the relevant departments in our company; (v) reviewing the relevant departments’ reporting on key risks and providing feedback; (vi) supervising the implementation of our risk management measures by the relevant departments; (vii) ensuring that the appropriate structure, processes and competencies are in place across our company; and (viii) reporting to our audit committee on our material risks;
- The relevant departments in our Company, including but not limited to the finance department, the general manager office, 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 common 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) prepare a risk management report annually for our chief executive officer’s review; (iv) continuously monitor the key risks relating to their operation or function; (v) implement appropriate risk responses where necessary; and (vi) develop and maintain an appropriate mechanism to facilitate the application of our risk management framework.

We consider that our Directors and members of our senior management possess the necessary knowledge and experience in providing good corporate governance oversight in connection with risk management and internal control.

### **Internal Control**

Our Board is responsible for establishing our internal control system and reviewing its effectiveness. 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:

- We have adopted various measures and procedures regarding each aspect of our business operation, such as related party transaction, risk management, environmental protection and occupational health and safety. For more information, see “— Health, Safety, Social and Environmental Matters” in this section. We have also adopted various measures and procedures regarding our business operation, for example. Our internal audit department conducts audit field work to monitor the implementation of our internal control policies, reports any weaknesses identified to our management and audit committee, and follows up on the rectification actions.

## BUSINESS

---

- We provide various training programs to keep our employees updated on relevant laws, regulations, and policies. Our new employees are required to attend compliance training programs soon after on-boarding and must pass tests which examine their understanding of the compliance issues addressed by the training programs. Our employees are also required to regularly attend on-site and online training sessions to keep them informed of recent updates in the relevant laws and regulations.
- Our Directors (who are responsible for monitoring the corporate governance of our Group), with help from our legal advisers, will also periodically review our compliance status with all relevant laws and regulations after the [REDACTED].
- We have established an audit committee which (i) makes recommendations to our Directors on the appointment and removal of external auditors; and (ii) reviews the financial statements and renders advice in respect to financial reporting as well as oversees internal control procedures of our Group.
- We have engaged Fosun International Capital Limited as our compliance adviser to provide advice to our Directors and management team until the end of the first fiscal year after the [REDACTED] regarding matters relating to the Listing Rules. Our compliance adviser is expected to ensure our use of funding complies with the section entitled “Future Plans and Use of [REDACTED]” in this document after the [REDACTED], as well as to provide support and advice regarding requirements of relevant regulatory authorities in a timely fashion.
- We have engaged a PRC law firm to advise us on and keep us informed on PRC laws and regulations after the [REDACTED]. 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 laws and regulations.
- We maintain strict anti-corruption policies and we believe we will therefore be less affected by the increasingly stringent measures taken by the PRC government to correct corruptive practices in the biopharmaceutical industry.

In addition, as part of our risk management measures, we have implemented specific measures against corruption and bribery, including providing anti-corruption and anti-bribery compliance training for our Directors, supervisors and senior management to enhance their knowledge and compliance of applicable laws and regulations. We require our employees, especially those involved in procurement and other business functions which are more susceptible to bribery and corruptions, to abide by our compliance requirements, and make necessary representations and warranties to the Company. We also have established a system of supervision that allows complaints and reports to be submitted to management regarding non-compliant behavior of our internal employees.

During the Track Record Period, we have regularly reviewed and enhanced our internal control system. We consider that our Directors and members of our senior management possess the necessary knowledge and experience in providing good corporate governance oversight in connection with risk management and internal control.



---

## RELATIONSHIP WITH CONTROLLING SHAREHOLDERS

---

### OVERVIEW

As of the Latest Practicable Date, Mr. KONG, Ms. ZHANG and Hengqin Luzhu LP held 58,294,513, 20,200,000 and 12,307,500 Shares, respectively, representing approximately 30.35%, 10.52% and 6.41% of our total issued Shares, respectively. As (i) Ms. ZHANG is the spouse of Mr. KONG, and (ii) Mr. KONG is the sole general partner of Hengqin Luzhu LP and can exercise the voting rights attached to the Shares held by Hengqin Luzhu LP in accordance with the partnership agreement entered into among the general and limited partners of Hengqin Luzhu LP, Mr. KONG, Ms. ZHANG and Hengqin Luzhu LP are considered to be a group of Controlling Shareholders, who collectively held approximately 47.28% of our total issued Shares as of the Latest Practicable Date.

Immediately following the completion of the [REDACTED] (assuming the [REDACTED] is not exercised), Mr. KONG, Ms. ZHANG, and Hengqin Luzhu LP will collectively hold approximately [REDACTED]% of our total issued Shares. Accordingly, Mr. KONG, Ms. ZHANG and Hengqin Luzhu LP will remain as our Controlling Shareholders immediately after [REDACTED].

Both Mr. KONG and Ms. ZHANG are our executive Directors. For further information of Mr. KONG and Ms. ZHANG, see “Directors, Supervisors and Senior Management” in this document. Hengqin Luzhu LP is our employee incentive platform. For further information of Hengqin Luzhu LP, see “History Development and Corporate Structure — Employee Incentive Scheme — Hengqin Luzhu LP” in this document.

### INDEPENDENCE FROM OUR CONTROLLING SHAREHOLDERS

The Controlling Shareholders confirm that as of the Latest Practicable Date, they did not have any interest in a business, apart from the business of our Group, which competes or is likely to compete, directly or indirectly, with our business, and requires disclosure under Rule 8.10 of the Listing Rules. Having considered the following factors, our Directors are satisfied that we are capable of carrying on our business independently of our Controlling Shareholders and their close associates after [REDACTED].

#### Operational Independence

Although our Controlling Shareholders will retain a controlling interest in us after [REDACTED], for the reasons stated below, we have full rights to make all decisions on, and to carry out, our own business operations independently. We have our independent and separate senior management team and our own staff to support the operations and management of our core business. We have registered the relevant intellectual property rights relating to relevant technologies of our business and our product candidates. We hold the licenses and qualifications necessary to carry on our current business, and have sufficient capital, facilities, technology and employees to operate the business independently from our Controlling Shareholders. We have access to suppliers and customers independently from and not connected to our Controlling Shareholders for sources of suppliers and customers.

Based on the above, our Directors are satisfied that there is no operational dependence by us on our Controlling Shareholders.

#### Management Independence

Our Board comprises three executive Directors, two non-executive Directors and three independent non-executive Directors. Both Mr. KONG and Ms. ZHANG are our executive Directors and our Controlling Shareholders.

---

## RELATIONSHIP WITH CONTROLLING SHAREHOLDERS

---

Each of our Directors is aware of his or her fiduciary duties as a Director which require, among others, that he or she must act for the benefit of and in the best interests of our Company and not allow any conflict between his or her duties as a Director and his or her personal interests. In the event that there is a potential conflict of interest arising out of any transaction to be entered into between our Group and our Directors or their respective close associates, the interested Director(s) shall abstain from voting on the relevant board meetings of our Company in respect of such transactions and shall not be counted in the quorum. Further, we believe our independent non-executive Directors will bring independent judgment to the decision-making process of our Board. See “— Corporate Governance” in this section for further details.

Based on the above, our Directors are satisfied that our Board as a whole together with our senior management team is able to perform the managerial role in our Group independently.

### Financial Independence

We have established our own finance department with a team of financial staff, who are responsible for financial control, accounting, and reporting functions of our Company, independent from our Controlling Shareholders. We can make financial decisions independently and our Controlling Shareholders do not intervene with our use of funds. As of the Latest Practicable Date, there were no loans, advances and balances due to and from our Controlling Shareholders, and no share pledges or guarantees provided by our Controlling Shareholders and their associates on our borrowings. Our source of funding is independent from our Controlling Shareholders and neither our Controlling Shareholders nor their respective associates had financed our operations during the Track Record Period. Our Directors also believe that we are able to obtain financing independently from our Controlling Shareholders. During the Track Record Period and up to the Latest Practicable Date, we had our own finance department and independent accounting systems.

Based on the above, our Directors are of the view that they and our senior management are capable of carrying on our business independently of, and do not place undue reliance on our Controlling Shareholders and their close associates after [REDACTED]. We have also established an Audit Committee comprising one non-executive Director and two independent non-executive Directors in compliance with Rule 3.21 of the Listing Rules.

### NON-COMPETITION UNDERTAKING

On March 30, 2023, our Controlling Shareholders entered into a non-competition undertaking in favor of our Company (for ourselves and on behalf of each of our subsidiaries from time to time) (the “**Non-competition Undertaking**”), pursuant to which each of our Controlling Shareholders has irrevocably undertaken to us on a joint and several basis that at any time during the Relevant Period (as defined below), each of our Controlling Shareholders shall, and shall procure that their respective close associates and/or companies controlled by them (other than our Group) shall:

- (i) not, directly or indirectly, be interested or involved or engaged in or carry out or concern with or acquire or hold any right or interest (in each case whether as a shareholder, partner, agent or otherwise and whether for profit, reward or otherwise) in any business which is or is about to be engaged in any business which competes or is likely to compete directly or indirectly with the business currently and from time to time engaged by our Group in the PRC and any other country or jurisdiction in which our Group carries on such businesses

## RELATIONSHIP WITH CONTROLLING SHAREHOLDERS

---

and/or in which any member of our Group carries on business mentioned above currently and from time to time (the “**Restricted Activity**”);

- (ii) not solicit any existing employee or then existing employee of our Group for employment by it/him/her or its/his/her close associates (excluding our Group);
- (iii) not, without the consent from our Company, make use of any information pertaining to the business of our Group which may have come to its/his/her knowledge in its/his/her capacity as our Controlling Shareholders or otherwise for any purpose of engaging, investing or participating in any Restricted Activity;
- (iv) if there is any project or new business opportunity that relates to the Restricted Activity, refer such project or new business opportunity to our Group for consideration;
- (v) not invest or participate in or carry out any project or business opportunity of the Restricted Activity; and
- (vi) procure its/his/her close associates (excluding our Group) not to invest or participate in or carry out any project or business opportunity of the Restricted Activity, unless pursuant to the exceptions set out below.

The above undertakings are subject to the exceptions that:

- (i) any of the close associates of our Controlling Shareholders (excluding our Group) is entitled to invest, participate and be engaged in or carry out any Restricted Activity or any project or business opportunity, regardless of value, which has been offered or made available to our Group, provided always that information about the principal terms thereof has been disclosed to our Company and our Directors, and our Company shall have, after review (taking into account whether the entering into of such project or business opportunity will be in the best interest of our Group and our subsidiaries) and approval by our Directors (including our independent non-executive Directors without the attendance by any Director with beneficial interest in such project or business opportunities at the meeting, in which resolutions have been duly passed by the majority of the independent non-executive Directors), confirmed its rejection in writing to be involved or engaged, or to participate or carry out, in the relevant Restricted Activity and provided also that the principal terms on which that relevant close associate of our Controlling Shareholders invests, participates or engages or carries on in the Restricted Activity are substantially the same as or not more favorable than those disclosed to our Company. Subject to the above, if the relevant close associate of our Controlling Shareholders decides to be involved, engaged, participate in or carry out the relevant Restricted Activity, whether directly or indirectly, the terms of such involvement, engagement, participation or carrying on must be disclosed to our Company and our Directors as soon as practicable; and

---

## RELATIONSHIP WITH CONTROLLING SHAREHOLDERS

---

- (ii) each of our Controlling Shareholders may either by itself/himself/herself individually or through its/his/her close associate(s) hold and/or be interested in any shares or other securities in any listed company which engages or is involved in any business or activity which directly or indirectly competes with the Restricted Activity, provided that our Controlling Shareholders and their respective close associates will not participate in or be otherwise involved in the management of that listed company, and (a) the total shareholding held by our Controlling Shareholders and their respective close associates in such listed company, whether directly or indirectly, do not, in aggregate, exceed five per cent of the issued share capital of such listed company; or (b) the business or activity conducted or engaged in by such listed company which is in direct or indirect competition with the Restricted Activity accounts for less than 10% of that listed company’s consolidated turnover for any financial year or consolidated assets as at any financial year end.

The Non-competition Undertaking is conditional on (i) the [REDACTED] granting [REDACTED] of, and permission to [REDACTED], all our H Shares in issue and to be issued under the [REDACTED] and our Shares which may be issued pursuant to the exercise of the [REDACTED]; and (ii) the obligations of the [REDACTED] under the [REDACTED] becoming unconditional (including, if relevant as a result of the waiver of any condition(s) by the [REDACTED]) and that the [REDACTED] not being terminated in accordance with their terms or otherwise.

For the above purpose, the “**Relevant Period**” means the period commencing from the [REDACTED] and shall expire on the earlier of the dates below:

- (i) as for our Controlling Shareholders, the date on which our Controlling Shareholders and their close associates (individually or taken as a whole) cease to own 10% or more of the then issued share capital of our Company directly or indirectly or cease to be the controlling shareholders of our Company for the purpose of the Listing Rules; and
- (ii) the date on which our Shares cease to be [REDACTED] on the Stock Exchange.

Under the Non-competition Undertaking, each of our Controlling Shareholders has unconditionally and irrevocably undertaken to our Group to allow our Directors, their respective representatives and the auditors of our Group to have sufficient access to the records of each of our Controlling Shareholders and their respective close associates to ensure compliance with the terms and conditions of the Non-competition Undertaking. Each of our Controlling Shareholders has unconditionally and irrevocably undertaken under the Non-competition Undertaking that he/she/it shall provide to us and our Directors (including our independent non-executive Directors) from time to time all information necessary for the annual review by our independent non-executive Directors with regard to compliance with the terms of the Non-competition Undertaking by our Controlling Shareholders. Each of our Controlling Shareholders has also unconditionally and irrevocably undertaken to make an annual declaration as to full compliance with the terms of the Non-competition Undertaking and a consent to disclose such letter in our annual report.

## RELATIONSHIP WITH CONTROLLING SHAREHOLDERS

---

### CORPORATE GOVERNANCE

Our Company will comply with the provisions of the Corporate Governance Code in Appendix 14 to the Listing Rules (the “**Corporate Governance Code**”), which sets out principles of good corporate governance.

Our Directors recognize the importance of good corporate governance in protection of our Shareholders’ interests. We would adopt the following measures to safeguard good corporate governance standards and to avoid potential conflict of interests between our Group and our Controlling Shareholders:

1. where a Shareholders’ meeting is to be held for considering proposed transactions in which our Controlling Shareholders or any of their respective associates has a material interest, our Controlling Shareholders will not vote on the resolutions and shall not be counted in the quorum in the voting;
2. our Company has established internal control mechanisms to identify connected transactions. Upon the [REDACTED], if our Company enters into connected transactions with our Controlling Shareholders or any of their close associates, our Company will comply with the applicable Listing Rules;
3. our independent non-executive Directors will review, on an annual basis, whether there is any conflict of interests between our Group and our Controlling Shareholders (the “**Annual Review**”) and provide impartial and professional advice to protect the interests of our minority Shareholders;
4. our Controlling Shareholders will undertake to provide all information necessary, including all relevant financial, operational and market information and any other necessary information as required by the independent non-executive Directors for the Annual Review;
5. our Company will disclose decisions (with basis) on matters reviewed by the independent non-executive Directors either in its annual report or by way of announcements;
6. where our Directors reasonably request the advice of independent professionals, such as financial advisors, the appointment of such independent professionals will be made at our Company’s expenses; and
7. we have appointed Fosun International Capital Limited as our compliance advisor to provide advice and guidance to use in respect of compliance with the Listing Rules, including various requirements relating to corporate governance.

Based on the above, our Directors are satisfied that sufficient corporate governance measures have been put in place to manage conflicts of interest between our Group and our Controlling Shareholders, and to protect minority Shareholders’ interests after the [REDACTED].

## SHARE CAPITAL

This section presents certain information regarding our share capital prior to and following the completion of the [REDACTED].

### BEFORE THE [REDACTED]

As of the Latest Practicable Date, our registered share capital was RMB192,063,032, divided into 192,063,032 Domestic Shares with a nominal value of RMB1.00 each.

### UPON COMPLETION OF THE [REDACTED]

Assuming the [REDACTED] is not exercised, the share capital of our Company immediately after the [REDACTED] will be as follows:

Description of Shares	Number of Shares	Approximate percentage of total share capital
Domestic Shares	[REDACTED]	[REDACTED]%
H Shares to be converted from Domestic Shares	[REDACTED]	[REDACTED]%
H Shares to be issued under the [REDACTED]	[REDACTED]	[REDACTED]%
<b>Total</b>	<b>[REDACTED]</b>	<b>100.00%</b>

*Note:* Please refer to “Corporate structure immediately after the completion of the [REDACTED]” in the section headed “History, Development and Corporate Structure” for details of the identities of the Shareholders whose Shares will remain as Domestic Shares and whose Shares will be converted into H Shares upon [REDACTED].

### OUR SHARES

The H Shares in issue following the completion of the [REDACTED] and the Domestic Shares are ordinary Shares in the share capital of the Company, and are considered as one class of Shares. However, apart from certain qualified domestic institutional investors in the PRC, qualified PRC investors under the Shanghai-Hong Kong stock exchanges connectivity mechanism (Shanghai-Hong Kong Stock Connect) and the Shenzhen-Hong Kong stock exchanges connectivity mechanism (Shenzhen-Hong Kong Stock Connect) and other persons entitled to hold H Shares pursuant to the relevant PRC laws and regulations or upon approval by any competent authorities, H Shares generally may not be [REDACTED] by, or [REDACTED] between, legal or natural persons of the PRC. On the other hand, Domestic Shares may only be [REDACTED] by, and [REDACTED] between, legal persons of the PRC, certain qualified foreign institution investors and qualified foreign strategic investors. H Shares may only be [REDACTED] and [REDACTED] in Hong Kong dollars. Domestic Shares, on the other hand, may only be [REDACTED] and [REDACTED] in Renminbi.

## SHARE CAPITAL

### RANKING

Domestic Shares and H Shares are regarded as one class of Shares under our Articles of Association and will rank pari passu with each other in all other respects and, in particular, will rank equally for all dividends or distributions declared, paid or made after the date of this document. Dividends in respect of our Shares may be paid by us in Hong Kong dollars or Renminbi. In addition to cash, dividends may be distributed in the form of Shares.

### CONVERSION OF OUR DOMESTIC SHARES INTO H SHARES

According to the regulations prescribed by the securities regulatory authorities of the State Council and our Articles of Association, the Domestic Shares may be converted into shares that are [REDACTED] and [REDACTED] on an overseas stock exchange subject to compliance with the requirements and procedures under the relevant laws and regulations in the PRC. In addition, such conversion, [REDACTED] and [REDACTED] shall also comply with the regulations, requirements and procedures prescribed by the relevant overseas stock exchange.

Upon completion of the [REDACTED] and pursuant to the approval of the CSRC dated November 11, 2022, [REDACTED] Domestic Shares will be converted to H Shares on a one-for-one basis and be [REDACTED] for [REDACTED] on the Stock Exchange as set out below.

<b>Shareholder</b>	<b>Number of Shares to be converted to H Shares upon completion of the [REDACTED]</b>
Ms. ZHANG	[REDACTED]
Hengqin Luzhu LP	[REDACTED]
Beijing Yizhuang	[REDACTED]
Beijing Yizhuang II	[REDACTED]
Beijing Science Sun	[REDACTED]
CCB International Capital Management (Tianjin) Ltd. (建銀國際資本管理(天津)有限公司)	[REDACTED]
Jinjiang Zhenrui Equity Investment Partnership (Limited Partnership) (晉江禎睿股權投資合夥企業(有限合夥));	[REDACTED]
Haikou Hengji Rongyu Investment Center (Limited Partnership) (海口恒基榮域投資中心(有限合夥))	[REDACTED]
Ms. JIANG	[REDACTED]
Tianjin Huapu Biopharmaceutical Technology Partnership (Limited Partnership) (天津華普生物醫藥科技合夥企業(有限合夥))	[REDACTED]

## SHARE CAPITAL

Shareholder	Number of Shares to be converted to H Shares upon completion of the [REDACTED]
Ms. ZHONG Siyu	[REDACTED]
Zhuhai Livzon Pharmaceutical Equity Investment Management Co., Ltd. (珠海市麗珠醫藥股權投資管理有限公司)	[REDACTED]
Hangzhou Taikun Equity Investment Fund Partnership (Limited Partnership) (杭州泰鯤股權投資基金合夥企業(有限合夥))	[REDACTED]
Jinjiang Xuanhong No.1 Equity Investment Partnership (Limited Partnership) (晉江軒弘壹號股權投資合夥企業(有限合夥))	[REDACTED]
Hainan Zhaoan Private Equity Fund Management Partnership (Limited Partnership) (海南兆安私募基金管理合夥企業(有限合夥))	[REDACTED]
Ms. CHEN Qingyun	[REDACTED]
Beijing Xinchuang Technology Phase I Venture Capital Center (Limited Partnership) (北京芯創科技一期創業投資中心(有限合夥))	[REDACTED]
Zibo Runxin Xinchuang Investment Partnership (Limited Partnership) (淄博潤信芯創投資合夥企業(有限合夥))	[REDACTED]
Gongqingcheng Zhenrui Equity Investment Partnership (Limited Partnership) (共青城臻銳股權投資合夥企業(有限合夥))	[REDACTED]
Shaanxi Jinou Investment Fund Partnership (Limited Partnership) (陝西金甌投資基金合夥企業(有限合夥))	[REDACTED]
Ms. KONG Xi	[REDACTED]
Zibo Runwen Kangju Equity Investment Partnership (Limited Partnership) (淄博潤文康聚股權投資合夥企業(有限合夥))	[REDACTED]
Mr. ZHOU Peng	[REDACTED]

If any other of the Domestic Shares are to be converted, [REDACTED] and [REDACTED] as H Shares on the Stock Exchange, on top of compliance with the requirements and procedures under the relevant laws and regulations in the PRC, the approval of the Stock Exchange will also be needed. We may apply for the [REDACTED] of all or any portion of the Domestic Shares on the Stock Exchange as H Shares to ensure that the conversion process can be completed promptly upon notice to the Stock Exchange and delivery of Shares for entry on the H Share register. Approval of Shareholders at a general meeting is not required for the conversion of such Shares and the [REDACTED] and [REDACTED] of such converted Shares on an overseas stock exchange.

When the relevant laws and regulations permit, the existing Shareholders, namely Mr. KONG and Beijing Xinyin Xinghong Equity Investment Partnership (Limited Partnership) (北京信銀興弘股權投資合夥企業(有限合夥)), may consider to convert their Domestic Shares into H Shares upon compliance with all necessary regulations, requirements and procedures.



## SHARE CAPITAL

### **[REDACTED] Review and Approval by the CSRC**

In accordance with 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》) announced by the CSRC, H-share listed companies which apply for the conversion of shares into H shares for listing and circulation on the Hong Kong Stock Exchange shall file the application with the CSRC according to the administrative licensing procedures necessary for the “examination and approval of public issuance and listing (including additional issuance) of overseas shares by a joint stock company”. An H-share listed company may apply for a “Full Circulation” separately or when applying for refinancing overseas. An unlisted domestic joint stock company may apply for a “Full Circulation” when applying for an overseas initial public offering.

The Company applied for a “Full Circulation” when applying for an overseas [REDACTED] with the CSRC on June 20, 2022, and submitted the application reports, authorization documents of the shareholders of Domestic Shares for which an H-share “Full Circulation” was applied, explanation about the compliance of share acquisition and other documents in accordance with the requirements of the CSRC. The Company has received the reply from the CSRC dated November 11, 2022, in relation to the approval of the overseas [REDACTED] and “Full Circulation”, pursuant to which, (1) the Company was approved to issue no more than [REDACTED] H Shares with a nominal value of RMB1.00 each, which are all ordinary shares, and upon this issuance the Company may be [REDACTED] on the Main Board of the Hong Kong Stock Exchange; (2) a total of [REDACTED] Domestic shares (with a nominal value of RMB1.00 each) held by certain Shareholders (the “**Full Circulation Participating Shareholders**”) were approved to be converted into H Shares, and the relevant Shares may be [REDACTED] on the Hong Kong Stock Exchange upon completion of the conversion. This reply shall remain effective within 12 months from the date of approval.

### **REGISTRATION OF SHARES NOT LISTED ON THE OVERSEAS STOCK EXCHANGE**

According to the Notice of Centralized Registration and Deposit of Non-overseas Listed Shares of Companies Listed on an Overseas Stock Exchange (關於境外上市公司非境外上市股份集中登記存管有關事宜的通知) issued by the CSRC, an overseas listed company is required to register its shares that are not listed on the overseas stock exchange with CSDCC within 15 Business Days upon listing and provide a written report to the CSRC regarding the centralized registration and deposit of its unlisted shares as well as the current offering and listing of shares.

### **CIRCUMSTANCES UNDER WHICH GENERAL MEETING IS REQUIRED**

For details of circumstances under which our Shareholders’ general meeting is required, see “Summary of Articles of Association” in Appendix VI to this document.

## SHARE CAPITAL

---

### LOCK-UP PERIODS

In accordance with the PRC Company Law, the shares issued prior to any public offering of shares by a company cannot be transferred within one year from the date on which such publicly offered shares are listed and traded on the relevant stock exchange. As such, the Shares issued by our Company prior to the issue of H Shares will be subject to such statutory restriction on transfer within a period of one year from the [REDACTED].

Our Directors, Supervisors and members of the senior management (as defined in our Articles of Association) of our Company shall declare their shareholdings in our Company and any changes in their shareholdings. Shares transferred by our Directors, Supervisors and such members of the senior management each year during their term of office shall not exceed 25% of their total respective shareholdings in our Company. The Shares that the aforementioned persons held in our Company cannot be transferred within one year from the date on which the shares are [REDACTED] and [REDACTED], nor within half a year after they leave their positions in our Company. The Articles of Association may contain other restrictions or conditions on the transfer of the Shares held by our Directors, Supervisors, members of senior management of our Company and other Shareholders. For further details, see “Summary of Articles of Association” in Appendix VI to this document.

## SUBSTANTIAL SHAREHOLDERS

So far as our Directors are aware, immediately following the completion of the [REDACTED] and without taking into account any H Shares which may be issued pursuant to the exercise of the [REDACTED], the following persons will have an interest or short position in the Shares or the underlying Shares which would fall to be disclosed to us and the Stock Exchange under the provisions of Divisions 2 and 3 of Part XV of the SFO or, will be, directly or indirectly, interested in 10% or more of the nominal value of any class of our share capital carrying rights to vote in all circumstances of general meetings of our Company or any other member of our Group:

Name of Shareholder	Nature of interest	As of the Latest Practicable Date		Immediately following the completion of the [REDACTED] (assuming no exercise of the [REDACTED])			
		Number of Domestic Shares <sup>(1)</sup>	Approximate percentage of shareholding in the total issued share capital of our Company	Number of Shares <sup>(1)</sup>	Description of Shares <sup>(9)</sup>	Approximate percentage of shareholding in our Domestic Shares/ H Shares (as appropriate) <sup>(9)</sup>	Approximate percentage of shareholding in the total issued share capital of our Company
Mr. KONG	Beneficial interest	58,294,513	30.35%	[REDACTED]	Domestic Shares	[REDACTED]%	[REDACTED]%
	Interest of spouse <sup>(2)</sup>	20,200,000	10.52%	[REDACTED]	H Shares	[REDACTED]%	[REDACTED]%
	Interest in controlled corporation <sup>(3)</sup>	12,307,500	6.41%	[REDACTED]	H Shares	[REDACTED]%	[REDACTED]%
Ms. ZHANG	Beneficial interest	20,200,000	10.52%	[REDACTED]	H Shares	[REDACTED]%	[REDACTED]%
	Interest of spouse <sup>(2)</sup>	58,294,513	30.35%	[REDACTED]	Domestic Shares	[REDACTED]%	[REDACTED]%
	Interest of spouse <sup>(2)</sup>	12,307,500	6.41%	[REDACTED]	H Shares	[REDACTED]%	[REDACTED]%
Hengqin Luzhu LP	Beneficial interest	12,307,500	6.41%	[REDACTED]	H Shares	[REDACTED]%	[REDACTED]%
Beijing Luzhu Kangrui Enterprise Management Partnership (Limited Partnership) (北京綠竹康瑞企業管理合夥企業 (有限合夥)) (“Beijing Luzhu Kangrui”)	Interest in controlled corporation <sup>(4)</sup>	12,307,500	6.41%	[REDACTED]	H Shares	[REDACTED]%	[REDACTED]%
Ms. PENG Ling (彭玲)	Interest in controlled corporation <sup>(4)</sup>	12,307,500	6.41%	[REDACTED]	H Shares	[REDACTED]%	[REDACTED]%
Beijing Yizhuang	Beneficial interest	19,645,000	10.23%	[REDACTED]	H Shares	[REDACTED]%	[REDACTED]%
Beijing Yizhuang II	Beneficial interest	18,324,696	9.54%	[REDACTED]	H Shares	[REDACTED]%	[REDACTED]%
E-town Sun	Interest in controlled corporation <sup>(5)</sup>	37,969,696	19.77%	[REDACTED]	H Shares	[REDACTED]%	[REDACTED]%
Saiding Fangde	Interest in controlled corporation <sup>(5)</sup>	37,969,696	19.77%	[REDACTED]	H Shares	[REDACTED]%	[REDACTED]%
Saide Ruibo	Interest in controlled corporation <sup>(5)</sup>	37,969,696	19.77%	[REDACTED]	H Shares	[REDACTED]%	[REDACTED]%
Mr. MA Biao (馬驍)	Interest in controlled corporation <sup>(5)(6)</sup>	51,721,196	26.93%	[REDACTED]	H Shares	[REDACTED]%	[REDACTED]%

## SUBSTANTIAL SHAREHOLDERS

Name of Shareholder	Nature of interest	As of the Latest Practicable Date		Immediately following the completion of the [REDACTED] (assuming no exercise of the [REDACTED])			
		Number of Domestic Shares <sup>(1)</sup>	Approximate percentage of shareholding in the total issued share capital of our Company	Number of Shares <sup>(1)</sup>	Description of Shares <sup>(9)</sup>	Approximate percentage of shareholding in our Domestic Shares/ H Shares (as appropriate) <sup>(9)</sup>	Approximate percentage of shareholding in the total issued share capital of our Company
Mr. MA Jianan (馬嘉楠)	Interest in controlled corporation <sup>(5)</sup>	37,969,696	19.77%	[REDACTED]	H Shares	[REDACTED]%	[REDACTED]%
Beijing Science Sun	Beneficial interest	13,751,500	7.16%	[REDACTED]	H Shares	[REDACTED]%	[REDACTED]%
CCB International Capital Management (Tianjin) Ltd. (建銀國際資本管理(天津)有限公司) (“CCB Capital”)	Beneficial interest	11,664,075	6.07%	[REDACTED]	H Shares	[REDACTED]%	[REDACTED]%
CCB International (China) Limited (建銀國際(中國)有限公司) (“CCB China”)	Interest in controlled corporation <sup>(7)</sup>	11,664,075	6.07%	[REDACTED]	H Shares	[REDACTED]%	[REDACTED]%
CCB International (Holdings) Limited (建銀國際(控股)有限公司) (“CCB Holdings”)	Interest in controlled corporation <sup>(7)</sup>	11,664,075	6.07%	[REDACTED]	H Shares	[REDACTED]%	[REDACTED]%
CCB Financial Holdings Limited (建行金融控股有限公司) (“CCB Financial”)	Interest in controlled corporation <sup>(7)</sup>	11,664,075	6.07%	[REDACTED]	H Shares	[REDACTED]%	[REDACTED]%
CCB International Group Holdings Limited (建行國際集團控股有限公司) (“CCB Group”)	Interest in controlled corporation <sup>(7)</sup>	11,664,075	6.07%	[REDACTED]	H Shares	[REDACTED]%	[REDACTED]%
China Construction Bank Corporation	Interest in controlled corporation <sup>(7)</sup>	11,664,075	6.07%	[REDACTED]	H Shares	[REDACTED]%	[REDACTED]%
Jinjiang Zhenrui Equity Investment Partnership (Limited Partnership) (晉江禎睿股權投資合夥企業(有限合夥)) (“Jinjiang Zhenrui”)	Beneficial Interest	7,776,050	4.05%	[REDACTED]	H Shares	[REDACTED]%	[REDACTED]%
Herui Venture Capital Fund Management (Shenzhen) Co., Ltd. (和瑞創業投資基金管理(深圳)有限公司) (“Herui VC”)	Interest in controlled corporation <sup>(8)</sup>	10,000,744	5.21%	[REDACTED]	H Shares	[REDACTED]%	[REDACTED]%
Mr. Chen Ruolin (陳若霖)	Interest in controlled corporation <sup>(8)</sup>	10,000,744	5.21%	[REDACTED]	H Shares	[REDACTED]%	[REDACTED]%
Mr. WANG Zhixian (王智顯)	Interest in controlled corporation <sup>(8)</sup>	10,000,744	5.21%	[REDACTED]	H Shares	[REDACTED]%	[REDACTED]%

*Notes:*

(1) All interests stated are long positions.

## SUBSTANTIAL SHAREHOLDERS

- (2) Mr. KONG and Ms. ZHANG are the spouse of each other. Accordingly, they are deemed to be interested in the same number of Shares that the other person is interested in for the purpose of the SFO.
- (3) As of the Latest Practicable Date, Mr. KONG was the sole general partner of Hengqin Luzhu LP. Therefore, Mr. KONG is deemed to be interested in the Shares held by Hengqin Luzhu LP under the SFO.
- (4) As of the Latest Practicable Date, Hengqin Luzhu LP was owned as to approximately 40.67% by Beijing Luzhu Kangrui, and Ms. PENG Ling (彭玲), one of our Supervisors and senior management, was the general partner of Beijing Luzhu Kangrui. Accordingly, (i) Beijing Luzhu Kangrui is deemed to be interested in the Shares held by Hengqin Luzhu LP; and (ii) Ms. PENG Ling is deemed to be interested in the Shares in which Beijing Luzhu Kangrui is interested in.
- (5) As of the Latest Practicable Date, (i) E-town Sun was the general partner and fund manager of Beijing Yizhuang and Beijing Yizhuang II, and in turn E-town Sun was owned as to approximately 34.00% and 46.00% by Saiding Fangde and Saide Ruibo, respectively; and (ii) Mr. MA Biao and Mr. MA Jianan (the son of Mr. MA Biao) were the respective general partner of Saiding Fangde and Saide Ruibo, holding approximately 60.00% and 80.00% partnership interest thereof, respectively. Further, Saiding Fangde and Saide Ruibo have confirmed that they are acting in concert with respect to their shareholdings in E-town Sun. Accordingly, under the SFO (i) E-town Sun is deemed to be interested in the Shares held by Beijing Yizhuang and Beijing Yizhuang II; (ii) Saiding Fangde and Saide Ruibo are deemed to be interested in the Shares in which E-town Sun is interested; (iii) Mr. MA Biao is deemed to be interested in the Shares in which Saiding Fangde is interested; and (iv) Mr. MA Jianan is deemed to be interested in the Shares in which Saide Ruibo is interested.
- (6) Mr. MA Biao is the Actual Controller of Beijing Science Sun and held approximately 49.51% of the issued shares of Beijing Science Sun as of the Latest Practicable Date. Mr. MA Biao is therefore deemed to be interested in the Shares held by Beijing Science Sun under the SFO.
- (7) As of the Latest Practicable Date, (i) CCB Capital was wholly-owned by CCB China, and in turn CCB China was wholly-owned by CCB Holdings; (ii) CCB Holdings was wholly-owned by CCB Group via CCB Financial; and (iii) CCB Group was wholly-owned by China Construction Bank. China Construction Bank is a listed company on the Shanghai Stock Exchange (stock code: 601939). Accordingly, each of CCB China, CCB Holdings, CCB Financial, CCB Group and China Construction Bank is deemed to be interested in the Shares in which CCB Capital is interested in under the SFO.
- (8) As of the Latest Practicable Date, (i) Herui VC was the general partner and fund manager of Jinjiang Zhenrui and Jinjiang Xuanhong No.1 Equity Investment Partnership (Limited Partnership) (晉江軒弘壹號股權投資合夥企業 (有限合夥)) (“**Jinjiang Xuanhong**”); and (ii) Herui VC was owned as to approximately 40.00%, 40.00% and 20.00% by Mr. Chen Ruolin (陳若霖), Mr. WANG Zhixian (王智顯) and Mr. LIN Bei (林貝), respectively. Jinjiang Zhenrui and Jinjiang Xuanhong are our [REDACTED] Investors and will respectively hold [REDACTED] Shares and [REDACTED] Shares upon completion of the [REDACTED]. Accordingly, under the SFO (i) Herui VC is deemed to be interested in the Shares held by Jinjiang Zhenrui and Jinjiang Xuanhong; and (ii) each of Mr. Chen Ruolin and Mr. WANG Zhixian is deemed to be interested in the Shares in which Herui VC is interested.
- (9) For the avoidance of doubt, both Domestic Shares and H Shares are ordinary Shares in the share capital of our Company, and are considered as one class of Shares.

Save as disclosed above, our Directors are not aware of any person who will, immediately following completion of the [REDACTED] (assuming the [REDACTED] is not exercised), have any interest and/or short positions in the Shares or underlying Shares which would fall to be disclosed under the provisions of Divisions 2 and 3 of Part XV of the SFO or, will be, directly or indirectly, interested in 10% or more of the nominal value of any class of our share capital carrying rights to vote in all circumstances at general meetings of our Company or any other member of our Group. Our Directors are not aware of any arrangement which may at a subsequent date result in a change of control of our Company.

## DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

### BOARD OF DIRECTORS

Our Board consists of eight Directors, comprising three executive Directors, two non-executive Directors and three independent non-executive Directors. Our Board is responsible and has general powers for the management and conduct of our business. The table below sets forth certain information in respect of the members of the Board:

Name	Age	Major position(s)	Date of joining our Group	Date of appointment as Director	Roles and responsibilities	Relationship with other Directors, Supervisors and senior management
Mr. KONG Jian (孔健)	59	Executive Director, general manager, chief scientist, chairman of our Board	July 2002	September 11, 2008	Overall strategic development and key business decisions, including scientific research and production of our Group	Spouse of Ms. ZHANG; uncle of Ms. KONG Xi (our Supervisor); father-in-law of Mr. LIU Siyu (one of the joint company secretaries of our Company and the secretary of our Board)
Ms. JIANG Xianmin (蔣先敏)	60	Executive Director, deputy general manager, chief medical officer, vice-chairlady of our Board	February 2002	June 28, 2013	Managing the clinical trials of the products of our Group	None
Ms. ZHANG Yanping (張琰平)	60	Executive Director, deputy general manager	January 2004	June 28, 2013	Managing the finance and procurement related matters of our Group	Spouse of Mr. KONG; aunt of Ms. KONG Xi (our Supervisor); mother-in-law of Mr. LIU Siyu (one of the joint company secretaries of our Company and the secretary of our Board)
Mr. MA Biao (馬驪)	59	Non-executive Director	August 2019	August 2, 2019	Providing management and strategic advice to our Group	None
Mr. KONG Shuangquan (孔雙泉)	48	Non-executive Director	August 2019	August 2, 2019	Providing management and strategic advice to our Group	None
Mr. LEUNG Wai Yip (梁偉業)	46	Independent non-executive Director	March 2023	March 30, 2023	Supervising and providing independent opinion to our Board	None

## DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Name	Age	Major position(s)	Date of joining our Group	Date of appointment as Director	Roles and responsibilities	Relationship with other Directors, Supervisors and senior management
Mr. LIANG Yeshe (梁治矢)	73	Independent non-executive Director	March 2023	March 30, 2023	Supervising and providing independent opinion to our Board	None
Ms. HOU Aijun (侯愛軍)	57	Independent non-executive Director	March 2023	March 30, 2023	Supervising and providing independent opinion to our Board	None

### Executive Directors

**Mr. KONG Jian (孔健)**, aged 59, is our executive Director, the general manager of our Company, the chief scientist and leader of the research and development team of our Group, and the chairman of our Board, and is primarily responsible for the overall strategic development and key business decisions, including scientific research and production of our Group. He is one of our Controlling Shareholders. Mr. KONG joined our Company in July 2002 as our general manager. He is also the leader of the research and development team of our Group. He was appointed as a Director on September 11, 2008, and re-designated as our executive Director on June 18, 2022. He is also the director, legal representative and general manager of Zhuhai Luzhu, the director of Hong Kong Luzhu, and the legal representative of Beijing Luzhu.

Mr. KONG has over 34 years of experience in the biopharmaceutical industry. Mr. Kong has participated in the successful development of five vaccines which have been commercialized, including three types of bacterial polysaccharide conjugate vaccines and two multi-valent meningococcal polysaccharide vaccines. In addition, Mr. Kong has developed vaccines and monoclonal antibodies under clinical investigation, including a recombinant herpes zoster vaccine, two monoclonal antibodies, a bispecific antibody and an inactivated enterovirus 71 vaccine. Prior to joining our Group, from October 1988 to 2002, he worked in the Beijing National Vaccine and Serum Institute of the Ministry of Health (衛生部北京生物製品研究所), a research institute primarily focused on microbiology and immunology research and productions of epidemic prevention products. He worked as the director of the Science and Technology Development Division (科技開發處處長) and manager of the immunodiagnostic laboratory (免疫診斷研究室主任) of the Beijing National Vaccine and Serum Institute of the Ministry of Health since October 2000, and was primarily responsible for scientific research of biological products. In March 2000, Mr. KONG was also accredited as a researcher in biomedical science at the Chinese Biologics Corporation (中國生物製品總公司), a state-owned institution primarily engaged in the research and production of vaccines and blood products.

Since April 2014, Mr. KONG was a limited partner holding approximately 1.65% interests in Beijing Baojin Jiaming Investment Management Center (Limited Partnership) (北京寶金嘉銘投資管理中心(有限合夥)), a limited liability partnership established in the PRC on June 12, 2012. Its business license was revoked on February 21, 2022 due to discontinuation of annual inspection filings by the general partner after cessation of business. As confirmed by Mr. KONG, the above partnership was solvent at the time of revocation of business license, there is no fraudulent act or misfeasance on the part of Mr. KONG leading to the revocation and he was not aware of any actual or potential claim that has been or will be made against him as a result of the revocation of business license of such company.

---

## DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

---

Mr. KONG obtained a bachelor degree in medicine from the School of Medicine in Shandong University (山東大學) (formerly known as the Shandong Medical University (山東醫學院)) in July 1985, and a postgraduate master degree in epidemiology from Tianjin Medical University (天津醫科大學) (formerly known as Tianjin School of Medicine (天津醫學院)) in September 1988.

Mr. KONG is the spouse of Ms. ZHANG, our executive Director, the uncle of Ms. KONG Xi, our Supervisor, and the father-in-law of Mr. LIU Siyu, one of the joint company secretaries of our Company and the secretary of our Board.

**Ms. JIANG Xianmin (蔣先敏)**, aged 60, is our executive Director, the deputy general manager of our Company, the chief medical officer and leader of the clinical development team of the Group, and the vice-chairlady of our Board, and is primarily responsible for the management of the clinical trials of the products of our Group. She is also the manager of our medical department. Ms. JIANG joined our Group in February 2002 as deputy general manager, mainly responsible for our Company’s R&D and clinical work and was appointed as the vice-chairlady of our Board since July 2013. Since 2018, she has been focusing on management of the clinical development programs and registration of our Company’s products. Ms. JIANG is the leader of the clinical development team of the Group. Ms. JIANG has led the development of our Meningococcal Group A and C Polysaccharide Conjugate Vaccine, Meningococcal Group A and C and Haemophilus Influenzae Type b Conjugate Vaccine, Group ACYW<sub>135</sub> Meningococcal Polysaccharide Vaccine, typhoid polysaccharide vaccine and tetanus toxoid vaccine. She was appointed as a Director on June 28, 2013, and was re-designated as an executive Director on June 18, 2022. She is also the supervisor of Zhuhai Luzhu.

Ms. JIANG has over 36 years of experience in the biopharmaceutical industry. Prior to joining our Group, from August 1986 to 2004, Ms. JIANG worked in the Beijing National Vaccine and Serum Institute of the Ministry of Health (衛生部北京生物製品研究所), a national research unit primarily focusing on the production and research of vaccines, blood-based products and diagnostic reagents, as an associate researcher and was primarily responsible for the research and development of immunodiagnostic reagents and monoclonal antibodies, and she has participated in various studies such as construction of hybridoma cell strains secreting McAbs to human erythrocyte surface antigen glycoprotein A and a study on anti-CEA response induced by anti-idiotypic antibody.

Ms. JIANG obtained a bachelor degree in medicine from the Xiangya School of Medicine of Central South University (中南大學湘雅醫學院) (formerly known as Hunan School of Medicine (湖南醫學院)) in August 1984. In January 1998, she was recognized as an associate researcher by Ministry of Health of the People’s Republic of China (中華人民共和國衛生部).

**Ms. ZHANG Yanping (張琰平)**, aged 60, is our executive Director and the deputy general manager of the Company, primarily responsible for the overall finance and procurement of our Group. She was appointed as a Director on June 28, 2013 and was re-designated as an executive Director on June 18, 2022. She is also one of our Controlling Shareholders. Ms. ZHANG joined our Group in January 2004 as a manager of the research and development department, and is currently our deputy general manager, mainly in charge of our finance department. At the same time, Ms. ZHANG is also our head of material department.



## DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Ms. ZHANG has over 37 years of experience in biopharmaceutical industry and has extensive experience in quality control, quality assurance, and pre-clinical safety studies of biological products. She has also led our Group to obtain GMP certification for our Meningococcal Group A and C Polysaccharide Conjugate Vaccine and Group ACYW<sub>135</sub> Meningococcal Polysaccharide Vaccine. Prior to joining our Group, from July 1985 to 2004, Ms. ZHANG worked as a technician at the Beijing National Vaccine and Serum Institute of the Ministry of Health (衛生部北京生物製品研究所), mainly participated in the preparation of intestinal bacteria and immunoglobulin diagnostic serum and the research of interferon-β antibody. In March 2000, Ms. ZHANG was appointed as a deputy researcher in biomedical science at the Chinese Biologics Corporation (中國生物製品總公司), a state-owned institution primarily engaged in the research and production of vaccines and blood products.

Ms. ZHANG obtained a bachelor degree in medicine from the School of Medicine in Shandong University (山東大學) (formerly known as the Shandong Medical University (山東醫學院)) in July 1985.

Ms. ZHANG is the spouse of Mr. KONG, our executive Director, the aunt of Ms. KONG Xi, our Supervisor and the mother-in-law of Mr. LIU Siyu, one of the joint company secretaries of our Company and the secretary of our Board.

### Non-executive Directors

**Mr. MA Biao (馬彪)**, aged 59, is our non-executive Director, primarily responsible for providing management and strategic advice to our Group. He was nominated by Beijing Science Sun as a Board representative and was appointed as a Director on August 2, 2019. Mr. MA Biao was re-designated as our non-executive Director on June 18, 2022.

Mr. MA Biao has over 23 years of experience in the pharmaceutical industry. From August 1999, Mr. MA Biao joined Beijing Science Sun, a company principally engaged in research, manufacture and sales of biological and biochemical pharmaceuticals and listed on the ChiNext board of the Shenzhen Stock Exchange (stock code: 300485) as the deputy general manager, and was appointed as its director and general manager in July 2001. Mr. MA Biao is the Actual Controller of Beijing Science Sun. He currently serves as the chairman of the board and the general manager of Beijing Science Sun, primarily responsible for overall management. Since February 2018, Mr. MA has served as a director of Beijing Eastern Biotech Co., Ltd. (北京東方百泰生物科技股份有限公司), a company principally engaged in the R&D and production of innovative antibody and macromolecular protein drugs, where he is an investor board representative primarily responsible for providing opinion and judgment to the board.

Mr. MA Biao obtained a master degree in biochemistry from Jilin University (吉林大學) in June 1989, and a doctorate degree in food science from the China Agricultural University (中國農業大學) in December 2008. Mr. MA Biao was also accredited as a researcher by Beijing Specialised Professions and Technique Titles Evaluation Committee (北京市高級專業技術職務評審委員會) in January 2017.

**Mr. KONG Shuangquan (孔雙泉)**, aged 48, is our non-executive Director, primarily responsible for providing management and strategic advice to our Group. He was nominated by Beijing Yizhuang as a Board representative and was appointed as a Director on August 2, 2019. Mr. KONG Shuangquan was re-designated as our non-executive Director on June 18, 2022.

## DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

From July 2004 to July 2010, Mr. KONG Shuangquan worked at the research and development department of Beijing Science Sun primarily responsible for the development of pharmaceutical drug. From July 2010 to September 2011, Mr. KONG Shuangquan also worked at TianXinFu (Beijing) Medical Appliance Co., Ltd. (天新福(北京)醫療器材股份有限公司, formerly known as Beijing TianXinFu Medical Appliance Co., Ltd. (北京天新福醫療器材股份有限公司)), a company principally engaged in the production of medical equipment involving regenerated medical biomaterials, serving as a manager of the research and development technology department and primarily responsible for the company's biomaterial product development. Subsequently, Mr. KONG Shuangquan re-joined Beijing Science Sun in September 2011, and he is currently the chief engineer of the research and development department of Beijing Science Sun, in charge of the company's technology and product development. Mr. KONG Shuangquan is also currently a director and deputy general manager of Beijing Huada Protein Research and Development Center Co., Ltd. (北京華大蛋白質研發中心有限公司), an investment entity of Beijing Science Sun, where he is primarily responsible for the company's daily operation and decision-making process. Beijing Huada Protein Research and Development Center Co., Ltd. is principally engaged in contract research, drug analysis and the provision of protein-based biologics services including protein expression and purification, recombinant protein, as well as antibody preparation and identification.

Mr. KONG Shuangquan obtained a master degree in microbiology and biochemical pharmacy from Jilin University (吉林大學) in June 2004. In November 2012, Mr. KONG Shuangquan was named as an assistant researcher by the Beijing Intermediate Professional Technical Position Appraisal Committee (北京中級專業技術職務評審委員會).

### Independent non-executive Directors

**Mr. LEUNG Wai Yip (梁偉業)**, aged 46, was appointed as an independent non-executive Director on March 30, 2023, primarily responsible for supervising and providing independent opinion to our Board.

Mr. LEUNG Wai Yip has approximately 20 years of experience in audit and financial management. Prior to joining our Group, from March 2000 to August 2005, he acted consecutively as the auditor, senior auditor and manager in the assurance and advisory business services department of Ernst & Young. From May 2007 to December 2010, Mr. LEUNG Wai Yip served as the financial controller and the company secretary of Tiangong International Company Limited (listed on the Stock Exchange, stock code: 826), mainly responsible for the initial public offering of the group and post-listing financial management and investor relationships. He has been the chief financial officer and company secretary of Chaowei Power Holdings Limited (listed on the Stock Exchange, stock code: 951) since December 2010, mainly responsible for the company's financial management, overseas acquisition and financing and investor relationships. Mr. LEUNG Wai Yip also served as an independent non-executive director of Miko International Holdings Limited (listed on the Stock Exchange, stock code: 1247) from December 2013 to February 2016. Since April 2018, he has also been appointed as an independent non-executive director and chairman of the audit committee of HPC Holdings Limited (listed on the Stock Exchange, stock code: 1742).

In addition, Mr. LEUNG Wai Yip was a director of Coyoh Limited, a company incorporated in Hong Kong on 8 June 2009 which did not commence any business ever. On 10 October 2014, Coyoh Limited was dissolved by striking off under Section 744(3) of the Companies Ordinance, pursuant to which if the Registrar of Companies in Hong Kong has reasonable cause to believe that a company is not carrying on business or in operation, the Registrar of Companies in Hong Kong may strike the name of the company off the register after the expiration of a specified period. Mr. LEUNG Wai Yip confirmed that

## DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Coyoh Limited was solvent and did not carry out any business at the time of it being struck off. Mr. LEUNG Wai Yip also confirmed he did not have any outstanding liabilities in relation to Coyoh Limited’s being struck off and Coyoh Limited had no outstanding liabilities at the time of it being struck off.

Mr. LEUNG Wai Yip obtained a degree of bachelor of commerce from the University of Alberta in June 1998 and a degree of master of business administration from the Hong Kong University of Science and Technology in November 2010 respectively. He has been a member of the American Institute of Certified Public Accountants since December 2002, and an associate member of the Hong Kong Society of Accountants since May 2003.

**Mr. LIANG Yeshe (梁冶矢)**, aged 73, was appointed as an independent non-executive Director on March 30, 2023, primarily responsible for supervising and providing independent opinion to our Board.

Mr. LIANG Yeshe has over 33 years of experience in the medical field. Since 1989, Mr. LIANG Yeshe joined the Peking University People’s Hospital (北京大學人民醫院) and his last position was the deputy director of the neurosurgery department.

Mr. LIANG Yeshe was a supervisor of Beijing Zhuoyue Tonghua Advertising Co., Ltd. (北京卓越通華廣告有限責任公司) (“**Beijing Zhuoyue**”), a limited liability company established in the PRC on January 31, 2002. The business license of Beijing Zhuoyue was revoked on October 8, 2013 as it did not conduct annual inspection. As confirmed by Mr. LIANG Yeshe, he was not involved in the operation and management of Beijing Zhuoyue, and there is no fraudulent act or misfeasance on his part leading to the revocation. Further, as confirmed by Mr. LIANG Yeshe, Beijing Zhuoyue was solvent at the time of revocation of its business license, and Mr. LIANG Yeshe was not aware of any actual or potential claim that has been or will be made against him as a result of the revocation of business license of Beijing Zhuoyue.

Mr. LIANG Yeshe obtained a postgraduate master degree in medicine from Tianjin Medical University (天津醫科大學) in September 1988.

**Ms. HOU Aijun (侯愛軍)**, aged 57, was appointed as an independent non-executive Director on March 30, 2023, primarily responsible for supervising and providing independent opinion to our Board.

Prior to joining our Group, from March 1992 to November 2009, she worked in the China Biotechnology Group Corporation (中國生物技術集團公司), a company principally engaged in the research and development of biological products and her last position was the deputy director of the research and development management department. She was mainly responsible for management of scientific research projects. In 2009, she joined China National Pharmaceutical Group Co., Ltd. (中國醫藥集團有限公司) (formerly known as China National Pharmaceutical Group Corporation (中國醫藥集團總公司)), a company principally engaged in the distribution, research and development and production of health-related products. She worked as the deputy manager of the research development management department (研發管理部). Subsequently in July 2010, she was appointed as the secretary general of the science and technology committee of the company, and in March 2018 she was further appointed as the deputy manager of the science and technology committee. In July 2018, she was further appointed to act as the deputy director of policy research office of the China National Pharmaceutical Group Co., Ltd. concurrently, mainly responsible for assisting its board of directors to in strategic decision-making process with reference to national policies and regulations in the medical industry.

Ms. HOU Aijun obtained a bachelor degree in applied biochemistry from the Department of Biology of the Peking University (北京大學) in July 1987.

## DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

### SUPERVISORS

The table below sets out certain information regarding our Supervisors:

Name	Age	Major position(s)	Date of joining our Group	Date of appointment as Supervisor	Roles and responsibilities	Relationship with other Directors, Supervisors and senior management
Ms. PENG Ling (彭玲)	42	Supervisor, chief technology officer	April 2015	July 19, 2019	Supervising the operating and financial activities of our Company, leading the quality control department	None
Ms. KONG Xi (孔茜)	30	Supervisor	July 2013	July 21, 2014	Supervising the operating and financial activities of our Company	Niece of Mr. KONG and Ms. ZHANG, our executive Directors
Mr. CHEN Liang (陳亮)	43	Supervisor	August 2021	April 26, 2022	Supervising the operating and financial activities of our Company	None

**Ms. PENG Ling (彭玲)**, aged 42, was appointed as a Supervisor on July 19, 2019. She joined our Group in April 2015 and served as the deputy manager of our quality control department. Ms. PENG Ling also acted as our Director from November 2018 to July 2019 before her appointment as a Supervisor in July 2019. She has been appointed as the manager of our quality control department since March 2020. Since December 2021 she has also been appointed as the assistant to general manager of our Company. In April 2022, she has been appointed as the chief technology officer of our Company. Ms. PENG Ling is primarily responsible for leading the quality control department and supervising the operating and financial activities of our Company.

Ms. PENG Ling obtained a bachelor degree from Shandong Normal University (山東師範大學) majoring in chemistry in July 2003, and in June 2006, she also obtained a master degree in organic chemistry from the same university.

---

## DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

---

**Ms. KONG Xi (孔茜)**, aged 30, was appointed as a Supervisor on July 21, 2014. She has been working as a technician in our quality control department since July 2013. Ms. KONG Xi is mainly responsible for supervising the operating and financial activities of our Company.

Ms. KONG Xi obtained a bachelor degree in bioengineering in June 2013 from Huaqiao University (華僑大學).

Ms. KONG Xi is the niece of Mr. KONG and Ms. ZHANG, our executive Directors.

**Mr. CHEN Liang (陳亮)**, aged 43, was appointed as a Supervisor on April 26, 2022. He joined our Group’s human resources and administration department in August 2021 as a manager. Mr. CHEN Liang is mainly responsible for supervising the operating and financial activities of our Company.

Prior to joining our Group, Mr. CHEN Liang worked as the chief executive officer for Beijing Jieyatai Zhongsheng Automobile Sales Co., Ltd. (北京捷亞泰中盛汽車銷售有限公司), a company primarily engaged in car sales, where he was primarily responsible for administration and human resource management.

Mr. CHEN Liang obtained a bachelor degree in law in July 2016 from Beihang University (北京航空航天大學) through attending long distance learning courses. He also obtained the professional qualifications of senior vocational management professional (level 1) (高級職業經理人(一級)) and the senior human resources management specialist (level 1) (高級人力資源管理師(一級)) in October 2015, and the professional qualification of safety evaluation professional (level 1) (安全評價師(一級)) in December 2018 from the Ministry of Human Resources and Social Security of the PRC (中華人民共和國人力資源和社會保障部).

Save as disclosed above and in this document, each of our Directors and Supervisors confirms with respect to himself or herself that he or she (1) did not hold other long positions or short positions in the Shares, underlying Shares, debentures of our Company or any associated corporation (within the meaning of Part XV of the SFO) as of the Latest Practicable Date; (2) had no other relationship with any Directors, Supervisors, senior management, substantial shareholders or Controlling Shareholders of our Company as of the Latest Practicable Date; (3) did not hold any other directorships in the three years prior to the Latest Practicable Date in any public companies of which the securities are listed on any securities market in Hong Kong and/or overseas; and (4) there are no other matters concerning our Director’s and Supervisor’s appointment that need to be brought to the attention of our Shareholders and the Stock Exchange or shall be disclosed pursuant to Rules 13.51(2)(h) to (v) of the Listing Rules.

## DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

### SENIOR MANAGEMENT

The table below sets out certain information regarding our senior management:

Name	Age	Major position(s)	Date of joining our Group	Date of appointment as senior management	Roles and responsibilities	Relationship with other Directors, Supervisors and senior management
Mr. KONG Jian (孔健)	59	Executive Director, general manager, chief scientist, chairman of our Board	July 2002	July 22, 2002	Overall strategic development and key business decisions, including scientific research and production of our Group	Spouse of Ms. ZHANG; uncle of Ms. KONG Xi (our Supervisor); father-in-law of Mr. LIU Siyu (one of the joint company secretaries of our Company and the secretary of our Board)
Ms. JIANG Xianmin (蔣先敏)	60	Executive Director, deputy general manager, chief medical officer, vice-chairlady of our Board	February 2002	February 20, 2002	Managing the clinical trials of the products of our Group	None
Ms. ZHANG Yanping (張琰平)	60	Executive Director, deputy general manager	January 2004	January 20, 2004	Managing the finance and procurement related matters of our Group	Spouse of Mr. KONG; aunt of Ms. KONG Xi (our Supervisor); mother-in-law of Mr. LIU Siyu (one of the joint company secretaries of our Company and the secretary of our Board)
Mr. ZHANG Hui (張輝)	54	Chief finance officer, head of global capital markets	June 2021	June 15, 2021	Overseeing the corporate financing of our Group	None
Mr. LIU Siyu (劉斯宇)	32	Joint company secretary of our Company, the secretary of our Board	September 2021	September 1, 2021	Handling daily affairs of our Board, assisting our Board in legal compliance matters and handling public relations of our Group	Son-in-law of Mr. KONG and Ms. ZHANG, our executive Directors

## DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Name	Age	Major position(s)	Date of joining our Group	Date of appointment as senior management	Roles and responsibilities	Relationship with other Directors, Supervisors and senior management
Ms. PENG Ling (彭玲)	42	Supervisor, chief technology officer	April 2015	December 11, 2018	Supervising the operating and financial activities of our Company, leading the quality control department	None
Ms. LU Lu (路露)	41	Deputy general manager of Zhuhai Luzhu	April 2021	December 1, 2021	Management of administration and human resources of our Group	None
Mr. HAN Chaowei (韓朝煒)	48	Head of manufacturing and engineering, deputy general manager of Zhuhai Luzhu	October 2020	October 19, 2020	Managing the commercial production and storage of our biological products	None
Ms. JIANG Lijuan (蔣莉娟)	56	Deputy general manager of Zhuhai Luzhu	December 2021	December 1, 2021	Quality management of the pharmaceutical manufacturing of our Group	None

**Mr. KONG Jian (孔健)**, see “— Board of Directors — Executive Directors” in this section for details.

**Ms. JIANG Xianmin (蔣先敏)**, see “— Board of Directors — Executive Directors” in this section for details.

**Ms. ZHANG Yanping (張琰平)**, see “— Board of Directors — Executive Directors” in this section for details.

## DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Mr. ZHANG Hui (張輝), aged 54, was appointed as our chief finance officer and the head of global capital markets in June 2021 and is primarily responsible for overseeing the corporate financing of our Group.

Mr. ZHANG Hui has over 20 years of experience in investment banking. Prior to joining our Group, Mr. ZHANG Hui served at the following investment banks and institutions:

Period of service	Name of company	Principal business	Position(s)
October 2003 to October 2005	DBS Bank Ltd., Beijing Branch (formerly known as the Development Bank of Singapore Ltd., Beijing Branch)	Financing business	Joined as a senior manager, and last position as the chief representative of the DBS Asia Capital Limited Beijing Representative Office (星展亞洲融資有限公司北京代表處)
August 2006 to December 2007	BNP Paribas Capital (Asia Pacific) Limited (formerly known as BNP Paribas Peregrine Capital Limited)	Investment and financing business	Senior vice president
December 2007 to December 2008	Lehman Brothers Securities Asia Limited	Investment and financing business	Senior vice president
April 2010 to February 2011	Deutsche Bank (listed on the Frankfurt Stock Exchange, stock code: DBK; and the New York Stock Exchange, stock code: DB)	Investment and financing business	Director of global capital markets
February 2011 to February 2012	Samsung Securities (Asia) Limited (listed on the Korean Stock Exchange, stock code: 016360)	Investment and financing business	Managing director and head of China in the investing banking and principal investments department
February 2012 to January 2015; and September 2016 to January 2021	Guosen Securities (HK) Capital Company Limited (listed on the Shenzhen Stock Exchange, stock code: 00273)	Investment and financing business	Managing director, head of investment banking division and head of global capital markets

Mr. ZHANG Hui obtained a bachelor degree in materials engineering from Shanghai Jiao Tong University (上海交通大學) in July 1992. He further obtained a master’s degree in management through long distance learning from the Australian National University in 2008. He is currently pursuing a master’s degree in pharmaceutical engineering through long distance learning at Wuhan Institute of Technology (武漢工程大學).



---

## DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

---

**Mr. LIU Siyu (劉斯宇)**, aged 32, was appointed as one of the joint company secretaries of our Company on June 18, 2022. He has served as the secretary of our Board since September 2021 and is primarily responsible for handling daily affairs and communications of our Board, assisting our Board in legal compliance and corporate governance matters, and handling external financing and public relations of our Group, including but not limited to liaising with our investors, relevant governmental authorities and the media.

Prior to joining our Group, from February 2015 to October 2015, he joined Xiaoyezi (Beijing) Technology Co., Ltd. (小葉子(北京)科技有限公司), a company primarily engaged in online music education with music-related Artificial Intelligence (AI) hardware products, where he served as a java engineer, mainly responsible for overseeing and managing technological issues of the company. From November 2015 to September 2021, he served as a java engineer of platform support center at Kuaishou Technology (快手科技) (listed on the Stock Exchange, stock code: 1024), a content community and social platform that principally provides live streaming services, online marketing services and other services.

Mr. LIU Siyu obtained a bachelor degree in network engineering from the Nanjing University of Posts and Telecommunications (南京郵電大學) in June 2013.

Mr. LIU Siyu is the son-in-law of Mr. KONG and Ms. ZHANG, our executive Directors.

**Ms. PENG Ling (彭玲)**, see “— Supervisors” in this section for details.

**Ms. LU Lu (路露)**, aged 41, joined our Group and was appointed as the manager of administration department of Zhuhai Luzhu in April 2021, and was promoted as the deputy general manager of Zhuhai Luzhu in December 2021. Ms. LU Lu is primarily responsible for the management of administration and human resources of our Group.

Ms. LU Lu has over 14 years of experience in the pharmaceutical industry. Prior to joining our Group, from July 2007 to November 2010, she served as a deputy chief clerk at Food and Drug Administration of Xinxiang City (新鄉市食品藥品監督管理局). In November 2010 to 2017, she joined the Political Consultative Conference Institute of Xinxiang City (新鄉市政協機關), during the period which she has served as the deputy manager of the personnel liaison department, and was later promoted as the manager of the same department in April 2013. From November 2017 to April 2021, she served as a deputy general manager at Zhuhai BesTest Bio-Tech Co., Ltd. (珠海百試通生物科技有限公司), a company principally engaged in production and sales of several types of SPF-grade rodent laboratory animals and provision of pharmacological and pharmacodynamic CRO services, where she was primarily responsible for overall management of personnel and administration of this company.

Ms. LU Lu obtained a bachelor degree in clinical medicine from Medical School of Zhengzhou University (鄭州大學醫學院) in July 2005. She further obtained a master’s degree in pharmacology from Jinan University (暨南大學) in June 2007.

## DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

**Mr. HAN Chaowei (韓朝煒)**, aged 48, joined our Group in October 2020 and has since then served as the deputy general manager of Zhuhai Luzhu. Mr. HAN Chaowei is our head of manufacturing and engineering and is mainly responsible for managing the commercial production and storage of our biological products, including vaccines, monoclonal antibody and bispecific antibody. At the same time, he is responsible for supervising the purchase, construction, installation and maintenance of production facilities, equipment and supporting utility facilities.

Mr. HAN Chaowei has over 23 years of experience in the pharmaceutical industry. Prior to joining our Group, in March 1999, he joined Pfizer Pharmaceuticals Ltd., a company principally engaged in the production of sterile and non-sterile active ingredients, as a chemist. He then served at Pfizer Asia Pacific Pte. Ltd., a company principally engaged in development, manufacturing and marketing of medicines for humans and animals, since October 2001 as a laboratory supervisor. From February 2006 to April 2007, he worked at Livzon Pharmaceutical Group Inc. (麗珠醫藥集團股份有限公司), a pharmaceutical company dually listed on the Stock Exchange (stock code: 1513) and the Shenzhen Stock Exchange (stock code: 000513), which principally engaged in the research and development, production and sales of pharmaceutical products. From July 2007 to July 2010, he served as a quality director at ReLIA Biological Engineering Co., Ltd. (瑞萊生物工程股份有限公司) (formerly known as ReLIA Biological Engineering (Shenzhen) Co., Ltd. (瑞萊生物工程(深圳)有限公司), a company principally engaged in the production of diagnostic reagent and medical equipment, where he was primarily responsible for quality management. From May 2010, he served as a quality manager at Shanghai Baxter Healthcare Co., Ltd. (上海百特醫療用品有限公司), a company principally engaged in the production of sterile injection (soft bag packaging), where he was primarily responsible for quality management of factories. In 2011, he served as a deputy general manager of operation at ReLIA Biotechnology Jiangsu Co., Ltd. (瑞萊生物科技江蘇有限公司) (formerly known as ReLIA Biotechnology (Jiangsu) Co., Ltd. (瑞萊生物科技(江蘇)有限公司), a company principally engaged in the production of diagnostic reagent and medical equipment, where he was primarily responsible for the construction and overall operation of factories in Jiangsu. From September 2016 to May 2020, he served as a vice president at Shenzhen Cheerland Biomedicine Investment Co., Ltd. (深圳市樂土生命科技投資有限公司), a company principally engaged in biomedicine and project investment.

Mr. HAN Chaowei obtained a bachelor degree in applied chemistry from Northeastern University (東北大學) in July 1997.

**Ms. JIANG Lijuan (蔣莉娟)**, aged 56, joined our Group in December 2021 and has since served as the deputy general manager of Zhuhai Luzhu. Ms. JIANG Lijuan is primarily responsible for quality management of the pharmaceutical manufacturing of our Group.

Ms. JIANG Lijuan has over 33 years of experience in the pharmaceutical industry. Prior to joining our Group, from July 1989 to July 2002, she served as a deputy director of new product development department at Xinyu Pharmaceutical Co., Ltd. (新宇藥業股份有限公司) (formerly known as Anhui Wanbei Pharmaceutical Co., Ltd. (安徽省皖北藥業股份有限公司), a company principally engaged in pharmaceutical manufacturing, where she was primarily responsible for pharmaceutical research and development. From August 2002 to December 2016, she served as a deputy chief engineer at Guangzhou Baiyunshan Xingqun (Pharmaceutical) Co., Ltd. (廣州白雲山星群(藥業)股份有限公司), a company principally engaged in pharmaceutical manufacturing and dually listed on the Stock Exchange (stock code: 0874) and the Shanghai Stock Exchange (stock code: 600332), where she was primarily responsible for pharmaceutical research and development and quality management of pharmaceutical manufacturing. In January 2017, she joined Hainan Hualon Pharmaceutical Co., Ltd. (海南皇隆製藥股份有限公司), a

## DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

company principally engaged in pharmaceutical manufacturing and quoted on the National Equities Exchange and Quotations (stock code: 834298), as a chief engineer where she was primarily responsible for management of pharmaceutical manufacturing and management of equipment. From October 2018 to March 2020, she served as a deputy general manager at Zhuhai Ebang Pharmaceutical Co., Ltd. (珠海億邦製藥有限責任公司) (formerly known as Zhuhai Ebang Pharmaceutical Stock Co., Ltd. (珠海億邦製藥股份有限公司), a company principally engaged in pharmaceutical manufacturing, where she was primarily responsible for pharmaceutical research and development and management of pharmaceutical manufacturing. Subsequently, she joined Guangzhou Lixin Pharmaceuticals Co., Ltd. (廣州市力鑫藥業有限公司), a company principally engaged in pharmaceutical research and development and pharmaceutical manufacturing, as a deputy general manager where she was primarily responsible for pharmaceutical research and development and quality management of pharmaceutical manufacturing, and was later also appointed as the responsible officer of quality management of such company in October 2020, until November 2021. Ms. JIANG Lijuan was appointed as a member of the 10th Professional Committee of Pharmaceutical Engineering of Guangdong Pharmaceutical Association (廣東省藥學會第十屆製藥工程專業委員會委員) and a specially-appointed expert for Guangzhou Biopharmaceutical Innovation Technology Association (廣州市生物醫藥創新技術協會特聘專家) in May 2021 and December 2021, respectively.

Ms. JIANG Lijuan obtained a bachelor degree in chemistry from Anhui University (安徽大學) in June 1989. She further obtained a master degree in medicinal chemistry from China Pharmaceutical University (中國藥科大學) in June 2002. Ms. JIANG Lijuan obtained a qualification as a senior pharmaceutical engineer by Guangdong Provincial Personnel Department (廣東省人事廳) in December 2001.

Save as disclosed above, each member of our senior management confirms with respect to himself/herself that he/she has not held any directorship in the last three years in any public companies, the securities of which are listed on any securities market in Hong Kong or overseas.

### JOINT COMPANY SECRETARIES

**Mr. LIU Siyu (劉斯宇)** joined our Company on September 1, 2021 and serves as a joint company secretary of our Company. He was appointed as the joint company secretary of our Company on June 18, 2022. For further biographic details of Mr. LIU Siyu, see “— Senior Management” in this section.

**Ms. YUEN Wing Yan, Winnie (袁穎欣)**, joined our Company and was appointed as the joint company secretary of our Company on 16 December 2022. She is a director of corporate services of Tricor Services Limited and she has been providing professional corporate services to various Hong Kong listed companies as well as multinational, private and offshore companies. Ms. YUEN Wing Yan, Winnie has over 25 years of experience in the corporate secretarial field, and she is currently the company secretary or joint company secretary of a number of listed companies on the Stock Exchange.

Ms. YUEN Wing Yan, Winnie is a Chartered Secretary, a Chartered Governance Professional and a fellow of both The Hong Kong Chartered Governance Institute (HKCGI) (formerly known as The Hong Kong Institute of Chartered Secretaries) and The Chartered Governance Institute (CGI) (formerly known as The Institute of Chartered Secretaries and Administrators) in the United Kingdom.

Ms. YUEN Wing Yan, Winnie is not an employee of our Company but will coordinate with Mr. LIU Siyu, the other joint company secretary, in discharging their duties as the joint company secretaries of our Company.

## DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

---

### BOARD COMMITTEES

Our Board delegates certain responsibilities to various committees. In accordance with the Corporate Governance Code set forth in Appendix 14 to the Listing Rules (the “**Corporate Governance Code**”), our Company has formed three Board committees, namely the Audit Committee, the Nomination Committee and the Remuneration Committee.

#### **Audit Committee**

Our Company has established an Audit Committee with written terms of reference in compliance with Rule 3.21 of the Listing Rules and paragraph D.3 of the Corporate Governance Code. The Audit Committee consists of three members, namely Ms. HOU Aijun, Mr. KONG Shuangquan and Mr. LEUNG Wai Yip, with Ms. HOU Aijun being the chairlady of the committee and Mr. LEUNG Wai Yip possessing the appropriate accounting or related financial management expertise in compliance with the requirements under Rules 3.10(2) and 3.21 of the Listing Rules. The main duties of the Audit Committee include but are not limited to:

- monitoring and evaluating the work of the external auditor;
- supervising the implementation of the internal audit system of our Company;
- being responsible for the communications among the management level of the company, the internal and external audit;
- reviewing and commenting on the financial reports of our Company;
- examining the financial reporting system, risk management and internal control systems of our Company;
- making recommendations to our Company on the appointment, reappointment and removal of the external auditor;
- performing daily management duties and implementing control on connected transactions; and
- performing such other duties determined by our Board.

#### **Remuneration Committee**

Our Company has established a remuneration committee with written terms of reference in compliance with Rule 3.25 of the Listing Rules and paragraph E.1 of the Corporate Governance Code. The Remuneration Committee consists of three members, namely Mr. LIANG Yeshe, Mr. KONG Jian, and Mr. LEUNG Wai Yip, with Mr. LIANG Yeshe being the chairman of the committee. The main duties of the Remuneration Committee include but are not limited to:

- formulating remuneration policies for Directors and senior management in accordance with the respective scope, responsibilities and significance of Directors and senior management and remuneration levels of similar positions in other enterprises within the same industry;

## DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

---

- making recommendations to our Board on the establishment of a formal and transparent procedure for developing remuneration policies;
- monitoring the implementation of remuneration system of our Company for the Directors and senior management;
- assessing the fulfillment of duties of Directors and senior management of our Group and appraising their annual performance; determining or making recommendations to our Board, with delegated responsibility, the remuneration packages of individual Directors and senior management;
- reviewing and approving compensation payable to Directors and senior management for any loss or termination of office or appointment to ensure that it is consistent with contractual terms and is otherwise fair and not excessive;
- reviewing and managing the employee incentive scheme(s) of our Company, including determining the scope of the eligible participants and conditions of a grant and auditing the exercise conditions; and
- performing such other duties determined by our Board.

### **Nomination Committee**

Our Company has established a nomination committee with written terms of reference in compliance with paragraph B.3 of the Corporate Governance Code. The Nomination Committee consists of three members, namely Mr. KONG Jian, Mr. LIANG Yeshe and Ms. HOU Aijun, with Mr. KONG Jian being the chairman of the committee. The main duties of the Nomination Committee include but are not limited to:

- making recommendation to our Board on its size and composition to complement the Company’s business operation and shareholding structure;
- reviewing and making recommendations to the selection standard and procedure of Directors and senior management;
- identifying individuals suitably qualified to become Directors and senior management and selecting or making recommendations to the board on the selection of individuals nominated for directorships or senior management positions;
- reviewing the structure, size and composition (including the skills, knowledge and experience) of the Board at least annually and making recommendations on any proposed changes to the Board to complement our Company’s corporate strategy;
- assessing the independence of independent non-executive Directors; and
- performing such other duties determined by our Board.

## DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

---

### CORPORATE GOVERNANCE

#### Deviation From the Corporate Governance Code

Pursuant to code provision C.2.1 of the Corporate Governance Code, companies listed on the Stock Exchange are expected to comply with, but may choose to deviate from the requirement that the responsibilities between the chairman and the chief executive should be segregated and should not be performed by the same individual. Mr. KONG currently serves as both the chairman of the Board and the general manager of our Company. While this will constitute a deviation from Code Provision C.2.1 of the Corporate Governance Code, our Board believes that this structure will not impair the balance of power and authority between our Board and the management of our Company, given that (i) our Board comprises three independent non-executive Directors, and we believe there is sufficient check and balance in our Board to protect the interests of our Group and its Shareholders; (ii) Mr. KONG is also one of the Controlling Shareholders of our Company, our Directors are of the view that vesting both roles on him helps to maintain the continuity of the policies and the stability of the operations of our Company. Our Board will continue to review the effectiveness of the corporate governance structure of our Group in order to assess whether separation of the roles of chairman and general manager is necessary.

#### Board Diversity

Our Company seeks to enhance the effectiveness of our Board and to maintain high standards of corporate governance by adopting a board diversity policy. Pursuant to this policy, we intend to achieve board diversity through the consideration of a number of factors at the selection of candidates to our Board, including but not limited to gender, age, cultural and educational background, ethnicity, professional experience, skills, knowledge and length of service. The ultimate decisions of board appointments will be based on merit and the contribution which the selected candidates will bring to our Board.

Our Board consists of five male members and three female members, with age range from 46 to 72 years old. Our Company has reviewed the membership, structure and composition of the Board, and is of the opinion that the structure of our Board is reasonable, and the experiences and skills of the Directors in various aspects and fields can enable our Company to maintain high standard of operation.

Our Nomination Committee is responsible for reviewing the diversity of our Board. After [REDACTED], our Nomination Committee will continue to monitor and evaluate the implementation of the board diversity policy from time to time to ensure its continued effectiveness and we will disclose in our corporate governance report about the implementation of the board diversity policy, including any measurable objectives set for implementing the board diversity policy and the progress on achieving these objectives on an annual basis. We will also continue to take steps to promote gender diversity at all levels of our Company.

## DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

---

### KEY TERMS OF EMPLOYMENT CONTRACTS

We normally enter into (i) an employment contract, and (ii) a confidentiality and non-competition agreement with our senior management members and other key personnel. Below sets forth the key terms of these contracts we enter into with our senior management and other key personnel.

#### Confidentiality

- *Scope of confidential information.* The employee shall keep our trade secrets and technical secrets confidential. Our trade secrets refer to information that may materially impact our competitive advantage and include but are not limited to customer information, marketing plans, procurement and pricing policies, financial information, and supply channels. Our technical secrets refer to technical information and data, and know-how that are not publicly available, and include but are not limited to biological materials, process design, manufacturing methods, testing reports, as well as any confidential information directly or indirectly provided by our Group or employees.
- *Confidentiality obligation.* The employee shall not disclose, disseminate, report, publish, transmit, transfer or otherwise make available to any third party (including our employees who are not privy to such confidential information) any confidential information of our Group and that of any third party to which we owe confidential obligations. The employee shall exercise reasonable care in observing his or her confidential obligation and shall not remove any confidential information from the premises of our Group and related companies. Upon the cessation of the employee's employment with our Group, or upon our request, the employee must return to our Group all documents, drawings, records, or any other means of record-keeping that contain our confidential information.
- *Confidential period.* The confidentiality obligation shall continue in force indefinitely after the cessation of the employee's employment with our Group, until the confidential information, either, (i) is publicly disclosed by our Group, or (ii) has been rendered public without the employee's breach of obligations stated herein.

#### Ownership of intellectual work products

- *Employee-developed technology.* As to technical inventions, technical secrets or other trade secret information related to our Group's business completed by the employee during his/her term of office, the employee shall promptly make a statement to our Group if he/she claims that he/she shall enjoy the intellectual property rights, and our Group shall then confirm whether they are non-employee-developed technologies. If the employee has any objection to our Group's ownership of the achievements, the dispute can be settled through negotiation and litigation. If the employee fails to make the declaration, it is presumed that the achievements belong to employee-developed technologies, and our Group has the full right to use such achievements for production and operation or transfer them to a third party.

---

## DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

---

### Non-competition terms

- *Non-competition obligation during employment term.* During the term of the employment with our Group, unless with our prior consent, the employee shall not engage in any business or engage in a course of employment that produces, or operates products, or provides services that are the same or similar to those offered by, our Group. The employee shall not assume any positions in, hold any interest in, nor operate on his or another’s behalf, any businesses, entities, or organizations that competes with, supplies or is connected to, or has any other interest in, our Group.
- *Non-competition obligation following termination of employment term.* Within 12-months after termination of the employment relationship between the employee and our Group, the employee shall not be employed or engaged in any forms or enter into any cooperative relationship with any other entity that is in competition with our Group or in the same industry as our Group.

### Compensation for breach

- If the employee breaches the obligations regarding confidentiality and invention assignment, our Group shall be entitled to seek damages for all economic losses arising from the breach; if the employee breaches the non-competition covenants, our Group shall be entitled to a certain liquidated sum determined with reference to the non-competition compensation originally payable to the employee.

## DIRECTORS’ AND SENIOR MANAGEMENT’S REMUNERATION

Our Company offers the executive Directors, Supervisors and members of senior management, who are also employees of our Company, emolument in the form of salaries, allowances, discretionary bonus, benefits in kind and share-based payments. Our independent non-executive Directors receive emolument based on their responsibilities (including being members or the chair of Board committees). We adopt a market and incentive-based employee emolument structure and implement a multi-layered evaluation system which focuses on performance and management goals. We have also adopted an employee incentive scheme for the purpose of attracting and retaining talents for our Group. See “Statutory and General Information — B. Further Information about the Business of our Company — 3. Employee Incentive Scheme” in Appendix VII to this document.

The aggregate amount of remuneration paid or payable to our Directors and Supervisors (including salaries, remuneration, pension, discretionary bonus, share-based payments and other welfares) for the two years ended December 31, 2021 and 2022, were approximately RMB47.6 million, and RMB85.3 million, respectively.

It is estimated that, under the arrangements currently in force, the aggregate amount of remuneration payable by us to our Directors and Supervisors for the year ending December 31, 2023 will be approximately RMB51.8 million (excluding any discretionary bonus but including historical share-based payment expenses).

For the two years ended December 31, 2021 and 2022, the aggregate amount of remuneration paid or payable to the five highest paid individuals of our Group were approximately RMB67.1 million and RMB87.6 million, respectively.



---

## DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

---

During the Track Record Period, no remuneration was paid to, or receivable by, our Directors, Supervisors or the five highest paid individuals of our Group as an inducement to join or upon joining our Group or as a compensation for loss of office in the Track Record Period. Further, none of our Directors had waived any emolument during the same period.

Except as disclosed above, no other payments have been paid, or are payable, by our Company or any of our subsidiaries to our Directors, Supervisors or the five highest paid individuals of our Group during the Track Record Period.

### COMPLIANCE ADVISOR

We have appointed Fosun International Capital Limited as our compliance advisor (the “**Compliance Advisor**”) upon the [REDACTED] of our Shares on the Stock Exchange in compliance with Rule 3A.19 of the Listing Rules. Pursuant to Rule 3A.23 of the Listing Rules, the Compliance Advisor will provide advice when consulted by our Company in relation to the followings:

- the publication of any regulatory announcement, circular or financial report;
- where a transaction, which might be a notifiable or connected transaction, is contemplated including share issues and share repurchases;
- where we procure to use the proceeds from the [REDACTED] in a manner different from that detailed in the document or where its business activities, developments or results deviate from any forecast, estimate, or other information in the document; and
- where the Stock Exchange makes an inquiry to our Company regarding unusual movement in the [REDACTED] or [REDACTED] of the Shares under Rule 13.10 of the Listing Rules.

The term of appointment of the compliance advisor shall commence on the [REDACTED] and is expected to end on the date on which our Company distributes its annual report in respect of our financial results for the first full financial year commencing after the [REDACTED] and this appointment may be subject to extension by mutual agreement.

### COMPETITION

Save as disclosed below, each of our Directors confirms that as of the Latest Practicable Date, he or she did not have any interest in a business which competes or is likely to compete, directly or indirectly, with our business and requires disclosure under Rule 8.10(2) of the Listing Rules.

#### Disclosed interest of Mr. MA Biao

*Beijing Eastern Biotech Co., Ltd.* (北京東方百泰生物科技股份有限公司) (“*Eastern Biotech*”)

Mr. MA Biao currently acts as a director of Eastern Biotech, a limited liability company established in the PRC and principally engaged in the R&D and production of innovative antibody and macromolecular protein drugs, where he is an investor board representative of Beijing Yizhuang, primarily responsible for providing opinion and judgment to the board. As of the Latest Practicable Date, Eastern Biotech was owned as to approximately 3.03% by Beijing Yizhuang. The clinical stage product

---

## DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

---

candidates of Eastern Biotech include (i) an anti-tumor necrosis factor (“TNF”)- $\alpha$  monoclonal antibody (the “**Eastern Biotech TNF- $\alpha$  Candidate**”); and (ii) an anti-vascular endothelial growth factor (“VEGF”) monoclonal antibody and an anti-VEGF receptor two antibody (together the “**Eastern Biotech VEGF Candidates**”), which are primarily for the treatment of colorectal cancer and lung cancer.

As the Eastern Biotech TNF- $\alpha$  Candidate is an anti-TNF- $\alpha$  monoclonal antibody, it might directly or indirectly compete with our anti-TNF- $\alpha$  monoclonal antibody injection candidate, K3. That said, the Eastern Biotech TNF- $\alpha$  Candidate is only one of the clinical stage product candidates developing by Eastern Biotech. According to the information provided by Eastern Biotech, (i) its research and development efforts primarily pertain to the treatment of oncology condition, diabetes, ophthalmology and respiratory diseases, with Nimotuzumab Injection (a monoclonal antibody targeting stage III / IV nasopharyngeal carcinoma with epidermal growth factor receptor expressions) as the core launched product of its subsidiary, Eastern Biotech Pharmaceutical Co., Ltd. (百泰生物藥業有限公司); and (ii) out of the clinical stage product candidates in its development pipeline, the Eastern Biotech TNF- $\alpha$  Candidate is the only product candidate for the treatment of autoimmune diseases.

As regards the Eastern Biotech VEGF Candidates, as we already transferred all assets and intellectual property rights in and to K11 (a humanized anti-VEGF monoclonal antibody injection product candidate) to Beijing Science Sun and only retained a right to royalty payment therefrom, and that the Eastern Biotech VEGF Candidates differ from our product candidates (including K193) in terms of, among others, mechanism of action and technology used in R&D and manufacturing, our Directors do not consider the Eastern Biotech VEGF Candidates to be in any direct or indirect competition with our product candidates.

Our Directors believe that we are capable of performing our business independently of, and at arm’s length from Eastern Biotech based on the following grounds:

- (i) Mr. MA Biao is only one of our non-executive Directors, and is not and will not be involved in the daily management and operation of both our Company (as a non-executive Director and a Board representative of Beijing Science Sun) and Eastern Biotech (as an investor board representative). Further, other than Mr. MA Biao, our Directors and members of our senior management do not hold any position in Eastern Biotech;
- (ii) we have appointed three independent non-executive Directors, comprising over one-third of our Board in order to promote the interests of our Company and our Shareholders as a whole;
- (iii) each of our Directors (including Mr. MA Biao) is aware of his/her fiduciary duties and responsibilities under the Listing Rules as a director, which require that he/she acts in the best interests of our Company and our Shareholders as a whole;
- (iv) Eastern Biotech’s research and development efforts primarily pertain to product candidates for the treatment of oncology condition, diabetes, ophthalmology and respiratory diseases. As discussed above, the Eastern Biotech TNF- $\alpha$  Candidate is only one of the product candidates being developed by Eastern Biotech, and out of the clinical stage product candidate of Eastern Biotech, it is the only product candidate for the treatment of autoimmune diseases. As such, our Directors consider that Eastern Biotech and our Company have different research and development focus areas that do not materially overlap with each other; and

---

## DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

---

- (v) our Company has established relevant corporate governance measures to avoid conflicts of interest between our Group and any Director, such as a Director shall abstain from voting and shall not be counted towards the quorum for voting on any matters which he/she might be in conflict of interest.

### *Beijing Science Sun*

Mr. MA Biao is the Actual Controller of Beijing Science Sun and held approximately 49.51% of the issued shares of Beijing Science Sun as of the Latest Practicable Date. Beijing Science Sun (being one of our [REDACTED] Investors) is a company listed on the ChiNext board of the Shenzhen Stock Exchange (stock code: 300485), and together with its subsidiaries (collectively, the “**Beijing Science Sun Group**”) are principally engaged in the research, manufacture and sales of biological and biochemical pharmaceuticals. Whilst the pharmaceutical products of the Beijing Science Sun Group include immunomodulatory drugs, insofar as tumor and autoimmune diseases are concerned, such immunomodulatory drugs can only be used for adjuvant therapy rather than direct treatment, and hence are fundamentally different from and not interchangeable with our product candidates, which are vaccines and antibody solutions for the prevention and treatment of tumor and autoimmune diseases (as applicable). On top of the above, for the investment entities of Beijing Science Sun Group of which the Beijing Science Sun Group was a substantial shareholder or a partner as of the Latest Practicable Date, such investment entities (other than our Group) do not engage in any business that materially compete or might materially compete with the principal businesses of our Group. The businesses carried out by such investment entities include, among others, venture capital investment, hemostatic biologics, trading of medical equipment and provision of protein-based biologics services, which are of different nature from that of our principal businesses. Accordingly, our Directors consider that Mr. MA Biao’s interest in Beijing Science Sun would not give rise to any material competition issue under Rule 8.10(2) of the Listing Rules.

Notwithstanding the above, the following measures are also in place to avoid any potential material competition issue between our Group and Mr. MA Biao’s interests in Beijing Science Sun under Rule 8.10(2) of the Listing Rules going forward:

- (i) Mr. MA Biao, being a non-executive Director, is not and will not be involved in the daily management and operation of our Company. As a non-executive Director, Mr. MA Biao will only be given information of our Group, such as our business development progress and financial and operational information, on an as-needed basis in his capacity as a non-executive Director;
- (ii) Mr. MA Biao is also subject to confidentiality obligation. He is not entitled to disclose, disseminate, report, publish, transmit, transfer or otherwise make available to any third party any confidential information of our Group, including our development strategies to be implemented, as well as financial and operational information that is not publicly available;
- (iii) where a Board meeting is to be held for considering matters in which a Director might have a conflict of interest, such Director shall abstain from voting and shall not be counted towards the quorum;

## DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

---

- (iv) we have appointed three independent non-executive Directors, comprising over one-third of our Board in order to promote the interests of our Company and our Shareholders as a whole. Where necessary, our independent non-executive Directors may engage professional advisors at our costs for advice on matters relating to any potential conflict of interest of our Directors; and
- (v) each of our Directors (including Mr. MA Biao) has attended the trainings provided by our Hong Kong legal advisers and is aware of his/her fiduciary duties and responsibilities under the Listing Rules as a director, which require that he/she acts in the best interests of our Company and our Shareholders as a whole. After the [REDACTED], our Directors will also endeavour to attend trainings as may be organized by our Hong Kong legal advisers or other professional bodies from time to time, so as to consolidate their understanding of the duties and responsibilities as a director of a [REDACTED] issuer.

Our Directors consider that the above measures are sufficient for the purpose of avoiding any potential material competition between our Group and Mr. MA Biao’s interests in Beijing Science Sun under Rule 8.10(2) of the Listing Rules.

### *E-town Sun*

As disclosed in “History, Development and Corporate Structure — [REDACTED] Investments — Background of the [REDACTED] Investors — 1. Beijing Yizhuang” in this document, Mr. MA Biao is regarded by Beijing Science Sun as the Actual Controller of E-town Sun. E-town Sun is primarily engaged in investment holding and investment fund managing, and in turn is the general partner and/or fund manager of a number of investment funds including Beijing Yizhuang and Beijing Yizhuang II (both being our [REDACTED] Investors). For the investment entities of E-town Sun (whether by itself or through the funds managed or controlled by it in its capacity as general partner) of which E-town Sun was a substantial shareholder or a partner as of the Latest Practicable Date, such investment entities (other than our Group) do not engage in any business that materially compete or might materially compete with the principal businesses of our Group. The businesses carried out by such investment entities include, among others, venture capital investment, gene therapy viral vector platform contract development and manufacturing, cardiovascular drug development and agricultural fertilizer, which are of different nature from that of our principal businesses. Further, in general E-town Sun is not involved in the daily operation and management of such investment entities. Accordingly, our Directors consider that Mr. MA Biao’s interest in E-town Sun would not give rise to any material competition issue under Rule 8.10(2) of the Listing Rules.

From time to time our non-executive Directors may serve on the boards of both private and public companies within the broader healthcare and biopharmaceutical industries. However, as these non-executive Directors are neither our Controlling Shareholders nor members of our executive management team, we do not believe that their interests in such companies as directors would render us incapable of carrying on our business independently from the other companies in which they may hold directorships from time to time.

## FINANCIAL INFORMATION

*You should read the following discussion and analysis in conjunction with our consolidated financial statements included in “Appendix I — Accountants’ Report” to this document, together with the accompanying notes. Our consolidated financial information has been prepared in accordance with IFRSs, which may differ in material aspects from generally accepted accounting principles in other jurisdictions. You should read the entire Accountants’ Report and not merely rely on the information contained in this section.*

*The following discussion and analysis contain forward-looking statements that reflect the current views with respect to future events and financial performance. These statements are based on assumptions and analysis made by us in light of our experience and perception of historical trends, current conditions and expected future developments, as well as other factors that we believe are appropriate under the circumstances. However, whether the actual outcome and developments will meet our expectations and predictions depends on a number of risks and uncertainties over which we do not have control. For details, please see “Forward-looking Statements” and “Risk Factors” in this document.*

### OVERVIEW

We are a biotechnology company committed to developing innovative human vaccines and therapeutic biologics to prevent and control infectious diseases and treat cancer and autoimmune diseases. Since our inception in 2001, we have focused on human medicine with our understanding of immunology and protein engineering and have established a comprehensive and advanced product pipeline covering human vaccine candidates, monoclonal antibody product candidates and bispecific antibody product candidates:

- Our independently developed recombinant herpes zoster vaccine candidate, LZ901 has a tetrameric molecular structure, and has demonstrated favorable immunogenicity, efficacy and safety profile in pre-clinical studies, while inducing strong specific humoral and cellular immunity.
- Our independently developed recombinant human anti-tumor necrosis factor (“TNF”)- $\alpha$  monoclonal antibody injection product candidate, K3, mainly used for the treatment of various autoimmune diseases, such as rheumatoid arthritis, ankylosing spondylitis and psoriasis, is a biosimilar of Humira<sup>®</sup> (adalimumab). In our Phase I clinical trial in China, K3 displayed pharmacokinetics consistent with adalimumab.
- Our independently developed bispecific antibody injection (CD19-CD3) product candidate for the treatment of B cell leukemia and lymphoma, K193, is a bispecific antibody with an asymmetric structure. In our pre-clinical studies, K193 displayed high *in vivo* and *in vitro* anti-tumor activity, and its optimized formulation is stable and convenient to use. K193’s unique mechanism of action endows it with a strong ability to treat various types of B cell lymphomas. The safe and controllable administration of K193 also reduces the impact of patient stress caused by medication administration.

## FINANCIAL INFORMATION

---

During the Track Record Period, we had loss and total comprehensive expense of RMB539.4 million and RMB725.2 million in 2021 and 2022, respectively. Substantially all of our loss and total comprehensive expense resulted from research and development expenses, administrative expenses and fair value losses on financial liabilities at FVTPL.

We expect to incur an increased amount of operating expenses, including increasing research and development expenses and administrative expenses, for at least the next several years as we conduct further pre-clinical research, continue the clinical development of, seek regulatory approval for and manufacturing of, our product candidates, launch and promote our pipeline products, and add personnel necessary to operate our business. Subsequent to the [REDACTED], we expect to incur costs associated with operating as a [REDACTED] company. We expect that our financial performance will fluctuate from period to period affected by the development status of our product candidates, regulatory approval timeline and commercialization of our product candidates after approval.

### BASIS OF PREPARATION

Our Company was established in Beijing, the PRC on November 9, 2001 as a limited liability company. Our Company was converted to a joint stock company with limited liability on July 19, 2013. For details, please see the paragraph headed “History, Development and Corporate Structure — Our Corporate Development” in this document.

The historical financial information has been prepared in accordance with accounting policies set out in Note 3.2 to the Accountants’ Report in Appendix I to this document, which conform with IFRSs issued by IASB. In addition, the historical financial information included applicable disclosures required by the Listing Rules and by the Hong Kong Companies Ordinance.

The historical financial information has been prepared on the historical cost basis except for certain financial instruments that are measured at fair values at the end of each reporting period. Historical cost is generally based on the fair value of the consideration given in exchange for goods and services.

Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date, regardless of whether that price is directly observable or estimated using another valuation technique. In estimating the fair value of an asset or a liability, we takes into account the characteristics of the asset or liability if market participants would take those characteristics into account when pricing the asset or liability at the measurement date. Fair value for measurement and/or disclosure purposes in the historical financial information is determined on such a basis, except for share-based payment transactions that are within the scope of IFRS 2 Share-based Payment, leasing transactions that are within the scope of IFRS 16 Leases, and measurements that have some similarities to fair value but are not fair value, such as net realizable value in IAS 2 Inventories or value in use in IAS 36 Impairment of Assets.

For financial instruments which are transacted at fair value and a valuation technique that unobservable inputs are to be used to measure fair value in subsequent periods, the valuation technique is calibrated so that at initial recognition the results of the valuation technique equals the transaction price.

## FINANCIAL INFORMATION

---

In addition, for financial reporting purposes, fair value measurements are categorized into Level 1, 2 or 3 based on the degree to which the inputs to the fair value measurements are observable and the significance of the inputs to the fair value measurement in its entirety, which are described as follows:

- Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities that the entity can access at the measurement date;
- Level 2 inputs are inputs, other than quoted prices included within Level 1, that are observable for the asset or liability, either directly or indirectly; and
- Level 3 inputs are unobservable inputs for the asset or liability.

## SIGNIFICANT FACTORS AFFECTING OUR RESULTS OF OPERATIONS

### Growth of China’s Vaccine Market

Our business expansion and revenue growth depend on the growth of the overall vaccine market in the PRC. Favorable government policies, technological advancement and increasing awareness and affordability of vaccination have driven the growth of the PRC vaccine industry. According to Frost & Sullivan, the vaccine market size in China is expected to increase from RMB92.6 billion in 2021 to RMB189.2 billion in 2025 with a CAGR of 19.5% from 2021 to 2025. The market is estimated to further rise to RMB301.9 billion in 2030 with a CAGR of 9.8% from 2025 to 2030. See “Industry Overview” in this document for the market size of the PRC vaccine market in general and for the markets of our vaccine product candidates.

In addition to the overall growth of the PRC vaccine market, we have benefited from and expect to continue to benefit from favorable industry trends such as public awareness and acceptance of vaccination in the wake of the COVID-19 pandemic outbreak. Furthermore, the growth of aging population has also contributed to and are expected to continue to contribute to the overall increase in the demand for vaccines. We believe we are well positioned to benefit from market opportunities in the fast-growing PRC vaccine industry and expect our results of operations to continue to improve in the future. For details, please see “Industry Overview” in this document.

### Our Ability to Successfully Develop and Commercialize Our Product Candidates

Our business and results of operations will be dependent on our receipt of regulatory approval for and successful commercialization of our product candidates. As of the Latest Practicable Date, we had established a comprehensive and advanced product pipeline covering human vaccine candidates, monoclonal antibody product candidates and bispecific antibody product candidates. As of the Latest Practicable Date, we had initiated a number of clinical trials for our product candidate, and we expect to initiate additional clinical trials in the future. For LZ901, our Core Product, we have initiated a Phase I clinical trial in January 2022 and completed the Phase I clinical trial and initiated a Phase II clinical trial in China in April 2022. We expect to complete the Phase II clinical trial in the second quarter of 2023, initiate a Phase III clinical trial in the second quarter of 2023, and file the BLA in the third quarter of 2024 for LZ901 to the NMPA. In addition, we have received IND approval from the FDA in July 2022 for LZ901 and initiated a Phase I clinical trial in the U.S. in February 2023. We plan to complete the Phase I clinical trial and initiate a Phase II clinical trial in the first quarter of 2024. Furthermore, we expect to complete the Phase II clinical trial in the second quarter of 2025, initiate a Phase III clinical trial in the fourth quarter of 2025, and complete the Phase III clinical trial in the second quarter of 2027.

## FINANCIAL INFORMATION

---

For K3, a biosimilar of adalimumab, we initiated our Phase I clinical trial in September 2018, and completed Phase I clinical trial in China in December 2019, which displayed pharmacokinetics consistent with adalimumab. We plan to initiate a Phase III clinical trial for K3 in the second quarter of 2023 and submit the BLA to the NMPA in the fourth quarter of 2024. We expect K3 to receive BLA approval from the NMPA in 2025. Please see “Business — Our Products and Product Candidates — Our Core Product and Clinical-Stage Product Candidates” in this document for more information on the development status of our product candidates.

Once our product candidates are commercialized, our business and results of operations will be driven by the market acceptance and supply of our commercialized products. To achieve successful launch of our product candidates, we intend to continue advancing clinical trials and registration of our pipeline, and our product commercialization process. For more details, see “Business — Our Strategies” in this document.

### Cost Structure

Our results of operations are significantly affected by our cost structure, which primarily consisted of research and development expenses and administrative expenses during the Track Record Period.

Research and development activities are crucial to our business. Our research and development expenses amounted to RMB43.0 million and RMB91.4 million in 2021 and 2022, respectively. Our research and development expenses primarily consisted of staff costs, including salaries, welfare and share-based payments to our research and development personnel, third-party contracting costs, costs of raw materials and depreciation and amortization. We expect our research and development expenses to increase significantly in the foreseeable future, as we initiate clinical trials for our pre-clinical product candidates and progress ongoing clinical trials into later stages

Our administrative expenses primarily consisted of staff costs, mainly including salaries, welfare and share-based payments to our administrative staff, depreciation and amortization, and others primarily representing office and utilities expenses, transportation and travel expenses, tax and surcharges and other miscellaneous administrative expenses. Our administrative expenses amounted to RMB60.2 million and RMB85.8 million in 2021 and 2022, respectively. We expect our administrative expenses to increase in the future to support our business expansion. We also anticipate increasing legal, compliance, accounting and investor relations expenses associated with being a [REDACTED] company. We also anticipate incurring selling expenses once we commercialize our product candidates.

### Funding for Our Operations

During the Track Record Period, we funded our operations primarily through capital contributions from our shareholders and equity financing. Going forward, with the continuing expansion of our business and our product pipeline, we may require further funding from our existing shareholders, through public or private [REDACTED], debt financing, collaborations and licensing arrangements or other sources. In the event of successful commercialization of one or more of our product candidates, we expect to fund our operations in part with revenue generated from sales of our products. Any fluctuation in our ability to fund our operations will impact our cash flow and our results of operations.



## FINANCIAL INFORMATION

---

### SIGNIFICANT ACCOUNTING POLICIES AND ESTIMATES

We have identified certain accounting policies that are significant to the preparation of our consolidated financial statements. Some of our accounting policies involve subjective assumptions and estimates, as well as complex judgments relating to accounting items. Estimates and judgments are continually re-evaluated and are based on historical experience and other factors, including industry practices and expectations of future events that we believe to be reasonable under the circumstances. We have not changed our assumptions or estimates in the past and have not noticed any material errors regarding our assumptions or estimates. Under current circumstances, we do not expect that our assumptions or estimates are likely to change significantly in the future. When reviewing our consolidated financial statements, you should consider (i) our critical accounting policies, (ii) the judgments and other uncertainties affecting the application of such policies, and (iii) the sensitivity of reported results to changes in conditions and assumptions.

#### Significant Accounting Policies

##### *Revenue from Contracts with Customers*

We recognize revenue when (or as) a performance obligation is satisfied, i.e. when “control” of the goods or services underlying the particular performance obligation is transferred to customers. A performance obligation represents a good and service (or a bundle of goods or services) that is distinct or a series of distinct goods or services that are substantially the same. Control is transferred over time and the revenue is recognized over time by reference to the progress towards complete satisfaction of the relevant performance obligation if one of the following criteria is met:

- The customer simultaneously receives and consumes the benefits provided by our Group’s performance as our Group performs;
- Our Group’s performance creates or enhances an asset that the customer controls as our Group performs; or
- Our Group’s performance does not create an asset with an alternative use to our Group and our Group has an enforceable right to payment for performance completed to date.

Otherwise, revenue is recognized at a point in time when the customer obtains control of the distinct good or service. A contract liability represents our Group’s obligation to transfer goods or services to a customer for which our Group has received consideration (or an amount of consideration is due) from the customer.

##### *Share-Based Payments*

Equity-settled share-based payments to employees are measured at the fair value of the equity instruments at the grant date.

The fair value of the equity-settled share-based payments determined at the grant date without taking into consideration all non-market vesting conditions is expensed on a straight-line basis over the vesting period, based on our Group’s estimate of equity instruments that will eventually vest, with a corresponding increase in equity (share-based payments reserve). At the end of each reporting period, our

## FINANCIAL INFORMATION

---

Group revises our estimate of the number of equity instruments expected to vest based on assessment of all relevant non-market vesting conditions. The impact of the revision of the original estimates, if any, is recognized in profit or loss such that the cumulative expense reflects the revised estimate, with a corresponding adjustment to the share-based payments reserve. For shares/share options that vest immediately at the date of grant, the fair value of the shares/share options granted is expensed immediately to profit or loss.

When share options are exercised, the amount previously recognized in share option reserve will be transferred to share premium. When the share options are forfeited after the vesting date or are still not exercised at the expiry date, the amount previously recognized in share option reserve will continue to be held in share-based payments reserve.

When shares granted are vested, the amount previously recognized in share-based payments reserve will be transferred to share premium.

When the terms and conditions of an equity-settled share-based payment arrangement are modified, the Group recognizes, as a minimum, the services received measured at the grant date fair value of the equity instruments granted, unless those equity instruments do not vest because of failure to satisfy a vesting condition (other than a market condition) that was specified at grant date. In addition, if the Group modifies the vesting conditions (other than a market condition) in a manner that is beneficial to the employees, for example, by reducing the vesting period, the Group takes the modified vesting conditions into consideration over the remaining vesting period.

The incremental fair value granted, if any, is the difference between the fair value of the modified equity instruments and that of the original equity instruments, both estimated as at the date of modification.

If the modification occurs during the vesting period, the incremental fair value granted is included in the measurement of the amount recognized for services received over the period from modification date until the date when the modified equity instruments are vested, in addition to the amount based on the grant date fair value of the original equity instruments, which is recognized over the remainder of the original vesting period.

If the modification reduces the total fair value of the share-based arrangement, or is not otherwise beneficial to the employee, the Group continues to account for the original equity instruments granted as if that modification had not occurred.

### ***Property, Plant and Equipment***

Property, plant and equipment are tangible assets that are held for use in the production or supply of goods or services, or for administrative purposes. Property, plant and equipment (other than construction in progress), are stated in the consolidated statements of financial position at cost, less subsequent accumulated depreciation and subsequent accumulated impairment losses, if any.

## FINANCIAL INFORMATION

---

Property, plant and equipment in the course of construction for production, supply or administrative purposes are carried at cost, less any recognized impairment loss. Costs include any costs directly attributable to bringing the asset to the location and condition necessary for it to be capable of operating in the manner intended by management and, for qualifying assets, borrowing costs capitalized, in accordance with the Group's accounting policy. Depreciation of these assets, on the same basis as other property, plant and equipment, commences when the assets are ready for their intended use.

When our Group makes payments for ownership interests of properties which includes both leasehold land and building elements, the entire consideration is allocated between the leasehold land and the building elements in proportion to the relative fair values at initial recognition. To the extent the allocation of the relevant payments can be made reliably, interest in leasehold land is presented as "right-of-use assets" in the consolidated statements of financial position. When the consideration cannot be allocated reliably between non-lease building element and undivided interest in the underlying leasehold land, the entire properties are classified as property, plant and equipment.

Depreciation is recognized so as to write off the cost of items of property, plant and equipment, other than construction in progress less their residual values over their estimated useful lives, using the straight-line method. The estimated useful lives, residual values and depreciation method are reviewed at the end of each reporting period, with the effect of any changes in estimate accounted for on a prospective basis.

An item of property, plant and equipment is derecognized upon disposal or when no future economic benefits are expected to arise from the continued use of the asset. Any gain or loss arising on the disposal or retirement of an item of property, plant and equipment is determined as the difference between the sales proceeds and the carrying amount of the asset and is recognized in profit or loss.

### ***Intangible asset***

#### *Intangible assets acquired separately*

Intangible assets with finite useful lives that are acquired separately are carried at costs less accumulated amortization and any accumulated impairment losses. Variable payments that are dependent on the Group's future activity are excluded from the initial measurement of intangible assets and instead are recognized as a liability when the condition that triggers the obligation occurs. The subsequent changes in the liability are recognized as an adjustment to the cost of the intangible assets if it is determined that the future payment is related to the cost of the assets or otherwise recognized as an expense in the period in which they are incurred.

Amortization for intangible assets with finite useful lives is recognized on a straight-line basis over their estimated useful lives. The estimated useful life and amortization method are reviewed at the end of each reporting period, with the effect of any changes in estimate being accounted for on a prospective basis.

## FINANCIAL INFORMATION

---

### *Research and Development Expenditure*

Expenditure on research activities is recognized as an expense in the period in which it is incurred. An internally-generated intangible asset arising from development activities (or from the development phase of an internal project) is recognized if, and only if, all of the following have been demonstrated:

- the technical feasibility of completing the intangible asset so that it will be available for use or sale;
- the intention to complete the intangible asset and use or sell it;
- the ability to use or sell the intangible asset;
- how the intangible asset will generate probable future economic benefits;
- the availability of adequate technical, financial and other resources to complete the development and to use or sell the intangible asset; and
- the ability to measure reliably the expenditure attributable to the intangible asset during its development.

The amount initially recognized for internally-generated intangible asset is the sum of the expenditure incurred from the date when the intangible asset first meets the recognition criteria listed above. Where no internally generated intangible asset can be recognized, development expenditure is recognized in profit or loss in the period in which it is incurred.

### *Financial Asset at FVTPL*

Financial assets that do not meet the criteria for being measured at amortized cost are measured at FVTPL. Financial assets at FVTPL are measured at fair value at the end of each reporting period, with any fair value gains or losses recognized in profit or loss. The net gain or loss recognized in profit or loss includes any interest earned on the financial asset and is included in the “other gains and losses, net” line item.

### *Financial Liabilities at FVTPL*

Financial liabilities are classified as at FVTPL when the financial liability is (i) contingent consideration of an acquirer in a business combination to which IFRS 3 Business Combinations applies, (ii) held for trading or (iii) designated as at FVTPL.

A financial liability other than a financial liability held for trading or contingent consideration of an acquirer in a business combination may be designated as at FVTPL upon initial recognition if:

- such designation eliminates or significantly reduces a measurement or recognition inconsistency that would otherwise arise; or

## FINANCIAL INFORMATION

---

- the financial liability forms part of a group of financial assets or financial liabilities or both, which is managed and its performance is evaluated on a fair value basis, in accordance with the Group's documented risk management or investment strategy, and information about the grouping is provided internally on that basis; or
- it forms part of a contract containing one or more embedded derivatives, and IFRS 9 permits the entire combined contract to be designated as at FVTPL.

For financial liabilities that are designated as at FVTPL, the amount of change in the fair value of the financial liability that is attributable to changes in the credit risk of that liability is recognized in other comprehensive income, unless the recognition of the effects of changes in the liability's credit risk in other comprehensive income would create or enlarge an accounting mismatch in profit or loss. Changes in fair value attributable to a financial liability's credit risk that are recognized in other comprehensive income are not subsequently reclassified to profit or loss; instead, they are transferred to accumulated losses upon derecognition of the financial liability.

### **Critical Accounting Judgments and Key Sources of Estimation Uncertainties**

In the application of the Group's accounting policies, which are described in Note 3 to the Accountants' Report in Appendix I to this document, our Directors are required to make judgments, estimates and assumptions about the carrying amounts of assets and liabilities that are not readily apparent from other sources. The estimates and associated assumptions are based on historical experience and other factors that are considered to be relevant. Actual results may differ from these estimates.

The estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognized in the period in which the estimate is revised if the revision affects only that period, or in the period of the revision and future periods if the revision affects both current and future periods.

### ***Research and development expenditures***

Development costs incurred on the Group's vaccines and therapeutic biologics pipelines are capitalized and deferred only when the Group can demonstrate the technical feasibility of completing the intangible asset so that it will be available for use or sale, the Group's intention to complete and the Group's ability to use or sell the asset, how the asset will generate future economic benefits, the availability of resources to complete the pipeline and the ability to measure reliably the expenditure during the development. Development costs which do not meet these criteria are expensed when incurred.

The Directors will assess the progress of each of the research and development projects and determine the criteria are met for capitalization. During the Track Record Period, all development costs are expensed when incurred.

## FINANCIAL INFORMATION

---

### *Fair Value Measurement of Financial Liabilities at FVTPL*

We has issued preference shares with preference rights including liquidation preferences, anti-dilution right and redemption right during the Track Record Period as set out in note 27 to the Accountant’s Report in Appendix I. We bifurcated the preference rights as financial liabilities at FVTPL of which no quoted prices in an active market exist. The fair value is established by using valuation techniques which include back-solve method and adopted equity allocation model. Valuation techniques are certified by an independent and recognized international business valuer before being implemented for valuation and are calibrated to ensure that outputs reflect market conditions. Valuation models established by the valuer make the maximum use of market inputs and rely as little as possible on our own specific data. However, it should be noted that some inputs, such as fair value of the ordinary shares of our Company, possibilities under different scenarios such as [REDACTED] and liquidation, time to liquidation and discount for lack of marketability, require management estimates. Management estimates and assumptions are reviewed periodically and are adjusted if necessary. Should any of the estimates and assumptions changed, it may lead to a change in the fair value of the other financial liabilities at FVTPL. The fair values of the preference rights are set out in note 27 to the Accountant’s Report in Appendix I.

In relation to the valuation of the financial liabilities at FVTPL, our Directors, based on the professional advice received, adopted the following procedures: (i) reviewed the terms of preference shares agreements; (ii) engaged independent business valuer, provided necessary financial and non-financial information so as to enable the valuer to perform valuation procedures and discussed with the valuer on relevant assumptions; (iii) carefully considered all information especially those non-market related information input, such as fair value of the ordinary shares of our Company, possibilities under different scenarios, time to liquidation and discount for lack of marketability, which require management assessments and estimates; and (iv) reviewed the valuation working papers and results prepared by the valuer. Based on the above procedures, our Directors are of the view that the valuation analysis performed by the valuer is fair and reasonable, and the financial statements of our Group are properly prepared.

Details of the fair value measurement of financial liabilities at FVTPL, particularly the fair value hierarchy, the valuation techniques and key inputs, including significant unobservable inputs, the relationship of unobservable inputs to fair value and reconciliation of level 3 measurements are disclosed in Notes 27 and 33 to the Historical Financial Information of Group for the Track Record Period as set out in the accountants’ report issued by the Reporting Accountants in accordance with Hong Kong Standard on Investment Circular Reporting Engagements 200 “Accountants’ Report on Historical Financial Information in Investment Circulars” issued by the Hong Kong Institute of Certified Public Accountants in Appendix I. The reporting accountants’ opinion on the Historical Financial Information of the Group for the Track Record Period as a whole is set out on I-2 of Appendix I.

## FINANCIAL INFORMATION

In relation to valuation analysis performed by valuer on the level 3 financial liabilities at FVTPL, the Sole Sponsor has conducted relevant due diligence work, including but not limited to (i) reviewed relevant notes to the Accountant’s Report in Appendix I to this document; (ii) reviewed the professional qualification of the valuer engaged by the Company for the financial liabilities at FVTPL measured within level 3 fair value measurement; (iii) reviewed relevant valuation documents prepared by the valuer; (iv) reviewed the terms of relevant agreements and documents regarding the financial liabilities at FVTPL; and (v) discussed with the Company, the Reporting Accountants and the valuer to understand, among others, (a) the audit work and accounting treatment of the relevant financial liabilities at FVTPL, (b) the relevant auditing standards regarding the relevant financial liabilities at FVTPL, (c) the valuation standards of the relevant financial liabilities at FVTPL including but not limited to the valuation standards established by the International Valuation Standards Counsel, and (d) the rationale, method, key assumption and basis of the valuation. Having considered the above, nothing has come to the Sole Sponsor’s attention that would cause the Sole Sponsor to question the relevant valuation work performed by the valuer for the said valuation.

### DESCRIPTION OF SELECTED COMPONENTS OF CONSOLIDATED STATEMENTS OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

The following table sets forth our consolidated statements of profit or loss and other comprehensive income for the periods indicated:

	Year ended December 31,	
	2021	2022
	<i>RMB’000</i>	<i>RMB’000</i>
Other income	6,896	13,923
Other gains and losses, net	10,794	15,100
Fair value loss of financial liabilities at FVTPL	(441,077)	(551,546)
Administrative expenses	(60,217)	(85,830)
Research and development expenses	(42,983)	(91,426)
Finance costs	(603)	(722)
[REDACTED] expenses	[REDACTED]	[REDACTED]
Other expenses	(9,041)	(3,137)
	<b>(539,357)</b>	<b>(725,180)</b>
Loss before tax	(539,357)	(725,180)
Income tax expense	–	–
	<b>(539,357)</b>	<b>(725,180)</b>
<b>Loss and total comprehensive expense for the year</b>	<b>(539,357)</b>	<b>(725,180)</b>

## FINANCIAL INFORMATION

### Other Income

During the Track Record Period, our other income primarily consisted of (i) rental income primarily due to the lease of our Beijing facility to a pharmaceutical company, (ii) income from sales of our testing kits primarily to pharmaceutical companies, local CDCs or distributors on an order basis, (iii) government grants, (iv) interest income on bank balances, and (v) interest income from rental deposits for the lease of our facility in Zhuhai.

Our government grants mainly included subsidies from local PRC governments which are specifically for (i) compensations of the capital expenditure incurred for purchase of plant and machinery and lease of assets in relation to research and development products, which are recognized over the useful life of assets and (ii) research and development activities, which are recognized upon compliance with the attached conditions.

The following table sets forth a breakdown of our other income for the periods indicated:

	Year ended December 31,			
	2021		2022	
	<i>RMB'000</i>	%	<i>RMB'000</i>	%
Rental income from investment property	2,350	34.1	–	–
Income from sales of testing kits	2,616	37.9	2,056	14.8
Government grants	1,889	27.4	11,618	83.4
Interest income on bank balances	25	0.4	223	1.6
Interest income from rental deposits	16	0.2	26	0.2
<b>Total</b>	<b>6,896</b>	<b>100.0</b>	<b>13,923</b>	<b>100.0</b>



## FINANCIAL INFORMATION

### Other Gains and Losses, Net

During the Track Record Period, our other gains and losses, net, primarily consisted of (i) fair value gains on financial assets at FVTPL mainly representing the gains from our wealth management products, (ii) loss on disposal of property, plant and equipment, and (iii) net foreign exchange gains.

The following table sets forth a breakdown of our other gains and losses, net, for the periods indicated:

	Year ended December 31,			
	2021		2022	
	<i>RMB'000</i>	%	<i>RMB'000</i>	%
Fair value gains on financial assets at FVTPL	10,804	100.1	13,868	91.8
Loss on disposal of property, plant and equipment	(11)	(0.1)	(3)	–
Foreign exchange gains, net	1	0.0	996	6.6
Gain on early termination of a lease	–	–	239	1.6
<b>Total</b>	<b>10,794</b>	<b>100.0</b>	<b>15,100</b>	<b>100.0</b>

### Fair Value Loss of Financial Liabilities at FVTPL

Our fair value loss of financial liabilities at FVTPL mainly represented the fair value change of our preference shares we issued in our Series A Financing, Series B Financing, Series B+ Financing and Series C Financing. Our obligations with respect to special rights granted to [REDACTED] Investors, other than information rights, were terminated in June 2022, and therefore we do not expect to incur additional fair value loss of financial liabilities thereafter.

### Administrative Expenses

During the Track Record Period, our administrative expenses primarily consisted of (i) staff costs for our administrative personnel, mainly including salaries and welfare and share-based payments primarily presenting share options and awards granted to our administrative personnel, (ii) depreciation and amortization of our facilities, right-of-use assets and equipment for administrative purposes, and (iii) others primarily representing office and utilities expenses, transportation and travel expenses, tax and surcharges and other miscellaneous administrative expenses.

## FINANCIAL INFORMATION

The following table sets forth a breakdown of our administrative expenses for the periods indicated:

	Year ended December 31,			
	2021		2022	
	<i>RMB'000</i>	%	<i>RMB'000</i>	%
Staff costs				
– salaries and welfares	6,165	10.2	9,883	11.5
– share-based payments	49,437	82.1	68,925	80.3
Depreciation and amortization	1,781	3.0	2,988	3.5
Others	2,834	4.7	4,034	4.7
<b>Total</b>	<b>60,217</b>	<b>100.0</b>	<b>85,830</b>	<b>100.0</b>

### Research and Development Expenses

During the Track Record Period, our research and development expenses primarily consisted of (i) staff costs for our research and development personnel, mainly including salaries and welfare and share-based payment primarily representing share options and awards granted to our research and development personnel, (ii) third-party contracting costs mainly representing testing fees, clinical expenses and assessment fees in connection with our research and development activities, (iii) costs of raw materials in support of our research and development activities, (iv) depreciation and amortization of our facilities, right-of-use assets and machinery for research and development purposes, and (v) other miscellaneous research and development expenses.

The following table sets forth a breakdown of our research and development expenses for the periods indicated:

	Year ended December 31,			
	2021		2022	
	<i>RMB'000</i>	%	<i>RMB'000</i>	%
Staff costs				
– salaries and welfare	5,118	11.9	12,380	13.5
– share-based payments	26,801	62.4	42,488	46.5
Sub-contracting costs	5,395	12.6	17,849	19.5
Costs of raw materials	1,268	3.0	7,941	8.7
Depreciation and amortization	4,312	10.0	6,787	7.4
Others	89	0.1	3,981	4.4
<b>Total</b>	<b>42,983</b>	<b>100.0</b>	<b>91,426</b>	<b>100.0</b>

The research and development expenditures, excluding share-based payments, incurred for our Core Product, increased from RMB6.2 million in 2021 to RMB38.2 million in 2022, primarily due to our initiations of the Phase I clinical trial and the Phase II clinical trial for LZ901 in China in 2022.

## FINANCIAL INFORMATION

Our research and development expenses increased from RMB43.0 million in 2021 to RMB91.4 million in 2022, largely due to (i) an increase of share-based payments of RMB15.7 million primarily arising from the share options and awards we granted to our research and development personnel and (ii) an increase of sub-contracting costs of RMB12.5 million mainly arising from our Phase I clinical trial and Phase II clinical trial for LZ901.

### Finance Costs

During the Track Record Period, our finance costs were RMB0.6 million and RMB0.7 million in 2021 and 2022, respectively, which represented interest expenses on lease liabilities mainly resulting from the lease of our facility in Zhuhai.

### Other Expenses

During the Track Record Period, our other expenses mainly consisted of (i) direct operating expenses incurred for investment property, mainly representing the depreciation and amortization and property tax of our leased-out Beijing facility, (ii) costs mainly arising from manufacturing and selling our testing kits, (iii) costs of issuing preference shares, and (iv) other miscellaneous expenses.

The following table sets forth a breakdown of our other expenses for the periods indicated:

	<b>Year ended December 31,</b>	
	<b>2021</b>	<b>2022</b>
	<i>RMB'000</i>	<i>RMB'000</i>
Direct operating expenses incurred for investment property	744	–
Cost of testing kits sold	853	590
Issue costs for the financial liabilities at FVTPL	6,194	2,547
Others	1,250	–
	<b>9,041</b>	<b>3,137</b>
<b>Total</b>	<b>9,041</b>	<b>3,137</b>

### Income Tax Expenses

We did not record any income tax expense during the Track Record Period. Our principal applicable taxes and tax rates are set forth as follows:

#### *Mainland China*

Under the law of the PRC on Enterprise Income Tax (the “**EIT Law**”) and implementation regulations of the EIT Law, the basic tax rate of our Company and our PRC subsidiary is 25%.

## FINANCIAL INFORMATION

---

Luzhu Biotechnology has been accredited as a High and New Technology Enterprise by the Science and Technology Bureau of Beijing and relevant authorities on October 31, 2018. Pursuant to the notice of the Ministry of Finance and the State Administration of Taxation on extending the loss carrying forward period of high and new technology enterprises and high-tech small and medium enterprises (Cai Shui 2018 No. 76), with effect from January 1, 2018, for qualified high and new technology enterprises and high-tech small and medium enterprises, the unutilized tax losses incurred in the previous 5 years can be utilized in 10 years from the year of loss. Our Company was qualified as high and new technology enterprise on October 31, 2018 and the unutilized tax losses of our Company incurred between 2013 to 2020 can be utilized in 10 years from the year of loss.

Pursuant to relevant laws and regulations promulgated by the State Administration of Taxation of the PRC effective from 2018 onwards, our PRC subsidiaries enjoy an accelerated deduction of 175% on qualifying research and development expenditures throughout the Track Record Period. As of December 31, 2021 and 2022, we had unused tax losses of approximately RMB93.0 million and RMB170.5 million, respectively. Please see Note 10 to Accountants’ Report set forth in Appendix I to this document for more details.

No provision for PRC income tax was made as our Company and our PRC subsidiary incurred tax losses during the Track Record Period.

Our Directors confirm that during the Track Record Period, we had made all the required tax filings and had paid all outstanding tax liabilities with the relevant tax authorities in the relevant jurisdictions and we are not aware of any outstanding or potential disputes with such tax authorities.

### *Hong Kong*

No Hong Kong profit tax was provided for as there was no estimated assessable profit of our Hong Kong subsidiary that was subject to Hong Kong profit tax during the Track Record Period.

## PERIOD-TO-PERIOD COMPARISON OF RESULTS OF OPERATIONS

### Year Ended December 31, 2022 Compared to Year Ended December 31, 2021

#### *Other Income*

Our other income increased from RMB6.9 million in 2021 to RMB13.9 million in 2022, primarily due to the increase of government grants of RMB9.7 million mainly related to subsidies to support our research and development activities in Zhuhai.

#### *Other Gains and Losses, Net*

Our net other gains increased from RMB10.8 million in 2021 to RMB15.1 million in 2022, primarily arising from an increase of fair value gains on financial assets at FVTPL of RMB3.1 million mainly as we purchased additional wealth management products using proceeds from our [REDACTED] Investments.

## FINANCIAL INFORMATION

---

### *Fair Value Loss of Financial Liabilities at FVTPL*

Our fair value loss of financial liabilities at FVTPL increased from RMB441.1 million in 2021 to RMB551.5 million in 2022, mainly due to relatively higher increase of valuation of our Company in 2022, as a result of the initiation of the Phase II clinical trial for LZ901 in China in April 2022. For details about the fair value change of our financial liabilities at FVTPL, please see Note 27 to the Accountants’ Report set forth in Appendix I to this document.

### *Administrative Expenses*

Our administrative expenses increased from RMB60.2 million in 2021 to RMB85.8 million in 2022, mainly arising from an increase of share-based payments of RMB19.5 million primarily in relation to share options and awards granted to our administrative personnel and an increase of salaries and welfare of RMB3.7 million primarily as a result of increased headcount and salary in our administrative team. For more details about our share-based payments, please see Note 31 to the Accountants’ Report set forth in Appendix I to this document.

### *Research and Development Expenses*

Our research and development expenses increased from RMB43.0 million in 2021 to RMB91.4 million in 2022, largely due to (i) an increase of share-based payments of RMB15.7 million primarily arising from the share options and awards we granted to our research and development personnel and (ii) an increase of sub-contracting costs of RMB12.5 million mainly arising from our Phase I clinical trial and Phase II clinical trial for LZ901.

### *Finance Costs*

Our finance costs remained stable in 2021 and 2022, amounting to RMB0.6 million and RMB0.7 million, respectively.

### *[REDACTED] Expenses*

We incurred [REDACTED] expenses of RMB[REDACTED] and RMB[REDACTED] in connection with the [REDACTED] in 2021 and 2022, respectively.

### *Other Expenses*

Our other expenses decreased from RMB9.0 million in 2021 to RMB3.1 million in 2022, largely due to a decrease of issue costs for the financial liabilities at FVTPL of RMB3.6 million, primarily representing the legal and professional fees we incurred for our Series B Financing and Series B+ Financing.

### *Loss and Total Comprehensive Expense for the Period*

As a result of the foregoing, our loss and total comprehensive expense increased from RMB539.4 million in 2021 to RMB725.2 million in 2022.

## FINANCIAL INFORMATION

### DISCUSSION OF CERTAIN SELECTED ITEMS FROM THE CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

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

	As of December 31,	
	2021	2022
	<i>RMB'000</i>	<i>RMB'000</i>
Total non-current assets	151,602	469,166
Total current assets	574,293	601,004
<b>Total assets</b>	<b>725,895</b>	<b>1,070,170</b>
Total non-current liabilities	1,286,998	38,590
Total current liabilities	23,422	94,114
<b>Net current assets</b>	<b>550,871</b>	<b>506,890</b>
<b>Total liabilities</b>	<b>1,310,420</b>	<b>132,704</b>
<b>Net (liabilities) assets</b>	<b>(584,525)</b>	<b>937,466</b>
Share capital	90,888	192,064
Reserves	(675,413)	745,402
<b>Total (deficits) equity</b>	<b>(584,525)</b>	<b>937,466</b>

## FINANCIAL INFORMATION

### Current Assets and Liabilities

The table below sets forth our current assets and current liabilities as of the dates indicated:

	As of December 31,		As of
	2021	2022	February 28,
	<i>RMB'000</i>	<i>RMB'000</i>	2023 <i>RMB'000</i> (unaudited)
<b>Current assets</b>			
Materials	5,323	2,535	2,467
Prepayments, deposits and other receivables	4,575	16,829	19,400
Financial assets at FVTPL	532,365	512,664	349,939
Bank balances and cash	32,030	68,976	207,254
<b>Total current assets</b>	<b>574,293</b>	<b>601,004</b>	<b>579,100</b>
<b>Current liabilities</b>			
Advance payments received and other payables	14,785	84,714	98,328
Contract liability	237	–	–
Deferred government grants	8,400	9,400	9,400
<b>Total current liabilities</b>	<b>23,422</b>	<b>94,114</b>	<b>107,728</b>
<b>Net current assets</b>	<b>550,871</b>	<b>506,890</b>	<b>471,372</b>

Our net current assets decreased from RMB550.9 million as of December 31, 2021 to RMB506.9 million as of December 31, 2022, largely due to (i) a decrease of financial assets at FVTPL of RMB19.7 million mainly as a result of an increase of redemption of wealth management products relating to the purchase of property and facilities in 2022; (ii) an increase of advance payments received and other payables of RMB69.9 million mainly representing payables for acquisition of property, plant and equipment relating to the balance of construction and equipment of our facility in Zhuhai, partially offset by an increase of bank balances and cash of RMB36.9 million primarily due to the redemption of mature wealth management products.

## FINANCIAL INFORMATION

### Property, Plant and Equipment

During the Track Record Period, our property, plant and equipment primarily consisted of (i) property, (ii) leasehold improvements, (iii) machinery, (iv) vehicles, (v) office equipment and (vi) construction in progress. The following table sets forth a breakdown of our property, plant and equipment as of the dates indicated:

	As of December 31,	
	2021	2022
	<i>RMB'000</i>	<i>RMB'000</i>
Property	3,745	2,569
Leasehold improvement	3,369	20,206
Machinery	6,846	51,840
Vehicles	1,037	769
Office equipment	884	1,429
Construction in progress	60,148	152,814
<b>Total</b>	<b>76,029</b>	<b>229,627</b>

Our property, plant and equipment increased from RMB76.0 million as of December 31, 2021 to RMB229.6 million as of December 31, 2022, mainly due to (i) an increase of leasehold improvement of RMB16.8 million, (ii) an increase of machinery of RMB45.0 million, and (iii) an increase of construction in progress of RMB92.7 million primarily reflecting additional progress and purchase of equipment of our manufacturing facilities under construction in Zhuhai.

### Right-of-Use Assets

Our right-of-use assets were primarily related to our land use rights and leased facilities for our operations during the Track Record Period.

Our right-of-use assets decreased from RMB66.2 million as of December 31, 2021 to RMB62.5 million as of December 31, 2022, primarily due to (i) an early termination of the lease of our Beijing facility and (ii) the amortization of our right-of-use assets in Zhuhai.

### Investment Property

Our investment property primarily represented the portion of our facility in Beijing leased to a pharmaceutical company. We recorded investment property of nil as of December 31, 2021 and December 31, 2022.



## FINANCIAL INFORMATION

### Prepayments, Deposits and Other Receivables

Our prepayments, deposits and other receivables mainly consisted of (i) prepayments for purchase of property, plant and equipment, (ii) prepayments for right-of-use assets, (iii) value added tax recoverable, (iv) prepayments to suppliers and service providers, (v) deferred share issue costs for [REDACTED], which represents the part of [REDACTED] costs that will be capitalized upon the completion of [REDACTED], (vi) prepayments for [REDACTED] expenses, (vii) rental deposits, (viii) other prepayments, and (ix) others. The following table sets forth a breakdown of our prepayments, deposits and other receivables as of the dates indicated:

	As of December 31,	
	2021	2022
	<i>RMB'000</i>	<i>RMB'000</i>
Prepayments for purchase of property, plant and equipment	1,983	108,921
Prepayments for right-of-use assets	–	45,277
Value added tax recoverable	7,115	19,129
Prepayments to suppliers and service providers	1,576	4,901
Deferred share issue costs for [REDACTED]	1,458	11,350
Prepayments for [REDACTED] expenses	[REDACTED]	[REDACTED]
Rental deposits	295	313
Other prepayments	360	19
Others	43	558
<b>Total</b>	<b>13,968</b>	<b>190,469</b>

Our prepayments, deposits and other receivables increased from RMB14.0 million as of December 31, 2021 to RMB190.5 million as of December 31, 2022, primarily as a result of (i) an increase of prepayments for purchase of property, plant and equipment of RMB106.9 million mainly representing prepayments for the project of our facility in Zhuhai and prepayments for the property in Beijing, (ii) an increase of prepayments for right-of-use assets of RMB45.3 million mainly relating to the purchase of property in Beijing, (iii) an increase of value added tax recoverable of RMB12.0 million largely relating to the purchase of property in Beijing, and (iv) an increase of deferred share issue costs for [REDACTED] of RMB9.9 million.

### Materials

During the Track Record Period, our materials mainly consisted of raw materials in support of our research and development activities and testing kits. Our materials decreased from RMB5.3 million as of December 31, 2021 to RMB2.5 million as of December 31, 2022, primarily as a result of a decrease of materials for research and development projects, mainly relating to the trial use and commissioning of the large equipment installed.

## FINANCIAL INFORMATION

---

### Financial Assets at FVTPL

During the Track Record Period, our financial assets at FVTPL mainly represented short-term and low-risk wealth management products issued by reputable commercial banks in the PRC. The expected but not guaranteed rates of return approximately ranged from 2.8% to 3.7% per annum. These wealth management products generally have a maturity date of 90 days, six months or a year or are redeemable on demand.

In accordance with our risk management, and investment strategy, we managed and evaluated the performance of these investments on a fair value basis and therefore these investments are designated as financial assets at fair value through profit or loss as of December 31, 2021 and 2022. Our financial assets at FVTPL decreased from RMB532.4 million as of December 31, 2021 to RMB512.7 million as of December 31, 2022 mainly as a result of an increase of redemption of wealth management products relating to the purchase of property and facilities in 2022.

We have implemented a series of treasury policies and internal control policies and rules regarding investment in wealth management products to ensure that the purpose of investment is to preserve capital and liquidity until free cash is used in our primary business and operation. Prior to making an investment, we ensure that there remains sufficient working capital for our business needs, operating activities, research and development and capital expenditures even after purchasing such wealth management products. We adopt a prudent approach in selecting financial products. Our investment decisions are made on a case-by-case basis and after due and careful consideration of a number of factors, such as duration of the investment and the expected returns. We prefer wealth management products that are redeemable on demand and the purchase of any wealth management product with a maturity date longer than 90 days is subject to approval from our general manager. Each month personnel from our finance department will prepare a wealth management products purchase plan, based on anticipated expenditures in the relevant month, operational expenses in the past months, and our then cash and bank balances, for the manager to review. The manager of our finance department will then submit the plan to our management to review and approve. In particular when the purchase amount of a single wealth management product is between RMB10 million and RMB50 million, approval from chairman of Board is required, and when the purchase amount is above RMB50 million, approval from the Board is required. To control our risk exposure, we have in the past sought, and may continue in the future to seek other low-risk financial products. Additionally, we mainly invest in financial products offered by reputable commercial banks in China. After making an investment, we closely monitor its performance and fair value on a regular basis. Our finance department will record details of each wealth management product, including purchase amount, redemption and return. A designated personnel from our finance department will actively monitor our expenditures and cash and bank balances. We will promptly redeem our wealth management products when we anticipate that our then cash and bank balances will not be sufficient for our operation in the next few days and the redemption is subject to approval by our deputy general manager. Upon the [REDACTED], our investment in wealth management products is subject to the compliance with Chapter 14 of the Listing Rules.

## FINANCIAL INFORMATION

### Bank Balances and Cash

During the Track Record Period, our bank balances and cash were denominated in Renminbi and US dollars. The following table sets forth a breakdown of our bank balances and cash as of the dates indicated:

	As of December 31,	
	2021	2022
	<i>RMB'000</i>	<i>RMB'000</i>
Cash on hand	5	–
Bank balances	32,025	68,976
<b>Total</b>	<b>32,030</b>	<b>68,976</b>

Our bank balances and cash increased from RMB32.0 million as of December 31, 2021 to RMB69.0 million as of December 31, 2022, primarily as a result of the redemption of mature wealth management products.

### Advance Payments Received and Other Payables

Our trade and other payables mainly included (i) payables for research and development activities, (ii) payables for acquisition of property, plant and equipment, (iii) accrued salaries and other allowances, (iv) accrued [REDACTED] expenses, (v) accrued share issue costs for [REDACTED], (vi) other tax payables and (vii) others. The following table sets forth a breakdown of advance payments received and other payables as at the dates indicated:

	As of December 31,	
	2021	2022
	<i>RMB'000</i>	<i>RMB'000</i>
Payables for research and development activities	1,013	2,424
Payables for acquisition of property, plant and equipment	9,473	67,093
Accrued salaries and other allowances	3,152	3,885
Accrued [REDACTED] expenses	[REDACTED]	[REDACTED]
Accrued share issue costs for [REDACTED]	335	3,638
Other tax payables	75	107
Others	35	46
<b>Total</b>	<b>14,785</b>	<b>84,714</b>

## FINANCIAL INFORMATION

Our advancement payments received and other payables increased from RMB14.8 million as of December 31, 2021 to RMB84.7 million as of December 31, 2022, primarily due to (i) an increase of payables for research and development activities of RMB1.4 million, (ii) an increase of accrued [REDACTED] expense of RMB[REDACTED], (iii) an increase of accrued share issues costs for [REDACTED] of RMB3.3 million in relation to the [REDACTED], and (iv) an increase of payables for acquisition of property, plant and equipment of RMB57.6 million, mainly representing the outstanding payment for the additional office equipment and machinery purchased by Zhuhai Luzhu.

### Contract Liability

Our contract liabilities mainly represented the prepayment for testing kits that we had not yet delivered to our customers. We recorded contract liabilities of RMB0.2 million and nil as of December 31, 2021 and 2022, respectively.

### Deferred Government Grants

Our deferred government grants mainly consisted of (i) grants related to purchase of plant and machinery and right-of-use assets, which are recognized over the useful life of the related assets and (ii) grants related to research and development activities, which are recognized upon compliance with the attached conditions. The following table sets forth the breakdown of our deferred government grants as of the dates indicated:

	As of December 31,	
	2021	2022
	RMB'000	RMB'000
Government grants related to		
– plant and machinery	18,023	17,828
– right-of-use assets	12,478	9,543
– research and development activities	16,800	9,400
<b>Total</b>	<b>47,301</b>	<b>36,771</b>

Our deferred government grants decreased from RMB47.3 million as of December 31, 2021 to RMB36.8 million as of December 31, 2022 primarily due to a release of deferred government grants related to right-of-use assets of RMB2.9 million and a release of deferred government grants related to research and development activities of RMB8.4 million. For more details of our deferred government grants, please see Note 26 to Accountants’ Report set forth in Appendix I to this document.

## FINANCIAL INFORMATION

---

### Lease Liabilities

Our lease liabilities were primarily related to our leases of properties for business operation and manufacturing. Our lease liabilities increased from RMB10.6 million as of December 31, 2021 to RMB11.2 million as of December 31, 2022, mainly arising from interests from discount of lease liabilities of a real property in Zhuhai as our offices, manufacturing and research and development facilities. For details about the leased property in Beijing, please see “Business — Properties” in this document.

### Financial Liabilities at FVTPL

Our financial liabilities at FVTPL primarily represented the preference shares we issued in Series A Financing, Series B Financing, Series B+ Financing and Series C Financing and the fair value change of financial liabilities at FVTPL is recognized in profit or loss. For more details, please see “History, Development and Corporate Structure — Our Corporate Development — Conversion into Joint Stock Limited Company and Major Shareholding Changes after the Conversion” in this document. Our financial liabilities at FVTPL decreased from RMB1,237.5 million as of December 31, 2021 to nil as of December 31, 2022 primarily due to the reclassification of the preference shares from financial liabilities to equity at their fair value given the termination of the preference rights including the liquidation preferences and anti-dilution right for the Series A Investors, Series B Investors, Series B+ Investors and Series C Investors upon the Company’s submission of the [REDACTED] application.

For movements in our financial liabilities at FVTPL, please see Note 27 to Accountants’ Report set forth in Appendix I to this document.

## LIQUIDITY AND CAPITAL RESOURCES

### Working Capital

Our primary uses of cash relate to the research and development of our product candidates and capital expenditures. During the Track Record Period, we primarily funded our working capital requirements through capital contributions from our shareholders and private equity financing. We monitor and maintain a level of cash and cash equivalents deemed adequate to finance our business operations and mitigate the effects of fluctuations in cash flows. Our net cash used in operating activities was RMB19.2 million and RMB77.3 million in 2021 and 2022, respectively. As our business develops and expands, we expect to generate net cash from our operating activities through the sales revenue of our future commercialized products. Going forward, we believe our liquidity requirements will be satisfied by a combination of our cash and cash equivalents and net proceeds from the [REDACTED]. As of December 31, 2022, we had cash and cash equivalents of RMB69.0 million. In addition, RMB512.7 million was recorded as financial assets at FVTPL as of December 31, 2022, which represented highly liquid investments in wealth management products and can be used to fund our working capital when necessary. As of December 31, 2022, we did not have unutilized banking facilities.

Taking into account the financial resources available to our Group, including cash and cash equivalents, financial assets at FVTPL, future operating cash flows in respective periods, and the estimated net proceeds from the [REDACTED], our Directors are of the view that we have sufficient working capital to cover at least 125% of our costs and expenses, including research and development expenses, administrative expenses, finance costs and other expenses (including any production costs), for

## FINANCIAL INFORMATION

at least the next 12 months from the date of this document. After making reasonable inquiries with the management of the Company about the working capital and future plans of the Group, and discussing with the Reporting Accountants about the Group’s liquidity on hand, nothing has come to the Sole Sponsor’s attention that would reasonably cause the Sole Sponsor to cast doubt on the Directors’ view above.

Our cash burn rate refers to our average monthly (i) net cash used in operating activities and (ii) capital expenditures (including purchase of property, plant and equipment and purchase of right-of-use assets). Taking into consideration the higher-than-before research and development expenses after LZ901 proceeded to its Phase III clinical trial in China and its Phase I clinical trials in the U.S., and assuming an average cash burn rate going forward of approximately 1.4 times the level for the 12 months ended December 31, 2022, we estimate that our cash and cash equivalents and financial assets at FVTPL, which were redeemable on demand as of December 31, 2022, or had been redeemed as of the date of this document, will be able to maintain our financial viability for approximately 13.3 months or, if we also take into account the estimated net proceeds (based on the low-end of the indicative [REDACTED]) from the [REDACTED], for approximately 18.6 months. We will continue to monitor our working capital closely and expect to raise our next round of financing, if needed, with a minimum buffer of twelve months.

### Selected Consolidated Cash Flow Statements Data

The following table sets forth our cash flows for the periods indicated:

	<b>Year ended December 31,</b>	
	<b>2021</b>	<b>2022</b>
	<i>RMB'000</i>	<i>RMB'000</i>
Operating cash flows before movements in working capital	(21,146)	(75,446)
Changes in working capital	1,981	(1,819)
Net cash flows used in operating activities	(19,165)	(77,265)
Net cash flows used in investing activities	(403,997)	(223,262)
Net cash flows from financing activities	454,991	336,978
Net increase in cash and cash equivalents	31,829	36,451
Cash and cash equivalents at beginning of the year	201	32,030
Effect of foreign exchange rate changes	–	495
<b>Cash and cash equivalents at end of the year</b>	<b>32,030</b>	<b>68,976</b>

## FINANCIAL INFORMATION

### Net Cash Flows Used in Operating Activities

Net cash used in operating activities in 2022 was RMB77.3 million. The difference between the loss before tax of RMB725.2 million and negative operating cash flow of RMB77.3 million was largely the result of adding back non-cash items of (i) fair value loss of financial liabilities at FVTPL of RMB551.5 million and (ii) equity-settled share-based payments of RMB111.4 million. Additional RMB1.8 million was recorded from changes in working capital, primarily including an increase in prepayments and other receivables of RMB14.4 million and an increase of advance payments received and other payables of RMB9.0 million.

Net cash used in operating activities in 2021 was RMB19.2 million. The difference between the loss before tax of RMB539.4 million and negative operating cash flow of RMB19.2 million was largely the result of adding back of non-cash items of (i) fair value loss of financial liabilities at FVTPL of RMB441.1 million and (ii) equity-settled share-based payments of RMB76.2 million. Additional RMB2.0 million was released from changes in working capital accounts, mainly including (i) an increase of deferred government grants related to research and development activities of RMB16.8 million, partially offset by (i) a decrease of advance payments received and other payables of RMB5.5 million, (ii) an increase of materials of RMB5.2 million and (iii) an increase of prepayments and other receivables of RMB4.3 million.

As a clinical-stage vaccine company, we plan to improve our net operating cash flow position in view of potential net operating cash inflows which we expect to generate after successful commercialization of our product candidates.

As our business develops, we expect to improve our negative cash flow position from our operations by generating more net cash from our operating activities, launching new products and improving our cost control and operating efficiencies.

- We plan to advance the clinical development and commercialization of our Core Product, LZ901, which is currently under phase II clinical trial in China. We expect to complete the Phase II clinical trial for LZ901 in China in the second quarter of 2023, initiate a multi-center, randomized, double-blind, placebo-controlled Phase III clinical trial comparing LZ901 against Shingrix<sup>®</sup> in the second quarter of 2023, file the BLA in the third quarter of 2024 for LZ901 to the NMPA, and commence commercialization once the BLA application is approved. LZ901 is expected to be priced at a retail price of approximately RMB500 to RMB800 an injection, with a total of two injections per treatment, which is more affordable compared to the retail price of the other commercially available herpes zoster vaccine in China, and has mild side effects. For more details, please see “Business — Our Products and Product Candidates — Our Core Product and Clinical-Stage Product Candidates — 1. LZ901 — Market Opportunities and Competition” in this document. Therefore, we expect that LZ901 will capture a large market share in the future and we will be able to improve our net operating cash flow position through sales of LZ901 in China. In addition, we initiated a Phase I clinical trial in the U.S. in February 2023. We plan to complete the Phase I clinical trial and initiate a Phase II clinical trial in the first quarter of 2024. We expect we will generate more cash from operating activities through sales of LZ901 in the U.S. after its approval and commercialization.

## FINANCIAL INFORMATION

---

- We plan to advance the clinical development and commercialization of K3. Based on the interview with the CDE of the NMPA in June 2022, it confirmed that our Phase I clinical trial in China was completed in December 2019 and it has no objection for us to proceed to Phase III clinical trial in China directly. Our PRC Legal Adviser is of the view that the CDE is the competent authority to give the above confirmations. We plan to initiate a Phase III clinical trial for K3 in China in the second quarter of 2023, complete the Phase III clinical trial in the second quarter of 2024 and submit a BLA to the NMPA in the fourth quarter of 2024. We expect K3 to receive BLA approval from the NMPA in 2025 and commence commercialization of K3 thereafter. We believe we will be able to improve our net operating cash flow position through sales of K3.
- We will also advance the research and development, clinical trials and commercialization of other product candidates in our pipeline. We are currently conducting phase I clinical trial for K193 and pre-clinical studies for Recombinant Varicella Vaccine, Recombinant Rabies Vaccine, K333 and K1932 in China. After these product candidates are approved, we expect we will generate more cash from operating activities through sales of these product candidates.
- We plan to adopt comprehensive measures to effectively control our cost and operating expenses leveraging our economies of scale. Our object is to optimize liquidity to gain a better return for our Shareholders and maintain adequate risk control. After our product candidates are commercialized, we plan to closely monitor and manage the settlement of our trade receivables to avoid credit losses. We will also closely monitor the settlement of our trade payables to achieve better cash flow position.

### Net Cash Flows Used in Investing Activities

Our net cash used in investing activities was RMB223.3 million in 2022, which is the net effect of purchase of financial assets at FVTPL of RMB1,521.1 million, purchase of property, plant and equipment of RMB208.2 million and payments for right-of-use assets of RMB45.3 million, partially offset by proceeds from disposal of financial assets at FVTPL of RMB1,554.6 million.

Our net cash used in investing activities was RMB404.0 million in 2021, which is the net effect of purchase of financial assets at FVTPL of RMB1,243.5 million, partially offset by proceeds from disposal of financial assets at FVTPL of RMB900.3 million.

### Net Cash Flows From Financing Activities

Our net cash from financing activities was RMB337.0 million in 2022, primarily as a result of issuance of financial liabilities at FVTPL in Series B+ Financing of RMB120.0 million and issuance of financial liabilities at FVTPL in Series C Financing of RMB218.0 million.

Our net cash from financing activities was RMB455.0 million in 2021, primarily as a result of issuance of financial liabilities at FVTPL in Series A Financing of RMB100.0 million and issuance of financial liabilities at FVTPL in Series B Financing of RMB350.0 million.



## FINANCIAL INFORMATION

### CASH OPERATING COSTS

The following table sets forth key information relating to our cash operating costs for the periods indicated:

	Year ended December 31,	
	2021	2022
	<i>RMB'000</i>	<i>RMB'000</i>
<b>R&amp;D costs</b>		
<i>R&amp;D costs for our Core Product</i>		
– Staff costs	2,199	6,859
– Third-party contracting costs	2,032	18,436
– Costs of raw materials	416	6,643
– Others	78	2,634
<i>R&amp;D costs for our other product candidates</i>		
– Staff costs	3,527	4,776
– Third-party contracting costs	3,391	2,558
– Costs of raw materials	852	1,298
– Others	82	407
Workforce employment costs <sup>(1)</sup>	3,143	9,164
Direct production costs <sup>(2)</sup>	–	–
Commercialization <sup>(2)</sup>	–	–
Contingency allowance	–	–
	<b>15,720</b>	<b>52,775</b>

*Notes:*

- (1) Workforce employment cost represents staff costs of non-research and development staff including salaries, bonus and retirement benefits.
- (2) We had not commenced product sales as of the Latest Practicable Date.

## FINANCIAL INFORMATION

### INDEBTEDNESS

The following table sets forth the components of our indebtedness as of the dates indicated:

	As of December 31,		As of February 28,
	2021	2022	2023
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i> (unaudited)
Financial liabilities at FVTPL	1,237,517	–	–
Lease liabilities			
– current	–	–	–
– non-current	10,580	11,219	11,326
<b>Total</b>	<b>1,248,097</b>	<b>11,219</b>	<b>11,326</b>

### Financial Liabilities at FVTPL

We issued preference issues in our Series A Financing, Series B Financing, Series B+ Financing and Series C Financing, which were designated as at financial liabilities at FVTPL on initial recognition. For more details, please see “— Discussion of Certain Selected Items from the Consolidated Statements of Financial Position — Financial Liabilities at FVTPL” in this section. In June 2022, our obligations with respect to special rights granted to [REDACTED] Investors, other than information rights, were terminated, and we do not expect to recognize any loss or gain on fair value change of preference shares thereafter.

Our Directors confirm that there have been no material defaults in our payment of trade or non-trade payables and bank borrowings, or breaches of covenants of our indebtedness during the Track Record Period and up to the date of this document.

We did not have any material mortgages, charges, debentures, loan capital, debt securities, loans, bank overdrafts or other similar indebtedness, finance lease or hire purchase commitments, liabilities under acceptances (other than normal trade bills), acceptance credits, which are either guaranteed, unguaranteed, secured or unsecured, or guarantees or other contingent liabilities as of February 28, 2023.

Since February 28, 2023 and up to the Latest Practicable Date, there had not been any material adverse change to our indebtedness.

## FINANCIAL INFORMATION

### CAPITAL EXPENDITURE

We regularly incur capital expenditures to expand and enhance our research and development facilities, establish our manufacturing capacities and increase our operating efficiency. Our capital expenditures primarily consisted of expenditures on leasehold improvement, machinery, construction in progress, leasehold lands and properties during the Track Record Period. Historically, we funded our capital expenditures mainly through capital contributions by our shareholders and equity financing. The following table sets forth our capital expenditures for the periods indicated:

	Year ended December 31,	
	2021	2022
	<i>RMB'000</i>	<i>RMB'000</i>
Purchase of property, plant and equipment	59,919	208,205
Purchase of right-of-use assets	18,585	45,316
<b>Total</b>	<b>78,504</b>	<b>253,521</b>

We expect to incur capital expenditures primarily to develop our facilities in Zhuhai and Beijing, and purchase of R&D machinery as well as purchase of equipment and machinery. We plan to finance such expenditures primarily with our existing cash and cash equivalents, net proceeds from the [REDACTED], and bank borrowings if necessary. We may adjust our capital expenditures for any given period according to our development plans or in light of market conditions and other factors we believe to be appropriate.

### CAPITAL COMMITMENTS

We had the following capital commitment as of the dates indicated:

	As of December 31,	
	2021	2022
	<i>RMB'000</i>	<i>RMB'000</i>
Contracted for but not provided in the Historical Financial Information	25,107	13,498
	<b>25,107</b>	<b>13,498</b>

### CONTINGENT LIABILITIES

As of December 31, 2021 and 2022, we did not have any contingent liabilities. As of the Latest Practicable Date, there had been no material changes or arrangements to our contingent liabilities.

## FINANCIAL INFORMATION

### OFF-BALANCE SHEET COMMITMENTS AND ARRANGEMENTS

Aside from our capital commitments of RMB13.5 million as disclosed above, we had not entered into any off-balance sheet transactions as of the Latest Practicable Date.

### KEY FINANCIAL RATIO

The table below sets forth our key financial ratio as of the dates indicated:

	As of December 31,	
	2021	2022
Current ratio <sup>(1)</sup>	24.5	6.4
Quick ratio <sup>(2)</sup>	24.5	6.4

*Notes:*

- (1) Current ratio represents current assets divided by current liabilities as of the same date.
- (2) Quick ratio represents current assets less inventories and divided by current liabilities as at the same date.

Our current ratio decreased from 24.5 as of December 31, 2021 to 6.4 as of December 31, 2022, mainly as a result of an increase of advance payments received and other payables of RMB69.9 million.

Our quick ratio was 24.5, and 6.4 as of December 31, 2021 and 2022, respectively, which was mainly in line with the movement of current asset ratio as discussed above.

### RELATED PARTY TRANSACTIONS

For details about our related party transactions during the Track Record Period, please see Note 36 of Appendix I to this document and “Business — Our Core Product and Clinical-Stage Product Candidates — 2. K3 — License, Rights and Obligation” in this document.

Our Directors believe that our transactions with the related party during the Track Record Period were conducted on an arm’s length basis, and they did not distort our results of operations or make our historical results not reflective of our future performance.

### RISK DISCLOSURE

We are exposed to a variety of financial risks, including market risk (currency risk, interest rate risk and other price risk), credit risk and liquidity. We manage and monitor these exposures to ensure appropriate measures are implemented on a timely and effective manner. For more details, please see Note 32 to Accountants’ Report set forth in Appendix I to this document.

## FINANCIAL INFORMATION

### Market Risk

#### *Foreign Currency Risk*

Our Group were primarily subject to foreign currency risk from the movement of the exchange rates between RMB against US\$. For more details, please see Note 32(i) to the Accountants’ Report set forth in Appendix I to this document. At the end of each reporting period, if the exchange rate of RMB had been weaken against US\$ by 5% and all other variables were held constant, our Group’s post-tax loss for each reporting period would increase as follow:

	Year ended December 31,	
	2021	2022
	RMB’000	RMB’000
Increase in post-tax loss	52	228

#### *Interest Risk*

Our Group’s fair value interest rate risk relates primarily to fixed-rate lease liabilities. Our Group are also exposed to cash flow interest risk in relation to variable-rate bank balances, which carry prevailing market interests. Our Group currently does not have a specified policy to manage our interest rate risk but will closely monitor our interest rate risk exposure in the future. For more details, please see Note 32(ii) to Accountants’ Report set forth in Appendix I to this document.

#### *Other Price Risk*

Our group is exposed to equity price risk through our Preference Shares measured at FVTPL and investments in financial products measured at FVTPL. For more details, please see Note 32(iii) to Accountants’ Report set forth in Appendix I to this document.

### Credit Risk

Our Group’s maximum exposure to credit risk which will cause a financial loss to the Group due to failure to discharge an obligation by the counterparties is arising from the carrying amount of the respective recognized financial assets as stated in the consolidated statements of financial position (including bank balances, financial assets at FVTPL and deposits and other receivables). Our Group does not hold any collaterals or other credit enhancement to cover its credit risks associated with its financial assets.

In order to minimize the credit risk, our Group monitors the exposure to credit risk on an on-going basis. Except for financial assets at FVTPL, our Group performed impairment assessment for each individual debt under ECL model at the end of each reporting period. For more details, please see Note 32 to Accountants’ Report set forth in Appendix I to this document.

## FINANCIAL INFORMATION

---

### Liquidity Risk

We monitor and maintain a level of cash and cash equivalents deemed adequate by our management to finance the operations and mitigate the effects of fluctuations in cash flows. For more details, please see Note 32 to Accountants’ Report set forth in Appendix I to this document.

### DIVIDEND

No dividend have been declared or paid by our Group during the Track Record Period. We currently expect to retain all future earnings for use in operation and expansion of our business, and currently do not have any dividend policy to declare or pay any dividends in the foreseeable future. The declaration and payment of any dividends in the future will be determined by our board of directors and subject to our Articles of Association and the PRC Company Law, and will depend on a number of factors, including the successful commercialization of our products as well as our earnings, capital requirements, overall financial condition and contractual restrictions. No dividend shall be declared or payable except out of our profits and reserves lawfully available for distribution. As confirmed by our PRC Legal Adviser, according to the PRC law, any future net profit that we make will have to be first applied to make up for our historically accumulated losses, after which we will be obliged to allocate 10% of our net profit to our statutory common reserve fund until such fund has reached more than 50% of our registered capital. We will therefore only be able to declare dividends after (i) all our historically accumulated losses have been made up for; and (ii) we have allocated sufficient net profit to our statutory common reserve fund as described above.

### DISTRIBUTABLE RESERVES

As of December 31, 2022, we did not have any distributable reserves.

### [REDACTED] EXPENSE

[REDACTED] expenses to be borne by us are estimated to be approximately RMB[REDACTED] (HK\$[REDACTED]), or [REDACTED]% of the gross proceeds estimated to be received by us from the [REDACTED] (at the [REDACTED] of HK\$[REDACTED] per Share, being the mid-point of the indicative [REDACTED] range, and assuming the [REDACTED] is not exercised). [REDACTED] expenses to be borne by us include (i) [REDACTED]-related expenses, including [REDACTED], of RMB[REDACTED] (HK\$[REDACTED]); (ii) fees and expenses of legal advisors and Reporting Accountants of RMB[REDACTED] (HK\$[REDACTED]); and (iii) other fees and expenses, including sponsor fees, of RMB[REDACTED] (HK\$[REDACTED]). As of December 31, 2022, we incurred a total of RMB[REDACTED] (HK\$[REDACTED]) in [REDACTED] expenses, among which RMB[REDACTED] was recognized in our consolidated statement of profit or loss and other comprehensive income, and RMB[REDACTED] was directly attributable to the issue of our [REDACTED] to the [REDACTED] and will be deducted from equity upon the [REDACTED].

## FINANCIAL INFORMATION

We estimate that additional [REDACTED] expenses of approximately RMB[REDACTED] (HK\$[REDACTED]) (including [REDACTED] of approximately RMB[REDACTED] (HK\$[REDACTED]), assuming the [REDACTED] is not exercised and based on the [REDACTED] of HK\$[REDACTED] per [REDACTED], being the mid-point of the indicative [REDACTED] range) will be incurred by our Company, approximately RMB[REDACTED] (HK\$[REDACTED]) of which is expected to be charged to our consolidated statements of profit or loss, and approximately RMB[REDACTED] (HK\$[REDACTED]) of which is directly attributable to the issue of our shares to the public and will be deducted from equity upon the [REDACTED]. The [REDACTED] expenses above are the latest practicable estimate for reference only, and the actual amount may differ from this estimate. The exchange rate used in translations between Hong Kong dollars and Renminbi above, including such [REDACTED] expenses incurred as of December 31, 2022, is set forth in “Information about This Document and the [REDACTED] — Exchange Rate Conversion”.

### PROPERTY VALUATION

Our selective property interests are set forth in the Property Valuation Report in Appendix III to this document. Savills Valuation and Professional Services (China) Limited, an independent property valuer, has valued our selective property interests as of February 28, 2023.

A reconciliation of the market value of our selective property interests as extracted from the Property Valuation Report as set out in Appendix III to this document as of February 28, 2023 and net book value of our selective property interests in our consolidated financial statements as of December 31, 2022 as required under Rule 5.07 of the Listing Rules is set forth below:

	<i>RMB'000</i>
Net book value of our selective property interests as of December 31, 2022	170,195
Movements during the two months ended February 28, 2023	12,210
Net book value of our selective property interests as of February 28, 2023	182,405
Valuation surplus	14,395
Valuation as of February 28, 2023 as set out in the Property Valuation Report in Appendix III to this document	196,800

### UNAUDITED [REDACTED] STATEMENT OF ADJUSTED CONSOLIDATED NET TANGIBLE ASSETS

The following unaudited [REDACTED] adjusted consolidated net tangible assets of the Group prepared in accordance with Rule 4.29 of the Listing Rules and with reference to Accounting Guideline 7 Preparation of Pro Forma Financial Information for inclusion in Investment Circulars issued by the Hong Kong Institute of Certified Public Accountants for illustration purposes only, and is set out here to illustrate the effect of the [REDACTED] on the consolidated net tangible assets of the Group attributable to owners of the parent as if the [REDACTED] had taken place on December 31, 2022.

## FINANCIAL INFORMATION

The unaudited [REDACTED] statement of adjusted consolidated net tangible assets of the Group has been prepared for illustrative purpose only and, because of its hypothetical nature, it may not give a true picture of the consolidated net tangible assets of our Group to owners of the parent had the [REDACTED] been completed as at December 31, 2022 or at any future dates.

	Audited consolidated net tangible assets of the Group attributable to owners of the Company as of December 31, 2022	Estimated net proceeds from the [REDACTED]	Unaudited [REDACTED] adjusted consolidated net tangible assets of the Group attributable to owners of the Company as of December 31, 2022	Unaudited [REDACTED] adjusted consolidated net tangible assets of the Group attributable to owners of the Company as of December 31, 2022 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>
Based on an [REDACTED] of HK\$[REDACTED] per Share	[934,029]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Based on an [REDACTED] of HK\$[REDACTED] per Share	[934,029]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

*Notes:*

- The audited consolidated net tangible assets of the Group attributable to owners of the Company as at December 31, 2022 is based on the consolidated net assets of the Group amounted to RMB937,466,000, with adjustments for intangible assets of the Group as at December 31, 2022 of RMB3,437,000 extracted from the Accountants' Report set forth in Appendix I to the document.
- The estimated net proceeds from the [REDACTED] are based on [REDACTED] new Shares to be issued at the [REDACTED] of HK\$[REDACTED] and HK\$[REDACTED] per [REDACTED], being the low end and high end of the indicated [REDACTED] range respectively, after deduction of the estimated [REDACTED] fees and other related expenses incurred or expected to be incurred by the Group, other than those expenses which had been recognized in profit or loss prior to December 31, 2022. The calculation of such estimated net proceeds does not take into account (i) any Shares which may be allotted and issued upon the exercise of the [REDACTED] or (ii) any Shares which may be issued or repurchased by the Company pursuant to the general mandates.  
  
For the purpose of the estimated net proceeds from the [REDACTED], the amount denominated in HK\$ has been converted into RMB at an exchange rate of HK\$1 to RMB0.87599, which was the exchange rate prevailing on April 10, 2023 with reference to the rate published by the People's Bank of China. No representation is made that HK\$ amounts have been, could have been or may be converted to RMB, or vice versa, at that rate or at any other rates or at all.
- The number of shares used for the calculation of unaudited [REDACTED] adjusted consolidated net tangible assets of the Group attributable to owners of the Company per Share is based on [REDACTED] Shares outstanding immediately following completion of the [REDACTED]. It does not take into account (i) any Shares which may be allotted and issued upon the exercise of the [REDACTED] or (ii) any Shares which may be issued or repurchased by the Company pursuant to the general mandates.
- The unaudited [REDACTED] adjusted consolidated net tangible assets of the Group attributable to owners of the Company per Share is converted from RMB to HK\$ at the rate of HK\$1 to RMB0.87599, which was the exchange rate prevailing on April 10, 2023 with reference to the rate published by the People's Bank of China. No representation is made that the RMB amounts have been, would have been or may be converted to HK\$, or vice versa, at that rate or at any other rates or at all.
- No adjustment has been made to the unaudited [REDACTED] adjusted consolidated net tangible assets of the Group attributable to owners of the Company as at December 31, 2022 to reflect any operating result or other transactions of the Group entered into subsequent to December 31, 2022.



## FINANCIAL INFORMATION

---

### NO MATERIAL ADVERSE CHANGE

Our Directors confirm that, up to the date of this document, other than as disclosed under “Recent Developments and No Material Adverse Change” in the “Summary” section in this document, there had been no material adverse change in our business, financial condition and results of operations since December 31, 2022, being the latest balance sheet date of our consolidated financial statements in the Accountants’ Report set out in Appendix I to this document, and up to the date of this document.

### DISCLOSURE UNDER RULES 13.13 TO 13.19 OF THE LISTING RULES

Our Directors confirm that, as of the Latest Practicable Date, there was no circumstance that would give rise to a disclosure requirement under Rules 13.13 to 13.19 of the Listing Rules.

## FUTURE PLANS AND USE OF [REDACTED]

### FUTURE PLANS AND PROSPECTS

See “Business — Our Strategies” in this document for a detailed description of our future plans.

### USE OF [REDACTED]

We estimate that the aggregate net proceeds to our Company from the [REDACTED] (after deducting [REDACTED] and other estimated expenses in connection with the [REDACTED] paid and payable by us taking into account any additional discretionary incentive fee and assuming that the [REDACTED] is not exercised and an [REDACTED] of HK\$[REDACTED] per Share, being the mid-point of the indicative [REDACTED] range of HK\$[REDACTED] to HK\$[REDACTED] per Share) will be approximately HK\$[REDACTED]. We currently intend to apply such net proceeds we will receive from this [REDACTED] for the following purposes:

1. approximately [59.9]%, or HK\$[REDACTED], will be used primarily for clinical development, manufacturing and commercialization of our Core Product, LZ901. Specifically:
  - a. approximately [41.3]%, or HK\$[REDACTED], will be used to fund ongoing and planned clinical trials in China and the U.S. for LZ901, of which [31.4]%, or HK\$[REDACTED], will be used to fund our ongoing and planned clinical trials in China between 2023 and 2024, and [9.9]%, or HK\$[REDACTED], will be used to fund our planned clinical trials in the U.S. between 2023 and 2025. We intend to add approximately ten research and development personnel, who will be responsible for the clinical development of LZ901 and K193. Additionally, in China, we are conducting the Phase II clinical trial for LZ901 and expect to complete the randomized, double-blinded and placebo-controlled Phase II clinical trial for LZ901 in the second quarter of 2023. We expect to initiate Phase III clinical trial in the second quarter of 2023 and file the BLA to the NMPA in the third quarter of 2024. We expect to conduct the Phase III clinical trial in multiple cities and to enroll approximately 30,000 subjects. We expect that (a) 80% to 85% of the allocated net proceeds will be used to fund third-party contracting services, primarily including clinical trial services and technical services, (b) 10% to 15% will be used to fund the purchase of raw materials, and (c) the remaining will be used to fund employee expenses. In the U.S., we have received IND approval from the FDA in July 2022 for LZ901 and initiated a Phase I clinical trial in February 2023, and we plan to initiate a Phase II clinical trial in the first quarter of 2024. We expect to use over 90% of the allocated net proceeds to fund third-party contracting services, primarily including clinical trial services and technical services, and the remaining will be used to fund the purchase of raw materials and employee expenses;
  - b. approximately [6.2]%, or HK\$[REDACTED], will be used to fund commercial manufacturing of LZ901 in 2024 or after. We expect to use (i) 80% to 85% of the allocated net proceeds to fund the purchase of raw materials, primarily including culture medium, glucose, gel, adjuvant and packaging materials, (ii) 15% to 20% to fund employee expenses, and (iii) the remaining to fund the purchase of manufacturing machinery, primarily including ultra-low temperature freezers, analytical balances and conductivity meters, utilities and other miscellaneous manufacturing activities; and

## FUTURE PLANS AND USE OF [REDACTED]

- c. approximately [12.4]%, or HK\$[REDACTED], will be used to fund marketing and sales activities. We plan to establish an in-house marketing and sales team for LZ901 and add approximately 200 members to the team by 2024. We also plan to promote awareness of herpes zoster and LZ901 among vaccinees, CDCs and KOLs. Please see “Business — Our Products and Product Candidates — Our Core Product and Clinical-Stage Product Candidates — 1. LZ901” in this document for more details about LZ901.
2. approximately [22.7]%, or HK\$[REDACTED], will be used primarily for clinical development and manufacturing of K3. In China, K3 is expected to primarily compete with biosimilars of adalimumab that have been launched or currently under development. According to Frost & Sullivan, (i) as of the Latest Practicable Date, there were six biosimilars of adalimumab approved in China and 10 biosimilars of adalimumab in development in China; and (ii) the average selling price of Humira<sup>®</sup> (under which brand name adalimumab is marketed by AbbVie Inc) per unit in China decreased from RMB5,572 in 2019 to RMB1,258 in 2020. In addition, it is commercially advisable to use the same facilities for Phase III clinical trial and production of K3 as using different facilities would incur substantial additional cost for technology transfer. It is therefore important to have sufficient production capacity for K3 to lower production cost and increase profit margin. K3 is indicated for the treatment of various autoimmune diseases, such as rheumatoid arthritis, ankylosing spondylitis and plaque psoriasis. The total combined prevalence of these three types of indications in China is expected to exceed 17 million in 2030 according to Frost & Sullivan. Therefore, with a lower price, we expect that there will be sufficient market demand for K3. Specifically:
  - a. approximately [16.5]%, or HK\$[REDACTED], will be used to fund planned clinical trials for K3 between 2023 and 2024. We plan to initiate a Phase III clinical trial for K3 in the second quarter of 2023 in China, and submit the BLA to the NMPA in the fourth quarter of 2024. We expect to conduct the Phase III clinical trial in multiple centers and to enroll approximately 600 participants. We expect to use (i) approximately 85% to 90% of the allocated net proceeds to fund third-party contracting services, primarily including clinical trial services and technical services, (ii) 5% to 10% to fund the purchase of raw materials, and (iii) the remaining to fund employee expenses; and
  - b. approximately [6.2]%, or HK\$[REDACTED], will be used to fund commercial manufacturing of K3 in 2024 or after. We expect to use (i) 75% to 80% of the allocated net proceeds to fund purchase of raw materials, primarily including culture medium, glucose, gel, excipients and packaging materials, (ii) 15% to 20% to fund employee expenses, and (iii) the remaining to fund the purchase of manufacturing machinery, primarily including ultra-low temperature freezers, peristaltic pump, analytical balances and conductivity meters, utilities and other miscellaneous manufacturing activities. The manufacturing machinery used for the commercial manufacturing for K3 is different from the machinery used for the commercial manufacturing of LZ901, because (i) the antigens or antibodies used for the manufacturing of LZ901 and K3 are different due to their different target genes, and thus we use different culture media for them based on their expression of the target

## FUTURE PLANS AND USE OF [REDACTED]

protein, (ii) the purification of LZ901 and K3 is different as the buffer solutions used in their purification process are not the same, and (iii) LZ901 product contains aluminum adjuvant, while K3 contains high protein concentration, which also requires different manufacturing machinery. In addition, the manufacturing machinery used for the clinical trials and commercial manufacturing for LZ901 and K3 is uncustomized and removable manufacturing machinery, such as ultra-low temperature freezer, which is different from the large-scale, customized and non-removable production facilities in relation to the construction of our facilities as mentioned below.

3. approximately [16.5]%, or HK\$[REDACTED], will be used primarily for construction of our commercial manufacturing facility in Zhuhai, which are large-scale, customized and non-removable production facilities. These facilities are different from the uncustomized and removable manufacturing machinery mentioned above in relation to the manufacturing for LZ901 and K3. We commenced construction of our second-phase Zhuhai manufacturing facility in April 2022, and expect to complete the construction of the main body of the buildings in the second-phase Zhuhai manufacturing facility in the second quarter of 2023, which is expected to commence pilot operations in relation to the production of K3 by the second quarter of 2023. When commencing the pilot operation, we will have completed the purification and decoration of the buildings, and purchased and installed production machinery and equipment used for the production of K3, and therefore, we will be ready for the production of K3. However, at that time, we will have only paid 15%-30% of the relevant expenses for the above-mentioned construction activities as a prepayment of the construction of K3 facilities and we plan to use proceeds from the [REDACTED] to support the payment of the balance of the construction activities in relation to the production of K3. At the time of the commencement of pilot operation, we will not have completed the construction activities in relation to the production of LZ901 and K193, and we will still need sufficient funds to support the purification and decoration of the buildings used for the production of LZ901 and K193, the purchase and installation of production machinery and equipment used to produce LZ901 and K193, and the construction of auxiliary facilities, such as comprehensive power center, laboratory animal room, garbage station, and sewage treatment station. We expect to use (i) 25% to 35% of the allocated net proceeds to fund the purification and decoration of the manufacturing buildings; (ii) 40% to 50% of the allocated net proceeds to fund the purchase and installation of production large-scale, customized and non-removable production machinery and equipment; and (iii) 20% to 30% of the allocated net proceeds to fund the construction of auxiliary facilities. Please see “Business — Manufacturing — Zhuhai Commercial Manufacturing Facilities” in this document for more details about our Zhuhai manufacturing facilities. According to Frost & Sullivan, the vaccination rate of people aged 50 or above in China is expected to increase to approximately 12.6% in 2030 from 0.1% in 2021. LZ901 is expected to be priced at a retail price of approximately RMB500 to RMB800 an injection, with a total of two injections per treatment, which is more affordable compared to the retail price of the other commercially available herpes zoster vaccine in China, and has mild side effects. For more details, please see “Business — Our Products and Product Candidates — Our Core Product and Clinical-Stage Product Candidates — 1. LZ901 — Market Opportunities and Competition” in this document. Therefore, we can reasonably believe that LZ901 will capture a large market share in the future. Considering the above factors, construction of the second-phase manufacturing facilities in Zhuhai is necessary to support the commercialization of LZ901

## FUTURE PLANS AND USE OF [REDACTED]

---

and we need to prepare the large-scale and customized production facilities in advance to support the commercialization of our product candidates. We expect to adjust our actual capacity based on then market conditions; and

4. approximately [0.9]%, or HK\$[REDACTED], will be used primarily for working capital and other general corporate purposes.

In the event that the net proceeds from the [REDACTED] are not sufficient to fund our expansion plan as disclosed above, we plan to utilize our internal capital resources or external financing as we believe appropriate to fund our future expansion.

To the extent that the net proceeds are not immediately applied to the above purposes, we intend to deposit the net proceeds into short-term demand deposits with licensed banks or financial institutions.

[REDACTED]

---

[REDACTED]

[REDACTED]

---

[REDACTED]

[REDACTED]

---

[REDACTED]



[REDACTED]

---

[REDACTED]

[REDACTED]

---

[REDACTED]

[REDACTED]

---

[REDACTED]

[REDACTED]

---

[REDACTED]

[REDACTED]

---

[REDACTED]

[REDACTED]

---

[REDACTED]

[REDACTED]

---

[REDACTED]

[REDACTED]

---

[REDACTED]



**STRUCTURE OF THE [REDACTED]**

---

[REDACTED]

**STRUCTURE OF THE [REDACTED]**

---

[REDACTED]

**STRUCTURE OF THE [REDACTED]**

---

[REDACTED]

**STRUCTURE OF THE [REDACTED]**

---

[REDACTED]

**STRUCTURE OF THE [REDACTED]**

---

[REDACTED]

**STRUCTURE OF THE [REDACTED]**

---

[REDACTED]

**STRUCTURE OF THE [REDACTED]**

---

[REDACTED]

**STRUCTURE OF THE [REDACTED]**

---

[REDACTED]



**STRUCTURE OF THE [REDACTED]**

---

[REDACTED]

**STRUCTURE OF THE [REDACTED]**

---

[REDACTED]

## HOW TO APPLY FOR [REDACTED]

---

[REDACTED]

## HOW TO APPLY FOR [REDACTED]

---

[REDACTED]

## HOW TO APPLY FOR [REDACTED]

---

[REDACTED]

## HOW TO APPLY FOR [REDACTED]

---

[REDACTED]

## HOW TO APPLY FOR [REDACTED]

---

[REDACTED]

## HOW TO APPLY FOR [REDACTED]

---

[REDACTED]



## HOW TO APPLY FOR [REDACTED]

---

[REDACTED]

## HOW TO APPLY FOR [REDACTED]

---

[REDACTED]

## HOW TO APPLY FOR [REDACTED]

---

[REDACTED]

## HOW TO APPLY FOR [REDACTED]

---

[REDACTED]

## HOW TO APPLY FOR [REDACTED]

---

[REDACTED]

## HOW TO APPLY FOR [REDACTED]

---

[REDACTED]

## HOW TO APPLY FOR [REDACTED]

---

[REDACTED]

## HOW TO APPLY FOR [REDACTED]

---

[REDACTED]



## HOW TO APPLY FOR [REDACTED]

---

[REDACTED]

## HOW TO APPLY FOR [REDACTED]

---

[REDACTED]

## HOW TO APPLY FOR [REDACTED]

---

[REDACTED]

## HOW TO APPLY FOR [REDACTED]

---

[REDACTED]

## HOW TO APPLY FOR [REDACTED]

---

[REDACTED]

## HOW TO APPLY FOR [REDACTED]

---

[REDACTED]

## HOW TO APPLY FOR [REDACTED]

---

[REDACTED]

## HOW TO APPLY FOR [REDACTED]

---

[REDACTED]



*The following is the text of a report set out on pages I-1 to [I-65], received from the Company’s reporting accountants, Deloitte Touche Tohmatsu, Certified Public Accountants, Hong Kong, for the purpose of incorporation in this document.*

**Deloitte.**

**德勤**

**ACCOUNTANTS’ REPORT ON HISTORICAL FINANCIAL INFORMATION TO THE DIRECTORS OF BEIJING LUZHU BIOTECHNOLOGY CO., LTD. AND CHINA INTERNATIONAL CAPITAL CORPORATION HONG KONG SECURITIES LIMITED**

**Introduction**

We report on the historical financial information of Beijing Luzhu Biotechnology Co., Ltd. (the “**Company**”) and its subsidiaries (together, the “**Group**”) set out on pages [I-3] to [I-65], which comprises the consolidated statements of financial position of the Group as at December 31, 2021 and 2022, the statements of financial position of the Company as at December 31, 2021 and 2022, and the consolidated statements of profit or loss and other comprehensive income, the consolidated statements of changes in equity and the consolidated statements of cash flows of the Group for each of the two years ended December 31, 2022 (the “**Track Record Period**”) and a summary of significant accounting policies and other explanatory information (together, the “**Historical Financial Information**”). The Historical Financial Information set out on pages [I-3] to [I-65] forms an integral part of this report, which has been prepared for inclusion in the document of the Company dated [[●] 2023] (the “**document**”) in connection with the initial [REDACTED] of shares of the Company on the Main Board of The Stock Exchange of Hong Kong Limited (the “**Stock Exchange**”).

**Directors’ responsibility for the Historical Financial Information**

The directors of the Company (the “**Directors**”) are responsible for the preparation of the Historical Financial Information that gives a true and fair view in accordance with the basis of preparation set out in Note 3.1 to the Historical Financial Information, and for such internal control as the Directors determine is necessary to enable the preparation of the Historical Financial Information that is free from material misstatement, whether due to fraud or error.

**Reporting accountants’ responsibility**

Our responsibility is to express an opinion on the Historical Financial Information and to report our opinion to you. We conducted our work in accordance with Hong Kong Standard on Investment Circular Reporting Engagements 200 “Accountants’ Reports on Historical Financial Information in Investment Circulars” issued by the Hong Kong Institute of Certified Public Accountants (the “**HKICPA**”). This standard requires that we comply with ethical standards and plan and perform our work to obtain reasonable assurance about whether the Historical Financial Information is free from material misstatement.

## APPENDIX I

## ACCOUNTANTS’ REPORT

Our work involved performing procedures to obtain evidence about the amounts and disclosures in the Historical Financial Information. The procedures selected depend on the reporting accountants’ judgment, including the assessment of risks of material misstatement of the Historical Financial Information, whether due to fraud or error. In making those risk assessments, the reporting accountants consider internal control relevant to the entity’s preparation of Historical Financial Information that gives a true and fair view in accordance with the basis of preparation set out in Note 3.1 to the Historical Financial Information in order to design procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity’s internal control. Our work also included evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by the Directors, as well as evaluating the overall presentation of the Historical Financial Information.

We believe that the evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

### **Opinion**

In our opinion, the Historical Financial Information gives, for the purposes of the accountants’ report, a true and fair view of the Group’s financial position as at December 31, 2021 and 2022, of the Company’s financial position as at December 31, 2021 and 2022 and of the Group’s financial performance and cash flows for the Track Record Period in accordance with the basis of preparation set out in Note 3.1 to the Historical Financial Information.

### **Report on matters under the Rules Governing the Listing of Securities on the Stock Exchange and the Companies (Winding Up and Miscellaneous Provisions) Ordinance**

#### *Adjustments*

In preparing the Historical Financial Information, no adjustments to the Underlying Financial Statements as defined on page [I-3] have been made.

#### *Dividends*

We refer to Note 14 to the Historical Financial Information which states that no dividend has been declared or paid by the Company and its subsidiaries in respect of the Track Record Period.

**[Deloitte Touche Tohmatsu**  
*Certified Public Accountants*  
Hong Kong  
[●] 2023]

**HISTORICAL FINANCIAL INFORMATION OF THE GROUP**

**Preparation of Historical Financial Information**

Set out below is the Historical Financial Information which forms an integral part of this accountants’ report.

The consolidated financial statements of the Group for the Track Record Period, on which the Historical Financial Information is based, have been prepared in accordance with the accounting policies which conform with International Financial Reporting Standards (“**IFRSs**”) issued by International Accounting Standards Board (the “**IASB**”) and were audited by us in accordance with Hong Kong Standards on Auditing issued by the HKICPA (“**Underlying Financial Statements**”).

The Historical Financial Information is presented in Renminbi (“**RMB**”) and all values are rounded to the nearest thousand (RMB’000) except when otherwise indicated.

APPENDIX I

ACCOUNTANTS’ REPORT

CONSOLIDATED STATEMENTS OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

	NOTES	For the year ended	
		December 31,	
		2021	2022
		RMB'000	RMB'000
Other income	6	6,896	13,923
Other gains and losses, net	8	10,794	15,100
Fair value loss of financial liabilities at fair value through profit or loss (“FVTPL”)	27	(441,077)	(551,546)
Administrative expenses		(60,217)	(85,830)
Research and development expenses		(42,983)	(91,426)
Finance costs	9	(603)	(722)
[REDACTED]		[REDACTED]	[REDACTED]
Other expenses	7	(9,041)	(3,137)
Loss before tax		(539,357)	(725,180)
Income tax expense	10	–	–
Loss and total comprehensive expense for the year	11	(539,357)	(725,180)
Loss per share (RMB)	15		
Basic		(5.94)	(4.98)
Diluted		(5.94)	(4.98)

**APPENDIX I**

**ACCOUNTANTS’ REPORT**

**CONSOLIDATED STATEMENTS OF FINANCIAL POSITION**

	<i>NOTES</i>	<b>As at December 31,</b>	
		<b>2021</b>	<b>2022</b>
		<i>RMB’000</i>	<i>RMB’000</i>
<b>NON-CURRENT ASSETS</b>			
Property, plant and equipment	16	76,029	229,627
Right-of-use assets	17	66,180	62,462
Investment property	18	–	–
Intangible assets	19	–	3,437
Prepayments, deposits and other receivables	21	9,393	173,640
		<u>151,602</u>	<u>469,166</u>
<b>CURRENT ASSETS</b>			
Materials	20	5,323	2,535
Prepayments, deposits and other receivables	21	4,575	16,829
Financial assets at FVTPL	22	532,365	512,664
Bank balances and cash	23	32,030	68,976
		<u>574,293</u>	<u>601,004</u>
<b>CURRENT LIABILITIES</b>			
Advance payments received and other payables	24	14,785	84,714
Contract liability		237	–
Deferred government grants	26	8,400	9,400
		<u>23,422</u>	<u>94,114</u>
<b>NET CURRENT ASSETS</b>		<u>550,871</u>	<u>506,890</u>
<b>TOTAL ASSETS LESS CURRENT LIABILITIES</b>		<u>702,473</u>	<u>976,056</u>
<b>NON-CURRENT LIABILITIES</b>			
Lease liabilities	25	10,580	11,219
Deferred government grants	26	38,901	27,371
Financial liabilities at FVTPL	27	1,237,517	–
		<u>1,286,998</u>	<u>38,590</u>
<b>NET (LIABILITIES) ASSETS</b>		<u>(584,525)</u>	<u>937,466</u>
<b>CAPITAL AND RESERVES</b>			
Share capital	28	90,888	192,064
Reserves		(675,413)	745,402
<b>TOTAL (DEFICITS) EQUITY</b>		<u>(584,525)</u>	<u>937,466</u>

**APPENDIX I**

**ACCOUNTANTS’ REPORT**

**STATEMENTS OF FINANCIAL POSITION OF THE COMPANY**

		<b>As at December 31,</b>	
	<i>NOTES</i>	<b>2021</b>	<b>2022</b>
		<i>RMB’000</i>	<i>RMB’000</i>
<b>NON-CURRENT ASSETS</b>			
Property, plant and equipment	<i>16</i>	8,921	9,948
Right-of-use assets	<i>17</i>	18,688	18,118
Investment property	<i>18</i>	–	–
Intangible assets	<i>19</i>	–	3,437
Investments in subsidiaries	<i>37</i>	101,343	384,050
Prepayments, deposits and other receivables	<i>21</i>	3,869	20,936
		<u>132,821</u>	<u>436,489</u>
<b>CURRENT ASSETS</b>			
Materials	<i>20</i>	598	462
Prepayments, deposits and other receivables	<i>21</i>	4,384	16,233
Financial assets at FVTPL	<i>22</i>	494,768	492,962
Bank balances and cash	<i>23</i>	32,024	59,001
		<u>531,774</u>	<u>568,658</u>
<b>CURRENT LIABILITIES</b>			
Advance payments received and other payables	<i>24</i>	4,788	17,549
Contract liability		237	–
		<u>5,025</u>	<u>17,549</u>
<b>NET CURRENT ASSETS</b>		<u>526,749</u>	<u>551,109</u>
<b>TOTAL ASSETS LESS CURRENT LIABILITIES</b>		<u>659,570</u>	<u>987,598</u>
<b>NON-CURRENT LIABILITIES</b>			
Deferred government grants		23	14
Financial liabilities at FVTPL	<i>27</i>	1,237,517	–
		<u>1,237,540</u>	<u>14</u>
<b>NET (LIABILITIES) ASSETS</b>		<u>(577,970)</u>	<u>987,584</u>
<b>CAPITAL AND RESERVES</b>			
Share capital	<i>28</i>	90,888	192,064
Reserves	<i>29</i>	(668,858)	795,520
<b>TOTAL (DEFICITS) EQUITY</b>		<u>(577,970)</u>	<u>987,584</u>

APPENDIX I

ACCOUNTANTS’ REPORT

CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

	Share capital	Share premium	Share-based payments reserve	Accumulated losses	Total
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i> <i>(Note 31)</i>	<i>RMB’000</i>	<i>RMB’000</i>
At January 1, 2021	78,580	39,462	4,194	(255,950)	(133,714)
Loss and total comprehensive expense for the year	–	–	–	(539,357)	(539,357)
Recognition of equity-settled share-based payments	–	–	76,238	–	76,238
Exercise of share options and vesting of shares granted	–	34,752	(34,752)	–	–
Issue of shares <i>(Note 28)</i>	12,308	–	–	–	12,308
At December 31, 2021	90,888	74,214	45,680	(795,307)	(584,525)
Loss and total comprehensive expense for the year	–	–	–	(725,180)	(725,180)
Recognition of equity-settled share-based payments	–	–	111,413	–	111,413
Exercise of Directors Options <i>(as defined and detailed in Note 31(d))</i>	8,695	90,907	(90,907)	–	8,695
Reclassification from financial liabilities at FVTPL <i>(Note 27)</i>	92,481	2,034,582	–	–	2,127,063
At December 31, 2022	192,064	2,199,703	66,186	(1,520,487)	937,466

**APPENDIX I**

**ACCOUNTANTS’ REPORT**

**CONSOLIDATED STATEMENTS OF CASH FLOWS**

	<i>NOTES</i>	<b>For the year ended</b>	
		<b>December 31,</b>	
		<b>2021</b>	<b>2022</b>
		<i>RMB’000</i>	<i>RMB’000</i>
<b>OPERATING ACTIVITIES</b>			
Loss before tax		(539,357)	(725,180)
Adjustment for:			
Fair value gains on financial assets at FVTPL	8	(10,804)	(13,868)
Foreign exchange gain		–	(495)
Depreciation of property, plant and equipment	11	2,389	5,286
Depreciation of investment property	11	436	–
Depreciation of right-of-use assets	11	3,717	4,463
Amortization of intangible assets	11	–	135
Loss on disposal of property, plant and equipment	8	11	3
Interest income	6	(41)	(249)
Gain on early termination of a lease	8	–	(239)
Finance costs	9	603	722
Fair value loss of financial liabilities at FVTPL	27	441,077	551,546
Issue costs for financial liabilities at FVTPL	7	6,194	2,547
Release of deferred government grants	6	(1,609)	(11,530)
Recognition of equity-settled share-based payments	11	76,238	111,413
Operating cash flows before movements in working capital		(21,146)	(75,446)
(Increase) decrease in materials		(5,242)	2,788
Increase in prepayments and other receivables		(4,284)	(14,376)
(Decrease) increase in advance payments received and other payables		(5,530)	9,006
Increase (decrease) in contract liability		237	(237)
Increase in deferred government grants related to research and development activities		16,800	1,000
<b>NET CASH USED IN OPERATING ACTIVITIES</b>		<b>(19,165)</b>	<b>(77,265)</b>



**APPENDIX I**

**ACCOUNTANTS’ REPORT**

	<i>NOTES</i>	<b>For the year ended</b>	
		<b>December 31,</b>	
		<b>2021</b>	<b>2022</b>
		<i>RMB’000</i>	<i>RMB’000</i>
<b>INVESTING ACTIVITIES</b>			
Interest received		25	223
Purchase of property, plant and equipment		(59,919)	(208,205)
Payments for right-of-use assets		(18,585)	(45,316)
Payments for rental deposits		(279)	(279)
Refund of rental deposits		–	318
Purchase of financial assets at FVTPL		(1,243,494)	(1,521,060)
Proceeds from disposal of financial assets at FVTPL		900,255	1,554,629
Government grants received related to plant and machinery	26	18,000	–
Payments for intangible assets	19	–	(3,572)
<b>NET CASH USED IN INVESTING ACTIVITIES</b>		<b>(403,997)</b>	<b>(223,262)</b>
<b>FINANCING ACTIVITIES</b>			
Payments of share issue costs for [REDACTED] (“[REDACTED]”)		(1,123)	(6,589)
Proceeds from issue of ordinary shares	28	12,308	8,695
Proceeds from issue of financial liabilities at FVTPL	27	450,000	338,000
Payments of issue costs for financial liabilities at FVTPL	7	(6,194)	(2,547)
Interest paid		–	(63)
Repayment of lease liabilities		–	(518)
<b>NET CASH FROM FINANCING ACTIVITIES</b>		<b>454,991</b>	<b>336,978</b>
<b>NET INCREASE IN CASH AND CASH EQUIVALENTS</b>		<b>31,829</b>	<b>36,451</b>
<b>CASH AND CASH EQUIVALENTS AT THE BEGINNING OF THE YEAR</b>		<b>201</b>	<b>32,030</b>
Effect of foreign exchange rate changes		–	495
<b>CASH AND CASH EQUIVALENTS AT THE END OF THE YEAR</b>	23	<b>32,030</b>	<b>68,976</b>

## APPENDIX I

## ACCOUNTANTS’ REPORT

### NOTES TO THE HISTORICAL FINANCIAL INFORMATION

#### 1. GENERAL INFORMATION

The Company was established as a limited liability company in Beijing, the People’s Republic of China (the “PRC”) on November 9, 2001. The Company was converted into a joint stock company with limited liability under the Company Law of the PRC on July 19, 2013. The address of the registered office and the principal place of business of the Company is No.3 Guangtong Street, Zhangjiawan, Tongzhou District, Beijing, PRC. The controlling shareholders of the Company are Mr. Kong Jian and his spouse, namely Ms. Zhang Yanping through their direct or indirect interests held in the Company.

The Company and its subsidiaries are principally engaged in research, development and production of vaccines and therapeutic biologics in the PRC.

The Historical Financial Information is presented in RMB, which is also the functional currency of the Company and its subsidiaries.

The statutory financial statements of the Company for the year ended December 31, 2021 were prepared in accordance with Accounting Standards for Business Enterprises issued by the Ministry of Finance of the PRC and were audited by Beijing Dongshen Dingli International Accounting Firm Co., Ltd. \* (北京東審鼎立國際會計師事務所有限責任公司). The audited statutory financial statements of the Company for the year ended December 31, 2022 are not yet due to be issued.

\* *English name is for identification purpose only.*

#### 2. APPLICATION OF IFRSs

For the purpose of preparing the Historical Financial Information for the Track Record Period, the Group has consistently applied the accounting policies which conform with IFRSs, which are effective for the accounting period beginning on January 1, 2022, throughout the Track Record Period.

##### **New and amendments to IFRSs in issue but not yet effective**

The Group has not early applied the following new and amendments to IFRSs that have been issued but are not yet effective:

IFRS 17	Insurance Contracts <sup>1</sup>
Amendments to IFRS 10 and IAS 28	Sale or Contribution of Assets between an Investor and its Associate or Joint Venture <sup>2</sup>
Amendments to IFRS 16	Lease Liability in a Sale and Leaseback <sup>3</sup>
Amendments to IAS 1	Classification of Liabilities as Current or Non-current <sup>3</sup>
Amendments to IAS 1	Non-current Liabilities with Covenants <sup>3</sup>
Amendments to IAS 1 and IFRS Practice Statement 2	Disclosure of Accounting Policies <sup>1</sup>
Amendments to IAS 8	Definition of Accounting Estimates <sup>1</sup>
Amendments to IAS 12	Deferred Tax related to Assets and Liabilities arising from a Single Transaction <sup>1</sup>

<sup>1</sup> Effective for annual periods beginning on or after January 1, 2023.

<sup>2</sup> Effective for annual periods beginning on or after a date to be determined.

<sup>3</sup> Effective for annual periods beginning on or after January 1, 2024.

The Directors anticipate that the application of the above new and amendments to IFRSs will have no material impact on the Group’s financial statements in the foreseeable future.

## APPENDIX I

## ACCOUNTANTS’ REPORT

### 3. BASIS OF PREPARATION OF HISTORICAL FINANCIAL INFORMATION AND SIGNIFICANT ACCOUNTING POLICIES

#### 3.1 Basis of preparation of Historical Financial Information

The Historical Financial Information has been prepared in accordance with the following accounting policies which conform with IFRSs issued by the IASB. For the purpose of preparation of the Historical Financial Information, information is considered material if such information is reasonably expected to influence decisions made by primary users. In addition, the Historical Financial Information included applicable disclosures required by the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited and by the Hong Kong Companies Ordinance.

The Historical Financial Information has been prepared on the historical cost basis except for certain financial instruments that are measured at fair values at the end of each reporting period, as explained in the accounting policies set out below.

Historical cost is generally based on the fair value of the consideration given in exchange for goods and services.

Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date, regardless of whether that price is directly observable or estimated using another valuation technique. In estimating the fair value of an asset or a liability, the Group takes into account the characteristics of the asset or liability if market participants would take those characteristics into account when pricing the asset or liability at the measurement date. Fair value for measurement and/or disclosure purposes in the Historical Financial Information is determined on such a basis, except for share-based payment transactions that are within the scope of IFRS 2 *Share-based Payment*, leasing transactions that are accounted for in accordance with IFRS 16 *Leases*, and measurements that have some similarities to fair value but are not fair value, such as net realizable value in IAS 2 *Inventories* or value in use in IAS 36 *Impairment of Assets*.

For financial instruments which are transacted at fair value and a valuation technique that unobservable inputs are to be used to measure fair value in subsequent periods, the valuation technique is calibrated so that at initial recognition the results of the valuation technique equals the transaction price.

In addition, for financial reporting purposes, fair value measurements are categorized into Level 1, 2 or 3 based on the degree to which the inputs to the fair value measurements are observable and the significance of the inputs to the fair value measurement in its entirety, which are described as follows:

- Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities that the entity can access at the measurement date;
- Level 2 inputs are inputs, other than quoted prices included within Level 1, that are observable for the asset or liability, either directly or indirectly; and
- Level 3 inputs are unobservable inputs for the asset or liability.

#### 3.2 Significant accounting policies

##### Basis of consolidation

The Historical Financial Information incorporates the financial statements of the Company and its subsidiaries. Control is achieved when the Company:

- has power over the investee;
- is exposed, or has rights, to variable returns from its involvement with the investee; and
- has the ability to use its power to affect its returns.

The Group reassesses whether or not it controls an investee if facts and circumstances indicate that there are changes to one or more of the three elements of control listed above.

## APPENDIX I

## ACCOUNTANTS’ REPORT

Consolidation of a subsidiary begins when the Group obtains control over the subsidiary and ceases when the Group loses control of the subsidiary. Specifically, income and expenses of a subsidiary acquired or disposed of during the year are included in the consolidated statements of profit or loss and other comprehensive income from the date the Group gains control until the date when the Group ceases to control the subsidiary.

Profit or loss and each item of other comprehensive income are attributed to the owners of the Company and to the non-controlling interests. Total comprehensive income of subsidiaries is attributed to the owners of the Company and to the non-controlling interests even if this results in the non-controlling interests having a deficit balance.

When necessary, adjustments are made to the financial statements of subsidiaries to bring their accounting policies in line with the Group’s accounting policies.

All intragroup assets and liabilities, equity, income, expenses and cash flows relating to transactions between members of the Group are eliminated in full on consolidation.

### **Investments in subsidiaries**

The investments in subsidiaries are stated at cost less accumulated impairment loss.

### **Revenue from contracts with customers**

The Group recognizes revenue when (or as) a performance obligation is satisfied, i.e. when “control” of the goods or services underlying the particular performance obligation is transferred to the customer.

A performance obligation represents a good or service (or a bundle of goods or services) that is distinct or a series of distinct goods or services that are substantially the same.

Control is transferred over time and revenue is recognized over time by reference to the progress towards complete satisfaction of the relevant performance obligation if one of the following criteria is met:

- the customer simultaneously receives and consumes the benefits provided by the Group’s performance as the Group performs;
- the Group’s performance creates or enhances an asset that the customer controls as the Group performs; or
- the Group’s performance does not create an asset with an alternative use to the Group and the Group has an enforceable right to payment for performance completed to date.

Otherwise, revenue is recognized at a point in time when the customer obtains control of the distinct good or service.

A contract liability represents the Group’s obligation to transfer goods or services to a customer for which the Group has received consideration (or an amount of consideration is due) from the customer.

Revenue from contracts with customers which is not derived from the Group’s ordinary course of business is presented as other income.

### **Leases**

#### *Definition of a lease*

A contract is, or contains, a lease if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration.

#### *The Group as lessee*

##### *Short-term leases*

The Group applies the short-term lease recognition exemption to leases of properties and office equipment that have a lease term of 12 months or less from the commencement date and do not contain a purchase option. Lease payments on short-term leases are recognized as expense on a straight-line basis over the lease term.

## APPENDIX I

## ACCOUNTANTS’ REPORT

### *Right-of-use assets*

The cost of right-of-use assets includes:

- the amount of the initial measurement of the lease liability;
- any lease payments made at or before the commencement date, less any lease incentives received;
- any initial direct costs incurred by the Group; and
- an estimate of costs to be incurred by the Group in dismantling and removing the underlying assets, restoring the site on which it is located or restoring the underlying asset to the condition required by the terms and conditions of the lease.

Right-of-use assets are measured at cost, less any accumulated depreciation and impairment losses, and adjusted for any remeasurement of lease liabilities.

Right-of-use assets are depreciated on a straight-line basis over the shorter of its estimated useful life and the lease term.

The Group presents right-of-use assets as a separate line item on the consolidated statements of financial position.

### *Refundable rental deposits*

Refundable rental deposits paid are accounted under IFRS 9 *Financial Instruments* and initially measured at fair value. Adjustments to fair value at initial recognition are considered as additional lease payments and included in the cost of right-of-use assets.

### *Lease liabilities*

At the commencement date of a lease, the Group recognizes and measures the lease liability at the present value of lease payments that are unpaid at that date. In calculating the present value of lease payments, the Group uses the incremental borrowing rate at the lease commencement date if the interest rate implicit in the lease is not readily determinable.

The lease payments include:

- fixed payments (including in-substance fixed payments) less any lease incentives receivable;
- variable lease payments that depend on an index or a rate, initially measured using the index or rate as at the commencement date;
- amounts expected to be payable by the Group under residual value guarantees;
- the exercise price of a purchase option if the Group is reasonably certain to exercise the option; and
- payments of penalties for terminating a lease, if the lease term reflects the Group exercising an option to terminate the lease.

After the commencement date, lease liabilities are adjusted by interest accretion and lease payments.

The Group presents lease liabilities as a separate line item on the consolidated statements of financial position.

### *Lease modifications*

For a lease modification that is not accounted for as a separate lease, the Group accounts for the remeasurement of the lease liability by decreasing the carrying amount of the right-of-use asset to reflect the partial or full termination of the lease for lease modifications that decrease the scope of the lease and making a corresponding adjustment to the right-of-use asset for all other lease modifications. The Group recognizes in profit or loss any gain or loss relating to the partial or full termination of the lease.

## APPENDIX I

## ACCOUNTANTS’ REPORT

### *The Group as a lessor*

#### *Classification and measurement of leases*

Leases for which the Group is a lessor are classified as finance or operating leases. Whenever the terms of the lease transfer substantially all the risks and rewards incidental to ownership of an underlying asset to the lessee, the contract is classified as a finance lease. All other leases are classified as operating leases.

Rental income from operating leases is recognized in profit or loss on a straight-line basis over the term of the relevant lease. Initial direct costs incurred in negotiating and arranging an operating lease are added to the carrying amount of the leased asset, and such costs are recognized as an expense on a straight-line basis over the lease term.

#### *Refundable rental deposits*

Refundable rental deposits received are accounted for under IFRS 9 and initially measured at fair value. Adjustments to fair value at initial recognition are considered as additional lease payments from lessees.

### **Foreign currencies**

In preparing the financial statements of each individual group entity, transactions in currencies other than the functional currency of that entity (foreign currencies) are recognized at the rates of exchanges prevailing on the dates of the transactions. At the end of each reporting period, monetary items denominated in foreign currencies are retranslated at the rates prevailing at that date. Non-monetary items that are measured in terms of historical cost in a foreign currency are not retranslated.

Exchange differences arising on the settlement of monetary items, and on the retranslation of monetary items, are recognized in profit or loss in the period in which they arise.

### **Borrowing costs**

All borrowing costs not directly attributable to the acquisition, construction or production of qualifying assets are recognized in profit or loss in the period in which they are incurred.

### **Government grants**

Government grants are not recognized until there is reasonable assurance that the Group will comply with the conditions attaching to them and that the grants will be received.

Government grants are recognized in profit or loss on a systematic basis over the periods in which the Group recognizes as expenses the related costs for which the grants are intended to compensate. Specifically, government grants whose primary condition is that the Group should purchase, construct or otherwise acquire non-current assets are recognized as deferred government grants in the Historical Financial Information and transferred to profit or loss on a systematic and rational basis over the useful lives of the related assets.

Government grants related to income that are receivable as compensation for expenses or losses already incurred or for the purpose of giving immediate financial support to the Group with no future related costs are recognized in profit or loss in the period in which they become receivable. Such grants are presented under “other income”.

### **Employee benefits**

#### *Retirement benefit costs*

Payments to state-managed retirement benefit scheme are recognized as an expense when employees have rendered services entitling them to the contributions.

#### *Short-term employee benefits*

Short-term employee benefits are recognized at the undiscounted amount of the benefits expected to be paid as and when employees rendered the services. All short-term employee benefits are recognized as an expense unless another IFRS requires or permits the inclusion of the benefit in the cost of an asset.

## APPENDIX I

## ACCOUNTANTS' REPORT

A liability is recognized for benefits accruing to employees (such as wages and salaries and annual leave) after deducting any amount already paid.

### **Share-based payments**

#### *Equity-settled share-based payment transactions*

##### *Shares/share options granted to employees*

Equity-settled share-based payments to employees are measured at the fair value of the equity instruments at the grant date.

The fair value of the equity-settled share-based payments determined at the grant date without taking into consideration all non-market vesting conditions is expensed on a straight-line basis over the vesting period, based on the Group's estimate of equity instruments that will eventually vest, with a corresponding increase in equity (share-based payments reserve). At the end of each reporting period, the Group revises its estimate of the number of equity instruments expected to vest based on assessment of all relevant non-market vesting conditions. The impact of the revision of the original estimates, if any, is recognized in profit or loss such that the cumulative expense reflects the revised estimate, with a corresponding adjustment to the share-based payments reserve. For shares/share options that vest immediately at the date of grant, the fair value of the shares/share options granted is expensed immediately to profit or loss.

When share options are exercised, the amount previously recognized in share-based payments reserve will be transferred to share premium. When the share options are forfeited after the vesting date or are still not exercised at the expiry date, the amount previously recognized in share-based payments reserve will continue to be held in share-based payments reserve.

When shares granted are vested, the amount previously recognized in share-based payments reserve will be transferred to share premium.

##### *Modification to the terms and conditions of the share-based payment arrangements*

When the terms and conditions of an equity-settled share-based payment arrangement are modified, the Group recognizes, as a minimum, the services received measured at the grant date fair value of the equity instruments granted, unless those equity instruments do not vest because of failure to satisfy a vesting condition (other than a market condition) that was specified at grant date. In addition, if the Group modifies the vesting conditions (other than a market condition) in a manner that is beneficial to the employees, for example, by reducing the vesting period, the Group takes the modified vesting conditions into consideration over the remaining vesting period.

The incremental fair value granted, if any, is the difference between the fair value of the modified equity instruments and that of the original equity instruments, both estimated as at the date of modification.

If the modification occurs during the vesting period, the incremental fair value granted is included in the measurement of the amount recognized for services received over the period from modification date until the date when the modified equity instruments are vested, in addition to the amount based on the grant date fair value of the original equity instruments, which is recognized over the remainder of the original vesting period.

If the modification reduces the total fair value of the share-based payment arrangement, or is not otherwise beneficial to the employee, the Group continues to account for the original equity instruments granted as if that modification had not occurred.

### **Taxation**

Income tax expense represents the sum of the tax currently payable and deferred tax.

The tax currently payable is based on taxable profit for the year. Taxable profit differs from loss before tax because of income or expense that are taxable or deductible in other years and items that are never taxable or deductible. The Group's liability for current tax is calculated using tax rates that have been enacted or substantively enacted by the end of each reporting period.

## APPENDIX I

## ACCOUNTANTS' REPORT

Deferred tax is recognized on temporary differences between the carrying amounts of assets and liabilities in the Historical Financial Information and the corresponding tax bases used in the computation of taxable profit. Deferred tax liabilities are generally recognized for all taxable temporary differences. Deferred tax assets are generally recognized for all deductible temporary differences to the extent that it is probable that taxable profits will be available against which those deductible temporary differences can be utilized. Such deferred tax assets and liabilities are not recognized if the temporary difference arises from the initial recognition (other than in a business combination) of assets and liabilities in a transaction that affects neither the taxable profit nor the accounting profit.

Deferred tax liabilities are recognized for taxable temporary differences associated with investments in subsidiaries, except where the Group is able to control the reversal of the temporary differences and it is probable that the temporary differences will not reverse in the foreseeable future. Deferred tax assets arising from deductible temporary differences associated with such investments are only recognized to the extent that it is probable that there will be sufficient taxable profits against which to utilize the benefits of the temporary differences and they are expected to reverse in the foreseeable future.

The carrying amount of deferred tax assets is reviewed at the end of each reporting period and reduced to the extent that it is no longer probable that sufficient taxable profits will be available to allow all or part of the asset to be recovered.

Deferred tax assets and liabilities are measured at the tax rates that are expected to apply in the period in which the liability is settled or the asset is realized, based on tax rate (and tax laws) that have been enacted or substantively enacted by the end of each reporting period.

The measurement of deferred tax liabilities and assets reflects the tax consequences that would follow from the manner in which the Group expects, at the end of each reporting period, to recover or settle the carrying amount of its assets and liabilities.

For the purposes of measuring deferred tax for leasing transactions in which the Group recognizes the right-of-use assets and the related lease liabilities, the Group first determines whether the tax deductions are attributable to the right-of-use assets or the lease liabilities.

For leasing transactions in which the tax deductions are attributable to the lease liabilities, the Group applies IAS 12 *Income Taxes* requirements to right-of-use assets and lease liabilities separately. Temporary differences relating to right-of-use assets and lease liabilities are not recognized at initial recognition and over the lease terms due to application of the initial recognition exemption. Temporary differences arising from subsequent revision to the carrying amounts of right-of-use assets and lease liabilities, resulting from remeasurement of lease liabilities and lease modifications, that are not subject to initial recognition exemption are recognized on the date of remeasurement or modification.

Deferred tax assets and liabilities are offset when there is a legally enforceable right to set off current tax assets against current tax liabilities and when they relate to income taxes levied to the same taxable entity by the same taxation authority.

Current and deferred tax are recognized in profit or loss.

### **Property, plant and equipment**

Property, plant and equipment are tangible assets that are held for use in the production or supply of goods or services, or for administrative purposes. Property, plant and equipment (other than construction in progress), are stated in the consolidated statements of financial position at cost, less subsequent accumulated depreciation and subsequent accumulated impairment losses, if any.

Property, plant and equipment in the course of construction for production, supply or administrative purposes are carried at cost, less any recognized impairment loss. Costs include any costs directly attributable to bringing the asset to the location and condition necessary for it to be capable of operating in the manner intended by management and, for qualifying assets, borrowing costs capitalized, in accordance with the Group's accounting policy. Depreciation of these assets, on the same basis as other property, plant and equipment, commences when the assets are ready for their intended use.



## APPENDIX I

## ACCOUNTANTS' REPORT

When the Group makes payments for ownership interests of properties which includes both leasehold land and building elements, the entire consideration is allocated between the leasehold land and the building elements in proportion to the relative fair values at initial recognition. To the extent the allocation of the relevant payments can be made reliably, interest in leasehold land is presented as "right-of-use assets" in the consolidated statements of financial position. When the consideration cannot be allocated reliably between non-lease building element and undivided interest in the underlying leasehold land, the entire properties are classified as property, plant and equipment.

Depreciation is recognized so as to write off the cost of property, plant and equipment, other than construction in progress less their residual values over their estimated useful lives, using the straight-line method. The estimated useful lives, residual values and depreciation method are reviewed at the end of each reporting period, with the effect of any changes in estimate accounted for on a prospective basis.

An item of property, plant and equipment is derecognized upon disposal or when no future economic benefits are expected to arise from the continued use of the asset. Any gain or loss arising on the disposal or retirement of an item of property, plant and equipment is determined as the difference between the sales proceeds and the carrying amount of the asset and is recognized in profit or loss.

### **Investment properties**

Investment properties are properties held to earn rentals and/or for capital appreciation.

Investment properties are initially measured at cost, including any directly attributable expenditure. Subsequent to initial recognition, investment properties are stated at cost less subsequent accumulated depreciation and any accumulated impairment losses. Depreciation is recognized so as to write off the cost of investment properties over their estimated useful lives and after taking into account of their estimated residual value, using the straight-line method.

If an investment property becomes owner-occupied as evidenced by commencement of owner-occupation, the cost of the relevant investment property and the related accumulated depreciation and impairment loss (if any) are transferred to property, plant and equipment.

### **Intangible assets**

#### *Intangible assets acquired separately*

Intangible assets with finite useful lives that are acquired separately are carried at costs less accumulated amortization and any accumulated impairment losses. Variable payments that are dependent on the Group's future activity are excluded from the initial measurement of intangible assets and instead are recognized as a liability when the condition that triggers the obligation occurs. The subsequent changes in the liability are recognized as an adjustment to the cost of the intangible assets if it is determined that the future payment is related to the cost of the assets or otherwise recognized as an expense in the period in which they are incurred.

Amortization for intangible assets with finite useful lives is recognized on a straight-line basis over their estimated useful lives. The estimated useful life and amortization method are reviewed at the end of each reporting period, with the effect of any changes in estimate being accounted for on a prospective basis.

#### *Research and development expenditure*

Expenditure on research activities is recognized as an expense in the period in which it is incurred.

An internally-generated intangible asset arising from development activities (or from the development phase of an internal project) is recognized if, and only if, all of the following have been demonstrated:

- the technical feasibility of completing the intangible asset so that it will be available for use or sale;
- the intention to complete the intangible asset and use or sell it;
- the ability to use or sell the intangible asset;

## APPENDIX I

## ACCOUNTANTS' REPORT

- how the intangible asset will generate probable future economic benefits;
- the availability of adequate technical, financial and other resources to complete the development and to use or sell the intangible asset; and
- the ability to measure reliably the expenditure attributable to the intangible asset during its development.

The amount initially recognized for internally-generated intangible asset is the sum of the expenditure incurred from the date when the intangible asset first meets the recognition criteria listed above. Where no internally generated intangible asset can be recognized, development expenditure is recognized in profit or loss in the period in which it is incurred.

### **Impairment on property, plant and equipment, intangible assets and right-of-use assets**

At the end of each reporting period, the Group reviews the carrying amounts of its property, plant and equipment, intangible assets with finite useful lives and right-of-use assets to determine whether there is any indication that those assets have suffered an impairment loss. If any such indication exists, the recoverable amount of the relevant asset is estimated in order to determine the extent of the impairment loss (if any).

The recoverable amount of property, plant and equipment, intangible assets and right-of-use assets are estimated individually. When it is not possible to estimate the recoverable amount individually, the Group estimates the recoverable amount of the cash-generating unit to which the asset belongs.

In testing a cash-generating unit for impairment, corporate assets are allocated to the relevant cash-generating unit when a reasonable and consistent basis of allocation can be established, or otherwise they are allocated to the smallest group of cash generating units for which a reasonable and consistent allocation basis can be established. The recoverable amount is determined for the cash-generating unit or group of cash-generating units to which the corporate asset belongs, and is compared with the carrying amount of the relevant cash-generating unit or group of cash-generating units.

Recoverable amount is the higher of fair value less costs of disposal and value in use. In assessing value in use, the estimated future cash flows are discounted to their present value using a pre-tax discount rate that reflects current market assessments of the time value of money and the risks specific to the asset (or a cash-generating unit) for which the estimates of future cash flows have not been adjusted.

If the recoverable amount of an asset (or a cash-generating unit) is estimated to be less than its carrying amount, the carrying amount of the asset (or a cash-generating unit) is reduced to its recoverable amount. For corporate assets or portion of corporate assets which cannot be allocated on a reasonable and consistent basis to a cash-generating unit, the Group compares the carrying amount of a group of cash-generating units, including the carrying amounts of the corporate assets or portion of corporate assets allocated to that group of cash-generating units, with the recoverable amount of the group of cash-generating units. In allocating the impairment loss, the impairment loss is allocated first to reduce the carrying amount of any goodwill (if applicable) and then to the other assets on a pro-rata basis based on the carrying amount of each asset in the unit or the group of cash-generating units. The carrying amount of an asset is not reduced below the highest of its fair value less costs of disposal (if measurable), its value in use (if determinable) and zero. The amount of the impairment loss that would otherwise have been allocated to the asset is allocated pro rata to the other assets of the unit or the group of cash-generating units. An impairment loss is recognized immediately in profit or loss.

Where an impairment loss subsequently reverses, the carrying amount of the asset (or cash-generating unit or a group of cash-generating units) is increased to the revised estimate of its recoverable amount, but so that the increased carrying amount does not exceed the carrying amount that would have been determined had no impairment loss been recognized for the asset (or a cash-generating unit or a group of cash-generating units) in prior years. A reversal of an impairment loss is recognized immediately in profit or loss.

## APPENDIX I

## ACCOUNTANTS' REPORT

### Cash and cash equivalents

For the purposes of the consolidated statements of cash flows, cash and cash equivalents consist of:

- (a) cash, which comprises of cash on hand and demand deposits, excluding bank balances that are subject to regulatory restrictions that result in such balances no longer meeting the definition of cash; and
- (b) cash equivalents, which comprises of short-term (generally with original maturity of three months or less), highly liquid investments that are readily convertible to a known amount of cash and which are subject to an insignificant risk of changes in value. Cash equivalents are held for the purpose of meeting short-term cash commitments rather than for investment or other purposes.

### Materials

Materials are mainly reagent and consumable materials for research and development purposes. Materials are stated at the lower of cost and recoverable amount, and expensed as they are consumed.

### Financial instruments

Financial assets and financial liabilities are recognized when a group entity becomes a party to the contractual provisions of the instrument. All regular way purchases or sales of financial assets are recognized and derecognized on a trade date basis. Regular way purchases or sales are purchases or sales of financial assets that require delivery of assets within the time frame established by regulation or convention in the market place.

Financial assets and financial liabilities are initially measured at fair value except for trade receivables arising from contracts with customers which are initially measured in accordance with IFRS 15 *Revenue from Contracts with Customers*. Transaction costs that are directly attributable to the acquisition or issue of financial assets and financial liabilities (other than financial assets or liabilities at FVTPL) are added to or deducted from the fair value of the financial assets or financial liabilities, as appropriate, on initial recognition. Transaction costs directly attributable to the acquisition of financial assets or financial liabilities at FVTPL are recognized immediately in profit or loss.

The effective interest method is a method of calculating the amortized cost of a financial asset or financial liability and of allocating interest income and interest expense over the relevant period. The effective interest rate is the rate that exactly discounts estimated future cash receipts and payments (including all fees and points paid or received that form an integral part of the effective interest rate, transaction costs and other premiums or discounts) through the expected life of the financial asset or financial liability, or, where appropriate, a shorter period, to the net carrying amount on initial recognition.

### Financial assets

#### *Classification and subsequent measurement of financial assets*

Financial assets that meet the following conditions are subsequently measured at amortized cost:

- the financial asset is held within a business model whose objective is to collect contractual cash flows; and
- the contractual terms give rise on specified dates to cash flows that are solely payments of principal and interest on the principal amount outstanding.

All other financial assets of the Group are subsequently measured at fair value.

#### *Amortized cost and interest income*

Interest income is recognized using the effective interest method for financial assets measured subsequently at amortized cost. Interest income is calculated by applying the effective interest rate to the gross carrying amount of a financial asset, except for financial assets that have subsequently become credit-impaired (see below). For financial assets that have subsequently become credit-impaired, interest income is recognized by applying the effective interest rate to the amortized cost of the financial asset from the next reporting period. If the

## APPENDIX I

## ACCOUNTANTS’ REPORT

credit risk on the credit-impaired financial instrument improves so that the financial asset is no longer credit-impaired, interest income is recognized by applying the effective interest rate to the gross carrying amount of the financial asset from the beginning of the reporting period following the determination that the asset is no longer credit impaired.

Interest income is recognized in profit or loss and included in the “other income” line item.

### *Financial assets at FVTPL*

The Group’s financial assets that do not meet the criteria for being measured at amortized cost are measured at FVTPL.

Financial assets at FVTPL are measured at fair value at the end of each reporting period, with any fair value gains or losses recognized in profit or loss. The net gain or loss recognized in profit or loss includes any interest earned on the financial asset and is included in the “other gains and losses, net” line item.

### *Impairment of financial assets*

The Group performs impairment assessment under expected credit loss (“ECL”) on financial assets (including bank balances, deposits and other receivables) which are subject to impairment assessment under IFRS 9. The amount of ECL is updated at each reporting date to reflect changes in credit risk since initial recognition.

Lifetime ECL represents the ECL that will result from all possible default events over the expected life of the relevant instrument. In contrast, 12-month ECL (“12m ECL”) represents the portion of lifetime ECL that is expected to result from default events that are possible within 12 months after the reporting date. Assessments are done based on the Group’s historical credit loss experience, adjusted for factors that are specific to the debtors, general economic conditions and an assessment of both the current conditions at the reporting date as well as the forecast of future conditions.

For all financial assets, the Group measures the loss allowance equal to 12m ECL, unless there has been a significant increase in credit risk since initial recognition, in which case the Group recognizes lifetime ECL. The assessment of whether lifetime ECL should be recognized is based on significant increases in the likelihood or risk of a default occurring since initial recognition.

### *Significant increase in credit risk*

In assessing whether the credit risk has increased significantly since initial recognition, the Group compares the risk of a default occurring on the financial instrument as at the reporting date with the risk of a default occurring on the financial instrument as at the date of initial recognition. In making this assessment, the Group considers both quantitative and qualitative information that is reasonable and supportable, including historical experience and forward-looking information that is available without undue cost or effort.

In particular, the following information is taken into account when assessing whether credit risk has increased significantly:

- an actual or expected significant deterioration in the financial instrument’s external (if available) or internal credit rating;
- significant deterioration in external market indicators of credit risk, e.g. a significant increase in the credit spread, the credit default swap prices for the debtor;
- existing or forecast adverse changes in business, financial or economic conditions that are expected to cause a significant decrease in the debtor’s ability to meet its debt obligations;
- an actual or expected significant deterioration in the operating results of the debtor;
- an actual or expected significant adverse change in the regulatory, economic, or technological environment of the debtor that results in a significant decrease in the debtor’s ability to meet its debt obligations.

Irrespective of the outcome of the above assessment, the Group presumes that the credit risk has increased significantly since initial recognition when contractual payments are more than 30 days past due, unless the Group has reasonable and supportable information that demonstrates otherwise.

## APPENDIX I

## ACCOUNTANTS’ REPORT

Despite the foregoing, the Group assumes that the credit risk on a debt instrument has not increased significantly since initial recognition if the debt instrument is determined to have low credit risk at the reporting date. A debt instrument is determined to have low credit risk if i) it has a low risk of default, ii) the borrower has a strong capacity to meet its contractual cash flow obligations in the near term and iii) adverse changes in economic and business conditions in the longer term may, but will not necessarily, reduce the ability of the borrower to fulfill its contractual cash flow obligations. The Group considers a debt instrument to have low credit risk when it has an internal or external credit rating of ‘investment grade’ as per globally understood definitions.

The Group regularly monitors the effectiveness of the criteria used to identify whether there has been a significant increase in credit risk and revises them as appropriate to ensure that the criteria are capable of identifying significant increase in credit risk before the amount becomes past due.

### *Definition of default*

The Group considers the following as constituting an event of default for internal credit risk management purposes as historical experience indicates that receivables that meet either of the following criteria are generally not recoverable.

- when there is a breach of financial covenants by the counterparty; or
- information developed internally or obtained from external sources indicates that the debtor is unlikely to pay its creditors, including the Group, in full (without taking into account any collaterals held by the Group).

Irrespective of the above, the Group considers that default has occurred when a financial asset is more than 90 days past due unless the Group has reasonable and supportable information to demonstrate that a more lagging default criterion is more appropriate.

### *Credit-impaired financial assets*

A financial asset is credit-impaired when one or more events of default that have a detrimental impact on the estimated future cash flows of that financial asset have occurred. Evidence that a financial asset is credit-impaired includes observable data about the following events:

- (a) significant financial difficulty of the issuer or the borrower;
- (b) a breach of contract, such as a default or past due event;
- (c) the lender(s) of the borrower, for economic or contractual reasons relating to the borrower’s financial difficulty, having granted to the borrower a concession(s) that the lender(s) would not otherwise consider; or
- (d) it is becoming probable that the borrower will enter bankruptcy or other financial reorganization.

### *Write-off policy*

The Group writes off a financial asset when there is information indicating that the counterparty is in severe financial difficulty and there is no realistic prospect of recovery, e.g. when the counterparty has been placed under liquidation or has entered into bankruptcy proceedings. Financial assets written off may still be subject to enforcement activities under the Group’s recovery procedures, taking into account legal advice where appropriate. A write-off constitutes a derecognition event. Any subsequent recoveries are recognized in profit or loss.

### *Measurement and recognition of ECL*

The measurement of ECL is a function of the probability of default, loss given default (i.e. the magnitude of the loss if there is a default) and the exposure at default. The assessment of the probability of default and loss given default is based on historical data adjusted by forward-looking information. Estimation of ECL reflects an unbiased and probability-weighted amount that is determined with the respective risks of default occurring as the weights.

Generally, the ECL is the difference between all contractual cash flows that are due to the Group in accordance with the contract and the cash flows that the Group expects to receive, discounted at the effective interest rate determined at initial recognition.

## APPENDIX I

## ACCOUNTANTS’ REPORT

Interest income is calculated based on the gross carrying amount of the financial asset unless the financial asset is credit impaired, in which case interest income is calculated based on amortized cost of the financial asset.

The Group recognizes an impairment gain or loss in profit or loss for all financial instruments by adjusting their carrying amount, with the exception of other receivables where the corresponding adjustment is recognized through a loss allowance account.

### *Derecognition of financial assets*

The Group derecognizes a financial asset only when the contractual rights to the cash flows from the asset expire, or when it transfers the financial asset and substantially all the risks and rewards of ownership of the asset to another entity.

On derecognition of a financial asset measured at amortized cost, the difference between the asset’s carrying amount and the sum of consideration received and receivable is recognized in profit or loss.

### *Financial liabilities and equity*

#### *Classification as debt or equity*

Debt and equity instruments issued by a group entity are classified as either financial liabilities or as equity in accordance with the substance of the contractual arrangements and the definitions of a financial liability and an equity instrument. The liability/equity classification made at initial recognition is reconsidered if there are changes to the contractual terms of the instrument.

#### *Equity instruments*

An equity instrument is any contract that evidences a residual interest in the assets of an entity after deducting all of its liabilities. Equity instruments issued by the Company are recognized at the proceeds received, net of direct issue costs.

Financial instruments issued by the Group, which include no contractual obligation for the Group to deliver cash or other financial assets are classified as equity instruments.

#### *Financial liabilities*

All financial liabilities are subsequently measured at amortized cost using the effective interest method or at FVTPL.

#### *Financial liabilities at FVTPL*

Financial liabilities are classified as at FVTPL when the financial liability is (i) contingent consideration of an acquirer in a business combination to which IFRS 3 *Business Combinations* applies, (ii) held for trading or (iii) designated as at FVTPL.

A financial liability other than a financial liability held for trading or contingent consideration of an acquirer in a business combination may be designated as at FVTPL upon initial recognition if:

- such designation eliminates or significantly reduces a measurement or recognition inconsistency that would otherwise arise; or
- the financial liability forms part of a group of financial assets or financial liabilities or both, which is managed and its performance is evaluated on a fair value basis, in accordance with the Group’s documented risk management or investment strategy, and information about the grouping is provided internally on that basis; or
- it forms part of a contract containing one or more embedded derivatives, and IFRS 9 permits the entire combined contract to be designated as at FVTPL.

For financial liabilities that are designated as at FVTPL, the amount of change in the fair value of the financial liability that is attributable to changes in the credit risk of that liability is recognized in other comprehensive income, unless the recognition of the effects of changes in the liability’s credit risk in other comprehensive income would create or enlarge an accounting mismatch in profit or loss. Changes in fair value attributable to a financial liability’s credit risk that are recognized in other comprehensive income are not subsequently reclassified to profit or loss; instead, they are transferred to accumulated losses upon derecognition of the financial liability.

## APPENDIX I

## ACCOUNTANTS’ REPORT

### *Financial liabilities at amortized cost*

Financial liabilities including other payables are subsequently measured at amortized cost, using the effective interest method.

### *Derecognition of financial liabilities*

The Group derecognizes financial liabilities when, and only when, the Group’s obligations are discharged, cancelled or have expired. The difference between the carrying amount of the financial liability derecognized and the consideration paid and payable is recognized in profit or loss.

#### **4. CRITICAL ACCOUNTING JUDGMENT AND KEY SOURCES OF ESTIMATION UNCERTAINTY**

In the application of the Group’s accounting policies, which are described in Note 3, the Directors are required to make judgments, estimates and assumptions about the carrying amounts of assets and liabilities that are not readily apparent from other sources. The estimates and associated assumptions are based on historical experience and other factors that are considered to be relevant. Actual results may differ from these estimates.

The estimates and underlying assumptions are reviewed on an on-going basis. Revisions to accounting estimates are recognized in the period in which the estimate is revised if the revision affects only that period, or in the period of the revision and future periods if the revision affects both current and future periods.

#### **Critical judgment in applying accounting policies**

The following is the critical judgment, apart from those involving estimations (see below), that the Directors have made in the process of applying the Group’s accounting policies and that have the most significant effect on the amounts recognized in the Historical Financial Information.

#### ***Research and development expenditures***

Development costs incurred on the Group’s vaccines and therapeutic biologics pipelines are capitalized and deferred only when the Group can demonstrate the technical feasibility of completing the intangible asset so that it will be available for use or sale, the Group’s intention to complete and use or sell the asset, how the asset will generate probable future economic benefits, the availability of adequate technical, financial and other resources to complete the pipeline, the Group’s ability to use or sell the asset and the ability to measure reliably the expenditure during the development. Development costs which do not meet these criteria are expensed when incurred.

The Directors assess the progress of each of the research and development projects and determine whether the criteria are met for capitalization. During the Track Record Period, all development costs are expensed when incurred.

#### **Key sources of estimation uncertainty**

The followings are the key assumptions concerning the future, and other key sources of estimation uncertainty at the end of the reporting period that may have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the coming twelve months.

#### ***Fair value measurement of financial liabilities at FVTPL***

No quoted prices in an active market are available for the Group’s financial liabilities at FVTPL. These financial liabilities were valued by the Directors with the assistance of an independent qualified professional valuer not connected to the Group, which has appropriate qualifications and experience in valuation of similar financial instruments. The fair value of these financial liabilities is established by using valuation techniques as disclosed in Notes 27 and 33. Valuation techniques are certified by the valuer before being implemented for valuation and are calibrated to ensure that outputs reflect market conditions. Valuation models established by the valuer make the maximum use of market inputs and rely as little as possible on the Group’s specific data. However, it should be noted that some inputs, such as possibilities under different scenarios such as [REDACTED], liquidation and redemption, require management estimates. The estimates and assumptions are reviewed periodically by the Directors and adjusted if necessary. Should any of the estimates and assumptions changed, it may lead to a change in the fair value of financial liabilities at FVTPL. The fair value of financial liabilities at FVTPL at December 31, 2021 was RMB1,237,517,000.

## APPENDIX I

## ACCOUNTANTS’ REPORT

### 5. SEGMENT INFORMATION

For the purposes of resources allocation and performance assessment, the executive directors of the Company, being the chief operating decision makers, review the consolidated results when making decisions about allocating resources and assessing performance of the Group as a whole and hence, the Group has only one operating and reportable segment and no further analysis of this single segment is presented.

The Group did not record any revenue during the Track Record Period. As at December 31, 2021 and 2022, the Group’s non-current assets excluding financial instruments amounted to RMB151,307,000 and RMB468,853,000 respectively are all located in Mainland China, accordingly, no analysis of geographical information is presented.

### 6. OTHER INCOME

	<b>For the year ended December 31,</b>	
	<b>2021</b>	<b>2022</b>
	<i>RMB’000</i>	<i>RMB’000</i>
Rental income from investment property	2,350	–
Income from sales of testing kits ( <i>Note</i> )	2,616	2,056
Government grants related to		
– Right-of-use assets and plant and machinery ( <i>Note 26</i> )	1,609	3,130
– Research and development activities ( <i>Note 26</i> )	–	8,400
– Others	280	88
Interest income on bank balances	25	223
Interest income from rental deposits	16	26
	<u>6,896</u>	<u>13,923</u>
Total	<u>6,896</u>	<u>13,923</u>

*Note:* An analysis of the Group’s income from sales of testing kits is as follows:

	<b>For the year ended December 31,</b>	
	<b>2021</b>	<b>2022</b>
	<i>RMB’000</i>	<i>RMB’000</i>
Type of goods		
Testing Kits	<u>2,616</u>	<u>2,056</u>
Timing of recognition		
At a point in time	<u>2,616</u>	<u>2,056</u>

During the Track Record Period, the Group sells testing kits to pharmaceutical companies. Sale of testing kits is not considered the principal business of the Group. For sales of testing kits to its customer, income is recognized when customer obtains control of the goods, being at the point the goods are delivered to the customer. The Group usually requires 100% upfront payments from its customers and occasionally allows a credit period of 30 days to its customers. The transaction price received by the Group is recognized as contract liability until the testing kits are delivered to the customer.

Sales of testing kits are for periods of one year or less. As permitted under IFRS 15, the transaction price allocated to these unsatisfied contracts is not disclosed.



**APPENDIX I**

**ACCOUNTANTS’ REPORT**

During the Track Record Period, income from sales of testing kits of the corresponding years contributing over 10% of such income of the Group are as follows:

	<b>For the year ended December 31,</b>	
	<b>2021</b>	<b>2022</b>
	<i>RMB'000</i>	<i>RMB'000</i>
Customer A	1,416	–
Customer B	409	853
Customer C	382	N/A*
Customer D	281	359
Customer E	N/A*	351
	<b><u>          </u></b>	<b><u>          </u></b>

\* The corresponding income did not contribute over 10% of total income from sales of testing kits of the Group for the relevant year.

**7. OTHER EXPENSES**

	<b>For the year ended December 31,</b>	
	<b>2021</b>	<b>2022</b>
	<i>RMB'000</i>	<i>RMB'000</i>
Direct operating expenses incurred for investment property	744	–
Cost of testing kits sold	853	590
Issue costs for financial liabilities at FVTPL	6,194	2,547
Others	1,250	–
	<b><u>          </u></b>	<b><u>          </u></b>
Total	<b><u>9,041</u></b>	<b><u>3,137</u></b>

**8. OTHER GAINS AND LOSSES, NET**

	<b>For the year ended December 31,</b>	
	<b>2021</b>	<b>2022</b>
	<i>RMB'000</i>	<i>RMB'000</i>
Fair value gains on financial assets at FVTPL	10,804	13,868
Loss on disposal of property, plant and equipment	(11)	(3)
Foreign exchange gains, net	1	996
Gain on early termination of a lease	–	239
	<b><u>          </u></b>	<b><u>          </u></b>
Total	<b><u>10,794</u></b>	<b><u>15,100</u></b>

**9. FINANCE COSTS**

	<b>For the year ended December 31,</b>	
	<b>2021</b>	<b>2022</b>
	<i>RMB'000</i>	<i>RMB'000</i>
Interest on lease liabilities	603	722
	<b><u>          </u></b>	<b><u>          </u></b>

APPENDIX I

ACCOUNTANTS’ REPORT

10. INCOME TAX EXPENSE AND DEFERRED TAXATION

**Income tax expense**

Under the law of the PRC on Enterprise Income Tax (the “EIT Law”) and implementation regulations of the EIT Law, the statutory tax rate of the Company and its PRC subsidiaries is 25%.

The Company has been accredited as a “High and New Technology Enterprise” by the Science and Technology Bureau of Beijing and relevant authorities on October 31, 2018 for a term of three years to October 31, 2021. Pursuant to the notice of the Ministry of Finance and the State Administration of Taxation on extending the loss carrying forward period of high and new technology enterprises and high-tech small and medium enterprises (Cai Shui 2018 No. 76), with effect from January 1, 2018, for qualified high and new technology enterprises and high-tech small and medium enterprises, the unutilized tax losses incurred in the previous 5 years can be utilized in 10 years from the year of loss. The Company was qualified as high and new technology enterprise from October 31, 2018 to October 31, 2021 and the unutilized tax losses of the Company incurred between year 2013 and year 2020 will be expired in 10 years from the year of loss.

No Hong Kong profit tax was provided for as there was no estimated assessable profit of the Group’s Hong Kong subsidiary that was subject to Hong Kong profit tax during the Track Record Period.

No provision for PRC income tax was made as the Company and its PRC subsidiaries incurred tax losses during the Track Record Period.

Income tax expense for the Track Record Period can be reconciled to loss before tax per the consolidated statements of profit or loss and other comprehensive income as follows:

	<b>For the year ended December 31,</b>	
	<b>2021</b>	<b>2022</b>
	<i>RMB’000</i>	<i>RMB’000</i>
Loss before tax	(539,357)	(725,180)
Tax at the statutory tax rate of 25%	(134,839)	(181,295)
Tax effect of expenses not deductible for tax purpose	120,918	152,320
Tax effect of income not taxable for tax purpose	–	(333)
Tax effect of super deduction for research and development expenses (Note)	(1,585)	(4,179)
Tax effect of deductible temporary differences not recognized	9,195	13,532
Tax effect of tax losses not recognized	6,311	19,955
	<u>–</u>	<u>–</u>

*Note:* Pursuant to Cai Shui 2018 No. 99 and Cai Shui 2021 No. 6, the Company and Luzhu Biopharmaceuticals (Zhuhai) Co., Ltd. \* (綠竹生物製藥(珠海市)有限公司) (“**Zhuhai Luzhu**”) are entitled to claim 175% qualified research and development expenses so incurred as tax deductible expenses when determining their assessable profits from January 1, 2018 to December 31, 2023.

\* *English name is for identification purpose only.*

**APPENDIX I**

**ACCOUNTANTS’ REPORT**

**Deferred taxation**

For the purpose of presentation in the consolidated statements of financial position, certain deferred tax assets and liabilities have been offset. The following is the analysis of the deferred tax balances for financial reporting purposes:

	<b>As at December 31,</b>	
	<b>2021</b>	<b>2022</b>
	<i>RMB'000</i>	<i>RMB'000</i>
Deferred tax assets	5,558	4,980
Deferred tax liabilities	(5,558)	(4,980)
	—	—
	<b>—</b>	<b>—</b>

The followings are the deferred tax liabilities and assets recognized and movements thereon during the Track Record Period:

	<b>Tax losses</b>	<b>Revaluation of property, plant and equipment and leasehold lands</b>	<b>Fair value gains on financial assets at FVTPL</b>	<b>Total</b>
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
At January 1, 2021	5,039	(4,805)	(234)	—
Credit (charge) to profit or loss	519	331	(850)	—
At December 31, 2021	5,558	(4,474)	(1,084)	—
(Charge) credit to profit or loss	(578)	331	247	—
At December 31, 2022	4,980	(4,143)	(837)	—

As at December 31, 2021 and 2022, the Group had estimated unused tax losses of approximately RMB93,001,000 and RMB170,512,000, respectively, which are available for offset against future profits. Deferred tax asset has been recognized in respect of approximately RMB22,232,000 and RMB19,922,000 of such losses as at December 31, 2021 and 2022. No deferred tax asset has been recognized in respect of the remaining approximately RMB70,769,000 and RMB150,590,000 due to the unpredictability of future profit streams as at December 31, 2021 and 2022.

APPENDIX I

ACCOUNTANTS’ REPORT

The unrecognized tax losses with expiry dates are disclosed in the following table:

	As at December 31,	
	2021	2022
	RMB'000	RMB'000
2024	7	12
2025	356	356
2026	9,534	11,838
2027	3,008	80,520
2028	37,862	37,862
2029	8,740	8,740
2030	11,262	11,262
Total	70,769	150,590

As at December 31, 2021 and 2022, the Group has deductible temporary differences of RMB36,781,000 and RMB90,907,000 in relation to the share-based payments expenses of the Directors Options. No deferred tax asset has been recognized in relation to such deductible temporary difference as it is not probable that taxable profit will be available against which the deductible temporary differences can be utilized.

11. LOSS FOR THE YEAR

	For the year ended December 31,	
	2021	2022
	RMB'000	RMB'000
Loss for the year has been arrived at after charging:		
Staff costs, including directors’ and supervisors’ remuneration		
– salaries and other allowances	10,968	21,037
– retirement benefits	733	1,625
– equity-settled share-based payments included in administrative expenses	49,437	68,925
– equity-settled share-based payments included in research and development expenses	26,801	42,488
Total staff costs	87,939	134,075
Auditor’s remuneration	19	27
[REDACTED] expenses	[REDACTED]	[REDACTED]
Depreciation of property, plant and equipment	2,389	5,286
Depreciation of right-of-use assets	3,717	4,463
Depreciation of investment property	436	–
Amortization of intangible assets	–	135
Total depreciation and amortization	6,542	9,884
Short-term lease expense	17	124
Cost of materials included in research and development expenses	1,334	7,941
Sub-contracting costs included in research and development expenses	5,395	17,849

APPENDIX I

ACCOUNTANTS’ REPORT

12. DIRECTORS’, CHIEF EXECUTIVE’S AND SUPERVISORS’ EMOLUMENTS

The emoluments paid or payable to the directors, chief executive and supervisors of the Company during the Track Record Period are as follows:

Year ended December 31, 2021

	Salaries and other allowances	Discretionary bonuses	Retirement benefits	Equity- settled share-based payments expense	Total
	<i>RMB'000</i>	<i>RMB'000</i> <i>(Note h)</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Executive directors:					
Mr. Kong Jian ( <i>Note a</i> )	304	200	33	26,205	26,742
Ms. Jiang Xianmin ( <i>Note b</i> )	292	200	–	12,262	12,754
Ms. Zhang Yanping ( <i>Note c</i> )	292	160	–	6,346	6,798
Sub-total	888	560	33	44,813	46,294
Non-executive directors:					
Mr. Ma Biao ( <i>Note d</i> )	–	–	–	–	–
Mr. Kong Shuangquan ( <i>Note e</i> )	–	–	–	–	–
Mr. Lin Lei ( <i>Note f</i> )	–	–	–	–	–
Sub-total	–	–	–	–	–
Supervisors:					
Ms. Peng Ling ( <i>Note g</i> )	250	143	30	456	879
Ms. Kong Xi ( <i>Note g</i> )	139	63	20	228	450
Sub-total	389	206	50	684	1,329
Total	1,277	766	83	45,497	47,623

APPENDIX I

ACCOUNTANTS’ REPORT

Year ended December 31, 2022

	Salaries and other allowances	Discretionary bonuses	Retirement benefits	Equity- settled share-based payments expense	Total
	<i>RMB'000</i>	<i>RMB'000</i> <i>(Note h)</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Executive directors:					
Mr. Kong Jian ( <i>Note a</i> )	485	82	43	39,282	39,892
Ms. Jiang Xianmin ( <i>Note b</i> )	430	190	–	6,935	7,555
Ms. Zhang Yanping ( <i>Note c</i> )	430	95	–	30,665	31,190
Sub-total	<u>1,345</u>	<u>367</u>	<u>43</u>	<u>76,882</u>	<u>78,637</u>
Non-executive directors:					
Mr. Ma Biao ( <i>Note d</i> )	–	–	–	–	–
Mr. Kong Shuangquan ( <i>Note e</i> )	–	–	–	–	–
Mr. Lin Lei ( <i>Note f</i> )	–	–	–	–	–
Sub-total	<u>–</u>	<u>–</u>	<u>–</u>	<u>–</u>	<u>–</u>
Supervisors:					
Ms. Peng Ling ( <i>Note g</i> )	365	72	37	4,804	5,278
Ms. Kong Xi ( <i>Note g</i> )	174	40	23	177	414
Mr. Chen Liang ( <i>Note g</i> )	156	13	21	779	969
Sub-total	<u>695</u>	<u>125</u>	<u>81</u>	<u>5,760</u>	<u>6,661</u>
Total	<u><u>2,040</u></u>	<u><u>492</u></u>	<u><u>124</u></u>	<u><u>82,642</u></u>	<u><u>85,298</u></u>

Notes:

- a. Mr. Kong Jian joined the Group in July 2002 as general manager. He was appointed as a director on September 11, 2008, and was re-designated as an executive director on June 18, 2022. Mr. Kong Jian is also the chief executive of the Company.
- b. Ms. Jiang Xianmin joined the Group in February 2002 as deputy general manager. She was appointed as a director on June 28, 2013, and was re-designated as an executive director on June 18, 2022.
- c. Ms. Zhang Yanping joined the Group in January 2004 as a manager of the research and development department, and is currently the deputy general manager. She was appointed as a director on June 28, 2013 and was re-designated as an executive director on June 18, 2022.
- d. Mr. Ma Biao was appointed as a director on August 2, 2019, and was re-designated as a non-executive director on June 18, 2022.
- e. Mr. Kong Shuangquan was appointed as a director on August 2, 2019, and was re-designated as a non-executive director on June 18, 2022.
- f. Mr. Lin Lei was appointed as a director on September 10, 2021, and resigned from his position of a director with effect from May 28, 2022.
- g. Ms. Peng Ling joined the Group in April 2015 and she was appointed as a supervisor on July 19, 2019. Ms. Kong Xi joined the Group in July 2013 and she was appointed as a supervisor on July 21, 2014. Mr. Chen Liang joined the Group in August 2021 and he was appointed as a supervisor on April 26, 2022.
- h. Discretionary bonuses are determined based on the Group’s performance, performance of the relevant individual within the Group and comparable market statistics.

**APPENDIX I**

**ACCOUNTANTS’ REPORT**

No independent non-executive director was appointed during the Track Record Period. Mr. Leung Wai Yip, Mr. Liang Yeshe and Ms. Hou Aijun were appointed as independent non-executive directors on March 30, 2023.

During the Track Record Period, certain directors and supervisors were granted shares or share options, in respect of their services to the Group, details are set out in Note 31 to the Historical Financial Information.

There were no arrangement under which a director, a supervisor of the Company or the chief executive waived or agreed to waive any remuneration during the Track Record Period.

**13. FIVE HIGHEST PAID EMPLOYEES**

The five highest paid employees of the Group included three and four directors or supervisors for the years ended December 31, 2021 and 2022, respectively, details of whose remuneration are set out in Note 12 above. Details of the remuneration for the remaining two and one employees who are not a director, a supervisor or chief executive of the Company for the Track Record Period were as follows:

	<b>For the year ended December 31,</b>	
	<b>2021</b>	<b>2022</b>
	<i>RMB'000</i>	<i>RMB'000</i>
Salaries and other allowances	822	1,727
Discretionary bonuses	280	154
Retirement benefits	33	55
Equity-settled share-based payments expense	19,674	1,779
<b>Total</b>	<b>20,809</b>	<b>3,715</b>

The number of the highest paid employees who are not the directors or supervisors whose remuneration fell within the following bands is as follows:

	<b>For the year ended December 31,</b>	
	<b>2021</b>	<b>2022</b>
	<i>No. of employees</i>	<i>No. of employees</i>
HK\$2,000,001 to HK\$2,500,000	1	–
HK\$4,000,001 to HK\$4,500,000	–	1
HK\$22,500,001 to HK\$23,000,000	1	–
<b>Total</b>	<b>2</b>	<b>1</b>

During the Track Record Period, no emoluments were paid by the Group to the directors, supervisors or the five highest paid employees as an inducement to join or upon joining the Group or as compensation for loss of office.





APPENDIX I

ACCOUNTANTS’ REPORT

16. PROPERTY, PLANT AND EQUIPMENT

The Group

	Property	Leasehold improvement	Machinery	Vehicles	Office equipment	Construction in progress	Total
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
COST							
At January 1, 2021	10,996	–	11,413	1,680	854	–	24,943
Additions	–	–	3,335	779	706	63,695	68,515
Transfer	–	3,547	–	–	–	(3,547)	–
Disposals	–	–	(97)	–	(140)	–	(237)
Transfer from investment property ( <i>Note 18</i> )	6,010	–	–	–	–	–	6,010
At December 31, 2021	17,006	3,547	14,651	2,459	1,420	60,148	99,231
Additions	–	–	7,218	–	825	150,844	158,887
Transfer	–	18,257	39,921	–	–	(58,178)	–
Disposals	–	–	(67)	–	(5)	–	(72)
At December 31, 2022	17,006	21,804	61,723	2,459	2,240	152,814	258,046
ACCUMULATED DEPRECIATION							
At January 1, 2021	(7,823)	–	(6,810)	(1,184)	(524)	–	(16,341)
Provided for the year	(740)	(178)	(1,088)	(238)	(145)	–	(2,389)
Disposals	–	–	93	–	133	–	226
Transfer from investment property ( <i>Note 18</i> )	(4,698)	–	–	–	–	–	(4,698)
At December 31, 2021	(13,261)	(178)	(7,805)	(1,422)	(536)	–	(23,202)
Provided for the year	(1,176)	(1,420)	(2,142)	(268)	(280)	–	(5,286)
Disposals	–	–	64	–	5	–	69
At December 31, 2022	(14,437)	(1,598)	(9,883)	(1,690)	(811)	–	(28,419)
CARRYING VALUES							
At December 31, 2021	3,745	3,369	6,846	1,037	884	60,148	76,029
At December 31, 2022	2,569	20,206	51,840	769	1,429	152,814	229,627

**APPENDIX I**

**ACCOUNTANTS’ REPORT**

**The Company**

	<u>Property</u>	<u>Machinery</u>	<u>Vehicles</u>	<u>Office equipment</u>	<u>Total</u>
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
<b>COST</b>					
At January 1, 2021	10,996	11,413	1,437	846	24,692
Additions	–	928	–	236	1,164
Disposals	–	(97)	–	(140)	(237)
Transfer from investment property (Note 18)	6,010	–	–	–	6,010
	<u>17,006</u>	<u>12,244</u>	<u>1,437</u>	<u>942</u>	<u>31,629</u>
At December 31, 2021	17,006	12,244	1,437	942	31,629
Additions	–	3,417	–	82	3,499
Disposals	–	(67)	(162)	(5)	(234)
	<u>17,006</u>	<u>15,594</u>	<u>1,275</u>	<u>1,019</u>	<u>34,894</u>
At December 31, 2022	17,006	15,594	1,275	1,019	34,894
<b>ACCUMULATED DEPRECIATION</b>					
At January 1, 2021	(7,823)	(6,810)	(1,169)	(524)	(16,326)
Provided for the year	(740)	(1,015)	(58)	(97)	(1,910)
Disposals	–	93	–	133	226
Transfer from investment property (Note 18)	(4,698)	–	–	–	(4,698)
	<u>(13,261)</u>	<u>(7,732)</u>	<u>(1,227)</u>	<u>(488)</u>	<u>(22,708)</u>
At December 31, 2021	(13,261)	(7,732)	(1,227)	(488)	(22,708)
Provided for the year	(1,176)	(1,176)	(26)	(83)	(2,461)
Disposals	–	64	154	5	223
	<u>(14,437)</u>	<u>(8,844)</u>	<u>(1,099)</u>	<u>(566)</u>	<u>(24,946)</u>
At December 31, 2022	(14,437)	(8,844)	(1,099)	(566)	(24,946)
<b>CARRYING VALUES</b>					
At December 31, 2021	<u>3,745</u>	<u>4,512</u>	<u>210</u>	<u>454</u>	<u>8,921</u>
At December 31, 2022	<u>2,569</u>	<u>6,750</u>	<u>176</u>	<u>453</u>	<u>9,948</u>

Property, plant and equipment other than construction in progress are depreciated using the straight-line method after taking into account of their estimated residual values with the following useful lives:

Property	10 to 20 years
Machinery	3 to 10 years
Vehicles	4 to 5 years
Office equipment	3 to 5 years
Leasehold improvement	Shorter of lease terms and 10 years

**APPENDIX I**

**ACCOUNTANTS’ REPORT**

**17. RIGHT-OF-USE ASSETS**

**The Group**

	<b>Leasehold lands</b>	<b>Leasehold properties</b>	<b>Total</b>
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
<b>COST</b>			
At January 1, 2021	24,336	796	25,132
Addition	26,364	23,546	49,910
At December 31, 2021	50,700	24,342	75,042
Addition	–	3,527	3,527
Early termination of a lease	–	(3,527)	(3,527)
At December 31, 2022	50,700	24,342	75,042
<b>ACCUMULATED DEPRECIATION</b>			
At January 1, 2021	(5,078)	(67)	(5,145)
Charge for the year	(1,098)	(2,619)	(3,717)
At December 31, 2021	(6,176)	(2,686)	(8,862)
Charge for the year	(1,098)	(3,365)	(4,463)
Early termination of a lease	–	745	745
At December 31, 2022	(7,274)	(5,306)	(12,580)
<b>CARRYING VALUES</b>			
At December 31, 2021	<u>44,524</u>	<u>21,656</u>	<u>66,180</u>
At December 31, 2022	<u>43,426</u>	<u>19,036</u>	<u>62,462</u>
	<b>For the year ended December 31,</b>		
	<b>2021</b>	<b>2022</b>	
	<i>RMB’000</i>	<i>RMB’000</i>	
Expense relating to short-term leases	17	124	
Total cash outflow for leases	<u>18,602</u>	<u>46,021</u>	

Right-of-use assets are depreciated on a straight-line basis over the lease terms.

The Group leases lands and properties to operate its business. These leases are made for fixed terms of 3 to 50 years. Lease terms are negotiated on an individual basis and contain different payment terms and conditions.

**APPENDIX I**

**ACCOUNTANTS’ REPORT**

The Group’s lease agreements do not contain any contingent rent nor any extension, termination option or purchase option for lessee. Other than leasehold lands, the lease agreements do not impose any covenants other than the security interests in the leased properties that are held by the lessor. Leased properties may not be used as security for borrowing purposes.

In determining the lease term and assessing the length of the non-cancellable period, the Group applies the definition of a contract and determines the period for which the contract is enforceable.

In addition, the Group owns buildings where its research and development facilities are primarily located. The Group is the registered owner of these property interests, including the underlying leasehold lands. Lump sum payments were made upfront to acquire these property interests. The leasehold land components of these owned properties are presented separately only if the payments made can be allocated reliably.

The Group regularly entered into short-term leases for properties and office equipment. As at December 31, 2021 and 2022, the portfolio of short-term leases is similar to the portfolio of short-term leases to which the short-term lease expense is disclosed in Note 11.

**The Company**

The Company leases lands to operate its business with fixed terms of 50 years.

	<b>Leasehold lands</b>	
	<i>RMB’000</i>	
<b>COST</b>		
At January 1, 2021, December 31, 2021 and 2022		<u>24,336</u>
<b>ACCUMULATED DEPRECIATION</b>		
At January 1, 2021		<u>(5,078)</u>
Charge for the year		<u>(570)</u>
At December 31, 2021		<u>(5,648)</u>
Charge for the year		<u>(570)</u>
At December 31, 2022		<u>(6,218)</u>
<b>CARRYING VALUES</b>		
At December 31, 2021		<u>18,688</u>
At December 31, 2022		<u>18,118</u>
	<b>For the year ended December 31,</b>	
	<b>2021</b>	<b>2022</b>
	<i>RMB’000</i>	<i>RMB’000</i>
Expense relating to short-term leases	14	120
Total cash outflow for leases	<u>14</u>	<u>120</u>

**APPENDIX I**

**ACCOUNTANTS’ REPORT**

**18. INVESTMENT PROPERTY**

**The Group and the Company**

The Company leased out a portion of its building under operating lease to a third party with fixed rental payable quarterly in 2021. The lease is denominated in RMB for a period from January 2018 to December 2021.

The lease contracts do not contain residual value guarantee and/or lessee’s option to purchase the property at the end of lease term.

	<b>Investment property</b>
	<i>RMB’000</i>
<b>COST</b>	
At January 1, 2021	6,010
Transfer to property, plant and equipment	<u>(6,010)</u>
At December 31, 2021	<u>–</u>
<b>DEPRECIATION AND IMPAIRMENT</b>	
At January 1, 2021	(4,262)
Provided for the year	(436)
Transfer to property, plant and equipment	<u>4,698</u>
At December 31, 2021	<u>–</u>
<b>CARRYING VALUES</b>	
At December 31, 2021	<u><u>–</u></u>

Investment property is depreciated over 20 years using the straight-line method after taking into account of its estimated residual value.

**APPENDIX I**

**ACCOUNTANTS’ REPORT**

**19. INTANGIBLE ASSETS**

**The Group and the Company**

	<b>License right</b>
	<i>RMB’000</i>
<b>COST</b>	
At January 1, 2021 and December 31, 2021	–
Addition	<u>3,572</u>
At December 31, 2022	<u>3,572</u>
<b>AMORTIZATION</b>	
At January 1, 2021 and December 31, 2021	–
Charge for the year	<u>(135)</u>
At December 31, 2022	<u>(135)</u>
<b>CARRYING VALUE</b>	
At December 31, 2022	<u><u>3,437</u></u>

In May 2022, the Company entered into a licensing agreement with an independent third party regarding a non-exclusive license right including intellectual property rights, compounds and products for the clinical trial and future production of the Group’s products. Under the terms of the agreement, the total upfront payment was cash consideration of British pound 440,000. The Group also agreed to pay the counterparty future clinical development milestone payments, commercialization milestone payments, as well as royalties on manufacturing and sales of the product under the corresponding research and development project using the rights under the licensing agreement.

The license right is amortized over 18 years which is based on the terms of the licensing agreement and the estimated duration of product sales, whichever is shorter.

**20. MATERIALS**

**The Group**

	<b>As at December 31,</b>	
	<b>2021</b>	<b>2022</b>
	<i>RMB’000</i>	<i>RMB’000</i>
Materials for research and development projects	5,186	2,370
Testing kits	<u>137</u>	<u>165</u>
Total	<u><u>5,323</u></u>	<u><u>2,535</u></u>

**APPENDIX I**

**ACCOUNTANTS’ REPORT**

**The Company**

	<u>As at December 31,</u>	
	<u>2021</u>	<u>2022</u>
	<i>RMB'000</i>	<i>RMB'000</i>
Materials for research and development projects	461	297
Testing kits	137	165
Total	<u>598</u>	<u>462</u>

**21. PREPAYMENTS, DEPOSITS AND OTHER RECEIVABLES**

**The Group**

	<u>As at December 31,</u>	
	<u>2021</u>	<u>2022</u>
	<i>RMB'000</i>	<i>RMB'000</i>
Prepayments for purchase of property, plant and equipment	1,983	108,921
Prepayments for right-of-use assets	–	45,277
Value added tax recoverable	7,115	19,129
Prepayments to suppliers and service providers	1,576	4,901
Deferred share issue costs for [REDACTED]	1,458	11,350
Prepayments for [REDACTED] expenses	[REDACTED]	[REDACTED]
Rental deposits	295	313
Other prepayments	360	19
Others	43	558
Total	<u>13,968</u>	<u>190,469</u>
Analysed as:		
Non-current	9,393	173,640
Current	4,575	16,829
Total	<u>13,968</u>	<u>190,469</u>

**APPENDIX I**

**ACCOUNTANTS’ REPORT**

**The Company**

	<b>As at December 31,</b>	
	<b>2021</b>	<b>2022</b>
	<i>RMB'000</i>	<i>RMB'000</i>
Prepayments for purchase of property, plant and equipment	6	–
Value added tax recoverable	3,863	936
Prepayments to suppliers and service providers	1,388	4,792
Deferred share issue costs for [REDACTED]	1,458	11,350
Prepayments for [REDACTED] expenses	[REDACTED]	[REDACTED]
Other prepayments	360	11
Amount due from a subsidiary ( <i>Note</i> )	–	20,000
Others	40	79
<b>Total</b>	<b>8,253</b>	<b>37,169</b>
Analysed as:		
Non-current	3,869	20,936
Current	4,384	16,233
<b>Total</b>	<b>8,253</b>	<b>37,169</b>

*Note:* The amount is non-trade in nature, unsecured, carries interest at a rate of 2.50% per annum and will mature in December 2024.

**22. FINANCIAL ASSETS AT FVTPL**

**The Group**

	<b>As at December 31,</b>	
	<b>2021</b>	<b>2022</b>
	<i>RMB'000</i>	<i>RMB'000</i>
Financial assets at FVTPL	532,365	512,664

**The Company**

	<b>As at December 31,</b>	
	<b>2021</b>	<b>2022</b>
	<i>RMB'000</i>	<i>RMB'000</i>
Financial assets at FVTPL	494,768	492,962

The Group and the Company invested in financial products managed by banks in the PRC which can be redeemed at any time or at maturity. There is no predetermined or guaranteed return for each product. Such financial products are accounted for as financial assets at FVTPL under IFRS 9.



**APPENDIX I**

**ACCOUNTANTS’ REPORT**

**23. BANK BALANCES AND CASH**

**The Group**

	<b>As at December 31,</b>	
	<b>2021</b>	<b>2022</b>
	<i>RMB'000</i>	<i>RMB'000</i>
Cash on hand	5	–
Bank balances	32,025	68,976
	<u>32,030</u>	<u>68,976</u>
Bank balances and cash denominated in:		
RMB	32,030	63,644
US\$	–	5,332
	<u>32,030</u>	<u>68,976</u>

Bank balances carry interest at market rates of 0.3% per annum and 0.01% to 1.9% per annum as at December 31, 2021 and 2022, respectively.

**The Company**

	<b>As at December 31,</b>	
	<b>2021</b>	<b>2022</b>
	<i>RMB'000</i>	<i>RMB'000</i>
Cash on hand	5	–
Bank balances	32,019	59,001
	<u>32,024</u>	<u>59,001</u>

All bank balances of the Company are denominated in RMB. Bank balances carry interest at market rates of 0.3% per annum and 0.25% to 1.90% per annum as at December 31, 2021 and 2022, respectively.

APPENDIX I

ACCOUNTANTS’ REPORT

24. ADVANCE PAYMENTS RECEIVED AND OTHER PAYABLES

The Group

	As at December 31,	
	2021	2022
	RMB'000	RMB'000
Payables for research and development activities	1,013	2,424
Payables for acquisition of property, plant and equipment	9,473	67,093
Accrued salaries and other allowances	3,152	3,885
Accrued [REDACTED] expenses	[REDACTED]	[REDACTED]
Accrued share issue costs for [REDACTED]	335	3,638
Other tax payables	75	107
Others	35	46
	<u>14,785</u>	<u>84,714</u>
Advance payments received and other payables denominated in:		
RMB	13,751	74,819
US\$	1,034	9,895
	<u>14,785</u>	<u>84,714</u>

The Company

	As at December 31,	
	2021	2022
	RMB'000	RMB'000
Payables for research and development activities	1,013	602
Payables for acquisition of property, plant and equipment	–	141
Accrued salaries and other allowances	2,632	1,959
Accrued [REDACTED] expenses	[REDACTED]	[REDACTED]
Accrued share issue costs for [REDACTED]	335	3,638
Other tax payables	71	73
Amount due to a subsidiary ( <i>Note</i> )	–	3,572
Others	35	43
	<u>4,788</u>	<u>17,549</u>
Advance payments received and other payables denominated in:		
RMB	3,754	7,654
US\$	1,034	9,895
	<u>4,788</u>	<u>17,549</u>

*Note:* The amount is non-trade in nature, unsecured, interest-free, and repayable on demand.

APPENDIX I

ACCOUNTANTS’ REPORT

25. LEASE LIABILITIES

The Group

Zhuhai Luzhu leases offices from September 2020 to September 2023. According to the lease agreement, the total rent of RMB841,000 is fully subsidized by the local government or exempted by the lessor if the rental subsidies were not received. Hence, no lease liabilities have been recognized for this lease. The fair value of the lease payments subsidized by the local government amounting to RMB796,000 at the commencement date was recognized as deferred government grants related to the right-of-use assets and the same amount was included in the cost of right-of-use assets correspondingly.

Zhuhai Luzhu leases a property from January 2021 to December 2030 for construction of its manufactory. According to the lease agreement, it is rent-free for the first six months and the rent for the next five years is fully subsidized by the local government or exempted by the lessor if the rental subsidies were not received. The rent for the remaining four and a half years is RMB15,672,000 in aggregate, payable on a monthly basis. At the commencement date, the lease liabilities amounting to RMB9,977,000 was recognized at the present value of the lease payments that are not yet paid, using the incremental borrowing rate of 6.05% per annum. The fair value of the lease payments subsidized by the local government amounting to RMB13,348,000 at the commencement date was recognized as deferred government grants related to the right-of-use assets (Note 26) and the same amount was included in the cost of right-of-use assets correspondingly. The rental deposit paid at initial recognition is RMB500,000, of which the adjustment to fair value amounted to RMB221,000 is considered as additional lease payments and included in the cost of right-of-use assets.

Luzhu Biologics (Beijing) Co. Limited\* (綠竹生物製品(北京)有限公司) (“Beijing Luzhu”) leases a property from April 2022 to April 2025 for research and development. The lease liabilities amounting to RMB3,488,000 was recognized at the present value of the lease payments that are not yet paid, using the incremental borrowing rate of 4.50% per annum. The rental deposit paid at initial recognition is RMB318,000, of which the adjustment to fair value amounted to RMB39,000 is considered as additional lease payments and included in the cost of right-of-use assets. On December 2, 2022, Beijing Luzhu entered into a supplementary agreement with the lessor to terminate the lease. Beijing Luzhu derecognized the right-of-use assets of RMB2,782,000 and lease liabilities of RMB2,990,000, resulting in a gain of RMB239,000 recognized in profit or loss after consideration of refund of rental deposits.

The exposure of the Group’s lease liabilities are as follows:

	<b>As at December 31,</b>	
	<b>2021</b>	<b>2022</b>
	<i>RMB’000</i>	<i>RMB’000</i>
Analysed for reporting purposes as:		
Non-current liabilities	10,580	11,219
	<u>10,580</u>	<u>11,219</u>
Lease liabilities payable:		
More than two years, but not exceeding five years	1,263	4,449
More than five years	9,317	6,770
	<u>10,580</u>	<u>11,219</u>

The Group does not face a significant liquidity risk with regard to its lease liabilities. Lease liabilities are monitored within the Group’s treasury function.

**APPENDIX I**

**ACCOUNTANTS’ REPORT**

**26. DEFERRED GOVERNMENT GRANTS**

**The Group**

	<b>As at December 31,</b>	
	<b>2021</b>	<b>2022</b>
	<i>RMB'000</i>	<i>RMB'000</i>
Current	8,400	9,400
Non-current	38,901	27,371
	<u>47,301</u>	<u>36,771</u>

**Movements of deferred government grants**

	<b>Deferred government grants related to</b>			
	<b>Plant and machinery</b>	<b>Right-of-use assets</b>	<b>Research and development activities</b>	<b>Total</b>
			<i>RMB'000</i>	
At January 1, 2021	32	730	–	762
Government grants received	18,000	–	16,800	34,800
Government grants recognized (Note 25)	–	13,348	–	13,348
Release of deferred government grants to profit or loss	(9)	(1,600)	–	(1,609)
At December 31, 2021	18,023	12,478	16,800	47,301
Government grant received	–	–	1,000	1,000
Release of deferred government grants to profit or loss	(195)	(2,935)	(8,400)	(11,530)
At December 31, 2022	<u>17,828</u>	<u>9,543</u>	<u>9,400</u>	<u>36,771</u>

Government grants include subsidies from local PRC governments which are specifically for (i) compensations of the capital expenditure incurred for purchase of plant and machinery and right-of-use assets, which are recognized over the useful life of the related assets and (ii) the research and development activities, which are recognized upon compliance with the attached conditions.

## APPENDIX I

## ACCOUNTANTS’ REPORT

### 27. FINANCIAL LIABILITIES AT FVTPL

#### The Group and the Company

##### Series A Financing

On July 23, 2019, the Company entered into an investment agreement with two independent investors (the “**Series A Financing**”), pursuant to which the investors shall make total investments of RMB250,000,000 (equivalent to RMB5.09 per share) in the Company as consideration for subscription of 49,112,500 ordinary shares with preference rights of the Company (“**Preference Shares**”). One of the investors (“**Investor A-I**”, also known as Beijing Science Sun Pharmaceutical Co., Ltd.\* (北京賽升藥業股份有限公司) (“**Beijing Science Sun**”), which appointed a director of the Company on August 2, 2019) paid RMB50,000,000 to subscribe for 9,822,500 Preference Shares in August 2019. The other investor (“**Investor A-II**”, which appointed a director of the Company on August 2, 2019) subscribed 39,290,000 Preference Shares at consideration of RMB200,000,000, among which RMB100,000,000 was paid in August 2019 for 19,645,000 Preference Shares and the remaining consideration of RMB100,000,000 would be paid until the Company has completed the phase I clinical trials and kicked off phase II clinical trials for product K-193 (the “**Investment Condition**”). Pursuant to the agreement entered among Investor A-II, Investor A-I and a related party of Investor A-II (“**Investor A-III**”) in February 2021, the remaining 19,645,000 Preference Shares would be subscribed by Investor A-I and Investor A-III instead of Investor A-II. The Investment Condition was subsequently waived by relevant parties in March 2021 and the remaining consideration of RMB100,000,000 was injected by Investor A-I and Investor A-III with amount of RMB20,000,000 and RMB80,000,000, respectively. Investor A-I, Investor A-II and Investor A-III, are hereinafter collectively referred to as the “Series A Investors”.

\* English name is for identification purpose only.

The key terms of the Series A Financing are summarized as follows:

#### (a) Anti-dilution right

If the Company issues new shares at a price lower than the price paid by the Series A Investors, the Series A Investors shall have the right to require: (1) Mr. Kong Jian and Ms. Zhang Yanping to transfer shares at nil consideration; (2) the Company to issue new shares at nil consideration; or (3) Mr. Kong Jian and Ms. Zhang Yanping or the Company to settle the difference in cash to Series A Investors, so that the net amount paid by the Series A Investors divided by the total number of shares obtained is not higher than the price of the newly issued shares.

#### (b) Redemption right

The investment from the Series A Investors shall be redeemed by the Company and/or Mr. Kong Jian and Ms. Zhang Yanping, at the option of the investors if the Company failed to complete a qualified [REDACTED] before December 31, 2022 (the date has been extended to December 31, 2025 upon signing of the Series B+ Financing agreement on December 31, 2021) and/or upon the occurrence of certain contingent events or default events.

The Series A Investors are entitled to receive the redemption amount equal to the original investment amount plus interest of 6% per annum or 8% per annum calculated on a simple basis.

Upon signing of the Series B+ Financing agreement as disclosed below, Series A Investors began to entitle the same redemption right with the Series B+ Investors since December 31, 2021.

##### Series B Financing

On August 30, 2021, the Company entered into an investment agreement (the “**Series B Financing**”) with several investors (collectively as the “**Series B Investors**”, one of the Series B Investors appointed a director of the Company on September 10, 2021), pursuant to which the Series B Investors shall subscribe 27,216,175 Preference Shares at an aggregate consideration of RMB350,000,000 (equivalent to RMB12.86 per share). The consideration was fully settled in September 2021.

## APPENDIX I

## ACCOUNTANTS’ REPORT

The key terms of the Series B Financing are summarized as follows:

**(a) Liquidation preferences**

In the event of any liquidation including deemed liquidation, dissolution or winding up of the Company, the Series B Investors shall be entitled to receive the amount equal to the original investment amount plus interest of 6% per annum calculated on a simple basis and any dividends that have been declared but not yet paid.

**(b) Anti-dilution right**

If the Company issue new shares at a price lower than the price paid by the Series B Investors, the Series B Investors shall have the right to require Mr. Kong Jian and Ms. Zhang Yanping to transfer shares or the Company to issue new shares to the Series B Investors at nil consideration, a minimum purchase price or nominal value permitted under the PRC laws, so that the amount paid by the Series B Investors divided by the total number of shares obtained is not higher than the price of the newly issued shares.

**(c) Redemption right**

The investment from the Series B Investors shall be redeemed by the Company and/or Mr. Kong Jian and Ms. Zhang Yanping, at the option of the investors if the Company failed to complete a qualified [REDACTED] before December 31, 2025 and/or upon the occurrence of certain contingent events. The Series B Investors shall be entitled to receive the redemption amount equal to the original investment amount plus interest of 6% per annum calculated on a simple basis.

### Series B+ Financing

On December 31, 2021, the Company entered into an investment agreement (the “**Series B+ Financing**”) with several investors (collectively as the “**Series B+ Investors**”), pursuant to which the Series B+ Investors shall subscribe 6,674,082 Preference Shares at an aggregate consideration of RMB120,000,000 (equivalent to RMB17.98 per share). The consideration was fully settled in January 2022.

The key terms of the Series B+ Financing are summarized as follows:

**(a) Liquidation preferences**

In the event of any liquidation including deemed liquidation, dissolution or winding up of the Company, the Series B+ Investors shall be entitled to receive the amount equal to the original investment amount plus interest of 6% per annum calculated on a simple basis and any dividends that have been declared but not yet paid.

**(b) Anti-dilution right**

If the Company issue new shares at a price lower than the price paid by the Series B+ Investors, the Series B+ Investors shall have the right to require Mr. Kong Jian and Ms. Zhang Yanping to transfer shares or the Company to issue new shares to the Series B+ Investors at nil consideration, a minimum purchase price or nominal value permitted under the PRC laws, so that the amount paid by the Series B+ Investors divided by the total number of shares obtained is not higher than the price of the newly issued shares.

**(c) Redemption right**

The investment from the Series B+ Investors shall be redeemed by the Company and/or Mr. Kong Jian and Ms. Zhang Yanping, at the option of the investors if a qualified [REDACTED] has not been consummated by December 31, 2025 and/or upon the occurrence of certain contingent events. The Series B+ Investors shall be entitled to receive the redemption amount equal to the original investment amount plus interest of 6% per annum calculated on a simple basis.

### Series C Financing

On June 16, 2022, the Company entered into an investment agreement (the “**Series C Financing**”) with several investors (collectively as the “**Series C Investors**”), pursuant to which the Series C Investors shall subscribe 9,478,262 Preference Shares at an aggregate consideration of RMB218,000,000 (equivalent to RMB23.00 per share). The consideration was fully settled in June 2022.

**APPENDIX I**

**ACCOUNTANTS’ REPORT**

The key terms of the Series C Financing are summarized as follows:

**(a) Liquidation preferences**

In the event of any liquidation including deemed liquidation, dissolution or winding up of the Company, the Series C Investors shall be entitled to receive the amount equal to the original investment amount plus interest of 6% per annum calculated on a simple basis and any dividends that have been declared but not yet paid.

**(b) Anti-dilution right**

If the Company issue new shares at a price lower than the price paid by the Series C Investors, the Series C Investors shall have the right to require Mr. Kong Jian and Ms. Zhang Yanping to transfer shares or the Company to issue new shares to the Series C Investors at nil consideration, a minimum purchase price or nominal value permitted under the PRC laws, so that the amount paid by the Series C Investors divided by the total number of shares obtained is not higher than the price of the newly issued shares.

**(c) Redemption right**

The investment from the Series C Investors shall be redeemed by Mr. Kong Jian and Ms. Zhang Yanping or any third parties nominated by the aforementioned and no redemption obligation is undertaken by the Group.

Upon signing of the Series C Financing agreement, the Series A Investors, Series B Investors, and Series B+ Investors began to entitle the same redemption right with the Series C Investors.

According to the Series C Financing agreement, the preference rights including the liquidation preferences and anti-dilution right for the Series A Investors, Series B Investors, Series B+ Investors and Series C Investors shall terminate upon the Company’s submission of the [REDACTED].

**Presentation and classification**

The Group has designated Preference Shares which contain redemption features and other embedded derivatives as financial liabilities at FVTPL on initial recognition.

The fair value change of Preference Shares is recognized to profit or loss except for the portion attributable to credit risk change which shall be recognized to other comprehensive income, if any. The Directors considered that the credit risk change on the financial liabilities that drive the fair value change of the financial liabilities during the Track Record Period is immaterial.

The movements in the financial liabilities at FVTPL are as follows:

	<b>Financial liabilities at FVTPL</b>
	<i>RMB’000</i>
At January 1, 2021	346,440
Addition	450,000
Change in fair value	441,077
	<hr/>
At December 31, 2021	1,237,517
Addition	338,000
Change in fair value	551,546
Reclassification (Note)	(2,127,063)
	<hr/>
At December 31, 2022	<hr/> <hr/> <hr/>

## APPENDIX I

## ACCOUNTANTS’ REPORT

*Note:* Upon signing of the Series C Financing agreement and the Company’s submission of the [REDACTED] in June 2022, the Preference Shares meet the definition of equity as the Group has no contractual obligation to deliver cash or a variable number of shares. Therefore, the Preference Shares were reclassified from financial liabilities to equity at their fair value, resulting in an increase of share capital of RMB92,481,000 and an increase of share premium of RMB2,034,582,000.

The fair value of the Preference Shares at December 31, 2021 were valued by the Directors with the assistance of an independent qualified professional valuer, which is not connected to the Group and has appropriate qualifications and experiences in valuation of similar instruments.

Back-solve method was used to determine the underlying equity value of the Company as at December 31, 2021 by reference to the issue price of the Series B+ Financing.

Hybrid method was adopted to allocate the equity value amongst different classes of shares of the Company at the end of the reporting period. The hybrid method is a hybrid between the probability-weighted expected return method (“PWERM”) and the option pricing method (“OPM”), estimating the probability-weighted value across multiple scenarios while using the OPM to estimate the allocation of value within one or more of those scenarios.

Under a PWERM, the values of various equity securities are estimated based on an analysis of future values for the enterprise, assuming various future outcomes. Share value is based on the probability-weighted present value of expected future investment returns, considering each of the possible future outcomes available to the enterprise, as well as the rights of each share class. Common future outcomes model might include [REDACTED], liquidation or redemption.

The OPM treats the rights of Preference Shares, ordinary shares and Directors Options as equivalent to that of call options on the Company’s equity value, with strike prices based on the liquidation preferences and redemption provisions of Preference Shares. Thus, the equity value of the ordinary shares can be determined by estimating the value of its portion of each of these call option rights.

Key valuation assumptions used to determine the fair value of the Series A Financing and Series B Financing are as follows:

	<b>As at December 31, 2021</b>
Time to [REDACTED]	1 year
Time to liquidation	4 years
Risk-free interest rate	2.51%
Volatility	56.49%
Dividend yield	–
Possibilities under liquidation scenario	0.1
Possibilities under [REDACTED] scenario	0.8
Possibilities under redemption scenario	0.1

Risk-free interest rate was estimated based on the China government bond yield curve with maturity matching to the expected exit period as at the valuation date.

Volatility was estimated on the valuation date based on median of historical volatilities of the comparable companies in the same industry for a period from the valuation date to expected [REDACTED], liquidation or redemption dates, where applicable.



## APPENDIX I

## ACCOUNTANTS’ REPORT

### 28. SHARE CAPITAL

#### The Company

	Number of shares	Share capital
	’000	RMB’000
<b>Issued and fully paid</b>		
As at January 1, 2021	78,580	78,580
Issue of ordinary shares ( <i>Note</i> )	12,308	12,308
At December 31, 2021	90,888	90,888
Exercise of Directors Options ( <i>Note 31(d)</i> )	8,695	8,695
Reclassification from financial liabilities at FVTPL ( <i>Note 27</i> )	92,481	92,481
At December 31, 2022	<u>192,064</u>	<u>192,064</u>

*Note:* In February 2021, the Company issued 12,308,000 ordinary shares to Zhuhai Hengqin Luzhu Enterprise Management Partnership (LP)\* (珠海橫琴綠竹企業管理合夥企業(有限合夥)) (“**Hengqin Luzhu LP**”) at par value of RMB1 per share. Further details of Hengqin Luzhu LP are set out in Note 31.

\* *English name is for identification purpose only.*

### 29. RESERVES

#### The Company

	Share premium	Share- based payments reserve	Accumulated loss	Total
	RMB’000	RMB’000 ( <i>Note 31</i> )	RMB’000	RMB’000
At January 1, 2021	39,462	4,194	(256,082)	(212,426)
Loss and total comprehensive expense for the year	–	–	(532,670)	(532,670)
Recognition of equity-settled share-based payments	–	76,238	–	76,238
Exercise of share options and vesting of shares granted	34,752	(34,752)	–	–
At December 31, 2021	74,214	45,680	(788,752)	(668,858)
Loss and total comprehensive expense for the year	–	–	(681,617)	(681,617)
Recognition of equity-settled share-based payments	–	111,413	–	111,413
Exercise of Directors Options ( <i>Note 31(d)</i> )	90,907	(90,907)	–	–
Reclassification from financial liabilities at FVTPL ( <i>Note 27</i> )	2,034,582	–	–	2,034,582
At December 31, 2022	<u>2,199,703</u>	<u>66,186</u>	<u>(1,470,369)</u>	<u>795,520</u>

APPENDIX I

ACCOUNTANTS’ REPORT

30. RETIREMENT BENEFITS PLANS

The PRC employees of the Group are members of a state-managed retirement benefits plan operated by the government of the PRC. The Company and its PRC subsidiaries are required to contribute a specified percentage of payroll costs to the retirement benefits plan to fund the employee benefits. The only obligation of the Group with respect to the retirement benefits plan is to make the specified contributions. The retirement benefits cost charged to profit or loss for the years ended December 31, 2021 and 2022 amounted to RMB733,000 and RMB1,625,000, respectively.

During the Track Record Period, the Group had no forfeited contributions under the above retirement benefit scheme which may be used by the Group to reduce the existing level of contributions. There were also no forfeited contributions available at December 31, 2021 and 2022 under such scheme which may be used by the Group to reduce the contribution payable in future years.

31. SHARE-BASED PAYMENT TRANSACTIONS

(a) Share options granted in 2019

On June 11, 2019, certain members of management and eligible employees of the Group were granted options to purchase a total of 3,600,000 ordinary shares of the Company from Mr. Kong Jian with an exercise price of RMB2.50 per share with the service condition of three years from the grant date and certain performance conditions (the “2019 Share Options”). The grantees can purchase the shares with the exercise price at any time on or before June 11, 2022. Mr. Kong Jian will repurchase those shares with the original exercise price from the grantees if they leave the Company on or before June 11, 2022. Included in the 2019 Share Options, 1,000,000 share options were granted to Ms. Jiang Xianmin, 500,000 share options were granted to Ms. Peng Ling, and 250,000 share options were granted to Ms. Kong Xi.

The following table discloses movements of the 2019 Share Options.

Category	Outstanding as at January 1, 2021	Grant during the year	Forfeited due to resignation during the year	Exercised during the year	Outstanding as at December 31, 2021
2019 Share Options	2,900,000	–	(350,000)	–	2,550,000

Category	Outstanding as at January 1, 2022	Grant during the year	Forfeited due to resignation during the year	Exercised during the year	Replaced by 2022 Restricted Shares during the year	Outstanding as at December 31, 2022
2019 Share Options	2,550,000	–	–	–	(2,550,000)	–

None of outstanding share options of the 2019 Share Options were exercisable as at December 31, 2021.

The total fair value of the 2019 Share Options determined at the grant date using the Binomial Option Pricing Model is RMB10,966,000.

APPENDIX I

ACCOUNTANTS’ REPORT

(b) Share options granted in 2020

On October 19, 2020, a senior management were granted an option to purchase a total of 400,000 ordinary shares of the Company from entities held by Mr. Kong Jian with an exercise price of RMB2.54 per share with the service condition of five years from the grant date (the “2020 Share Options”). The grantee can purchase the shares at any time on or before October 19, 2025. Mr. Kong Jian will repurchase those shares with the original exercise price from the grantee plus interest of 10% per annum calculated on a simple basis if the grantee leaves the Company on or before October 19, 2025.

The following table discloses movements of the 2020 Share Options.

Category	Outstanding as at January 1, 2021	Grant during the year	Forfeited due to resignation during the year	Exercised during the year	Outstanding as at December 31, 2021
2020 Share Options	400,000	–	–	–	400,000

Category	Outstanding as at January 1, 2022	Grant during the year	Forfeited due to resignation during the year	Exercised during the year	Replaced by 2022 Restricted Shares during the year	Outstanding as at December 31, 2022
2020 Share Options	400,000	–	–	–	(400,000)	–

None of outstanding share options of the 2020 Share Options were exercisable as at December 31, 2021.

The total fair value of the 2020 Share Options determined at the grant date using the Binomial Option Pricing Model is RMB3,804,000.

(c) Share awards/options granted in 2021

(c-i) Share awards

On February 7, 2021, Ms. Zhang Yanping transferred a total of 800,000 ordinary shares of the Company to Ms. Jiang Xianmin, an executive director, at the consideration of RMB2.54 per share with no condition (“2021 Share Awards I”). The fair value of ordinary shares is approximately RMB11.44 per share at the grant date and the Group recognized a share-based payment expense of RMB7,118,000 during the year ended December 31, 2021.

On February 7, 2021, Ms. Zhang Yanping also transferred a total of 1,100,000 ordinary shares of the Company to a senior management at the consideration of RMB2.54 per share with no condition (“2021 Share Awards II”) (together with 2021 Share Awards I, hereinafter collectively referred to as the “2021 Share Awards”). This senior management departed from the Group in September 2021 and transferred all of the 1,100,000 ordinary shares of the Company to Ms. Zhang Yanping at nil consideration, as the consideration payable by this senior management to Ms. Zhang Yanping for the transfer of such 1,100,000 shares in February 2021 had not been settled. The Group recognized a share-based payment expense of RMB9,788,000 during the year ended December 31, 2021.

APPENDIX I

ACCOUNTANTS’ REPORT

(c-ii) *Share options*

Hengqin Luzhu LP was established in the PRC as a limited partnership on January 14, 2021 as an employee incentive platform of the Group and is controlled by Mr. Kong Jian, the sole general partner of Hengqin Luzhu LP.

On February 1, 2021, April 7, 2021, June 15, 2021 and August 2, 2021, certain directors, senior management and eligible employees were granted options to purchase a total of 3,500,000 ordinary shares of the Company through Hengqin Luzhu LP (“**February 2021 Options**”, “**April 2021 Options**”, “**June 2021 Options**” and “**August 2021 Options**”, hereinafter collectively referred to as the “**2021 Share Options**”).

The conditions of the 2021 Share Options are described as follows:

February 2021 Options: Included in the 2,000,000 share options granted, the grantees can purchase 1,000,000 shares at grant date immediately and 1,000,000 shares upon completion of the Series B Financing.

April 2021 Options: The grantee can purchase no more than 400,000 shares at any time on or before April 7, 2026. Hengqin Luzhu LP will repurchase those shares with the original exercise price from the grantee plus interest of 5% per annum calculated on a simple basis if the grantee leaves the Group on or before April 7, 2026.

June 2021 Options: Included in the 600,000 share options granted, the grantees can purchase 100,000 shares, 200,000 shares, 200,000 shares and 100,000 shares upon completion of the Series B Financing, Series C Financing, a qualified [REDACTED] and a qualified [REDACTED] before December 31, 2022 with market value no less than HK\$10 billion, respectively. Hengqin Luzhu LP will repurchase those shares with the original exercise price from the grantees plus interest of 5% per annum calculated on a simple basis if the grantees leave the Group on or before June 15, 2023.

August 2021 Options: Included in the 500,000 share options granted, the grantee can purchase 100,000 shares, 200,000 shares and 200,000 shares upon completion of the Series B Financing, acceptance of investigational new drug application for LZ901 in the United States of America and completion of a qualified [REDACTED], respectively. Hengqin Luzhu LP will repurchase those shares with the original exercise price from the grantee if the grantee leaves the Group on or before August 2, 2023.

The following table discloses movements of the 2021 Share Options.

Categories	Outstanding as at January 1, 2021	Grant during the year	Forfeited due to resignation during the year	Exercised during the year	Outstanding as at December 31, 2021
February 2021 Options	–	2,000,000	–	(2,000,000)	–
April 2021 Options	–	400,000	–	–	400,000
June 2021 Options	–	600,000	–	–	600,000
August 2021 Options	–	500,000	–	–	500,000
	–	3,500,000	–	(2,000,000)	1,500,000

APPENDIX I

ACCOUNTANTS’ REPORT

Categories	Outstanding as at January 1, 2022	Grant during the year	Forfeited due to resignation during the year	Exercised during the year	Cancelled during the year	Replaced by 2022 Restricted Shares during the year	Outstanding as at December 31, 2022
April 2021 Options	400,000	-	-	-	-	(400,000)	-
June 2021 Options	600,000	-	-	-	(75,000)	(525,000)	-
August 2021 Options	500,000	-	-	-	(500,000)	-	-
	<u>1,500,000</u>	<u>-</u>	<u>-</u>	<u>-</u>	<u>(575,000)</u>	<u>(925,000)</u>	<u>-</u>

None of outstanding share options of the 2021 Share Options were exercisable as at December 31, 2021.

The following assumptions were used to calculate the fair values of the 2021 Share Options as at grant date:

	February 2021 Options	April 2021 Options	June 2021 Options	August 2021 Options
Grant date share price	RMB11.44	RMB11.44	RMB11.44	RMB11.44
Exercise price	RMB2.54	RMB2.54	RMB1.00– RMB5.14	RMB5.09
Expected volatility	54.33%	56.92%	55.85%	57.46%
Option life	1.5 years	5 years	2 years	2 years
Dividend yield	0%	0%	0%	0%
Risk-free interest rate	2.65%	3.06%	2.62%	2.30%

The Group has used the discounted cash flow method to determine the underlying equity value of the Company and adopted the equity value allocation model to determine the fair value of the ordinary shares for February 2021 Options. The Group has used the back-solve method to determine the underlying equity value of the Company and adopted the equity value allocation model to determine the fair value of the ordinary shares for April 2021 Options, June 2021 Options and August 2021 Options with reference to the issue price of the Series B Financing. The fair values of the 2021 Share Options determined at the grant date using the Binomial Option Pricing Model are as follows:

	February 2021 Options	April 2021 Options	June 2021 Options	August 2021 Options
	RMB'000	RMB'000	RMB'000	RMB'000
Fair value at grant date	17,846	3,802	3,585	3,503

The expected volatility measured at the standard deviation is based on the historical data of the daily share price movement of comparable companies. The fair value of an option varies with different variables of certain subjective assumptions.

(d) **Directors Options**

On August 30, 2021, share options were granted to three executive directors of the Company with an exercise price of RMB1.00 per share (the “**Directors Options**”) with the condition that phase II clinical trials for product LZ901 is kicked off or a new round of financing is completed and pre-investment valuation is not less than RMB4 billion. The number of shares to be purchased will be equal to 5% of the then issued shares of the Company.

APPENDIX I

ACCOUNTANTS’ REPORT

The following table discloses movements of the Directors Options.

Category	Outstanding as at January 1, 2021	Grant during the year	Forfeited due to resignation during the year	Exercised during the year	Outstanding as at December 31, 2021
Directors Options	–	8,694,513	–	–	8,694,513
Category	Outstanding as at January 1, 2022	Grant during the year	Forfeited due to resignation during the year	Exercised during the year	Outstanding as at December 31, 2022
Directors Options	8,694,513	–	–	(8,694,513)	–

None of outstanding share options of the Directors Options were exercisable as at December 31, 2021. The total fair value of the Directors Options determined at the grant date using the Binomial Option Pricing Model is RMB90,907,000.

The following assumptions were used to calculate the fair values of the Directors Options as at grant date:

	Directors Options
Grant date share price	RMB11.44
Exercise price	RMB1.00
Expected volatility	65.97%
Expected option life	0.83 years
Dividend yield	0%
Risk-free interest rate	2.27%

The Group has adopted the equity value allocation model to determine the fair value of the ordinary shares with reference to the issue price of the Series B Financing. The expected volatility measured at the standard deviation is based on the historical data of the daily share price movement of comparable companies. The fair value of an option varies with different variables of certain subjective assumptions.

As phase II clinical trials for product LZ901 was kicked off in April 2022, the condition of the Directors Options has been fulfilled during the year ended December 31, 2022. On May 27, 2022, all the Directors Options were exercised and 8,694,513 ordinary shares of the Company were issued at a price of RMB1.00 per share, resulting in an increase of share capital of RMB8,695,000. The amount previously recognized in share-based payments reserve of RMB90,907,000 in relation to the Directors Options were transferred to share premium.

(e) 2022 Restricted Shares

On April 14, 2022 and April 26, 2022, Zhuhai Luzhu Kangrui Enterprise Management Partnership (LP)\* (珠海綠竹康瑞企業管理合夥企業(有限合夥)) (“**Zhuhai Luzhu Kangrui**”) and Beijing Luzhu Kangrui Enterprise Management Partnership (LP)\* (北京綠竹康瑞企業管理合夥企業(有限合夥)) (“**Beijing Luzhu Kangrui**”) were established in the PRC, respectively, as employee incentive platforms of the Group through an award of Hengqin Luzhu LP’s shares.

In April 2022, an employee incentive scheme was implemented to incentive certain eligible employees of the Group to retain them for the continual operation and development of the Group or to replace certain outstanding share options.

APPENDIX I

ACCOUNTANTS’ REPORT

In April 2022, restricted shares representing 8,110,132 ordinary shares of par value of RMB1 each in the share capital of the Company (the “RSs”) were granted to certain eligible employees (the “2022 Restricted Shares”). Including (i) an aggregate of 7,450,000 restricted shares of Zhuhai Luzhu Kangrui and Beijing Luzhu Kangrui were granted, representing 7,450,000 ordinary shares of par value of RMB1 each in the share capital of the Company with the price of RMB2.54, RMB5.09 or RMB7.19 each RS; (ii) 1,942,320 restricted shares of Hengqin Luzhu LP were granted representing 660,132 ordinary shares of par value of RMB1 each in the share capital of the Company with the price of RMB2.94 each RS. Included in 8,110,132 RSs, 3,875,000 RSs were granted to replace the 2019 Share Options, 2020 Share Options, April 2021 Options and June 2021 Options and the remaining 4,235,132 RSs were newly granted.

The consideration was fully settled in May 2022. The vesting of the RSs granted is conditional upon the fulfillment of requisite service conditions until end of the lock up period required by the securities and futures commission or the Stock Exchange after the completion of a qualified [REDACTED]. The employees have to transfer out their RSs to the person or entity designated by Mr. Kong Jian, the general partner of Hengqin Luzhu LP, at the original grant price, if their employments with the Group were terminated within the vesting period.

Included in the 2022 Restricted Shares, 1,000,000 RSs were granted to Ms. Jiang Xianmin, 110,000 RSs were granted to Ms. Zhang Yan Ping, 1,154,000 RSs were granted to Ms. Peng Ling, 250,000 RSs were granted to Ms. Kong Xi and 130,000 RSs were granted to Mr. Chen Liang.

The following table discloses movements of the 2022 Restricted Shares.

Category	Outstanding as at January 1, 2022	Grant during the year	Forfeited due to resignation during the year	Vested during the year	Outstanding as at December 31, 2022
2022 Restricted Shares	–	8,140,132	(30,000)	–	8,110,132

The total fair value of 2022 Restricted Shares is RMB157,385,000 at the grant date which were determined with reference to the issue price of the Series C Financing after deducting the purchase price. The fair values of the 2019 Share Options, 2020 Share Options, April 2021 Options and June 2021 Options at the modification date were RMB52,288,000, RMB8,280,000, RMB8,301,000 and RMB9,166,000, respectively and the incremental fair value granted of RMB283,000 will be recognized in profit or loss over the expected vesting period, with a corresponding adjustment to reserves.

(f) Controlling Shareholders Restricted Shares

On June 18, 2022, Mr. Kong Jian and Ms. Zhang Yanping were granted 350,000 and 10,000,000 restricted shares of Hengqin Luzhu LP representing 118,952 and 3,398,680 ordinary shares of par value of RMB1 each in the share capital of the Company, respectively, with the price of RMB1.00 each restricted share (the “Controlling Shareholders Restricted Shares”).

The consideration was fully settled as at December 31, 2022 and the vesting of the restricted shares granted is conditional upon the fulfillment of requisite service conditions until end of the lock up period required by the securities and futures commission or the Stock Exchange after the completion of a qualified [REDACTED]. The grantees have to transfer out their restricted shares at the original grant price, if their employments with the Group were terminated within the vesting period.

The following table discloses movements of the Controlling Shareholders Restricted Shares.

Category	Outstanding as at January 1, 2022	Grant during the year	Forfeited due to resignation during the year	Vested during the year	Outstanding as at December 31, 2022
Controlling Shareholders Restricted Shares	–	3,517,632	–	–	3,517,632

The total fair value of Controlling Shareholders Restricted Shares is RMB70,556,000 at the grant date which were determined with reference to the issue price of the Series C Financing after deducting the purchase price.

**APPENDIX I**

**ACCOUNTANTS’ REPORT**

The share-based payment expense of the Group recognized during the Track Record Period are as follows:

	<b>For the year ended December 31,</b>	
	<b>2021</b>	<b>2022</b>
	<i>RMB'000</i>	<i>RMB'000</i>
2019 Share Options	1,798	740
2020 Share Options	684	318
2021 Share Awards	16,906	–
2021 Share Options	20,069	3,667
Directors Options	36,781	54,126
2022 Restricted Shares	–	31,276
Controlling Shareholders Restricted Shares	–	21,286
<b>Total</b>	<b>76,238</b>	<b>111,413</b>

**32. FINANCIAL INSTRUMENTS**

**The Group**

*Categories of financial instruments*

	<b>As at December 31,</b>	
	<b>2021</b>	<b>2022</b>
	<i>RMB'000</i>	<i>RMB'000</i>
<b>Financial assets</b>		
Amortized costs	32,368	69,847
Financial assets at FVTPL	532,365	512,664
	<b>564,733</b>	<b>582,511</b>
<b>Financial liabilities</b>		
Amortized cost	11,558	80,722
Financial liabilities at FVTPL	1,237,517	–
	<b>1,249,075</b>	<b>80,722</b>
Lease liabilities	<b>10,580</b>	<b>11,219</b>



**APPENDIX I**

**ACCOUNTANTS’ REPORT**

**The Company**

*Categories of financial instruments*

	<b>As at December 31,</b>	
	<b>2021</b>	<b>2022</b>
	<i>RMB’000</i>	<i>RMB’000</i>
<b>Financial assets</b>		
Amortized cost	32,064	79,080
Financial assets at FVTPL	494,768	492,962
	<u>526,832</u>	<u>572,042</u>
<b>Financial liabilities</b>		
Amortized cost	2,085	15,517
Financial liabilities at FVTPL	1,237,517	–
	<u>1,239,602</u>	<u>15,517</u>

**Financial risk management objectives and policies**

The Group’s and the Company’s major financial instruments include deposits and other receivables, bank balances and cash, financial assets at FVTPL, other payables, lease liabilities and financial liabilities at FVTPL. Details of these financial instruments are disclosed in the respective notes. The risks associated with these financial instruments include market risk (currency risk, interest rate risk and other price risk), credit risk and liquidity risk. The policies on how to mitigate these risks are set out below. The management manages and monitors these exposures to ensure appropriate measures are implemented on a timely and effective manner.

**Market risk**

(i) *Currency risk*

**The Group**

As at the end of each reporting period, the Group had the following monetary assets and monetary liabilities denominated in currencies other than RMB.

	<b>As at December 31,</b>	
	<b>2021</b>	<b>2022</b>
	<i>RMB’000</i>	<i>RMB’000</i>
<b>Assets</b>		
US\$	–	5,332
	<u>–</u>	<u>5,332</u>
<b>Liabilities</b>		
US\$	1,034	9,895
	<u>1,034</u>	<u>9,895</u>

**APPENDIX I**

**ACCOUNTANTS’ REPORT**

**The Company**

As at the end of each reporting period, the Company had the following monetary liabilities denominated in currencies other than RMB.

	<b>As at December 31,</b>	
	<b>2021</b>	<b>2022</b>
	<i>RMB'000</i>	<i>RMB'000</i>
Liabilities		
US\$	1,034	9,895

Sensitivity analysis

The Group and the Company were primarily subject to foreign currency risk from the movement of the exchange rates between RMB against US\$. At the end of each reporting period, if the exchange rate of RMB had been weakened against US\$ by 5% and all other variables were held constant, the Group’s and the Company’s post-tax loss for each reporting period would increase as follows. For a 5% strengthening of RMB against US\$, there would be an opposite impact on the post-tax loss for the year.

**The Group**

	<b>Increase in post-tax loss</b>	
	<b>For the year ended December 31,</b>	
	<b>2021</b>	<b>2022</b>
	<i>RMB'000</i>	<i>RMB'000</i>
US\$	52	228

**The Company**

	<b>Increase in post-tax loss</b>	
	<b>For the year ended December 31,</b>	
	<b>2021</b>	<b>2022</b>
	<i>RMB'000</i>	<i>RMB'000</i>
US\$	52	495

(ii) *Interest rate risk*

The Group’s and the Company’s fair value interest rate risk relates primarily to fixed-rate lease liabilities (Note 25) and fixed-rate Preference Shares (Note 27). The Group and the Company are also exposed to cash flow interest risk in relation to variable-rate bank balances (Note 23) which carry prevailing market interests and financial products (Note 22). The Group currently does not have a specified policy to manage its interest rate risk but will closely monitor their interest rate risk exposure in the future. No sensitivity analysis on cash flow interest rate risk is presented as the management considers the sensitivity on interest rate risk on bank balances and financial products is insignificant.

## APPENDIX I

## ACCOUNTANTS’ REPORT

### (iii) Other price risk

The Group and the Company are exposed to other price risk through Preference Shares measured at FVTPL and investments in financial products measured at FVTPL.

Sensitivity analyses for Preference Shares with fair value measurement categorized within Level 3 were disclosed in Note 33. The management of the Group considers the fluctuation in fair value changes on financial products is insignificant, taking into account the short-term duration of such financial products.

### *Credit risk and impairment assessment*

The Group’s and the Company’s maximum exposure to credit risk which will cause a financial loss to the Group and the Company due to failure to discharge an obligation by the counterparties is arising from the carrying amount of the respective recognized financial assets (including bank balances, financial assets at FVTPL, deposits and other receivables). The Group and the Company do not hold any collaterals or other credit enhancement to cover the credit risks associated with its financial assets.

In order to minimize the credit risk, the Group and the Company monitor the exposure to credit risk on an on-going basis. Except for financial assets at FVTPL, the Group and the Company individually assessed the expected credit losses on its financial assets measured at amortized cost, mainly including bank balances, deposits and other receivables, on the basis of a loss rate approach at the end of each reporting period. The estimated loss rates are estimated based on historical observed default rates over the expected life of the debtors and are adjusted for forward-looking information that is available without undue cost or effort.

The Group’s and the Company’s internal credit risk grading assessment comprises the following categories:

<b>Internal credit rating</b>	<b>Description</b>	<b>Financial assets</b>
Low risk	The counterparty has a low risk of default and does not have any past-due amounts	12m ECL
Watch list	Debtor frequently repays after due dates but usually settle the amounts in full	12m ECL
Doubtful	There have been significant increases in credit risk since initial recognition through information developed internally or external resources	Lifetime ECL — not credit-impaired
Loss	There is evidence indicating the asset is credit-impaired	Lifetime ECL — credit-impaired
Write-off	There is evidence indicating that the debtor is in severe financial difficulty and the Group and the Company have no realistic prospect of recovery	Amount is written off

### *Bank balances*

The Group’s and the Company’s bank balances are placed with state-owned banks or commercial banks with high credit ratings in the Mainland China. Therefore, the credit risk on bank balances is insignificant and no loss allowance was recognized.

The Group has concentration risk with approximately 99.9% of the Group’s bank balances placed with bank A at December 31, 2021 and with approximately 19.9%, 28.5%, 36.5% and 13.3% of the Group’s bank balances placed with bank A, bank B, bank C and bank D at December 31, 2022.

The Company has concentration risk with approximately 99.9% of the Company’s bank balances placed with bank A at December 31, 2021 and with approximately 21.0%, 30.0%, 38.4% and 10.6% of the Company’s bank balances placed with bank A, bank B, bank C and bank D at December 31, 2022.

APPENDIX I

ACCOUNTANTS’ REPORT

*Deposits and other receivables*

The counterparties of the Group’s and the Company’s deposits and other receivables are subsidiaries of local government or a listed company in the PRC or employees of the Group. The Group and the Company assessed the ECL for its deposits and other receivables individually based on internal credit rating which, in the opinion of the Directors, there is no significant increase in credit risk since initial recognition. No loss allowance was made for deposits and other receivables, the estimated loss rates are limited as the historical observed default rates of counterparties above are minimal, therefore the Group and the Company assessed the ECL for deposits and other receivables are insignificant.

Other than the concentration of credit risks of bank balances mentioned above, the Group and the Company do not have any other significant concentration of credit risk.

*Liquidity risk*

In management of the liquidity risk, the Group and the Company monitor and maintain levels of cash and cash equivalents deemed adequate by the management to finance the Group’s and the Company’s operations and mitigate the effects of fluctuations in cash flows. The Group relies on shareholders’ investment as a significant source of liquidity.

The following table details the Group’s and the Company’s remaining contractual maturity for its financial liabilities based on the agreed repayment terms. The table has been drawn up based on the undiscounted cash flows of financial liabilities based on the earliest date on which the Group and the Company can be required to pay. The table includes both interest and principal cash flows.

**The Group**

	Interest rates						Total	Carrying amount
		On demand	Within 180 days	181 days to 365 days	1-5 years	>5 years	undiscounted cash flows	
	%	RMB’000	RMB’000	RMB’000	RMB’000	RMB’000	RMB’000	RMB’000
At December 31, 2021								
Other payables	N/A	-	11,558	-	-	-	11,558	11,558
Financial liabilities at FVTPL	6.00	-	-	-	776,908	-	776,908	1,237,517
		-	11,558	-	776,908	-	788,466	1,249,075
Lease liabilities	6.05	-	-	-	1,666	14,006	15,672	10,580
At December 31, 2022								
Other payables	N/A	-	80,722	-	-	-	80,722	80,722
Lease liabilities	6.05	-	-	-	5,064	10,608	15,672	11,219

APPENDIX I

ACCOUNTANTS’ REPORT

The Company

	Interest rates	On demand	Within 180 days	181 days to 365 days	1-5 years	>5 years	Total undiscounted cash flows	Carrying amount
	%	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
At December 31, 2021								
Other payables	N/A	-	2,085	-	-	-	2,085	2,085
Financial liabilities at FVTPL	6.00	-	-	-	776,908	-	776,908	1,237,517
		-	2,085	-	776,908	-	778,993	1,239,602

	Interest rates	On demand	Within 180 days	181 days to 365 days	1-5 years	>5 years	Total undiscounted cash flows	Carrying amount
	%	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
At December 31, 2022								
Other payables	N/A	3,572	11,945	-	-	-	15,517	15,517

33. FAIR VALUE MEASUREMENTS OF FINANCIAL INSTRUMENTS

Some of the Group’s and the Company’s financial instruments are measured at fair value for financial reporting purposes. In estimating the fair value, the Group and the Company use market-observable data to the extent it is available. Where Level 1 inputs are not available, the Group and the Company determine the appropriate valuation techniques and inputs for fair value measurements and works closely with the qualified valuer to establish the appropriate valuation techniques and inputs to the model.

Except for financial assets at FVTPL and financial liabilities at FVTPL as set out below, there is no financial instrument measured at fair value on a recurring basis.

Financial assets

The Group

NOTE	Fair value as at		Fair value hierarchy	Valuation techniques and key inputs	
	December 31,				
	2021	2022			
	RMB'000	RMB'000			
Financial assets at FVTPL	22	532,365	512,664	Level 2	Redemption value quoted by banks.

The Company

NOTE	Fair value as at		Fair value hierarchy	Valuation techniques and key inputs	
	December 31,				
	2021	2022			
	RMB'000	RMB'000			
Financial assets at FVTPL	22	494,768	492,962	Level 2	Redemption value quoted by banks.

APPENDIX I

ACCOUNTANTS’ REPORT

*Financial liabilities*

**The Group and the Company**

	NOTE	Fair value as at		Fair value hierarchy	Valuation techniques and key inputs	Significant unobservable inputs	Relationships of unobservable inputs to fair value
		December 31,					
		2021	2022				
		RMB'000	RMB'000				
Financial liabilities at FVTPL	27	1,237,517	–	Level 3	Back-solve method, PWERM and OPM	Volatility	The higher the volatility, the higher the fair value, and vice versa (Note).

Note: If the volatility was 5% higher to 61.49% or 5% lower to 51.49% while holding all other variables constant, the carrying amount of financial liabilities at FVTPL would increase by RMB742,000 or decrease by RMB742,000 as at December 31, 2021.

Details of reconciliation of Level 3 fair value measurement for the financial liabilities at FVTPL are set out in Note 27.

The Directors consider that the carrying amounts of financial assets and financial liabilities recorded at amortized cost in the Historical Financial Information approximate their respective fair values at the end of each reporting period.

**34. RECONCILIATION OF LIABILITIES ARISING FROM FINANCING ACTIVITIES**

**The Group**

The table below details changes in the Group’s liabilities arising from financing activities, including both cash and non-cash changes. Liabilities arising from financing activities are those for which cash flows were, or future cash flows will be classified in the Group’s consolidated statements of cash flows as cash flows from financing activities.

	Lease liabilities	Financial liabilities at FVTPL	Issue costs for financial liabilities at FVTPL	Accrued share issue costs for [REDACTED]	Total
	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
At January 1, 2021	–	346,440	–	–	346,440
Financing cash flows	–	450,000	(6,194)	(1,123)	442,683
Commencement of lease	9,977	–	–	–	9,977
Interest expenses recognized	603	–	–	–	603
Fair value changes	–	441,077	–	–	441,077
Deferred share issue costs for [REDACTED]	–	–	–	1,458	1,458
Issue costs incurred	–	–	6,194	–	6,194
At December 31, 2021	10,580	1,237,517	–	335	1,248,432
Financing cash flows	(581)	338,000	(2,547)	(6,589)	328,283
Commencement of lease	3,488	–	–	–	3,488
Interest expenses recognized	722	–	–	–	722
Early termination of a lease	(2,990)	–	–	–	(2,990)
Fair value changes	–	551,546	–	–	551,546
Reclassification	–	(2,127,063)	–	–	(2,127,063)
Deferred share issue costs for [REDACTED]	–	–	–	9,892	9,892
Issue costs incurred	–	–	2,547	–	2,547
At December 31, 2022	11,219	–	–	3,638	14,857

**APPENDIX I**

**ACCOUNTANTS’ REPORT**

**35. MAJOR NON-CASH TRANSACTIONS**

During the year ended December 31, 2021, the Group entered into a new lease agreement for the use of leased properties for 10 years. On the lease commencement, the Group recognized right-of-use assets, lease liabilities and deferred government grants of RMB23,325,000, RMB9,977,000 and RMB13,348,000 respectively as detailed in Note 25.

During the year ended December 31, 2022, the Group entered into a new lease agreement for the use of leased properties for 3 years. On the lease commencement, the Group recognized right-of-use assets and lease liabilities of RMB3,488,000 and RMB3,488,000 respectively.

**36. RELATED PARTY BALANCES AND TRANSACTIONS**

- a. The Group had the following related party transactions and related parties balance during the Track Record Period:

**The Group and the Company**

	<b>For the year ended December 31,</b>	
	<b>2021</b>	<b>2022</b>
	<i>RMB'000</i>	<i>RMB'000</i>
Purchase of services from related parties		
Beijing Science Sun	47	–
	<b>47</b>	<b>–</b>

- b. Compensation of key management personnel

The emoluments of key management during the Track Record Period are as follows:

	<b>For the year ended December 31,</b>	
	<b>2021</b>	<b>2022</b>
	<i>RMB'000</i>	<i>RMB'000</i>
Short-term employee benefits	3,575	5,621
Retirement benefits	147	258
Equity-settled share-based payments	47,438	92,217
	<b>51,160</b>	<b>98,096</b>

APPENDIX I

ACCOUNTANTS’ REPORT

37. PARTICULARS OF SUBSIDIARIES OF THE COMPANY

As at December 31, 2021 and 2022, the investments in subsidiaries of the Company comprise i) capital injection to Zhuhai Luzhu of RMB100,000,000 was paid as at December 31, 2021 and RMB100,000,000 was paid in April 2022; ii) deemed investment to Zhuhai Luzhu of RMB1,343,000 and RMB13,566,000 as at December 31, 2021 and 2022 for share options of the Company granted to employees of Zhuhai Luzhu; iii) capital injection to Hong Kong Luzhu of HK\$100,000 (equivalent to RMB81,000) was paid in March 2022; iv) a deemed investment in Hong Kong Luzhu of RMB18,911,000 in March 2022; v) capital injection to Beijing Luzhu of RMB150,000,000 was paid as at December 31, 2022; and vi) deemed investment to Beijing Luzhu of RMB1,492,000 during the year ended December 31, 2022 for share options of the Company granted to employees of Beijing Luzhu.

Name of the subsidiaries	Place/date of establishment	Issued and fully paid share capital/ registered capital	Equity interest attributable to the Company		Date of the report	Principal activities
			December 31, 2021	December 31, 2022		
Zhuhai Luzhu <i>(Note i)</i>	PRC November 29, 2018	Registered capital of RMB200,000,000 and paid-in capital of RMB200,000,000	100%	100%	100%	research, development and production of vaccines and therapeutic biologics
Luzhu Biologics (Hong Kong) Co., Limited (“ <b>Hong Kong Luzhu</b> ”) <i>(Note ii)</i>	Hong Kong December 20, 2021	Registered capital of HK\$100,000 and issued and paid share capital of HK\$100,000	100%	100%	100%	inactive
Beijing Luzhu <i>(Note iii)</i>	PRC March 31, 2022	Registered capital of RMB150,000,000 and issued and paid share capital of RMB150,000,000	–	100%	100%	research, development and production of vaccines and therapeutic biologics

Notes:

- i. The subsidiary is a limited liability company. The financial statements of Zhuhai Luzhu for the year ended December 31, 2021 were prepared in accordance with Accounting Standards for Business Enterprises issued by the Ministry of Finance of the PRC and were audited by Talent Certified Public Accountants\* (天衡會計師事務所). The financial statements of Zhuhai Luzhu for the year ended December 31, 2022 were prepared in accordance with Accounting Standards for Business Enterprises issued by the Ministry of Finance of the PRC and were audited by Deloitte Touche Tohmatsu Certified Public Accountants LLP..
- ii. No audited statutory financial statements have been prepared for Hong Kong Luzhu as the statutory financial statements are not yet due to be issued.
- iii. The audited statutory financial statements of Beijing Luzhu for the year ended December 31, 2022 are not yet due to be issued.

\* English name is for identification purpose only.



## APPENDIX I

## ACCOUNTANTS’ REPORT

### 38. CAPITAL RISK MANAGEMENT

The Group manages its capital to ensure that entities in the Group will be able to continue as a going concern while maximizing the return to shareholders through the optimization of the debt and equity balance. The Group’s overall strategy remains unchanged during the Track Record Period.

The capital structure of the Group consists of net debt, which includes the lease liabilities and financial liabilities at FVTPL as disclosed in Notes 25 and 27, net of cash and cash equivalents and equity attributable to owners of the Company, comprising issued share capital and reserves.

The Directors review the capital structure on a continuous basis taking into account the cost of capital and the risks associated with each class of capital. Based on recommendations of the Directors, the Group will balance its overall capital structure through new share issues as well as the issue of new debts.

### 39. CAPITAL COMMITMENTS

	As at December 31,	
	2021	2022
	<i>RMB’000</i>	<i>RMB’000</i>
Contracted for but not provided in the Historical Financial Information	25,107	13,498

Capital commitments are related to expenditures in respect of the acquisition of equipment and machineries and a construction project.

### 40. EVENTS AFTER THE REPORTING PERIOD

There are no material subsequent events undertaken by the Company or by the Group after December 31, 2022 and up to the date of this report.

### 41. SUBSEQUENT FINANCIAL STATEMENTS

No audited financial statements have been prepared by the Company or any of its subsidiaries in respect of any period subsequent to December 31, 2022.

**APPENDIX II                      UNAUDITED [REDACTED] FINANCIAL INFORMATION**

The information set out in this Appendix does not form part of the accountants’ report on the historical financial information of the Group for each of the two years ended December 31, 2022 (the “Accountants’ Report”) prepared by Deloitte Touche Tohmatsu, Certified Public Accountants, Hong Kong, the Company’s Reporting Accountants, as set out in Appendix I to this document, and is included herein for information only. The unaudited [REDACTED] financial information should be read in conjunction with the section headed “Financial Information” in this document and the Accountants’ Report set out in Appendix I to this document.

**A.      UNAUDITED [REDACTED] STATEMENT OF ADJUSTED CONSOLIDATED NET TANGIBLE ASSETS OF THE GROUP ATTRIBUTABLE TO OWNERS OF THE COMPANY**

The following unaudited [REDACTED] statement of adjusted consolidated net tangible assets of the Group attributable to owners of the Company prepared in accordance with paragraph 4.29 of the Listing Rules is set out below to illustrate the effect of the [REDACTED] on the audited consolidated net tangible assets of the Group attributable to owners of the Company at December 31, 2022 as if the [REDACTED] had taken place on that date.

The unaudited [REDACTED] statement of adjusted consolidated net tangible assets of the Group attributable to owners of the Company has been prepared for illustrative purposes only and, because of its hypothetical nature, it may not give a true picture of the consolidated net tangible assets of the Group attributable to owners of the Company as at December 31, 2022 or any future dates.

The following unaudited [REDACTED] statement of adjusted consolidated net tangible assets of the Group attributable to owners of the Company is prepared based on the audited consolidated net tangible assets of the Group attributable to owners of the Company as at December 31, 2022 as derived from the Accountants’ Report, the text of which is set out in Appendix I to this document, and adjusted as described below:

	Audited consolidated net tangible assets of the Group attributable to owners of the Company as at December 31, 2022	Estimated [REDACTED] from the [REDACTED]	Unaudited [REDACTED] adjusted consolidated net tangible assets of the Group attributable to owners of the Company as at December 31, 2022	Unaudited [REDACTED] adjusted consolidated net tangible assets of the Group attributable to owners of the Company as at December 31, 2022 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>
Based on an [REDACTED] of HK\$[REDACTED] per Share	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Based on an [REDACTED] of HK\$[REDACTED] per Share	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

## APPENDIX II                      UNAUDITED [REDACTED] FINANCIAL INFORMATION

*Notes:*

1. The audited consolidated net tangible assets of the Group attributable to owners of the Company as at December 31, 2022 is based on the consolidated net assets of the Group amounted to RMB937,466,000, with adjustments for intangible assets of the Group as at December 31, 2022 of RMB3,437,000 extracted from the Accountants’ Report set forth in Appendix I to the document.
2. The estimated [REDACTED] from the [REDACTED] are based on [REDACTED] new Shares to be issued at the [REDACTED] of HK\$[REDACTED] and HK\$[REDACTED] per [REDACTED], being the low end and high end of the indicated [REDACTED] range respectively, after deduction of the estimated [REDACTED] fees and other related expenses incurred or expected to be incurred by the Group, other than those expenses which had been recognized in profit or loss prior to December 31, 2022. The calculation of such estimated [REDACTED] does not take into account (i) any Shares which may be allotted and issued upon the exercise of the [REDACTED] or (ii) any Shares which may be issued or repurchased by the Company pursuant to the general mandates.

For the purpose of the estimated [REDACTED] from the [REDACTED], the amount denominated in HK\$ has been converted into RMB at an exchange rate of HK\$1 to RMB0.87599, which was the exchange rate prevailing on April 10, 2023 with reference to the rate published by the People’s Bank of China. No representation is made that HK\$ amounts have been, could have been or may be converted to RMB, or vice versa, at that rate or at any other rates or at all.

3. The number of shares used for the calculation of unaudited [REDACTED] adjusted consolidated net tangible assets of the Group attributable to owners of the Company per Share is based on [REDACTED] Shares outstanding immediately following completion of the [REDACTED]. It does not take into account (i) any Shares which may be allotted and issued upon the exercise of the [REDACTED] or (ii) any Shares which may be issued or repurchased by the Company pursuant to the general mandates.
4. The unaudited [REDACTED] adjusted consolidated net tangible assets of the Group attributable to owners of the Company per Share is converted from RMB to HK\$ at the rate of HK\$1 to RMB0.87599, which was the exchange rate prevailing on April 10, 2023 with reference to the rate published by the People’s Bank of China. No representation is made that the RMB amounts have been, would have been or may be converted to HK\$, or vice versa, at that rate or at any other rates or at all.
5. No adjustment has been made to the unaudited [REDACTED] adjusted consolidated net tangible assets of the Group attributable to owners of the Company as at December 31, 2022 to reflect any operating result or other transactions of the Group entered into subsequent to December 31, 2022.

**APPENDIX II                      UNAUDITED [REDACTED] FINANCIAL INFORMATION**

---

[REDACTED]

**APPENDIX II                      UNAUDITED [REDACTED] FINANCIAL INFORMATION**

---

[REDACTED]

**APPENDIX II                      UNAUDITED [REDACTED] FINANCIAL INFORMATION**

---

[REDACTED]

## APPENDIX III

## PROPERTY VALUATION REPORT

*The following is the text of a letter, a summary of values and valuation report prepared for the purpose of incorporation in this document received from Savills Valuation and Professional Services (China) Limited, an independent valuer, in connection with their opinion of values of the properties held by the Group as at February 28, 2023.*

The Directors  
Beijing Luzhu Biotechnology Co., Ltd.  
No. 3 Guangtong Street  
Zhangjiawan  
Tongzhou District  
Beijing  
PRC



Savills Valuation and  
Professional Services (China) Limited  
1208, 12/F  
1111 King's Road, Taikoo Shing  
Hong Kong

T: (852) 2801 6100  
F: (852) 2530 0756

savills.com

[REDACTED]

Dear Sirs,

### INSTRUCTIONS

In accordance with your instructions for us to value the properties situated in the People's Republic of China (the “PRC”) in which Beijing Luzhu Biotechnology Co., Ltd. (the “Company”) and/or its subsidiaries (hereinafter together referred to as the “Group”) have interests, we confirm that we have carried out inspections, made relevant enquiries and obtained such further information as we consider necessary for the purpose of providing you with our opinion of market values of the properties as at February 28, 2023 (the “valuation date”) for incorporation in a public [REDACTED] document.

### BASIS OF VALUATION

Our valuation of each of the properties is our opinion of its market value which we would define as intended to mean “the estimated amount for which an asset or liability should exchange on the valuation date between a willing buyer and a willing seller in an arm's length transaction after proper marketing and where the parties had each acted knowledgeably, prudently and without compulsion”.

Moreover, market value is understood as the value of an asset or liability estimated without regard to costs of sale and purchase (or transaction) and without offset for any associated taxes or potential taxes.

Our valuation has been undertaken in accordance with the HKIS Valuation Standards 2020 of The Hong Kong Institute of Surveyors (“HKIS”), which incorporates the International Valuation Standards (“IVS”), and (where applicable) the relevant HKIS or jurisdictional supplement. We have also complied with the requirements set out in Chapter 5 and Practice Note 12 of the Rules Governing the Listing of Securities issued by the Stock Exchange of Hong Kong Limited.

## **APPENDIX III**

## **PROPERTY VALUATION REPORT**

### **IDENTIFICATION AND STATUS OF THE VALUER**

The subject valuation exercise is handled by our Mr. Anthony C.K. Lau. Mr. Lau is a Director of Savills Valuation and Professional Services (China) Limited ("SVPSCL") and a Member of the HKIS (General Practice Division) with over 29 years' experience in valuation of properties in the PRC and has sufficient knowledge of the relevant market, the skills and understanding to handle the subject valuation exercise competently.

Prior to your instructions for us to provide this valuation services in respect of the properties, SVPSCL had not been involved in valuation of the properties in the past 12 months.

We are independent of the Company and its subsidiaries. We are not aware of any instances which would give rise to potential conflict of interest from SVPSCL or Mr. Lau in the subject exercise. We confirm SVPSCL and Mr. Lau are in the position to provide objective and unbiased valuation for the properties.

### **PROPERTY CATEGORISATION AND VALUATION METHODOLOGY**

In valuing Property No. 1, which is held by the Group under development in the PRC, we have valued this property on the basis that it will be developed and completed in accordance with the latest development proposal provided to us by the Group. We have assumed that all consents, approvals and licenses from relevant government authorities for the development proposal have been obtained without onerous conditions or delays. In arriving at our opinion of value, we have adopted the Direct Comparison Method by making reference to comparable sales transactions as available in the market and also taken into account the cost that will be incurred to complete the development to reflect the quality of the completed development.

In valuing Property No. 2, which is held by the Group for future development in the PRC, we have valued this property by the Direct Comparison Method by making reference to sales of comparable properties as available in the market.

### **TITLE INVESTIGATION**

We have been provided with copies of the title documents relating to the properties. However, we have not searched the original documents to verify ownership or to ascertain the existence of any amendments which may not appear on the copies provided to us. In the course of our valuation, we have relied to a considerable extent on the information given by the Group and the legal opinion issued by the Group's legal adviser, Commerce & Finance Law Offices, regarding the title to the properties.

### **SOURCE OF INFORMATION**

We have relied to a considerable extent on information given by the Group and have accepted information on such matters as planning approvals, statutory notices, easements, tenure, particulars of occupancy, completion date, floor areas and all other relevant matters. Dimensions, measurements and areas included in the valuation report are based on the information contained in the documents provided to us and are therefore only approximations. No on-site measurements have been taken. We have no reason to doubt the truth and accuracy of the information provided to us by the Group, which is material to our valuation. We are also advised by the Group that no material facts have been omitted from the information supplied. We consider that we have been provided with sufficient information to reach an informed view.



## APPENDIX III

## PROPERTY VALUATION REPORT

### VALUATION ASSUMPTIONS

In valuing the properties in the PRC, unless otherwise stated, we have assumed that transferable land use rights of the properties for their specific terms at nominal annual land use fee have been granted and that any land grant premium payable have already been fully paid. Unless otherwise stated, we have also assumed that the Group has a good legal title to the properties and has free and uninterrupted rights to occupy, use, transfer, lease or assign the properties for the whole of the unexpired terms as granted.

No allowance has been made in our valuation for any charges, mortgages or amounts owing on any property nor for any expenses or taxation which may be incurred in effecting a sale. Unless otherwise stated, it is assumed that the properties are free from encumbrances, restrictions and outgoings of an onerous nature which could affect their values.

### SITE INSPECTION

We have inspected the exterior and where possible, the interior of the properties. Site inspections of the properties were carried out by our Ms. Nico Yao in February 2023. Ms. Yao has over 8 years' experience in valuation of properties in the PRC. During the course of our inspections, we did not note any serious defects. However, no structural survey has been made and we are therefore unable to report that the properties are free from rot, infestation or any other structural defect. No test has been carried out to any of the services.

### CURRENCY

Unless otherwise stated, all money amounts stated are in Renminbi ("RMB").

We enclose herewith our summary of values and valuation report.

Yours faithfully,

For and on behalf of

**Savills Valuation and Professional Services (China) Limited**

Anthony C.K. Lau

*MRICS MHKIS RPS (GP)*

Director

*Note:* Mr. Anthony C.K. Lau is a professional surveyor who has over 29 years' experience in valuation of properties in the PRC.

**APPENDIX III**

**PROPERTY VALUATION REPORT**

**SUMMARY OF VALUES**

<u>No.</u>	<u>Property</u>	<u>Market value in existing state as at February 28, 2023</u>	<u>Interest attributable to the Group</u>	<u>Market value in existing state attributable to the Group as at February 28, 2023</u>
<b>Group I — Property held by the Group under development in the PRC</b>				
1.	Dingjiawan Project I (定家灣項目一期), Xiangtian Road East and Anwan Road South, Sanzao Town, Jinwan District, Zhuhai, Guangdong Province, PRC	189,000,000	100%	189,000,000
	Sub-total:	<u>189,000,000</u>		<u>189,000,000</u>
<b>Group II — Property held by the Group for future development in the PRC</b>				
2.	Dingjiawan Project II (定家灣項目二期), Xiangtian Road East and Anwan Road South, Sanzao Town, Jinwan District, Zhuhai, Guangdong Province, PRC	7,800,000	100%	7,800,000
	Sub-total:	<u>7,800,000</u>		<u>7,800,000</u>
	<b>Total:</b>	<b><u><u>196,800,000</u></u></b>		<b><u><u>196,800,000</u></u></b>

**APPENDIX III**

**PROPERTY VALUATION REPORT**

**VALUATION REPORT**

**GROUP I — PROPERTY HELD BY THE GROUP UNDER DEVELOPMENT IN THE PRC**

<b>No.</b>	<b>Property</b>	<b>Description and tenure</b>	<b>Particulars of occupancy</b>	<b>Market value in existing state as at February 28, 2023</b>
1.	Dingjiawan Project I (定家灣項目一期), Xiangtian Road East and Anwan Road South, Sanzao Town, Jinwan District, Zhuhai, Guangdong Province, PRC	<p>Dingjiawan Project (the “Development”) is an industrial development being erected on a parcel of land with a site area of 69,366.15 sq.m.</p> <p>The Development is located in Sanzao Town of Jinwan District in Zhuhai. The immediate locality is an industrial area with some low-rise buildings scattering along the main roads of the district. It takes approximately a 40-minutes’ drive from the property to the city centre of Zhuhai.</p> <p>According to the information provided by the Group, the property will have a total gross floor area of approximately 71,560.00 sq.m. upon completion. Details of the uses and approximate gross floor areas of the property are as follows:</p>	As at the valuation date, the property was under construction.	<p>RMB189,000,000 (Renminbi One Hundred and Eighty Nine Million)</p> <p>(100% interest attributable to the Group: RMB189,000,000 (Renminbi One Hundred and Eighty Nine Million))</p>

**APPENDIX III**

**PROPERTY VALUATION REPORT**

<u>No.</u>	<u>Property</u>	<u>Description and tenure</u>	<u>Particulars of occupancy</u>	<u>Market value in existing state as at February 28, 2023</u>
		<b>Use</b>	<b>Approximate Gross Floor Area (sq.m.)</b>	
		Production Plant (Building No. 1)	23,780.00	
		Production Plant (Building No. 2)	15,000.00	
		Production Plant (Building No. 3)	15,000.00	
		Production Plant (Building No. 4)	15,000.00	
		Integrated Power Centre (Building No. 7)	2,410.00	
		Animal Experiment Room (Building No. 8)	200.00	
		Garbage Station (Building No. 9)	100.00	
		Guard Room No. 1	40.00	
		Guard Room No. 2	30.00	
		<b>Total:</b>	<b><u>71,560.00</u></b>	

APPENDIX III

PROPERTY VALUATION REPORT

No.	Property	Description and tenure	Particulars of occupancy	Market value in existing state as at February 28, 2023
		As advised by the Group, the construction of the property was commenced in April 2022 and is scheduled for completion in April 2023.		
		The land use rights of the property have been granted for a term expiring on January 14, 2071 for industrial use.		

Notes:

1. Pursuant to the State-owned Land Grant Contract – No. 440404-2021-000001 dated January 6, 2021, the land use rights of a parcel of land of the property with a site area of 69,366.15 sq.m. have been granted to Luzhu Biopharmaceuticals (Zhuhai) Co., Ltd. (綠竹生物製藥(珠海市)有限公司) (“Zhuhai Luzhu”), a wholly-owned subsidiary of the Company, for a term of 50 years for industrial use at a land grant fee of RMB25,596,110.  
  
As advised by the Group, the property only comprises portion of the land parcel as stated in the contract mentioned above.
2. Pursuant to the State-owned Land Use Certificate – Yue (2021) Zhu Hai Shi Bu Dong Chan Quan No. 0035989 dated April 15, 2021, the land use rights of the property with a site area of 69,366.15 sq.m. have been granted to Zhuhai Luzhu for a term expiring on 14 January 2071 for industrial use.  
  
As advised by the Group, the property only comprises portion of the land parcel as stated in the certificate mentioned above.
3. Pursuant to the Construction Land Planning Permit – Di Zi No. 440404202100005 dated January 18, 2021, Zhuhai Luzhu was permitted to use a parcel of land with a site area of 69,366.15 sq.m. for industrial use.  
  
As advised by the Group, the property only comprises portion of the land parcel as stated in the permit mentioned above.
4. Pursuant to the Construction Work Planning Permit – Jian Zi No. (Jin Wan) 2021-093 dated August 30, 2021, the approved construction scale of the property is 71,560.00 sq.m.
5. Pursuant to the Construction Work Commencement Permit – No. 440404202204110199 dated April 11, 2022, the construction work of the property with a construction scale of 71,560.00 sq.m. was approved for commencement.
6. As advised by the Group, the total construction cost incurred as at the valuation date was approximately RMB151,000,000 and the estimated outstanding construction cost for completion of the property will be approximately RMB54,000,000. We have taken into account the aforesaid amounts in our valuation.
7. The market value of the property as if completed as at the valuation date is estimated to be RMB276,000,000.
8. We have been provided with a legal opinion on the title to the property issued by the Group’s PRC legal adviser, which contains, inter alia, the following information:
  - i. Zhuhai Luzhu legally owns the property and is entitled to transfer, lease, mortgage or by other legal means dispose of the property.
9. In undertaking our valuation of the property as if completed, we have made reference to various market comparables of similar developments which have characteristics comparable to the property. The unit rates of these comparables are in a range from RMB3,200 to 5,500/sq.m. for industrial units. Due adjustments to the unit rates of these comparables have been made to reflect factors including but not limited to location, size, building age and building quality in arriving at the key assumptions.

**APPENDIX III**

**PROPERTY VALUATION REPORT**

**GROUP II — PROPERTY HELD BY THE GROUP FOR FUTURE DEVELOPMENT IN THE PRC**

<u>No.</u>	<u>Property</u>	<u>Description and tenure</u>	<u>Particulars of occupancy</u>	<u>Market value in existing state as at February 28, 2023</u>
2.	Dingjiawan Project II (定家灣項目二期), Xiangtian Road East and Anwan Road South, Sanzao Town, Jinwan District, Zhuhai, Guangdong Province, PRC	<p>Dingjiawan Project (the “Development”) is an industrial development being erected on a parcel of land with a site area of 69,366.15 sq.m.</p> <p>The Development is located in Sanzao Town of Jinwan District in Zhuhai. The immediate locality is an industrial area with some low-rise buildings scattering along the main roads of the district. It takes approximately a 40-minutes’ drive from the property to the city centre of Zhuhai.</p> <p>According to the information provided by the Group, the property will have a total gross floor area of approximately 54,090.00 sq.m. upon completion.</p> <p>The land use rights of the property have been granted for a term expiring on January 14, 2071 for industrial use.</p>	As at the valuation date, the property was vacant land.	<p>RMB7,800,000 (Renminbi Seven Million and Eight Hundred Thousand)</p> <p>(100% interest attributable to the Group: RMB7,800,000 (Renminbi Seven Million and Eight Hundred Thousand))</p>

*Notes:*

1. Pursuant to the State-owned Land Grant Contract – No. 440404-2021-000001 dated January 6, 2021, the land use rights of a parcel of land of the property with a site area of 69,366.15 sq.m. have been granted to Luzhu Biopharmaceuticals (Zhuhai) Co., Ltd. (綠竹生物製藥(珠海市)有限公司) (“Zhuhai Luzhu”), a wholly-owned subsidiary of the Company, for a term of 50 years for industrial use at a land grant fee of RMB25,596,110.

As advised by the Group, the property only comprises portion of the land parcel as stated in the contract mentioned above.

2. Pursuant to the State-owned Land Use Certificate – Yue (2021) Zhu Hai Shi Bu Dong Chan Quan No. 0035989 dated April 15, 2021, the land use rights of the property with a site area of 69,366.15 sq.m. have been granted to Zhuhai Luzhu for a term expiring on January 14, 2071 for industrial use.

As advised by the Group, the property only comprises portion of the land parcel as stated in the certificate mentioned above.

## APPENDIX III

## PROPERTY VALUATION REPORT

---

3. Pursuant to the Construction Land Planning Permit – Di Zi No. 440404202100005 dated January 18, 2021, Zhuhai Luzhu was permitted to use a parcel of land with a site area of 69,366.15 sq.m. for industrial use.

As advised by the Group, the property only comprises portion of the land parcel as stated in the permit mentioned above.

4. We have been provided with a legal opinion on the title to the property issued by the Group's PRC legal adviser, which contains, inter alia, the following information:

i. Zhuhai Luzhu legally owns the property and is entitled to transfer, lease, mortgage or by other legal means dispose of the property.

5. In undertaking our valuation of the property, we have made reference to various industrial land sales transactions which have characteristics comparable to the property. The accommodation values of the comparables are in the range from RMB168 to RMB170/sq.m. Due adjustments to the accommodation values of these transactions have been made to reflect factors including but not limited to land use term, accessibility, surrounding environment and location in arriving at key assumptions.

## PRC LAWS AND REGULATIONS RELATING TO TAXATION

### Taxation on Dividends

#### *Individual Investor*

Pursuant to the Individual Income Tax Law of the PRC (《中華人民共和國個人所得稅法》) (the “**IIT Law**”), which was last amended on August 31, 2018 and came into effect on January 1, 2019 and the Implementation Provisions of the Individual Income Tax Law of the PRC (《中華人民共和國個人所得稅法實施條例》), which was last amended on December 18, 2018 and came into effect on January 1, 2019, for individual income including interest, dividend and bonus, shall pay individual income tax with applicable proportional tax rate of 20%. Unless otherwise provided by the competent financial and taxation authorities under the State Council, all the interest, dividend and bonus are deemed as derived from the PRC whether the payment place is in the PRC. Pursuant to the Circular on Certain Issues Concerning the Policies of Individual Income Tax (《關於個人所得稅若干政策問題的通知》) promulgated by the Ministry of Finance and the State Administration of Taxation on May 13, 1994, overseas individuals are exempted from the individual income tax for dividends or bonuses received from foreign-invested enterprises.

#### *Enterprise Investors*

In accordance with the Enterprise Income Tax Law of the People’s Republic of China (《中華人民共和國企業所得稅法》) (the “**EIT Law**”), which was amended on December 29, 2018 and became effective on the same date, and the Implementation Provisions of the Enterprise Income Tax Law of the PRC (《中華人民共和國企業所得稅法實施條例》), which was amended on April 23, 2019 and became effective on the same date, a non-resident enterprise is generally subject to enterprise income tax at a rate of 10% on PRC-sourced income (including dividends received from a PRC resident enterprise that issues shares in Hong Kong), if it does not have an establishment or premise in the PRC or has an establishment or premise in the PRC but its PRC-sourced income has no real connection with such establishment or premise. The aforesaid income tax payable for non-resident enterprises are deducted at source, where the payer of the income is required to withhold the income tax from the amount to be paid to the non-resident enterprise when such payment is made or due.

The Circular on Issues Relating to the Withholding of Enterprise Income Tax by PRC Resident Enterprises on Dividends Paid to Overseas Non-Resident Enterprise Shareholders of H Shares (《關於中國居民企業向境外H股非居民企業股東派發股息代扣代繳企業所得稅有關問題的通知》) (Guo Shui Han [2008] No. 897), which was issued by the SAT on November 6, 2008, further clarified that a PRC-resident enterprise must withhold enterprise income tax at a rate of 10% on the dividends of 2008 and onwards that it distributes to overseas non-resident enterprise shareholders of H Shares. In addition, the Response to Questions on Levying Enterprise Income Tax on Dividends Derived by Non-resident Enterprise from Holding Stock such as B Shares (《關於非居民企業取得B股等股票股息徵收企業所得稅問題的批覆》) (Guo Shui Han [2009] No. 394), which was issued by the SAT and came into effect on July 24, 2009, further provides that any PRC-resident enterprise whose shares are listed on overseas stock exchanges must withhold and remit enterprise income tax at a rate of 10% on dividends of 2008 and onwards that it distributes to non-resident enterprises. Such tax rate may be further modified pursuant to the tax treaty or agreement that China has entered into with a relevant country or area, where applicable.



## APPENDIX IV

## TAXATION AND FOREIGN EXCHANGE

Pursuant to the Arrangement between the Mainland and the Hong Kong Special Administrative Region on the Avoidance of Double Taxation and the Prevention of Fiscal Evasion (《內地和香港特別行政區關於對所得避免雙重徵稅和防止偷漏稅的安排》), which was signed on August 21, 2006, the Chinese Government may levy taxes on the dividends paid by a Chinese company to Hong Kong residents (including natural persons and legal entities) in an amount not exceeding 10% of the total dividends payable by the Chinese company. If a Hong Kong resident directly holds 25% or more of the equity interest in a Chinese company, then such tax shall not exceed 5% of the total dividends payable by the Chinese company. The Fifth Protocol of the Arrangement between the Mainland of China and the Hong Kong Special Administrative Region on the Avoidance of Double Taxation and the Prevention of Fiscal Evasion (《〈內地和香港特別行政區關於對所得避免雙重徵稅和防止偷漏稅的安排〉第五議定書》), which came in to effect on December 6, 2019, adds a criteria for the qualification of entitlement to enjoy treaty benefits. Although there may be other provisions under the Arrangement, the treaty benefits under the criteria shall not be granted in the circumstance where relevant gains, after taking into account all relevant facts and conditions, are reasonably deemed to be one of the main purposes for the arrangement or transactions which will bring any direct or indirect benefits under this Agreement, except when the grant of benefits under such circumstance is consistent with relevant objective and goal under the Arrangement. The application of the dividend clause of tax agreements is subject to the requirements of PRC tax law documents, such as the Notice of the State Administration of Taxation on the Issues Concerning the Application of the Dividend Clauses of Tax Agreements (《國家稅務總局關於執行稅收協定股息條款有關問題的通知》) (Guo Shui Han [2009] No. 81).

### *Tax Treaties*

Non-PRC resident investors residing in countries which have entered into treaties for the avoidance of double taxation with the PRC or residing in Hong Kong or Macau are entitled to a reduction of the withholding taxes imposed on the dividends received from PRC companies. The PRC currently has entered into Avoidance of Double Taxation Treaties/Arrangements with a number of countries and regions including Hong Kong, Macau, Australia, Canada, France, Germany, Japan, Malaysia, the Netherlands, Singapore, the United Kingdom and the United States. Non-PRC resident enterprises entitled to preferential tax rates in accordance with the relevant income tax agreements or arrangements are required to apply to the Chinese tax authorities for a refund of the withholding tax in excess of the agreed tax rate, and the refund payment is subject to approval by the Chinese tax authorities.

### **Taxation on Share Transfer**

#### *Individual Investor*

According to the IIT Law and its implementation provisions, gains realized on the sale of equity interests in the PRC resident enterprises are subject to individual income tax at a rate of 20%.

Pursuant to the Circular of Declaring that Individual Income Tax Continues to be Exempted over Income of Individuals from the 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》) (Cai Shui Zi [1998] No. 61) issued by the MOF and the State Administration of Taxation on March 20, 1998, from January 1, 1997, income of individuals from transfer of the shares of listed enterprises continues to be exempted from individual income tax. On December 31, 2009, the MOF, the State Administration of Taxation and CSRC jointly issued the Circular on Related Issues on Levying Individual Income Tax over the Income Received by Individuals from the 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》)

## APPENDIX IV

## TAXATION AND FOREIGN EXCHANGE

(Cai Shui [2009] No. 167), which became effective on December 31, 2009, states that individuals’ income from the transfer of listed shares on the Shanghai Stock Exchange and the Shenzhen Stock Exchange shall continue to be exempted from individual income tax, except for the relevant shares which are subject to sales restriction (as defined in the Supplementary Notice on Issues Concerning the Levy of Individual Income Tax on Individuals’ Income from the Transfer of Restricted Stocks of Listed Companies (《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) jointly issued by the above three departments on November 10, 2010).

As of the Latest Practicable Date, no aforesaid provisions had expressly provided that whether individual income tax shall be levied from non-Chinese resident individuals on the transfer of shares in PRC resident enterprises listed on overseas stock exchanges. To the knowledge of the Company, in practice, the PRC tax authorities have not levied income tax from non-PRC resident individuals on gains from the transfer of PRC resident enterprises listed on overseas stock exchange. However, there is no assurance that the PRC tax authorities will not change these practices which could result in levying income tax on non-PRC resident individuals on gains from the sale of H shares.

### *Enterprise Investors*

In accordance with the EIT Law and its implementation provisions, a non-resident enterprise is generally subject to enterprise income tax at the rate of a 10% on PRC-sourced income, including gains derived from the disposal of equity interests in a PRC resident enterprise, if it does not have an establishment or premise in the PRC or has an establishment or premise in the PRC but its PRC-sourced income has no real connection with such establishment or premise. Such income tax payable for non-resident enterprises are deducted at source, where the payer of the income are required to withhold the income tax from the amount to be paid to the non-resident enterprise when such payment is made or due. Such tax may be reduced or exempted pursuant to relevant tax treaties or agreements on avoidance of double taxation.

### *Stamp Duty*

Pursuant to the Provisional Regulations of the PRC on Stamp Duty (《中華人民共和國印花稅暫行條例》), which came into effect on October 1, 1988 and amended on January 8, 2011, and the Implementation Provisions of Provisional Regulations of the PRC on Stamp Duty (《中華人民共和國印花稅暫行條例施行細則》), which came into effect on October 1, 1988, PRC stamp duty only applies to specific proof executed or received within the PRC, having legally binding force in the PRC and protected under the PRC laws, thus the requirements of the stamp duty imposed on the transfer of shares of PRC listed companies shall not apply to the acquisition and disposal of H Shares by non-PRC investors outside of the PRC.

## **Major Taxes on the Company in the PRC**

### *Enterprise Income Tax Law*

According to the Enterprise Income Tax Law of the People’s Republic of China (《中華人民共和國企業所得稅法》) (the “**Enterprise Income Tax Law**”), which was amended on December 29, 2018 and became effective on the same date and the Regulation on the Implementation of the Enterprise Income Tax Law of the People’s Republic of China (《中華人民共和國企業所得稅法實施條例》), which was amended on April 23, 2019 and became effective on the same date, the applicable enterprise income tax

## APPENDIX IV

## TAXATION AND FOREIGN EXCHANGE

rate of both domestic and foreign-funded enterprises shall be 25%. Enterprises are classified into resident and non-resident enterprises. A resident enterprise shall pay enterprise income tax on its incomes derived from both inside and outside China. For a non-resident enterprise having offices or establishments inside China, it shall pay enterprise income tax on its incomes derived from China as well as on incomes that it earns outside China but which has real connection with the said offices or establishments, the enterprise income tax rate applicable shall be 25%. For a non-resident enterprise having no office or establishment inside China, or for a non-resident enterprise whose incomes have no actual connection to its office or establishment inside China, it shall pay enterprise income tax on the incomes derived from China the enterprise income tax rate applicable shall be 10%.

### *Value-Added Tax*

According to the Interim Regulations of the PRC on Value-Added Tax (《中華人民共和國增值稅暫行條例》) which was promulgated by the State Council on December 13, 1993, and amended on November 10, 2008, February 6, 2016 and November 19, 2017, and the Detailed Rules for the Implementation of the Provisional Regulations of the PRC on Value-added Tax (《中華人民共和國增值稅暫行條例實施細則》) which was promulgated by the Ministry of Finance on December 25, 1993 and subsequently amended on December 15, 2008 and October 28, 2011 (collectively, the “**VAT Law**”), all enterprises and individuals that engage in the sale of goods, the provision of processing, repair and replacement services, sales of service, intangible assets and real estate and the importation of goods within the territory of the PRC shall pay value-added tax at the rate of 0%, 6%, 11% and 17% for the different goods it sells and different services it provides, except when specified otherwise.

According to the Notice on the Adjustment to VAT Rates (《關於調整增值稅稅率的通知》) (Cai Shui [2018] No. 32), promulgated by the MOF and the State Administration of Taxation on April 4, 2018 and became effective as of May 1, 2018, the VAT rates of 17% and 11% applicable to the taxpayers who have VAT taxable sales activities or imported goods are adjusted to 16% and 10%, respectively.

According to the Announcement on Relevant Policies for Deepening Value-Added Tax Reform (《關於深化增值稅改革有關政策的公告》) (2019 No. 39 of MOF, State Administration of Taxation and General Administration of Customs), promulgated by the MOF, the State Administration of Taxation and the General Administration of Customs on March 20, 2019 and became effective on April 1, 2019, the VAT rates of 16% and 10% applicable to the taxpayers who have VAT taxable sales activities or imported goods are adjusted to 13% and 9%, respectively.

### **PRC LAWS AND REGULATIONS RELATING TO FOREIGN EXCHANGE**

Foreign currencies conversion is mainly subject to the Administrative Regulations on Foreign Exchange of the PRC (《中華人民共和國外匯管理條例》) (the “**Foreign Exchange Administrative Regulations**”) promulgated by the PRC State Council on January 29, 1996 and latest amended on August 5, 2008 and the Administrative Provisions on the Settlement, Sales and Payment of Foreign Exchange (《結匯、售匯及付匯管理規定》) (the “**Settlement Provisions**”) promulgated by the People’s Bank of China on June 20, 1996. Under such regulations, RMB is generally freely convertible to foreign currencies for current account transactions (such as trade and service-related foreign exchange transactions and dividend payments), but not for capital account transactions (such as capital transfer, direct investment, securities investment, derivative products or loans), except where a prior approval from the SAFE and/or its competent local counterparts is obtained.

## APPENDIX IV

## TAXATION AND FOREIGN EXCHANGE

According to the Decision of the State Council on Canceling and Adjusting A Batch of Items Requiring Administrative Approval (《國務院關於取消和調整一批行政審批項目等事項的決定》) issued by the State Council on October 23, 2014, State Administration of Foreign Exchange (the “SAFE”) and its branches canceled the review and approval on the foreign exchange settlement for the repatriation of funds raised abroad under the overseas listed foreign capital stock account.

According to the Notice on Relevant Issue Concerning the Administration of Foreign Exchange for Overseas Listing (《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, the domestic companies shall register the overseas listed with the foreign exchange control bureau located at its registered address in 15 working days after the completion of the overseas listing and issuance. The funds raised by the domestic companies through overseas listing may be repatriated to China or deposited overseas, provided that the intended use of the fund shall be consistent with the contents of the document and other public disclosure documents.

According to the Notice of State Administration of Foreign Exchange on Reforming and Standardizing Capital Account Foreign Exchange Settlement Administration Policies (《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》) issued by SAFE on June 9, 2016, it has been specified clearly in the relevant policies that, for the capital account foreign exchange income subject to voluntary foreign exchange settlement (including the repatriation of the proceeds from overseas listing), the domestic institutions may conduct the foreign exchange settlement at the banks according to their operation needs. The proportion of the capital account foreign exchange income subject to voluntary foreign exchange settlement was tentatively set as 100%, provided that SAFE may adjust the aforesaid proportion according to the international payment balance status in good time.

## APPENDIX V SUMMARY OF PRINCIPAL LEGAL AND REGULATORY PROVISIONS

*This Appendix summarizes certain aspects of PRC laws and regulations, which are relevant to the Company’s operations and business. Laws and regulations relating to taxation in the PRC are discussed separately in “Appendix IV — Taxation and Foreign Exchange” to this document. This Appendix also contains a summary of certain Hong Kong legal and regulatory provisions, including summaries of certain material differences between the PRC Company Law and the Companies (Winding Up and Miscellaneous Provisions) Ordinance, certain requirements of the Listing Rules and additional provisions required by the Stock Exchange for inclusion in the articles of association of PRC issuers. The principal objective of this summary is to provide potential [REDACTED] with an overview of the principal laws and regulatory provisions applicable to the Company. This summary is not intended to include all the information which are important to the potential [REDACTED]. For discussion of laws and regulations which are relevant to the Company’s business, see “Regulatory Overview” in this document.*

### PRC LAWS AND REGULATIONS

#### The PRC Legal System

The PRC legal system is based on the PRC Constitution (hereinafter referred to as the “**Constitution**”) and is made up of statutes, administrative regulations, local regulations, autonomous regulations, separate regulations, rules and regulations of State Council departments, rules and regulations of local governments, laws of special administrative regions and international treaties of which the PRC government is the signatory and other regulatory documents. Court judgments do not constitute legally binding precedents, although they are used for the purposes of judicial reference and guidance.

According to the Constitution and the Legislation Law of the PRC (hereinafter referred to as the “**Legislation Law**”), the National People’s Congress (hereinafter referred to as the “**NPC**”) and its Standing Committee are empowered to exercise the legislative power of the State. The NPC has the power to formulate and amend basic laws governing State organs, civil, criminal and other matters. The Standing Committee of the NPC formulates and amends the laws other than those required to be enacted by the NPC and to supplement and amend parts of the laws enacted by the NPC during the adjournment of the NPC, provided that such supplements and amendments are not in conflict with the basic principles of such laws.

The State Council is the highest organ of state administration and has the power to formulate administrative regulations based on the Constitution and laws. The people’s congresses of the provinces, autonomous regions and municipalities and their standing committees may formulate local regulations based on the specific circumstances and actual needs of their respective administrative areas, provided that such regulations do not contravene any provision of the Constitution, laws or administrative regulations. The people’s congresses of cities divided into districts and their respective standing committees may formulate local regulations on aspects such as urban and rural construction and management, environmental protection and historical and cultural protection based on the specific circumstances and actual needs of such cities, provided that such local regulations do not contravene any provision of the Constitution, laws, administrative regulations and local regulations of their respective provinces or autonomous regions. If the law provides otherwise on the formulation of local regulations by cities divided into districts, those provisions shall prevail. Such local regulations will come into effect after being reported to and approved by the standing committees of the people’s congresses of the relevant provinces or autonomous regions. The standing committees of the people’s congresses of the provinces or autonomous regions shall examine the legality of local regulations submitted for approval,

## APPENDIX V SUMMARY OF PRINCIPAL LEGAL AND REGULATORY PROVISIONS

and such approval shall be granted within four months if they are not in conflict with the Constitution, laws, administrative regulations and local regulations of the relevant provinces or autonomous regions. Where, during the examination for approval of local regulations of cities divided into districts by the standing committees of the people’s congresses of the provinces or autonomous regions, conflicts are identified with the rules and regulations of the people’s governments of the provinces or autonomous regions, a decision should be made to resolve the issue. People’s congresses of national autonomous areas have the power to enact autonomous regulations and separate regulations in light of the political, economic and cultural characteristics of the ethnic groups in the areas concerned.

The ministries and commissions of the State Council, PBOC, NAO and the subordinate institutions with administrative functions directly administered by the State Council may formulate departmental rules and regulations within the permissions of their respective departments based on the laws and administrative regulations, and the decisions and orders of the State Council. Provisions of departmental rules should be the matters related to the enforcement of the laws and administrative regulations, and the decisions and orders of the State Council. The people’s governments of the provinces, autonomous regions, municipalities and cities or autonomous prefectures divided into districts may formulate rules and regulations based on the laws, administrative regulations and local regulations of such provinces, autonomous regions and municipalities.

Pursuant to the Resolution of the Standing Committee of the NPC Providing an Improved Interpretation of the Law (全國人民代表大會常務委員會關於加強法律解釋工作的決議) passed on June 10, 1981, in cases where the scope of provisions of laws or decrees needs to be further defined or additional stipulations need to be made, the Standing Committee of the NPC shall provide interpretations or make stipulations by means of decrees. Issues related to the application of laws in a court trial should be interpreted by the Supreme People’s Court, issues related to the application of laws in a prosecution process of the procuratorate should be interpreted by the Supreme People’s Procuratorate, and issues related to laws other than the abovementioned should be interpreted by the State Council and the competent authorities. The State Council and its ministries and commissions are also vested with the power to give interpretations of the administrative regulations and departmental rules which they have promulgated. At the regional level, the power to interpret regional regulations is vested in the regional legislative and administrative authorities which promulgate such regulations.

### **The PRC Judicial System**

Under the Constitution, the Law of Organization of the People’s Court of the PRC (2018 Revision) (中華人民共和國人民法院組織法(2018修訂)) and the Law of Organization of the People’s Procuratorate of the PRC (2018 Revision) (中華人民共和國人民檢察院組織法(2018修訂)), the people’s courts of the PRC are divided into the Supreme People’s Court, the local people’s courts at all levels and special people’s courts. The local people’s courts at all levels are divided into three levels, namely, the basic people’s courts, the intermediate people’s courts and the higher people’s courts. The basic people’s courts may set up certain people’s tribunals based on the status of the region, population and cases. The Supreme People’s Court shall be the highest judicial organ of the state. The Supreme People’s Court shall supervise the administration of justice by the local people’s courts at all levels and by the special people’s courts. The people’s courts at a higher level shall supervise the judicial work of the people’s courts at lower levels. The people’s procuratorates of the PRC are divided into the Supreme People’s Procuratorate, the local people’s procuratorates at all levels, Military Procuratorates and other special people’s procuratorates. The Supreme People’s Procuratorate shall be the highest procuratorial organ. The Supreme People’s Procuratorate shall direct the work of the local people’s procuratorates at all levels and of the special people’s procuratorates; the people’s procuratorates at higher levels shall direct the work of those at lower levels.

## APPENDIX V SUMMARY OF PRINCIPAL LEGAL AND REGULATORY PROVISIONS

The people’s courts employ a two-tier appellate system, i.e., judgments or rulings of the second instance at the people’s courts are final. A party may appeal against the judgment or ruling of the first instance of a local people’s court. The people’s procuratorate may present a protest to the people’s courts at the next higher level in accordance with the procedures stipulated by the laws. In the absence of any appeal by the parties and any protest by the people’s procuratorate within the stipulated period, the judgments or rulings of the people’s courts shall become final. Judgments or rulings of the second instance of the intermediate people’s courts, the higher people’s courts and the Supreme People’s Court and those of the first instance of the Supreme People’s Court are final. However, if the Supreme People’s Court or the people’s courts at the next higher level finds any definite errors in a legally effective final judgment or ruling of the people’s court at a lower level, or if the chief judge of a people’s court at any level finds any definite errors in a legally effective final judgment or ruling of such court, the case can be retried according to judicial supervision procedures.

The Civil Procedure Law of the PRC (中華人民共和國民事訴訟法) (hereinafter referred to as the “**PRC Civil Procedure Law**”) adopted on April 9, 1991 and amended three times on October 28, 2007, August 31, 2012 and June 27, 2017 respectively, prescribes the conditions for instituting a civil action, the jurisdiction of the people’s court, the procedures for conducting a civil action, and the procedures for enforcement of a civil judgment or ruling. All parties to a civil action conducted within the PRC must abide by the PRC Civil Procedure Law. A civil case is generally heard by the court located in the defendant’s place of domicile. The court of jurisdiction in respect of a civil action may also be chosen by explicit agreement among the parties to a contract, provided that the people’s court having jurisdiction should be located at places directly connected with the disputes, such as the plaintiff’s or the defendant’s place of domicile, the place where the contract is executed or signed or the place where the object of the action is located. Meanwhile, such choice shall not in any circumstances contravene the regulations of differential jurisdiction and exclusive jurisdiction.

A foreign individual, a person without nationality, a foreign enterprise or a foreign organization is given the same litigation rights and obligations as a citizen, a legal person or other organizations of the PRC when initiating actions or defending against litigations at a people’s court. Should a foreign court limit the litigation rights of PRC citizens or enterprises, the PRC court may apply the same limitations to the citizens or enterprises of such foreign country. A foreign individual, a person without nationality, a foreign enterprise or a foreign organization must engage a PRC lawyer in case he or it needs to engage a lawyer for the purpose of initiating actions or defending against litigations at a people’s court. In accordance with the international treaties to which the PRC is a signatory or participant or according to the principle of reciprocity, a people’s court and a foreign court may request each other to serve documents, conduct investigation and collect evidence and conduct other actions on its behalf. A people’s court shall not accommodate any request made by a foreign court which will result in the violation of sovereignty, security or public interests of the PRC.

All parties to a civil action shall perform the legally effective judgments and rulings. If any party to a civil action refuses to abide by a judgment or ruling made by a people’s court or an award made by an arbitration tribunal in the PRC, the other party may apply to the people’s court for the enforcement of the same within two years subject to application for postponed enforcement or revocation. If a party fails to satisfy within the stipulated period a judgment which the court has granted an enforcement approval, the court may, upon the application of the other party, mandatorily enforce the judgment against such party.

## APPENDIX V SUMMARY OF PRINCIPAL LEGAL AND REGULATORY PROVISIONS

Where a party requests for enforcement of an effective judgment or ruling made by a people’s court, but the opposite party or his property is not within the territory of the People’s Republic of China, the party may directly apply to the foreign court with jurisdiction for recognition and enforcement of the judgment or ruling, or the people’s court may, in accordance with the provisions of international treaties to which the PRC is a signatory or in which the PRC is a participant or according to the principle of reciprocity, request for recognition and enforcement by the foreign court. Similarly, for an effective judgment or ruling made by a foreign court that requires recognition and enforcement by a people’s court of the PRC, a party may directly apply to an intermediate people’s court of the PRC with jurisdiction for recognition and enforcement of the judgment or ruling, or the foreign court may, in accordance with the provisions of international treaties to which its country and the PRC are signatories or in which its country is a participant or according to the principle of reciprocity, request for recognition and enforcement by the people’s court, unless the people’s court considers that the recognition or enforcement of such judgment or ruling would violate the basic legal principles of the PRC, its sovereignty or national security or would not be in social and public interest.

### **The Company Law of the People’s Republic of China, Trial Administrative Measures of Overseas Securities Offering and Listing by Domestic Companies and the Guidelines for Articles of Association of Listed Companies**

The Company Law of the People’s Republic of China (hereinafter referred to as the “**PRC Company Law**”) was adopted by the Standing Committee of the Eighth NPC at its Fifth Session on December 29, 1993 and came into effect on July 1, 1994. It was successively amended on December 25, 1999, August 28, 2004, October 27, 2005, December 28, 2013 and October 26, 2018. The newly revised PRC Company Law has been implemented since October 26, 2018.

On February 17, 2023, CSRC promulgated the Trial Administrative Measures of Overseas Securities Offering and Listing by Domestic Companies (hereinafter referred to the “**Trial Administrative Measures**”), which came into effect on March 31, 2023. The Trial Administrative Measures are designated in accordance with the Securities Law and other laws and are applicable to domestic enterprises that issue securities overseas or list their securities overseas for trading. On February 17, 2023, CSRC promulgated the Guidelines for the Application of Regulatory Rules — Overseas Issuance and Listing Category No. 1, stipulating that direct issuance and listing by domestic companies shall abide by the relevant provisions of the Trial Administrative Measures and refer to the Guidelines for Articles of Association of Listed Companies and other relevant provisions of CSRC on corporate governance to formulate its articles of association and standardize corporate governance.

Set out below is a summary of the major provisions of the PRC Company Law and the Trial Administrative Measures of Overseas Securities Offering and Listing by Domestic Companies.

#### **General**

A “joint stock limited company” refers to a corporate legal person incorporated in China under the PRC Company Law with independent legal person properties and entitlements to such legal person properties. The liability of the company for its own debts is limited to the total amount of all assets it owns and the liability of its shareholders for the company is limited to the extent of the shares they subscribe for.



## APPENDIX V SUMMARY OF PRINCIPAL LEGAL AND REGULATORY PROVISIONS

### Incorporation

A company may be established by promotion or subscription. A company shall have a minimum of two but no more than 200 people as its promoters, over half of which must have a domicile within the PRC. Companies established by promotion are companies of which the registered capital is the total share capital subscribed for by all the promoters registered with the company's registration authorities. No share offering shall be made before the shares subscribed for by promoters are fully paid up. For companies established by share offering, the registered capital is the total paid-up share capital as registered with the company's registration authorities. If laws, administrative regulations and State Council decisions provide otherwise on paid-in registered capital and the minimum registered capital, a company should follow such provisions.

For companies incorporated by way of promotion, the promoters shall subscribe in writing for the shares required to be subscribed for by them and pay up their capital contributions under the articles of association. Procedures relating to the transfer of titles to non-monetary assets shall be duly completed if such assets are to be contributed as capital. Promoters who fail to pay up their capital contributions in accordance with the foregoing provisions shall assume default liabilities in accordance with the covenants set out in the promoters' agreements. After the promoters have confirmed the capital contribution under the articles of association, a board of directors and a board of supervisors shall be elected and the board of directors shall apply for registration of establishment by filing the articles of association with the company registration authorities, and other documents as required by the law or administrative regulations.

For companies incorporated by way of subscription, not less than 35% of the total number of shares must be subscribed for by the promoters, unless otherwise provided by laws or administrative regulations. A promoter who offers shares to the public must publish a prospectus and prepare a subscription letter to be completed, signed and sealed by subscribers, specifying the number and amount of shares to be subscribed for and the subscribers' addresses. The subscribers shall pay up monies for the shares they subscribe for. Where a promoter is offering shares to the public, such offer shall be underwritten by security companies established under PRC law, and underwriting agreements shall be entered into. A promoter offering shares to the public shall also enter into agreements with banks in relation to the receipt of subscription monies. The receiving banks shall receive and keep in custody the subscription monies, issue receipts to subscribers who have paid the subscription monies and is obliged to furnish evidence of receipt of those subscription monies to relevant authorities. After the subscription monies for the share issue have been paid in full, a capital verification institution established under PRC laws must be engaged to conduct a capital verification and furnish a certificate thereof. The promoters shall preside over and convene an inauguration meeting within 30 days from the date of the full payment of subscription money. The inauguration meeting shall be formed by the promoters and subscribers. Where the shares issued remain undersubscribed by the deadline stipulated in the document, or where the promoter fails to convene an inauguration meeting within 30 days of the subscription monies for the shares issued being fully paid up, the subscribers may demand that the promoters refund the subscription monies so paid together with the interest at bank rates of a deposit for the same period. Within 30 days after the conclusion of the inauguration meeting, the board of directors shall apply to the company registration authority for registration of the establishment of the company. A company is formally established and has the capacity of a legal person after approval of registration has been given by the relevant company registration authority for industry and commerce and a business license has been issued.

## **APPENDIX V SUMMARY OF PRINCIPAL LEGAL AND REGULATORY PROVISIONS**

A company's promoters shall be liable for: (1) the debts and expenses incurred in the establishment process jointly and severally if the company cannot be incorporated; (2) the subscription monies paid by the subscribers together with interest at bank rates of deposit for the same period jointly and severally if the company cannot be incorporated; and (3) the compensation of any damages suffered by the company in the course of its establishment as a result of the promoters' fault.

### **Share Capital**

The promoters may make a capital contribution in currencies, or non-monetary assets such as in kind or intellectual property rights or land use rights which can be appraised with monetary value and transferred lawfully, except for assets which are prohibited from being contributed as capital by the laws or administrative regulations. If a capital contribution is made in non-monetary assets, a valuation of the assets contributed must be carried out pursuant to the provisions of the laws or administrative regulations on valuation without any over-valuation or under-valuation.

The issuance of shares shall be conducted in a fair and equitable manner. Each share of the same class must carry equal rights. Shares issued at the same time and within the same class must be issued on the same conditions and at the same price. The same price per share shall be paid by any share subscriber (whether an entity or an individual). The share offering price may be equal to or greater than the nominal value of the share, but may not be less than the nominal value.

A company must obtain the approval of or file with the CSRC to offer its shares to the overseas public.

Under the PRC Company Law, a company issuing registered share certificates shall maintain a shareholder registry which sets forth the following matters: (1) the name and domicile of each shareholder; (2) the number of shares held by each shareholder; (3) the serial numbers of shares held by each shareholder; and (4) the date on which each shareholder acquired the shares.

### **Increase in Share Capital**

Pursuant to the relevant provisions of the PRC Company Law, where a company is issuing new shares, resolutions shall be passed at general meeting in accordance with the articles of association in respect of the class and amount of the new shares, the issue price of the new shares, the commencement and end dates for the issue of the new shares and the class and amount of the new shares proposed to be issued to existing shareholders.

When a company launches a public issue of new shares to the public after being approved by or filed with the CSRC, a new share offering document and financial accounting report must be announced and a subscription letter must be prepared. After the new shares issued by the company has been paid up, the change must be registered with the company registration authority and a public announcement must be made accordingly. Where an increase in registered capital of a company is made by means of an issue of new shares, the subscription of new shares by shareholders shall be made in accordance with the relevant provisions on the payment of subscription monies for the establishment of a company.

## APPENDIX V SUMMARY OF PRINCIPAL LEGAL AND REGULATORY PROVISIONS

### Reduction of Share Capital

A company shall reduce its registered capital in accordance with the following procedures prescribed by the PRC Company Law: (1) the company shall prepare a balance sheet and an inventory of assets; (2) the reduction of registered capital must be approved by shareholders at general meeting; (3) the company shall notify its creditors within 10 days and publish an announcement in newspapers within 30 days from the date on which the resolution approving the reduction was passed; (4) the creditors of the company are entitled to require the company to repay its debts or provide guarantees for such debts within 30 days from receipt of the notification or within 45 days from the date of the announcement if he/she/it has not received any notification; and (5) the company must apply to the company registration authority for change in registration.

### Repurchase of Shares

Pursuant to the PRC Company Law, a company may not repurchase its own shares other than for the following purposes: (1) reducing its registered capital; (2) merging with other companies which hold its shares; (3) granting shares to its employees as incentives; (4) acquiring its shares at the request of its shareholders who vote in a shareholders' general meeting against a resolution regarding a merger and division; (5) utilizing the shares for conversion of listed corporate bonds which are convertible into shares; and (6) where it is necessary for the listed company to safeguard the value of the company and the interests of its shareholders. The acquisition by a company of its own shares on the grounds set out in item (1) to (2) above shall be approved by way of a resolution of a shareholders' general meeting; the acquisition by a company of its own shares in circumstances as set out in items (3), (5) and (6) above may be approved by way of a resolution at a board meeting with two-third or more of the directors present in accordance with the provisions of the company's articles of association or the authorization of the shareholders' general meeting.

Following the acquisition by a company of its own shares in accordance with these requirements, such shares shall be canceled within 10 days from the date of the acquisition under the circumstance in item (1); such shares shall be transferred or canceled within six months under the circumstances in items (2) or (4); the total shares held by the Company shall not exceed 10% of the total shares issued by the Company and such shares shall be transferred or canceled within three years under the circumstances in items (3), (5) or (6).

A listed company shall perform its information disclosure obligations in accordance with the provisions of the Securities Law of People's Republic of China when acquiring its own shares. The acquisition by a listed company of its own shares in circumstances as set out in items (3), (5) and (6) of this article shall be conducted through open centralized trading.

The Company shall not accept the shares of the Company as the subject of pledge.

## APPENDIX V SUMMARY OF PRINCIPAL LEGAL AND REGULATORY PROVISIONS

### Transfer of Shares

Shares held by shareholders may be transferred legally. Pursuant to the PRC Company Law, a shareholder should effect a transfer of his shares on a stock exchange established in accordance with laws or by any other means as required by the State Council. Registered shares may be transferred after the shareholders endorse the back of the share certificates or in other manner specified by laws and administrative regulations. Following the transfer, the company shall enter the names and addresses of the transferees into its share register. No changes of registration in the share register described above shall be effected during a period of 20 days prior to convening a shareholders' general meeting or 5 days prior to the record date for the purpose of determining entitlements to dividend distributions, unless otherwise stipulated by laws on the registration of changes in the share register of listed companies. The transfer of bearer share certificates shall become effective upon the delivery of the certificates to the transferee by the shareholder.

Pursuant to the PRC Company Law, shares held by promoters may not be transferred within one year of the establishment of the company. Shares of the company issued prior to the public issue of shares may not be transferred within one year of the date of the company's listing on a stock exchange. Directors, supervisors and the senior management of a company shall declare to the company their shareholdings in it and changes in such shareholdings. The shares transferrable by them during each year of their term of office shall not exceed 25 percent of their total shareholdings in the company. They shall not transfer the shares they hold within one year from the date of the company's listing on a stock exchange, nor within six months after they leave their positions in the company. The articles of association may set out other restrictive provisions in respect of the transfer of shares in the company held by its directors, supervisors and the senior management.

### Shareholders

Under the PRC Company Law, the rights of shareholders include the rights: (1) to receive a return on assets, participate in significant decision-making and select management personnel; (2) to request the people's court to revoke any resolution passed on a shareholders' general meeting or a meeting of the board of directors that has been convened or whose voting has been conducted in violation of the laws, regulations or the articles of association, or any resolution the contents of which is in violation of the articles of association, provided that such petition shall be submitted within 60 days of the passing of such resolution; (3) to transfer the shares of the shareholders in accordance with the law; (4) to attend or appoint a proxy to attend shareholders' general meetings and exercise the voting rights thereat; (5) to inspect the articles of association, share register, counterfoil of company debentures, minutes of shareholders' general meetings, board resolutions, resolutions of the board of supervisors and financial and accounting reports, and to make suggestions or inquiries in respect of the company's operations; (6) to receive dividends in respect of the number of shares held; (7) to participate in distribution of residual properties of the company in proportion to their shareholdings upon the liquidation of the company; and (8) any other shareholders' rights provided for in laws, administrative regulations, other normative documents and the articles of association.

The obligations of shareholders include the obligation to abide by the company's articles of association, to pay the subscription monies in respect of the shares subscribed for, to be liable for the company's debts and liabilities to the extent of the amount of subscription monies agreed to be paid in respect of the shares taken up by them and any other shareholder obligation specified in the articles of association.

## APPENDIX V SUMMARY OF PRINCIPAL LEGAL AND REGULATORY PROVISIONS

### Shareholders' General Meetings

The general meeting is the organ of authority of the company, which exercises its powers in accordance with the PRC Company Law. The general meeting may exercise the following powers: (1) to decide on the company's operational objectives and investment plans; (2) to elect and dismiss the directors and supervisors not being representative(s) of employees and to decide on the matters relating to the remuneration of directors and supervisors; (3) to review and approve the reports of the board of directors; (4) to review and approve the reports of the board of supervisors or the reports of the supervisors; (5) to review and approve the company's annual financial budgets proposals and final accounts proposals; (6) to review and approve the company's profit distribution proposals and loss recovery proposals; (7) to decide on any increase or reduction of the company's registered capital; (8) to decide on the issue of corporate bonds; (9) to decide on merger, division, dissolution and liquidation of the company or change of its corporate form; (10) to amend the company's articles of association; and (11) to exercise any other authority stipulated in the articles of association.

Pursuant to the PRC Company Law and the Guidelines for the Articles of Association of Listed Companies, a shareholders' general meeting is required to be held once every year within six months after the end of the previous accounting year. An extraordinary general meeting is required to be held within two months upon the occurrence of any of the following: (1) the number of directors is less than the number required by law or less than two-thirds of the number specified in the articles of association; (2) the total outstanding losses of the company amounted to one-third of the company's total paid-in share capital; (3) shareholders individually or in aggregate holding 10% or more of the company's shares request to convene an extraordinary general meeting; (4) the board deems necessary; (5) the board of supervisors so proposes; or (6) any other circumstances as provided for in the articles of association.

A shareholders' general meeting shall be summoned by the board of directors and presided over by the chairman of the board of directors. In the event that the chairman is incapable of performing or is not performing his duties, the meeting shall be presided over by the vice chairman. In the event that the vice chairman is incapable of performing or is not performing his duties, a director recommended by half or more of the directors shall preside over the meeting. Where the board of directors is incapable of performing or is not performing its duties, the board of supervisors shall summon and preside over the shareholders' general meeting in a timely manner. If the board of supervisors fails to summon and preside over the shareholders' general meeting, shareholders individually or in aggregate holding 10% or more of the company's shares for 90 days or more consecutively may summon and preside over the shareholders' general meeting on their own initiative.

In accordance with the PRC Company Law, a notice of the general meeting stating the date and venue of the meeting and the matters to be considered at the meeting shall be given to all shareholders 20 days prior to the meeting. A notice of extraordinary general meeting shall be given to all shareholders 15 days prior to the meeting.

Pursuant to the PRC Company Law, shareholders present at a shareholders' general meeting have one vote for each share they hold, save that the the company shall have no voting right for the shares held by itself.

## APPENDIX V SUMMARY OF PRINCIPAL LEGAL AND REGULATORY PROVISIONS

An accumulative voting system may be adopted for the election of directors and supervisors at the general meeting pursuant to the provisions of the articles of association or a resolution of the general meeting. Under the accumulative voting system, each share shall be entitled to the number of votes equivalent to the number of directors or supervisors to be elected at the general meeting, and shareholders may consolidate their votes for one or more directors or supervisors when casting a vote.

Pursuant to the PRC Company Law, resolutions of the general meeting must be passed by more than half of the voting rights held by shareholders present at the meeting, with the exception of resolutions relating to merger, division or dissolution of the company, increase or reduction of registered share capital, change of corporate form or amendments to the articles of association, in each case of which must be passed by more than two-thirds of the voting rights held by the shareholders present at the meeting. Pursuant to the Guidelines for the Articles of Association of Listed Companies, matters such as the purchase or sale of material assets or guarantees in excess of thirty percent of a company's latest audited total assets within one year and share incentive schemes shall be approved by special resolutions of shareholders in general meetings. Where the PRC Company Law and the articles of association provide that the transfer or acquisition of significant assets or the provision of external guarantees by the company and such other matters must be approved by way of resolution of the general meeting, the board of directors shall summon a shareholders' general meeting as soon as possible to vote on such matters. A shareholder may entrust a proxy to attend the general meeting on his/her behalf. The proxy shall present the shareholders' power of attorney to the company and exercise voting rights within the scope of authorization. Minutes shall be prepared in respect of matters considered at the general meeting and the chairperson and directors attending the meeting shall endorse such minutes by signature. The minutes shall be kept together with the shareholders' attendance register and the proxy forms.

### **Board of Directors**

A company shall have a board of directors, which shall consist of 5 to 19 members. Members of the board of directors may include staff representatives, who shall be democratically elected by the company's staff at a staff representative assembly, general staff meeting or otherwise. The term of a director shall be stipulated in the articles of association, provided that no term of office shall last for more than three years. A director may serve consecutive terms if re-elected. A director shall continue to perform his/her duties as a director in accordance with the laws, administrative regulations and the articles of association until a duly reelected director takes office, if re-election is not conducted in a timely manner upon the expiry of his/her term of office or if the resignation of director results in the number of directors being less than the number prescribed by the law.

Under the PRC Company Law, the board of directors may exercise its powers: (1) to convene shareholders' general meetings; (2) to implement the resolutions passed by the shareholders at the shareholders' general meetings; (3) to decide on the company's operational plans and investment proposals; (4) to formulate proposal for the company's annual financial budgets and final accounts; (5) to formulate the company's profit distribution proposals and loss recovery proposals; (6) to formulate proposals for the increase or reduction of the company's registered capital and the issue of corporate bonds; (7) to formulate proposals for the merger, division or dissolution of the company or change of corporate form; (8) to decide on the setup of the company's internal management organs; (9) to appoint or dismiss the company's manager and decide on his/her remuneration and, based on the manager's recommendation, to appoint or dismiss any deputy general manager and financial officer of the company and to decide on their remunerations; (10) to formulate the company's basic management system; and (11) to exercise any other authority stipulated in the articles of association.

## APPENDIX V SUMMARY OF PRINCIPAL LEGAL AND REGULATORY PROVISIONS

Meetings of the board of directors shall be convened at least twice each year. Notices of meeting shall be given to all directors and supervisors 10 days before the meeting. Interim board meetings may be proposed to be convened by shareholders representing more than 10% of the voting rights, more than one-third of the directors or the board of supervisors. The chairman shall convene the meeting within 10 days of receiving such proposal, and preside over the meeting. The board of directors may otherwise determine the means and the period of notice for convening an interim board meeting. Meetings of the board of directors shall be held only if more than half of the directors are present. Resolutions of the board of directors shall be passed by more than half of all directors. Each director shall have one vote for a resolution to be approved by the board. Directors shall attend board meetings in person. If a director is unable to attend for any reason, he/she may appoint another director to attend the meeting on his/her behalf by a written power of attorney specifying the scope of authorization. Meanwhile, the board of directors shall keep minutes of resolutions passed at board meetings. The minutes shall be signed by the directors present at the meeting.

If a resolution of the board of directors violates the laws, administrative regulations or the articles of association or resolutions of the general meeting, and as a result of which the company sustains serious losses, the directors participating in the resolution are liable to compensate the company. However, if it can be proved that a director expressly objected to the resolution when the resolution was voted on, and that such objection was recorded in the minutes of the meeting, such director shall be relieved from that liability.

Under the PRC Company Law, the following person may not serve as a director in a company: (1) a person with no capacity for civil conduct or with limited capacity for civil conduct; (2) a person who has been convicted of an offense of corruption, bribery, embezzlement, misappropriation of property or sabotage of the socialist economic order, or who has been deprived of his political rights due to committing of crimes, in each case where less than five years have not elapsed since the date of completion of the sentence; (3) a person who has been a former director, factory manager or manager of a company or an enterprise that has entered into insolvent liquidation and who was personally liable for the insolvency of such company or enterprise, where less than three years have elapsed since the date of the completion of the bankruptcy and liquidation of the company or enterprise; (4) a person who has been a legal representative of a company or an enterprise that has had its business license revoked due to violations of the law or has been ordered to close down by law and the person was personally responsible, where less than three years have not elapsed since the date of such revocation; and (5) a person who is liable for a relatively large amount of debts that are overdue.

In addition, pursuant to the Guidelines for the Articles of Association of Listed Companies, where a director of a company is a natural person who has been subject to a securities market entry prohibition measure imposed by the CSRC, he/she shall not act as a company director until the period of such measure has expired.

Where a company elects or appoints a director to which any of the above circumstances applies, such election or appointment shall be null and void. A director to which any of the above circumstances applies during his/her term of office shall be dismissed by the company.

## APPENDIX V SUMMARY OF PRINCIPAL LEGAL AND REGULATORY PROVISIONS

Under the PRC Company Law, the board shall have a chairman and may have vice chairmen. The chairman and the vice chairman shall be elected with approval of more than half of all the directors. The chairman shall convene and preside over board meetings and review the implementation of board resolutions. The vice chairman shall assist the chairman to perform his/her duties. Where the chairman is incapable of performing, or is not performing his/her duties, the duties shall be performed by the vice chairman. Where the vice chairman is incapable of performing, or is not performing his/her duties, a director jointly elected by more than half of the directors shall perform his/her duties.

### Board of Supervisors

A company shall have a board of supervisors composed of not less than three members. The board of supervisors shall consist of representatives of the shareholders and an appropriate proportion of representatives of the company's staff, among which the proportion of representatives of the company's staff shall not be less than one-third, and the actual proportion shall be determined in the articles of association. Representatives of the company's staff at the board of supervisors shall be democratically elected by the company's staff at the staff representative assembly, general staff meeting or otherwise. The board of supervisors shall appoint a chairman and may appoint a vice chairman. The chairman and the vice chairman of the board of supervisors shall be elected by more than half of all the supervisors. Directors and senior management members shall not act concurrently as supervisors.

The chairman of the board of supervisors shall summon and preside over board of supervisors meetings. Where the chairman of the board of supervisors is incapable of performing, or is not performing his/her duties, the vice chairman of the board of supervisors shall summon and preside over board of supervisors meetings. Where the vice chairman of the board of supervisors is incapable of performing, or is not performing his/her duties, a supervisor elected by more than half of the supervisors shall summon and preside over board of supervisors meetings.

Each term of office of a supervisor is three years and he/she may serve consecutive terms if re-elected. A supervisor shall continue to perform his/her duties as a supervisor in accordance with the laws, administrative regulations and the articles of association until a duly re-elected supervisor assumes office, if re-election is not conducted in a timely manner upon the expiry of his/her term of office or if the resignation of supervisor results in the number of supervisors being less than the quorum.

The board of supervisors may exercise the following powers: (1) to review the company's financial position; (2) to supervise the directors and senior management in their performance of their duties and to propose the removal of directors and senior management who have violated laws, regulations, the articles of association or resolutions of the shareholders' general meetings; (3) when the acts of a director or a senior management personnel are detrimental to the company's interests, to require the director and senior management to correct these acts; (4) to propose the convening of extraordinary shareholders' general meetings and to summon and preside over shareholders' general meetings when the board fails to perform the duty of summoning and presiding over shareholders' general meetings under the PRC Company Law; (5) to submit proposals to the shareholders' general meetings; (6) to bring law suits against directors and senior management personnel pursuant to the relevant provisions of the PRC Company Law; and (7) to exercise any other authority stipulated in the articles of association.

Supervisors may present at board meetings and make inquiries or proposals in respect of the resolutions of the board. The board of supervisors may investigate any irregularities identified in the operation of the company and, when necessary, may engage an accounting firm to assist its work at the cost of the company.



## **APPENDIX V SUMMARY OF PRINCIPAL LEGAL AND REGULATORY PROVISIONS**

### **Manager and Senior Management**

Under the relevant requirements of the PRC Company Law, a company shall have a manager who shall be appointed or removed by the board of directors. Meanwhile, under the relevant requirements of the Guidelines for the Articles of Association of Listed Companies, the manager shall report to the board of directors and exercise the following powers: (1) to manage the production and operation and administration of the company and arrange for the implementation of the resolutions of the board of directors; (2) to arrange for the implementation of the company's annual operation plans and investment proposals; (3) to formulate proposals for the establishment of the company's internal management organs; (4) to formulate the fundamental management system of the company; (5) to formulate the company's specific rules and regulations; (6) to recommend the appointment or dismissal of any deputy manager and any financial officer of the company; (7) to appoint or dismiss management personnel (other than those shall be appointed or dismissed by the board of directors); and (8) to exercise any other authority granted by the board of directors. Other provisions in the articles of association on the manager's powers shall also be complied with. The manager shall be present at meetings of the board of directors. However, the manager shall have no voting rights at meetings of the board of directors unless he/she concurrently serves as a director. According to the PRC Company Law, senior management refers to manager, deputy manager, financial controller, secretary to the board of a listed company and other personnel stipulated in the articles of association.

### **Duties of Directors, Supervisors, General Managers and Other Senior Management**

Directors, supervisors and senior management are required under the PRC Company Law to comply with the relevant laws, administrative regulations and the articles of association, and owe the duties of loyalty and diligence to the company. Directors, supervisors and management personnel are prohibited from abusing their authority in accepting bribes or other unlawful income and from misappropriating the company's property. Furthermore, directors and senior management are prohibited from: (1) misappropriating company funds; (2) depositing company funds into accounts under their own names or the names of other individuals; (3) loaning company funds to others or providing guarantees in favor of others supported by company's property in violation of the articles of association or without approval of the general meeting or the board of directors; (4) entering into contracts or transactions with the company in violation of the articles of association or without approval of the general meeting; (5) using their position to procure business opportunities for themselves or others that should have otherwise been available to the company or operating businesses similar to that of the company for their own benefits or on behalf of others without approval of the general meeting; (6) accepting for their own benefit commissions from a third party for transactions conducted with the company; (7) unauthorized disclosure of confidential information of the company; and (8) other acts in violation of their duty of loyalty to the company. Income generated by directors or senior management in violation of aforementioned shall belong to the company.

A director, supervisor or senior management who contravenes law, administrative regulation or the articles of association in the performance of his/her duties resulting in any loss to the company shall be liable to the company for compensation.

Where a director, supervisor or senior management is required to attend a shareholders' general meeting, such director, supervisor or senior management shall attend the meeting and answer the inquiries from shareholders. Directors and senior management shall furnish all true information and data to the board of supervisors, without impeding the discharge of duties by the board of supervisors or supervisors.

## APPENDIX V SUMMARY OF PRINCIPAL LEGAL AND REGULATORY PROVISIONS

Where a director or senior management contravenes laws, administrative regulations or the articles of association in the performance of his/her duties resulting in any loss to the company, shareholder(s) holding individually or in aggregate more than 1% of the company's shares consecutively for more than 180 days may request in writing that the board of supervisors institute litigation at the people's court. Where the supervisory violates the laws or administrative regulations or the articles of association in the discharge of its duties resulting in any loss to the company, such shareholder(s) may request in writing that the board of directors institute litigation at the people's court on its behalf. If the board of supervisors or the board of directors refuses to institute litigation after receiving such written request from the shareholder(s), or fails to institute litigation within 30 days of the date of receiving the request, or in case of emergency where failure to institute litigation immediately will result in irrecoverable damage to the company's interests, such shareholder(s) shall have the power to institute litigation directly at the people's court in its own name for the company's benefit. For other parties who infringe the lawful interests of the company resulting in loss to the company, such shareholder(s) may institute litigation at the people's court in accordance with the procedure described above. Where a director or senior management contravenes any laws, administrative regulations or the articles of association in infringement of shareholders' interests, a shareholder may also institute litigation at the people's court.

Pursuant to the Guidelines for the Articles of Association of Listed Companies, senior management personnel of a company shall faithfully perform their duties and safeguard the best interests of the company and all its shareholders. Senior management of a company shall be liable for compensation in accordance with the law if they fail to faithfully perform their duties or breach their duty of good faith and cause damage to the interests of the company and holders of public shares.

### **Finance and Accounting**

Under the PRC Company Law, A company shall establish its own financial and accounting systems according to the laws, administrative regulations and the regulations of the competent financial departments under the State Council. At the end of each accounting year, a company shall prepare a financial report which shall be audited by an accounting firm in accordance with laws. The financial and accounting reports shall be prepared in accordance with laws, administrative regulations and the regulations of the financial departments under the State Council. The company's financial and accounting reports shall be made available for shareholders' inspection at the company within 20 days before the convening of an annual general meeting. A joint stock limited company that makes public stock offerings must announce its financial and accounting reports.

When distributing each year's profits after taxation, the company shall set aside 10% of its profits after taxation for the company's statutory common reserve fund until the fund has reached more than 50% of the PRC company's registered capital. When the company's statutory common reserve fund is not sufficient to make up for the company's losses for the previous years, the current year's profits shall first be used to make good the losses before any allocation is set aside for the statutory common reserve fund. After the company has made allocations to the statutory common reserve fund from its profits after taxation, it may, upon passing a resolution at a shareholders' general meeting, make further allocations from its profits after taxation to the discretionary common reserve fund. After the company has made good its losses and made allocations to its discretionary common reserve fund, the remaining profits after taxation shall be distributed in proportion to the number of shares held by the shareholders, except for those which are not distributed in a proportionate manner as provided by the articles of association.

## **APPENDIX V SUMMARY OF PRINCIPAL LEGAL AND REGULATORY PROVISIONS**

Profits distributed to shareholders by a resolution of a shareholders' general meeting or the board of directors before losses have been made good and allocations have been made to the statutory common reserve fund in violation of the requirements described above must be returned to the company. The company shall not be entitled to any distribution of profits in respect of its own shares held by it.

The premium over the nominal value per share of the company on issue and other income as required by relevant governmental department to be treated as the capital reserve fund shall be accounted for as the capital reserve fund. The common reserve fund of a company shall be applied to make good the company's losses, expand its business operations or increase its capital. The capital reserve fund, however, shall not be used to make good the company's losses. Upon the transfer of the statutory common reserve fund into capital, the balance of the fund shall not be less than 25% of the registered capital of the company before such transfer.

The company shall have no accounting books other than the statutory books. The company's assets shall not be deposited in any account opened under the name of an individual.

### **Appointment and Dismissal of Auditors**

Pursuant to the PRC Company Law, the engagement or dismissal of an accounting firm responsible for the company's auditing shall be determined by a shareholders' general meeting or the board of directors in accordance with the articles of association. The accounting firm should be allowed to make representations when the general meeting or the board of directors conducts a vote on the dismissal of the accounting firm. The company should provide true and complete accounting evidence, accounting books, financial and accounting reports and other accounting information to the engaged accounting firm without any refusal or withholding or falsification of data.

Pursuant to the Guidelines for the Articles of Association of Listed Companies, the company engages an accounting firm that complies with the provisions of the Securities Law to carry out audit of accounting statements, verification of net assets and other related advisory services for a period of one year, which is renewable.

### **Profit Distribution**

According to the PRC Company Law, a company shall not distribute profits before losses are covered and the statutory common reserve fund is provided.

### **Amendments to the Articles of Association**

Pursuant to PRC Company Law, the resolution of a shareholders' general meeting regarding any amendment to a company's articles of association requires affirmative votes by more than two-thirds of the votes held by shareholders attending the meeting. According to the Guidelines for the Articles of Association of Listed Companies, if the amendments to the articles of association approved by the resolution of the general meeting of shareholders are subject to approval by the competent authority, they must be reported to the competent authority for approval; if they involve company registration matters, the modification registration shall be handled according to law. Where the amendments to the articles of association belong to information required to be disclosed by laws and regulations, such amendments shall be announced in accordance with the regulations.

## APPENDIX V SUMMARY OF PRINCIPAL LEGAL AND REGULATORY PROVISIONS

### Dissolution and Liquidation

Under the PRC Company Law, a company shall be dissolved for any of the following reasons: (1) the term of its operation set out in the articles of association has expired or other events of dissolution specified in the articles of association have occurred; (2) the shareholders have resolved at a shareholders' general meeting to dissolve the company; (3) the company shall be dissolved by reason of its merger or division; (4) the business license of the company is revoked or the company is ordered to close down or to be dissolved in accordance with the laws; or (5) the company is dissolved by the people's court in response to the request of shareholders holding shares that represent more than 10% of the voting rights of all shareholders of the company, on the grounds that the operation and management of the company has suffered serious difficulties that cannot be resolved through other means, rendering ongoing existence of the company a cause for significant losses to the shareholders' interests.

In the event of paragraph (1) above, the company may carry on its existence by amending its articles of association. The amendments to the articles of association in accordance with the provisions described above shall require the approval of more than two-thirds of voting rights of shareholders attending a shareholders' general meeting.

Where the company is dissolved under the circumstances set forth in paragraph (1), (2), (4) or (5) above, it should establish a liquidation committee within 15 days of the date on which the dissolution matter occurs. The liquidation committee shall be composed of directors or any other person determined by a shareholders' general meeting. If a liquidation committee is not established within the stipulated period, the company's creditors can apply to the people's court for setting up a liquidation committee with designated relevant personnel to conduct the liquidation. The people's court should accept such application and form a liquidation committee to conduct liquidation in a timely manner.

The liquidation committee may exercise following powers during the liquidation: (1) to sort out the company's assets and to prepare a balance sheet and an inventory of assets; (2) to notify the company's creditors or publish announcements; (3) to deal with any outstanding business related to the liquidation; (4) to pay any overdue tax together with any tax arising during the liquidation process; (5) to settle the company's claims and liabilities; (6) to handle the company's remaining assets after its debts have been paid off; and (7) to represent the company in any civil procedures.

The liquidation committee shall notify the company's creditors within ten days of its establishment, and publish an announcement in newspapers within 60 days. A creditor shall lodge his claim with the liquidation committee within 30 days of receipt of the notification or within 45 days of the date of the announcement if he has not received any notification.

A creditor shall report all matters relevant to his claimed creditor's rights and furnish relevant evidence. The liquidation committee shall register such creditor's rights. The liquidation committee shall not make any settlement to creditors during the period of the claim. Upon disposal of the company's property and preparation of the required balance sheet and inventory of assets, the liquidation committee shall draw up a liquidation plan and submit this plan to a shareholders' general meeting or a people's court for endorsement. The remaining part of the company's assets, after payment of liquidation expenses, employee wages, social insurance expenses and statutory compensation, outstanding taxes and the company's debts, shall be distributed to shareholders in proportion to shares held by them. The company shall continue to exist during the liquidation period, although it cannot conduct operating activities that are not related to the liquidation. The company's property shall not be distributed to shareholders before repayments are made in accordance with the requirements described above.

## **APPENDIX V SUMMARY OF PRINCIPAL LEGAL AND REGULATORY PROVISIONS**

Upon liquidation of the company’s property and preparation of the required balance sheet and inventory of assets, if the liquidation committee becomes aware that the company does not have sufficient assets to meet its liabilities, it must apply to a people’s court for a declaration of bankruptcy in accordance with the laws. Following such declaration by the people’s court, the liquidation committee shall hand over the administration of the liquidation to the people’s court.

Upon completion of the liquidation, the liquidation committee shall prepare a liquidation report and submit it to the shareholders’ general meeting or the people’s court for verification, and to the company registration authority for the cancelation of company registration, and an announcement of its termination shall be published. Members of the liquidation committee shall be faithful in the discharge of their duties and shall perform their liquidation duties in compliance with laws. Members of the liquidation committee shall be prohibited from abusing their authority in accepting bribes or other unlawful income and from misappropriating the company’s properties. Members of the liquidation committee who have caused the company or its creditors to suffer from any loss due to intentional fault or gross negligence, shall be liable for making compensations to the company or its creditors. In addition, liquidation of a company declared bankrupt according to laws shall be processed in accordance with the laws on corporate bankruptcy.

### **Overseas Listing**

According to the Trial Administrative Measures, overseas listing of a company shall be filed with CSRC. Where an issuer conducts an overseas initial public offering or listing, it shall file with CSRC within 3 working days after submitting the issuance and listing application documents overseas. The remittance and cross-border flow of funds related to overseas issuance and listing of domestic enterprises shall comply with national regulations on cross-border investment and financing, foreign exchange management and cross-border RMB management.

Pursuant to the Notice on Arrangements for the Filing and Administration of Overseas Listing by Domestic Enterprises, domestic enterprises that have received the instrument of approval from the CSRC for the overseas public offering of shares and listing (including additional issuance) of joint stock companies may continue to promote their overseas listing during the validity period of the instrument of approval. Where the overseas issuance and listing did not complete upon expiration of the instrument of approval, filing shall be carried out as required.

### **Loss of Share Certificates**

A shareholder may, in accordance with the procedures of public notice for assertion of claim set out in the PRC Civil Procedure Law, apply to a people’s court if his share certificate(s) in registered form is either stolen, lost or destroyed, for a declaration that such certificate(s) will no longer be valid. After the people’s court declares that such certificate(s) shall be invalid. After the people’s court has so declared, the said shareholder may apply to the company for re-issuance of the share certificate(s).

## APPENDIX V SUMMARY OF PRINCIPAL LEGAL AND REGULATORY PROVISIONS

### Merger and Division

Under the PRC Company Law, a merger agreement shall be signed by merging companies and the involved companies shall prepare respective balance sheets and inventory of assets. The companies shall within 10 days of the date of passing the resolution approving the merger notify their respective creditors and publicly announce the merger in Newspapers within 30 days. A creditor may, within 30 days from the date of reception of the notification, or within 45 days from the date of the announcement if he has not received such notification, request the company to settle any outstanding debts or provide corresponding guarantees.

In case of a merger, the credits and debts of the merging parties shall be assumed by the surviving or the new company. In case of a division, the company's assets shall be divided and a balance sheet and an inventory of assets shall be prepared. When a resolution regarding the company's division is approved, the company should notify all its creditors within 10 days of the date of passing such resolution and publicly announce the division in newspapers within 30 days. Unless an agreement in writing is reached with creditors before the company's division in respect of the settlement of debts, the liabilities of the company which have accrued prior to the division shall be jointly borne by the divided companies.

Changes in the registration as a result of the merger or division shall be registered with the relevant administration authority for industry and commerce.

### The PRC Securities Laws, Regulations and Regulatory Regimes

The PRC has promulgated a series of regulations that relate to the issue and trading of the Shares and disclosure of information. In October 1992, the State Council established the Securities Committee and CSRC. The Securities Committee is responsible for coordinating the drafting of securities regulations, formulating securities-related policies, planning the development of securities markets, directing, coordinating and supervising all securities related institutions in the PRC and administering CSRC. CSRC is the regulatory arm of the Securities Committee and is responsible for the drafting of regulatory provisions governing securities markets, supervising securities companies, regulating public offerings of securities by PRC companies in the PRC or overseas, regulating the trading of securities, compiling securities-related statistics and undertaking relevant research and analysis. In April 1998, the State Council consolidated the Securities Committee and CSRC and reformed CSRC.

On April 22, 1993, the State Council promulgated the Provisional Regulations Concerning the Issue and Trading of Shares (股票發行與交易管理暫行條例) governing the application and approval procedures for public offerings of shares, issuing of and trading of shares, takeovers by listed companies, deposit, clearing and transfer of shares, the disclosure of information, investigation, penalties and dispute resolutions with respect to a listed company.

On December 25, 1995, the State Council promulgated the Special Regulations of the State Council Concerning Domestic Listed Foreign Shares of Joint Stock Limited Companies (國務院關於股份有限公司境內上市外資股的特別規定). These regulations principally govern the issue, subscription, trading and declaration of dividends and other distributions of domestic listed foreign shares and disclosure of information of joint stock limited companies having domestic listed foreign shares.

## APPENDIX V SUMMARY OF PRINCIPAL LEGAL AND REGULATORY PROVISIONS

The PRC Securities Law (中華人民共和國證券法) (the “**Securities Law**”) took effect on July 1, 1999 and was revised as of August 28, 2004, October 27, 2005, June 29, 2013, August 31, 2014 and December 28, 2019, respectively. The latest Securities Law came into force on March 1, 2020. It was the first national securities law in the PRC, and is divided into 14 chapters and 226 articles comprehensively regulating activities in the PRC securities market, including the issue and trading of securities, takeovers by listed companies and the duties and responsibilities of the securities exchanges, securities companies, securities clearing institutions and securities regulatory authorities. Article 224 of the PRC Securities Law provides that domestic enterprises shall satisfy the relevant requirements of the State Council when it issues shares or lists shares outside the PRC directly or indirectly. Currently, the issue and trading of foreign issued securities (including shares) are principally governed by the regulations and rules promulgated by the State Council and CSRC.

### **Arbitration and Enforcement of Arbitral Awards**

The Arbitration Law of the PRC (2017 Amendment) (中華人民共和國仲裁法(2017修正)) (the “**PRC Arbitration Law**”) was enacted by the Standing Committee of the NPC on August 31, 1994, which became effective on September 1, 1995 and was amended on August 27, 2009 and September 1, 2017. It is applicable to, among other matters, economic disputes involving foreign parties where all parties have entered into a written agreement to resolve disputes by arbitration before an arbitration committee constituted in accordance with the PRC Arbitration Law. The PRC Arbitration Law provides that an arbitration committee may, before the promulgation of arbitration regulations by the PRC Arbitration Association, formulate interim arbitration provisions in accordance with the PRC Arbitration Law and the PRC Civil Procedure Law. Where the involved parties have agreed to settle disputes by means of arbitration, a people’s court will refuse to handle a legal proceeding initiated by one of the parties at such people’s court, unless the arbitration agreement is rendered invalid.

The Listing Rules require contracts between the company and each director or supervisor shall include arbitration clauses. Pursuant to such clause, whenever a dispute or claim arises from right or obligation provided in the articles of association, the PRC Company Law or other relevant laws and administrative regulations concerning the affairs of the company between (1) a holder of overseas listed foreign shares and the company; (2) a holder of overseas listed foreign shares and a holder of domestic shares; or (3) a holder of overseas listed foreign shares and the company’s directors, supervisors or other management personnel, such parties shall be required to refer such dispute or claim to arbitration at either the China International Economic and Trade Arbitration Commission (“**CIETAC**”) or the Hong Kong International Arbitration Centre (“**HKIAC**”). Disputes in respect of the definition of shareholder and disputes in relation to the company’s shareholder registry need not be resolved by arbitration. If the party seeking arbitration elects to arbitrate the dispute or claim at the HKIAC, then either party may apply to have such arbitration conducted in Shenzhen in accordance with the securities arbitration rules of the HKIAC.

Under the PRC Arbitration Law and PRC Civil Procedure Law, an arbitral award shall be final and binding on the parties involved in the arbitration. If one party fails to comply with the arbitral award, the other party to the award may apply to a people’s court for its enforcement. However, the people’s court may refuse to enforce an arbitral award made by an arbitration commission if there is any procedural irregularity (including but not limited to irregularity in the composition of the arbitration tribunal, the jurisdiction of the arbitration commission, or the making of an award on matters beyond the scope of the arbitration agreement or outside the jurisdiction of the arbitration commission).

## APPENDIX V SUMMARY OF PRINCIPAL LEGAL AND REGULATORY PROVISIONS

Any party seeking to enforce an award of a foreign affairs arbitration organ of the PRC against a party who or whose property is not located within the PRC may apply to a foreign court with jurisdiction over the relevant matters for recognition and enforcement of the award. Likewise, an arbitral award made by a foreign arbitral body may be recognized and enforced by a PRC court in accordance with the principle of reciprocity or any international treaties concluded or acceded to by the PRC.

The PRC acceded to the Convention on the Recognition and Enforcement of Foreign Arbitral Awards (the “**New York Convention**”) passed on June 10, 1958 pursuant to a resolution passed by the Standing Committee of the NPC on December 2, 1986. The New York Convention provides that all arbitral awards made in a state which is a party to the New York Convention shall be recognized and enforced by other parties thereto subject to their rights to refuse enforcement under certain circumstances, including where the enforcement of the arbitral award is against the public policy of that state. At the time of the PRC’s accession to the Convention, the Standing Committee of the NPC declared that (1) the PRC will only apply the New York Convention to the recognition and enforcement of arbitral awards made in the territories of other parties based on the principle of reciprocity; and (2) the New York Convention will only apply to disputes deemed under PRC laws to be arising from contractual or non-contractual mercantile legal relations.

An arrangement for mutual enforcement of arbitral awards between Hong Kong and the Supreme People’s Court of China was reached. The Supreme People’s Court of China adopted the Arrangements on the Mutual Enforcement of Arbitral Awards between the Mainland and the Hong Kong Special Administrative Region on June 18, 1999, which went into effect on February 1, 2000. The arrangements reflect the spirit of the New York Convention. Under the arrangements, the awards by the Mainland arbitral bodies recognized by Hong Kong may be enforced in Hong Kong and the awards by the Hong Kong arbitral bodies may also be enforced in the Mainland China. If the Mainland court finds that the enforcement of awards made by the Hong Kong arbitral bodies in the Mainland will be against public interests of the Mainland, the awards may not be enforced.

### **SUMMARY OF MATERIAL DIFFERENCES BETWEEN HONG KONG AND PRC COMPANY LAW**

The Hong Kong laws applicable to a company incorporated in Hong Kong are the Companies Ordinance and the Companies (Winding Up and Miscellaneous Provisions) Ordinance and are supplemented by common law and the rules of equity that are applicable to Hong Kong. As a joint stock limited company established in the PRC that is seeking a [REDACTED] of shares on the Stock Exchange, the Company is governed by the PRC Company Law and all other rules and regulations promulgated pursuant to the PRC Company Law.

Set out below is a summary of certain material differences between Hong Kong Company Law applicable to a company incorporated in Hong Kong and the PRC Company Law applicable to a joint stock limited company incorporated under the PRC Company Law. This summary is, however, not intended to be an exhaustive comparison.



## APPENDIX V SUMMARY OF PRINCIPAL LEGAL AND REGULATORY PROVISIONS

### **Incorporation of Company**

Under Hong Kong company law, a company with share capital, shall be incorporated by the Registrar of Companies in Hong Kong and the company will acquire an independent corporate existence upon its incorporation. A company may be incorporated as a public company or a private company. Pursuant to the Companies Ordinance, the articles of association of a private company incorporated in Hong Kong shall contain provisions that restrict a member’s right to transfer shares. A public company’s articles of association do not contain such provisions.

Under the PRC Company Law, a joint stock limited company may be incorporated by promotion or subscription. The amended PRC Company Law which came into effect on October 26, 2018 has no provision on the minimum registered capital of joint stock companies, except that laws, administrative regulations and State Council decisions have separate provisions on paid-in registered capital and the minimum registered capital of joint stock, in which case the company should follow such provisions.

### **Share Capital**

Under Hong Kong law, the directors of a Hong Kong company may, with the prior approval of the shareholders if required, issue new shares of the company. The PRC Company Law provides that any increase in our registered capital must be approved by or filed with our shareholders’ general meeting and the relevant PRC governmental and regulatory authorities. There are no such minimum capital requirements on a Hong Kong company under Hong Kong law.

Under the PRC Securities Law, a company which is approved by the relevant securities regulatory authority to list its shares on a stock exchange must have a total share capital of not less than RMB30 million. There is no such restriction on companies incorporated in Hong Kong under Hong Kong law.

Under the PRC Company Law, the shares may be subscribed for in the form of money or non-monetary assets (other than assets not entitled to be used as capital contributions under relevant laws and administrative regulations). For non-monetary assets to be used as capital contributions, appraisals and transfer procedures of property rights must be carried out to ensure no over-valuation or under-valuation of the assets. There is no such restriction on a Hong Kong company under Hong Kong law.

### **Restrictions on Shareholding and Transfer of Shares**

Under PRC law, our Domestic Shares, which are denominated and subscribed for in Renminbi, may only be subscribed for and traded by the government or government authorized departments, PRC legal persons, natural persons, qualified foreign institutional investors, or eligible foreign strategic investors. Overseas listed shares, which are denominated in Renminbi and subscribed for in a foreign currency other than Renminbi, may only be subscribed for, and traded by investors from Hong Kong, Macau or Taiwan or any country and territory outside the PRC, or qualified domestic institutional investors. However, qualified institutional investors and individual investors may trade Southbound Hong Kong trading Link and Northbound Shanghai trading Link (or the Northbound Shenzhen trading Link) shares via participating in Shanghai-Hong Kong Stock Connect and Shenzhen-Hong Kong Stock Connect.

## APPENDIX V SUMMARY OF PRINCIPAL LEGAL AND REGULATORY PROVISIONS

Under the PRC Company Law, a promoter of a joint stock limited company is not allowed to transfer the shares it holds for a period of one year after the date of establishment of the company. Shares in issue prior to the public offering cannot be transferred within one year from the [REDACTED] of the shares on a stock exchange. Shares in a joint stock limited company held by its directors, supervisors and senior management transferred each year during their term of office shall not exceed 25% of the total shares they held in the company, and the shares they held in the company cannot be transferred within one year from the [REDACTED] of the shares, and also cannot be transferred within half a year after such person has left office. The articles of association may set other restrictive requirements on the transfer of the company’s shares held by its directors, supervisors and senior management. There are no such restrictions on shareholdings and transfers of shares under Hong Kong law apart from six-month lockup on the company’s issue of shares and the 12-month lockup on controlling shareholders’ disposal of shares.

### **Financial Assistance for Acquisition of Shares**

The PRC Company Law does not prohibit or restrict a joint stock limited company or its subsidiaries from providing financial assistance for the purpose of an acquisition of its own or its holding company’s shares. However, the Guidelines for the Articles of Association of Listed Companies stipulate that a company or a subsidiary of a company (including an affiliated enterprise of a company) shall not provide any financial assistance in the form of a gift, advance, guarantee, compensation or loan to a person who purchases or proposes to purchase shares in the company.

### **Variation of Class Rights**

The PRC Company Law has no special provision relating to variation of class rights. However, the PRC Company Law states that the State Council can promulgate separate regulations relating to other kinds of shares.

Under the Companies Ordinance, no rights attached to any class of shares can be varied except (i) with the approval of a special resolution of the holders of the relevant class at a separate meeting, (ii) with the consent in writing of the holders representing at least 75% of the total voting rights of holders of the relevant class of shares, or (iii) if there are provisions in the articles of association relating to the variation of those rights, then in accordance with those provisions.

### **Directors, Senior Management and Supervisors**

The PRC Company Law, unlike Hong Kong Company Law, does not contain any requirements relating to the declaration of directors’ interests in material contracts, restrictions on companies providing certain benefits to directors and guarantees in respect of directors’ liability and prohibitions against compensation for loss of office without shareholders’ approval.

### **Board of Supervisors**

Under the PRC Company Law, a joint stock limited company’s directors and members of the senior management are subject to the supervision of board of supervisors. There is no mandatory requirement for the establishment of board of supervisors for a company incorporated in Hong Kong. The Guidelines for the Articles of Association of Listed Companies stipulate that supervisors shall abide by the laws, administrative regulations and the articles of association of the company, owe the company a duty of

## APPENDIX V SUMMARY OF PRINCIPAL LEGAL AND REGULATORY PROVISIONS

loyalty and diligence, and shall not use their authority to accept bribes or other illegal income or misappropriate the property of the company.

### **Derivative Action by Minority Shareholders**

According to Hong Kong law, as permitted by court, shareholders may initiate a derivative action on behalf of the company against directors who have any misconduct to the company if the directors control a majority of votes at a general meeting, thereby effectively preventing a company from suing the directors in breach of their duties in its own name.

The PRC Company Law provides shareholders of a joint stock limited company with the right so that in the event where the directors and senior management violate their obligations and cause damages to a company, the shareholders individually or jointly holding more than 1% of the shares in the company for more than 180 consecutive days may request in writing the board of supervisors to initiate proceedings in the people’s court. In the event that the board of supervisors violates their obligations and cause damages to company, the above said shareholders may send written request to the board of directors to initiate proceedings in the people’s court. Upon receipt of aforesaid written request from the shareholders, if the board of supervisors or the board of directors refuses to initiate such proceedings, or has not initiated proceedings within 30 days from the date of receipt of the request, or if under urgent situations, failure of initiating immediate proceeding may cause irremediable damages to the company, the above said shareholders shall, for the benefit of the company’s interests, have the right to initiate proceedings directly to the people’s court in their own name.

The Guidelines for the Articles of Association of Listed Companies also provide other remedies against the directors, supervisors and senior management who breach their duties to the company. In addition, as a condition to the listing of shares on the Stock Exchange, each director and supervisor of a joint stock limited company is required to give an undertaking in favor of the company acting as agent for the shareholders. This allows minority shareholders to take action against directors and supervisors of the company in default.

### **Protection of Minorities**

Under Hong Kong law, a shareholder who complains that the business of a company incorporated in Hong Kong are conducted in a manner unfairly prejudicial to his interests may petition to the Court to make an appropriate order to give relief to the unfairly prejudicial conduct. Alternatively, pursuant to the Companies (Winding Up and Miscellaneous Provisions) Ordinance, a shareholder may seek to wind up the company on the just and equitable ground. In addition, on the application of a specified number of members, the Financial Secretary may appoint inspectors who are given extensive statutory powers to investigate the affairs of a company incorporated or registered in Hong Kong.

According to the PRC Company Law, in the event that the company encounters substantial difficulties in its operation and management and its continuance shall cause a significant loss to the interest of its shareholders, and where this cannot be resolved through other means, the shareholders who hold more than 10% of the total shareholders’ voting rights of the company may present a petition to the People’s Court for the dissolution of the company. However, the Guidelines for the Articles of Association of Listed Companies stipulate that the controlling shareholder or the actual controller of a company shall not use its related party relationship to harm the interests of the company. Those who violate the regulations and caused losses to the company shall be liable for compensation.

## APPENDIX V SUMMARY OF PRINCIPAL LEGAL AND REGULATORY PROVISIONS

### Notice of Shareholders’ General Meetings

Under the PRC Company Law, notice of a shareholders’ annual general meeting and an extraordinary shareholders meeting must be given to shareholders at least 20 days and 15 days before the meeting, respectively.

For a company incorporated in Hong Kong, the minimum period of notice is 14 days in the case of an annual general meeting. Further, where a meeting involves consideration of a resolution requiring special notice, the company must also give its shareholders notice of the resolution at least 14 days before the meeting. The notice period for the annual shareholders’ general meeting is 21 days.

### Quorum for Shareholders’ General Meetings

Under the Companies Ordinance, the quorum for a general meeting must be at least two members unless the articles of association of the company otherwise provided. For companies with only one shareholder, the quorum must be one shareholder. The PRC Company Law does not specify the quorum for a shareholders’ general meeting.

### Voting

Under the Companies Ordinance, an ordinary resolution is passed by a simple majority of affirmative votes cast by shareholders present in person, or by proxy, at a general meeting, and a special resolution is passed by not less than three-fourths of affirmative votes cast by shareholders present in person, or by proxy, at a general meeting.

Under the PRC Company Law, the passing of any resolution requires more than one-half of the affirmative votes held by our shareholders present at a shareholders’ meeting except in cases such as proposed amendments to our articles of association, increase or decrease of registered capital, merger, division, dissolution or transformation, which require two-thirds of the affirmative votes cast by shareholders present at a shareholders’ general meeting.

Pursuant to the Guidelines for the Articles of Association of Listed Companies, matters such as the purchase or sale of material assets or guarantees in excess of thirty percent of a company’s latest audited total assets within one year and share incentive schemes shall be approved by special resolutions of shareholders in general meetings.

### Financial Disclosure

Under the PRC Company Law, a joint stock limited company is required to make available at the company for inspection by shareholders its financial report 20 days before its shareholders’ annual general meeting. In addition, a joint stock limited company of which the shares are publicly issued must publish its financial report. The Companies Ordinance requires a company incorporated in Hong Kong to send to every shareholder a copy of its financial statements, auditors’ report and directors’ report, which are to be presented before the company’s annual general meeting, not less than 21 days before such meeting. A joint stock limited company is required under the PRC law to prepare its financial statements in accordance with the PRC GAAP.

## **APPENDIX V SUMMARY OF PRINCIPAL LEGAL AND REGULATORY PROVISIONS**

### **Information on Directors and Shareholders**

The PRC Company Law gives shareholders the right to inspect the company's articles of association, minutes of the shareholders' general meetings, share register, counterfoil of company debentures, resolutions of board meetings, resolutions of the board of supervisors and financial and accounting reports, which is similar to the shareholders' rights of Hong Kong companies under Hong Kong law.

### **Receiving Agent**

Under the PRC Company Law and the laws of Hong Kong, dividends once declared are debts payable to shareholders. The limitation period for debt recovery action under the laws of Hong Kong is six years, while under the PRC laws this limitation period is three years.

### **Corporate Reorganization**

Corporate reorganization involving a company incorporated in Hong Kong may be effected in a number of ways, such as a transfer of the whole or part of the business or property of the company in the course of voluntary winding up to another company pursuant to Section 237 of the Companies (Winding Up and Miscellaneous Provisions) Ordinance or a compromise or arrangement between the company and its creditors or between the company and its shareholders under Section 237 and Division 2 of Part 13 of the Companies Ordinance, which requires the sanction of the court. In addition, subject to the shareholders' approval, an intra-group wholly-owned subsidiary company may also be amalgamated horizontally or vertically under the Companies Ordinance.

Under PRC law, merger, division, dissolution or change the form of a joint stock limited company has to be approved by shareholders in general meeting.

### **Dispute Arbitration**

In Hong Kong, disputes between shareholders on the one hand, and a company incorporated in Hong Kong or its directors on the other hand, may be resolved through legal proceedings in the courts. The Guidelines for the Articles of Association of Listed Companies provide that shareholders may sue shareholders, shareholders may sue directors, supervisors, managers and other senior management of the company, and shareholders may sue the company, and the company may sue its shareholders, directors, supervisors, managers and other senior management personnel.

### **Statutory Reserve Fund Withdrawal**

Under the PRC Company Law, when a joint stock limited company allocating the after-tax profits of the current year, the Company shall allocate (10%) ten percent of its profit to the statutory common reserve fund. There are no corresponding provisions under Hong Kong law.

## **APPENDIX V SUMMARY OF PRINCIPAL LEGAL AND REGULATORY PROVISIONS**

### **Remedies of the Company**

Under the PRC Company Law, if a director, supervisor or senior management in carrying out his duties infringes any law, administrative regulation or the articles of association of a company, which results in damage to the company, that director, supervisor or senior management should be responsible to the company for such damages. In addition, the Listing Rules require listed companies' articles of association to provide for remedies of the company similar to those available under Hong Kong law (including rescission of the relevant contract and recovery of profits from a director, supervisor or senior management).

### **Dividends**

The company has the power in certain circumstances to withhold, and pay to the relevant tax authorities, any tax payable under PRC law on any dividends or other distributions payable to a shareholder. Under Hong Kong law, the limitation period for an action to recover a debt (including the recovery of dividends) is six years, whereas under PRC laws, the relevant limitation period is three years. The company must not exercise its powers to forfeit any unclaimed dividend in respect of shares until after the expiry of the applicable limitation period.

### **Fiduciary Duties**

In Hong Kong, directors owe fiduciary duties to the company, including the duty not to act in conflict with the company's interests. Furthermore, the Companies Ordinance has codified the directors' statutory duty of care.

Under the PRC Company Law, directors, supervisors and senior management shall assume the duty of loyalty and diligence.

### **Closure of Register of Shareholders**

The Companies Ordinance requires that the register of shareholders of a company must not generally be closed for the registration of transfers of shares for more than 30 days (extendable to 60 days under certain circumstances) in a year, whereas, as required by the PRC Company Law, registered shares shall be transferred by the shareholders by endorsement or in other manners prescribed by laws and administrative regulations; after the transfer, the company shall record the name or names and domicile of the transferee in the register of shareholders. No change in the register of shareholders as stipulated in the preceding paragraph shall be registered within twenty days prior to the shareholders' meeting or within five days prior to the base date of the company's decision to distribute dividends. However, if the law provides otherwise for the registration of changes in the register of shareholders of a listed company, such provisions shall apply.

## APPENDIX VI

## SUMMARY OF ARTICLES OF ASSOCIATION

This Appendix contains a summary of the principal provisions of the Articles of Association adopted by the Company on April 10, 2023, which will become effective on the date on which the H Shares are [REDACTED] on the Hong Kong Stock Exchange. The main purpose of this Appendix is to provide potential [REDACTED] with an overview of the Articles of Association of the Company, and therefore it may not contain all the information that is important for potential [REDACTED].

### SHARES AND REGISTERED CAPITAL

Shares of the Company shall take the form of share certificates. The shares issued by the Company shall be denominated in RMB. The par value per share is RMB1.00.

The Company shall issue shares in an open, fair and just manner, and each share of the same class shall have the same rights.

Shares of the same class issued at the same time shall be issued on the same conditions and at the same price. Any entity or individual shall pay the same price for each of the shares for which it or he or she subscribes for.

### INCREASE, DECREASE AND REPURCHASE OF SHARES

#### Capital Increase

The Company may, based on its business and development needs and in accordance with the laws, regulations and the securities regulatory rules of the place where the Company’s shares are [REDACTED], increase its capital in the following ways, subject to separate resolutions of the shareholders’ general meeting:

1. Public offering of shares;
2. Non-public issuance of shares;
3. distributing bonus shares to its existing shareholders;
4. Conversion of capital reserve into share capital;
5. other means as is stipulated by laws, administrative regulations, or as approved by securities regulatory rules of the place where the Company’s shares are [REDACTED] and relevant regulatory authorities.

#### Capital reduction

The Company may reduce its registered capital. When the company needs to reduce its registered capital, it must prepare a balance sheet and an inventory of assets.

The Company shall reduce its registered capital in accordance with the procedures stipulated in the Company Law, the Hong Kong Listing Rules and other relevant regulations and the Articles of Association.

## APPENDIX VI

## SUMMARY OF ARTICLES OF ASSOCIATION

### Shares repurchase

The Company shall not buy back its shares, except in one of the following circumstances:

1. reducing the registered capital of the Company;
2. merging with another company that holds shares in the Company;
3. using shares for employee stock ownership plan or equity incentives;
4. shareholders who object to resolutions of the general meeting on merger or division of the Company requesting the Company to buy back their shares;
5. to use the shares for conversion of corporate bonds issued by the Company which are convertible into shares;
6. where it is necessary for the Company to preserve its value and shareholders' interest.

The Company may repurchase its shares through public centralised trading or other methods recognised by laws, administrative regulations, the CSRC and the stock exchange where the Company's shares are [REDACTED], and shall comply with applicable laws, administrative regulations, departmental rules and the securities regulatory rules of the place where the Company's shares are [REDACTED].

Where the Company repurchases its shares under the circumstances set out in items 1 and 2 above, a resolution shall be passed at the general meeting of the Company. Where the Company repurchases its shares under the circumstances set out in items 3, 5 and 6 above, a resolution may be passed at a Board meeting attended by more than two-thirds of the directors in accordance with the provisions of the Articles of Association or as authorised by the general meeting. Where the securities regulatory rules of the place where the shares of the Company are [REDACTED] provide otherwise, such provisions shall prevail, provided that such provisions are not in violation of the Company Law, the Securities Law, the Administrative Measures and the Guidelines for the Articles of Association of Listed Companies.

Where the Company repurchases its shares under the circumstances set out in item 1 above, such shares shall be cancelled within 10 days from the date of repurchase; where the Company repurchases its shares under the circumstances set out in items 2 and 4, such shares shall be transferred or cancelled within 6 months; where the Company repurchases its shares under the circumstances set out in items 3, 5 and 6, the total number of shares held by the Company shall not exceed 10% of the total issued shares of the Company, and such shares shall be transferred or cancelled within 3 years.

### Transfer of Shares

Shares of the Company held by the promoters shall not be transferred within one year from the date of establishment of the Company. Shares issued by the Company prior to the public [REDACTED] of shares shall not be transferred within one year from the date on which the Company's shares are [REDACTED] and [REDACTED] on the Hong Kong Stock Exchange.



## APPENDIX VI

## SUMMARY OF ARTICLES OF ASSOCIATION

Directors, supervisors and senior management of the Company shall declare to the Company their shareholdings in the Company and any changes thereof, and shall not transfer more than 25% of the total number of shares of the Company held by them each year during their terms of office; the shares of the Company held by them shall not be transferred within one year from the date on which the shares of the Company are [REDACTED] and [REDACTED]. The above personnel shall not transfer the shares of the Company held by them within half a year after they leave the Company.

If the Company's shareholders holding 5% (excluding the recognized clearing houses or their agents as defined in the relevant ordinances in force under the laws of Hong Kong from time to time) or above shares of the Company, Directors, Supervisors, senior management officers sell shares or other securities with an equity nature within six months after buying the same or buy shares or securities within six months after selling the same, the earnings arising therefrom shall belong to the Company and the Board shall recover such earnings. However, the restriction shall not be applicable to any sale of shares by a securities company holding 5% or above of the Company's shares as a result of its purchase and underwriting of the untaken shares after [REDACTED] and other circumstances stipulated by CSRC.

The shares or other securities with an equity nature held by Directors, Supervisors, senior management officers and natural person shareholders referred to in the preceding paragraph include the shares or other securities with an equity nature held by their spouses, parents, children, and any of the above which is held by using others' accounts.

If the Company's Board does not comply with the provision of the first paragraph, the shareholders can request the Board to do so within 30 days. If the Board does not enforce such right within the aforesaid period, the shareholders are entitled to commence litigations in the people's court in their own names for the interests of the Company.

If the Company's Board does not enforce the provision of the first paragraph of this Article, the responsible Directors shall assume joint and severally liable in accordance with the laws.

### REGISTER OF MEMBERS

The Company shall establish a register of shareholders in accordance with the evidence provided by the securities registration authority. The register of shareholders shall be sufficient evidence of the shareholders' shareholdings in the Company, except where there is evidence to the contrary.

The Company shall enter into a share custody agreement with the share registrar, regularly enquire the information of substantial shareholders and the changes in shareholdings (including pledge of equity interests) of substantial shareholders, and keep abreast of the shareholding structure of the Company. The original of register of holders of H Shares shall be maintained in Hong Kong and made available for inspection by shareholders. However, the Company may suspend registration of shareholders (if necessary) in accordance with applicable laws and regulations and the securities regulatory rules of the place where the Company's shares are [REDACTED]; a copy of the register of shareholders of H shares shall be kept at the Company's domicile.

## APPENDIX VI

## SUMMARY OF ARTICLES OF ASSOCIATION

When the Company convenes a general meeting, distributes dividends, conducts liquidation or engages in other activities that require the confirmation of the identity of shareholders, the Board or the convener of the general meeting shall determine the record date in accordance with the provisions of the securities regulatory rules of the place where the Company's shares are [REDACTED]. Shareholders whose names appear on the register of shareholders after the close of trading on the record date shall be the shareholders entitled to relevant interests.

### Rights and Obligations of Shareholders

Shareholders of the Company shall enjoy the following rights:

1. to receive dividends and other distributions in proportion to the number of shares held;
2. to request, summon, preside over, attend or appoint a proxy to attend shareholders' general meetings and speak at the shareholders' general meetings in accordance with the laws, and to exercise the corresponding voting rights (except where a shareholder is required by the securities regulatory rules of the place where the Company's shares are [REDACTED] to abstain from voting on a particular matter);
3. to supervise the operation of the Company, making suggestions or enquiries;
4. to transfer, give or pledge the shares held by them in accordance with the laws, administrative regulations and the Articles of Association;
5. to review the Articles of Association, the register of members (including the register of holders of H Shares), counterfoils of corporate bonds, minutes of general meetings, resolutions of the Board meetings, resolutions of the Board of Supervisors meetings and financial and accounting reports;
6. in the event of the termination or liquidation of the Company, to participate in the distribution of remaining assets of the Company in proportion to the number of shares held;
7. to request the Company to buy back the shares of shareholders objecting to resolutions of the general meeting concerning merger or division of the Company;
8. other rights stipulated by laws, administrative regulations, departmental rules, securities regulatory rules of the place where the Company's shares are [REDACTED] or the Articles of Association.

Shareholders of the Company shall assume the following obligations:

1. to abide by laws, administrative regulations and the Articles of Association;
2. to pay subscription monies according to the number of shares subscribed and the method of subscription;
3. not to make divestment unless in the circumstances stipulated by laws and regulations;

## APPENDIX VI

## SUMMARY OF ARTICLES OF ASSOCIATION

4. not to abuse the rights of shareholders to damage the interests of the Company or that of other shareholders; not to abuse the independent status of the Company as a legal person and the limited liability of shareholders to damage the interests of the creditors of the Company;
5. other obligations imposed by laws, administrative regulations, securities regulatory rules of the place where the Company's shares are [REDACTED] and the Articles of Association.

Shareholders of the Company who abuse their shareholders' rights and cause losses to the Company or other shareholders shall be liable for compensation in accordance with the law. Shareholders of the Company who abuse the independent status of the Company as a legal person and the limited liability of shareholders to evade debts and seriously damage the interests of the creditors of the Company shall bear joint and several liabilities for the debts of the Company.

### RESTRICTIONS ON RIGHTS OF THE CONTROLLING SHAREHOLDERS

The controlling shareholders and de facto controllers of the Company shall not use their connected relations to damage the interests of the Company. If the violation causes losses to the Company, it shall be liable for compensation.

The controlling shareholders and de facto controllers of the Company shall have fiduciary duties towards the Company and its [REDACTED] shareholders. The controlling shareholder shall exercise its rights as a capital contributor in strict compliance with the laws. The controlling shareholder shall not damage the legitimate rights and interests of the Company and [REDACTED] shareholders by means of profit distribution, asset restructuring, external investment, fund appropriation, loan guarantee, etc., and shall not use its controlling status to damage the interests of the Company and [REDACTED] shareholders.

### GENERAL MEETING

#### General Provisions of General Meetings

The shareholders' general meeting is the organ of authority of the Company and shall exercise the following functions and powers:

1. to decide on the Company's business policies and investment plans;
2. to elect and replace directors and supervisors who are not employee representatives and to decide on matters relating to the remuneration of directors and supervisors;
3. to consider and approve the reports of the Board;
4. To consider and approve the report of the Board of Supervisors;
5. to consider and approve the annual financial budgets and final accounts of the Company;
6. to consider and approve the Company's profit distribution plans and loss recovery plans;
7. to resolve on the increase or reduction of the registered capital of the Company;

## APPENDIX VI

## SUMMARY OF ARTICLES OF ASSOCIATION

8. to resolve on the issue of corporate bonds;
9. to resolve on the merger, division, dissolution, liquidation or change of corporate form of the Company;
10. amendments to the Articles of Association;
11. to resolve on the appointment and dismissal of the accounting firm of the Company;
12. to consider and approve the guarantee matters stipulated in Article 42 of the Articles of Association;
13. to consider the purchase or disposal of material assets within one year with an amount exceeding 30% of the latest audited total assets of the Company;
14. to consider and approve the change in use of [REDACTED];
15. to consider share incentive schemes and employee share ownership schemes;
16. to consider other matters required by laws, administrative regulations, departmental rules, the securities regulatory rules of the place where the Company's shares are [REDACTED] or the Articles of Association to be decided by the general meeting.

The above-mentioned powers of general meeting shall not be exercised by the Board or other institutions or individuals by way of authorization. In addition to the above matters, the general meeting may authorise or entrust the Board and/or its authorised persons to handle the matters authorised or entrusted by it without violating the laws and regulations and the mandatory provisions of the relevant laws, regulations and regulatory rules of the place where the Company's shares are [REDACTED].

General meetings are divided into annual general meetings and extraordinary general meetings. The annual general meeting shall be convened once a year within six months after the end of the previous accounting year.

The Company shall convene an extraordinary general meeting within two months from the date of occurrence of any of the following circumstances:

- (1) the number of directors is less than the number stipulated in the Company Law or less than two-thirds of the number specified in the Articles of Association;
- (2) when the unrecovered losses of the Company amount to one-third of the total amount of its paid-up share capital;
- (3) when shareholders individually or jointly holding 10% or more of the Company's shares so request;
- (4) when deemed necessary by the Board;

## APPENDIX VI

## SUMMARY OF ARTICLES OF ASSOCIATION

- (5) when proposed by the Board of Supervisors;
- (6) other circumstances stipulated by laws, administrative regulations, departmental rules, securities regulatory rules of the place where the Company's shares are [REDACTED] or the Articles of Association.

If the extraordinary general meeting is convened in accordance with the securities regulatory rules of the place where the Company's shares are [REDACTED], the actual date of the extraordinary general meeting may be adjusted according to the approval progress of the stock exchange where the Company's shares are [REDACTED] (if applicable).

### Summoning of General Meetings

General meetings shall be summoned by the Board. The publication of the notice of the general meeting (including the supplemental notice) shall comply with the relevant laws and regulations and the securities regulatory rules of the place where the Company's shares are [REDACTED].

The independent non-executive Directors are entitled to propose to the Board to convene an extraordinary general meeting. The Board shall, in accordance with the laws, administrative regulations, the securities regulatory rules of the place where the Company's shares are [REDACTED] and the Articles of Association, give a written reply on whether or not to convene the extraordinary general meeting within 10 days after receiving the proposal from the independent non-executive Directors.

If the Board agrees to convene the extraordinary general meeting, a notice of such meeting shall be issued within five days after the resolution of the Board is passed. If the Board does not agree to convene the extraordinary general meeting, it shall explain the reasons and make an announcement.

The Board of Supervisors shall have the right to propose to the Board to convene an extraordinary general meeting in writing. The Board shall, in accordance with the laws, administrative regulations, the securities regulatory rules of the place where the Company's shares are [REDACTED] and the Articles of Association, give a written reply on whether to convene the extraordinary general meeting or not within 10 days after receipt of the proposal.

If the Board agrees to convene the extraordinary general meeting, a notice of such meeting shall be issued within 5 days after the resolution of the Board is passed. Any changes to the original proposal made in the notice shall be approved by the Board of Supervisors.

If the Board does not agree to convene the extraordinary general meeting or fails to give a reply within 10 days after receiving the proposal, the Board shall be deemed to be unable or fail to perform the duty of convening the general meeting, and the Board of Supervisors may summon and preside over the meeting on its own.

Shareholders individually or jointly holding 10% or more of the Company's shares shall have the right to request the Board of Directors in writing to convene an extraordinary general meeting. The Board shall, in accordance with the laws, administrative regulations, the securities regulatory rules of the place where the shares of the Company are [REDACTED] and the Articles of Association, give a written reply on whether to convene the extraordinary general meeting or not within 10 days after receipt of the proposal.

## APPENDIX VI

## SUMMARY OF ARTICLES OF ASSOCIATION

If the Board agrees to convene the extraordinary general meeting, a notice of such meeting shall be issued within five days after the resolution of the Board is passed. Any change to the original request made in the notice shall be subject to the consent of the relevant shareholders.

If the Board does not agree to convene an extraordinary general meeting or does not reply within 10 days upon receipt of the proposal, the shareholders individually or jointly holding more than 10% of the Company's shares shall have the right to propose to the Board of Supervisors to convene an extraordinary general meeting, and such proposal shall be made in writing.

If the Board of Supervisors agrees to convene the extraordinary general meeting, it shall issue a notice of general meeting within 5 days upon receipt of the request. Any changes to the original request in the notice shall be approved by the relevant shareholders.

If the Board of Supervisors fails to issue the notice of the general meeting within the prescribed period, it shall be deemed that the Board of Supervisors will not convene and preside over the general meeting, and shareholders individually or jointly holding 10% or more of the Company's shares for more than 90 consecutive days may summon and preside over the meeting by themselves.

### **Proposals at General Meetings**

When the Company convenes a general meeting, the Board, the Board of Supervisors and shareholders individually or jointly holding more than 3% of the Company's shares shall have the right to submit proposals to the Company.

Shareholders individually or jointly holding 3% or more of the Company's shares may submit ad hoc proposals in writing to the convener 10 days before a general meeting is convened. The convener shall issue a supplementary notice of the general meeting within two days upon receipt of the proposal to announce the contents of the provisional proposal. For the publication of the supplementary notice of the general meeting, if there are special provisions in the securities regulatory rules of the place where the shares of the Company are [REDACTED], such provisions shall prevail, provided that such provisions are not in violation of the Company Law, the Securities Law, the Administrative Measures and the Guidelines for the Articles of Association of Listed Companies. If the general meeting is postponed due to the issuance of a supplementary notice of the general meeting pursuant to the securities regulatory rules of the place where the Company's shares are [REDACTED], the general meeting shall be postponed pursuant to the securities regulatory rules of the place where the Company's shares are [REDACTED].

Except as provided in the preceding paragraph or the securities regulatory rules of the place where the Company's shares are [REDACTED], the convener shall not amend the proposals set out in the notice of the general meeting or add any new proposals after issuing the notice of the general meeting.

### **NOTICE OF GENERAL MEETING**

The convener shall notify all shareholders by way of announcement 21 days before the annual general meeting and shall notify all shareholders by way of announcement 15 days before the extraordinary general meeting.

## APPENDIX VI

## SUMMARY OF ARTICLES OF ASSOCIATION

A notice of the Company shall be given in the following manner:

1. by hand;
2. by mail;
3. by way of announcement;
4. by publishing on the websites designated by the Company and the Hong Kong Stock Exchange, subject to the laws, administrative regulations and the listing rules of the stock exchange where the Company’s shares are [REDACTED];
5. other means stipulated by laws, administrative regulations, rules, securities regulatory rules of the place where the Company’s shares are [REDACTED] or the Articles of Association.

### Convening of General Meetings

All shareholders registered on the record date or their proxies are entitled to attend the general meeting. They shall exercise their voting rights in accordance with the relevant laws, regulations and the Articles of Association.

Individual shareholders who attend the meeting in person shall produce their identity cards or other effective document or proof of identity and stock account cards. Proxies of individual shareholders shall produce their valid identity cards and the power of attorney of the shareholder.

Shareholder that is a legal person may be represented at the meeting by its legal representative or a proxy appointed by it (which will be regarded as if the legal person shareholder was present in person) to exercise its rights (including the right to vote). If a legal representative attends the meeting, he/she should produce his/her identity card and valid proof that he/she is a legal representative; if a proxy attends the meeting, the proxy should produce his/her identity card and documents proving that he/she has been appointed by such legal person (unless a shareholder is a recognised clearing house as defined in the relevant ordinances in force from time to time under the laws of Hong Kong or the securities regulatory rules of the place where the shares of the company are [REDACTED] or its nominee (hereinafter referred to as a “**Recognised Clearing House**”))

If the shareholder is a Recognised Clearing House, the Recognised Clearing House may authorise one or more persons as it thinks fit to act as its representative (s) at any shareholders’ general meeting or any class shareholders’ meeting or any creditors’ meeting; however, if more than one person are so authorised, the power of attorney shall specify the number and class of shares in respect of which each such person is authorised, and the power of attorney shall be signed by the authorised personnel of the Recognised Clearing House. The person so authorised may attend the meeting on behalf of the recognised clearing house (without being required to present share certificate, notarized authorization and/or further evidence to prove that he/she is duly authorised) to exercise the rights as if he/she was an individual shareholder of the Company (and was entitled to the same legal rights as other shareholders, including hair and voting rights).

The proxy form shall contain a statement that in the absence of instructions from the shareholder the proxy may vote as he/she thinks fit.

## APPENDIX VI

## SUMMARY OF ARTICLES OF ASSOCIATION

If the proxy form is signed by a person authorised by the principal, the power of attorney or other authorization documents shall be notarized. The instrument appointing a proxy, the notarized power of attorney or other authorization documents shall be placed at the domicile of the Company or at such other place as specified in the notice convening the meeting.

If the principal is a legal person, its legal representative or such person as is authorised by resolution of its board of directors or other governing body to act as its representative may attend the general meeting of the Company and exercise the shareholder's rights.

### Resolutions of General Meetings

Resolutions of the general meeting are divided into ordinary resolutions and special resolutions.

Ordinary resolutions shall be passed by votes representing more than half of the voting rights represented by the shareholders (including proxies) present at the meeting.

A special resolution shall be passed by votes representing more than two-thirds of the voting rights represented by the shareholders (including proxies) present at the meeting.

The following matters shall be approved by ordinary resolutions at a general meeting:

1. work reports of the Board and the Board of Supervisors;
2. profit distribution plans and loss recovery plans formulated by the Board;
3. appointment and removal of members of the Board and the Board of Supervisors, their remuneration and method of payment;
4. Annual budget and final accounts of the Company;
5. annual reports of the Company;
6. matters other than those required by the laws, administrative regulations, the securities regulatory rules of the place where the shares of the Company are [REDACTED] or the Articles of Association to be adopted by special resolution.

The following matters shall be approved by special resolutions at a general meeting:

1. increase or reduction of the registered capital of the Company;
2. division, division, merger, dissolution and liquidation of the Company;
3. amendments to the Articles of Association;
4. purchase or disposal of material assets or provision of guarantee by the Company within 12 consecutive months with an amount exceeding 30% of the latest audited total assets of the Company;
5. share incentive scheme;



## APPENDIX VI

## SUMMARY OF ARTICLES OF ASSOCIATION

6. other matters stipulated by laws, administrative regulations, the securities regulatory rules of the place where the Company's shares are [REDACTED] or the Articles of Association, the Rules of Procedure of the General Meeting, and other matters considered by the general meeting, by way of ordinary resolution, to have a material impact on the Company and need to be approved by special resolution.

### DIRECTORS AND BOARD OF DIRECTORS

#### Directors

Directors shall be elected or replaced by the shareholders' general meeting, and may be removed by the shareholders' general meeting before the expiry of their terms of office. The term of office of the Directors shall be 3 years, and they may be re-elected and re-appointed in accordance with the provisions of the securities regulatory rules of the place where the Company's shares are [REDACTED].

The term of office of the Directors shall commence from the date of their appointment until the expiry of the term of the current session of the Board. If the term of office of a director expires but re-election is not made responsively, the said director shall continue fulfilling the duties as director pursuant to laws, administrative regulations, departmental rules and the Articles of Association until a new director is elected.

### THE BOARD

The Company shall have a board of directors which shall be accountable to the general meeting. The Board shall consist of 5 to 15 directors, including one chairman and one vice chairman. The number of independent non-executive Directors shall not be less than three and shall represent more than one-third of the total number of Directors at any time.

The Board shall exercise the following powers:

1. to summon general meetings and report its work to the general meetings;
2. to implement the resolutions of the general meeting;
3. to decide on the Company's business plans and investment plans;
4. to formulate the Company's annual financial budgets and final accounts;
5. to formulate the Company's profit distribution plans and loss recovery plans;
6. to formulate proposals for the increase or reduction of the Company's registered capital, the issue of bonds or other securities and listing plans;
7. to formulate plans for material acquisitions, purchase of shares of the Company or merger, division, dissolution and change of corporate form of the Company;

## APPENDIX VI

## SUMMARY OF ARTICLES OF ASSOCIATION

8. to decide on the Company's external investment, acquisition and disposal of assets, pledge of assets, external guarantees, entrusted wealth management, connected transactions, external donations and other matters within the scope authorised by the general meeting;
9. to decide on the establishment of the Company's internal management structure;
10. to decide on the appointment or dismissal of the Company's general manager, secretary to the Board and other senior management, and decide on their remuneration, rewards and punishments; to decide on the appointment or dismissal of the Company's deputy general manager, chief financial officer and other senior management based on the nomination of the general manager, and decide on their remuneration, rewards and punishments;
11. to formulate the basic management system of the Company;
12. to formulate proposals for any amendment to the Articles of Association;
13. to manage the information disclosure of the Company;
14. to propose to the general meeting the appointment or replacement of the accounting firm that audits the Company;
15. to listen to the work report of the general manager of the Company and inspect the work of the general manager;
16. other functions and powers conferred by laws, administrative regulations, departmental rules, securities regulatory rules of the place where the Company's shares are [REDACTED] or the Articles of Association.

Matters beyond the scope of authorization of the general meeting shall be submitted to the general meeting for consideration.

### General Manager

The general manager shall be accountable to the Board and exercise the following powers:

1. to be in charge of the production, operation and management of the Company, organise the implementation of the resolutions of the Board and report to the Board;
2. to organise the implementation of the Company's annual business plan and investment plan;
3. to draft plans for the establishment of the Company's internal management structure;
4. to draft the basic management system of the Company;
5. to formulate the specific rules and regulations of the Company;

## APPENDIX VI

## SUMMARY OF ARTICLES OF ASSOCIATION

6. to propose to the Board to appoint or dismiss deputy general managers and financial controller of the Company;
7. to appoint or dismiss management personnel other than those required to be appointed or dismissed by the Board;
8. to exercise other powers conferred by the Articles of Association or the Board.

The general manager is to attend board meetings.

### Secretary to the Board

The Company shall have a secretary to the Board, who shall be responsible for the preparation of the general meetings and Board meetings of the Company, keeping of documents, management of shareholders' information of the Company and handling matters such as information disclosure.

The secretary to the Board shall comply with the relevant provisions of laws, administrative regulations, departmental rules and the Articles of Association.

### BOARD OF SUPERVISORS

The Company shall have a Board of Supervisors. The Board of Supervisors shall consist of three Supervisors and shall have one chairman. The chairman of the Board of Supervisors shall be elected by more than half of all Supervisors.

The board of supervisors shall comprise shareholder representatives and an appropriate proportion of the company's staff representatives, of which the proportion of staff representatives shall not be less than one-third. The employee representatives of the Board of Supervisors shall be democratically elected by the Company's employees at the employee representative assembly, employee meeting or otherwise.

The Board of Supervisors exercises the following powers:

1. it shall review the regular reports of the Company prepared by the Board and to provide written review opinions;
2. to examine the financial affairs of the Company;
3. to supervise the directors and senior management in their performance of their duties and to propose the removal of directors and senior management who have violated laws, administrative regulations, the Articles of Association or the resolutions of the shareholders' general meetings;
4. to demand rectification from a Director or senior management when the acts of such persons are detrimental to the interests of the Company;

## APPENDIX VI

## SUMMARY OF ARTICLES OF ASSOCIATION

5. to propose the convening of extraordinary general meetings and to summon and preside over general meetings when the Board fails to perform the duty of summoning and presiding over general meetings under the Company Law;
6. to submit proposals to the general meeting;
7. to initiate proceedings against directors and senior management in accordance with Article 151 of the Company Law;
8. To investigate any irregularities identified in the operation of the Company; if necessary, to engage professional institutions such as accounting firms and law firms to assist its work at the expense of the Company.

Resolutions of the Board of Supervisors shall be passed by more than half of the supervisors.

### FINANCIAL AND ACCOUNTING SYSTEM

The Company shall establish its financial and accounting system in accordance with the laws, administrative regulations and the requirements of the relevant state authorities.

The annual reports and interim reports of the Company are prepared in accordance with the relevant laws, administrative regulations, the requirements of the CSRC and the stock exchanges where the Company's shares are [REDACTED].

### NOTICES

A notice of the Company shall be given in the following manner:

1. by hand;
2. by mail;
3. by way of announcement;
4. by publishing on the websites designated by the Company and the Hong Kong Stock Exchange, subject to the laws, administrative regulations and the listing rules of the stock exchange where the Company's shares are [REDACTED];
5. other means stipulated by laws, administrative regulations, rules, securities regulatory rules of the place where the Company's shares are [REDACTED] or the Articles of Association.

Subject to the securities regulation rules of the place where the Company's shares are [REDACTED], where a notice of the Company is published by way of announcement, the said notice shall be deemed as received by all relevant persons once it is published.

## APPENDIX VI

## SUMMARY OF ARTICLES OF ASSOCIATION

### Dissolution and Liquidation of the Company

The Company shall be dissolved for the following reasons:

1. the term of its operations as is stipulated in the Articles of Association has expired or events of dissolution specified in the Articles of Association have occurred;
2. the shareholders' general meeting resolves to dissolve the Company;
3. dissolution is necessary due to merger or division of the Company;
4. the Company's business licence is revoked, the Company is ordered to close down or be revoked in accordance with the law;
5. Where the Company encounters serious difficulties in its operation and management and its continuous existence will cause significant losses to the interests of shareholders, and such difficulties cannot be resolved through other means, shareholders holding more than 10% of the voting rights of all shareholders of the Company may request the People's Court to dissolve the Company.

Where the Company is dissolved pursuant to items 1, 2, 4 and 5 above, a liquidation committee shall be established and the liquidation shall commence within 15 days after the occurrence of the cause of dissolution. The liquidation committee shall be composed of directors or persons determined by the shareholders' general meeting. If a liquidation committee is not established within the time limit, the creditors may apply to the people's court to designate relevant personnel to form a liquidation committee to carry out liquidation.

The liquidation committee shall notify creditors within 10 days from the date of its establishment, and publish an announcement in a newspaper recognised by the stock exchange where the Company's shares are [REDACTED] within 60 days.

If the liquidation committee discovers that the Company's assets are insufficient to repay its debts after cleaning up the Company's assets and preparing a balance sheet and an inventory of assets, it shall apply to the People's Court for a declaration of insolvency in accordance with the law.

Upon completion of the liquidation, the liquidation committee shall prepare a liquidation report which shall be submitted to the shareholders' general meeting or the people's court for confirmation, and shall submit the same to the company registration authority, apply for cancellation of the company's registration, and publish an announcement on the termination of the company.

## APPENDIX VI

## SUMMARY OF ARTICLES OF ASSOCIATION

---

### AMENDMENTS TO THE ARTICLES

The Company shall amend the Articles of Association in any of the following circumstances:

- (1) After the amendments are made to the Company Law or relevant laws, administrative regulations, departmental rules and securities regulatory rules of the place where the shares of the Company are [REDACTED], the provisions of the Articles of Association are in conflict with the amended laws, administrative regulations, departmental rules and securities regulatory rules of the place where the shares of the Company are [REDACTED];
- (2) there is a change in the Company's situation, which is inconsistent with the matters recorded in the Articles of Association;
- (3) the shareholders' general meeting decides to amend the Articles of Association.

The amendments to the Articles of Association adopted by the shareholders' general meeting shall be submitted to the competent authorities for approval if they are subject to approval by the competent authorities. If there is any change relating to the registered particulars of the Company, application shall be made for registration of the changes in accordance with the laws.

## APPENDIX VII

## STATUTORY AND GENERAL INFORMATION

### A. FURTHER INFORMATION ABOUT OUR GROUP

#### 1. Incorporation of Our Company

Our predecessor company was established in the PRC with an initial registered capital of RMB500,000. On July 19, 2013, our Company was converted to a joint stock company with limited liability under the PRC Company Law. The registered office and headquarters of our Company in the PRC is No.3 Guangtong Street, Zhangjiawan, Tongzhou District, Beijing. Accordingly, our corporate structure and Articles of Association are subject to the relevant laws and regulations of the PRC. For details of the relevant PRC laws and regulatory provisions and a summary of our Articles of Association, see Appendices IV and V to this document, respectively.

Our registered place of business in Hong Kong is at 5/F, Manulife Place, 348 Kwun Tong Road, Kowloon, Hong Kong. We were registered as a non-Hong Kong Company under Part 16 of the Companies Ordinance on April 26, 2022. Ms. YUEN Wing Yan, Winnie, one of our joint company secretaries, has been appointed as our authorized representatives for the acceptance of service of process and notices in Hong Kong. Her address for acceptance of service of process is 5/F, Manulife Place, 348 Kwun Tong Road, Kowloon, Hong Kong.

#### 2. Changes in the Share Capital of Our Company

As of the date of incorporation of our predecessor company, Beijing Luzhu Biotechnology Limited Liability Company (北京綠竹生物技術有限責任公司) on November 9, 2001, our registered capital was RMB500,000, which was fully paid up by Ms. ZHANG and two Independent Third Parties. On July 19, 2013, our Company was converted to a joint stock company with limited liability. Our total issued share capital was RMB55,000,000 divided into 55,000,000 Shares with a nominal value of RMB1.00 each.

The following alterations in the total issued share capital of our Company have taken place within the two years immediately preceding the date of this document:

- (a) pursuant to an investment cooperation agreement dated February 2, 2021 entered into by our Company and Hengqin Luzhu LP, our employee incentive platform, Hengqin Luzhu LP subscribed for the increased share capital of our Company of RMB12,307,500 at par value of RMB1.00 per Share. As a result of such subscription, the total issued share capital of our Company increased from RMB127,692,500 to RMB140,000,000, and such increase in share capital was registered with Beijing Tongzhou Market Supervision and Management Bureau (北京市通州區市場監督管理局) on February 25, 2021;
- (b) pursuant to an investment agreement dated August 30, 2021 entered into by our Company with, among others, (i) CCB International Capital Management (Tianjin) Ltd. (建銀國際資本管理(天津)有限公司); (ii) Jinjiang Zhenrui Equity Investment Partnership (Limited Partnership) (晉江禎睿股權投資合夥企業(有限合夥)); (iii) Zhuhai Livzon Pharmaceutical Equity Investment Management Co., Ltd. (珠海市麗珠醫藥股權投資管理有限公司) (iv) Hangzhou Taikun Equity Investment Fund Partnership (Limited Partnership) (杭州泰鯤股權投資基金合夥企業(有限合夥)); (v) Haikou Hengji Rongyu Investment Center (Limited Partnership) (海口恒基榮域投資中心(有限合夥)) (“**Hengji Rongyu**”) and (vi) Beijing Xinchuang Technology Phase I Venture Capital Center (Limited

## APPENDIX VII

## STATUTORY AND GENERAL INFORMATION

Partnership) (北京芯創科技一期創業投資中心(有限合夥)) (the “**Series B Investors**”), the Series B Investors subscribed for the increased share capital of our Company of RMB27,216,175 at a consideration of RMB350.0 million. As a result of such subscription, the total issued share capital of our Company increased from RMB140,000,000 to RMB167,216,175, and such increase in share capital was registered with Beijing Tongzhou Market Supervision and Management Bureau on October 28, 2021;

- (c) pursuant to an investment agreement dated December 31, 2021 entered into by our Company with, among others, (i) Hainan Zhaoan Private Equity Fund Management Partnership (Limited Partnership) (海南兆安私募基金管理合夥企業(有限合夥)); (ii) Hengji Rongyu; (iii) Gongqingcheng Zhenrui Equity Investment Partnership (Limited Partnership) (共青城臻銳股權投資合夥企業(有限合夥)); (iv) Jinjiang Xuanhong No.1 Equity Investment Partnership (Limited Partnership) (晉江軒弘壹號股權投資合夥企業(有限合夥)); and (v) Shaanxi Jinou Investment Fund Partnership (Limited Partnership) (陝西金甌投資基金合夥企業(有限合夥)) (the “**Series B+ Investors**”), the Series B+ Investors subscribed for the increased share capital of our Company of RMB6,674,082 at a consideration of RMB120.0 million. As a result of such subscription, the total issued share capital of our Company increased from RMB167,216,175 to RMB173,890,257 and such increase in share capital was registered with Beijing Tongzhou Market Supervision and Management Bureau on January 28, 2022;
- (d) on May 13, 2022, we resolved to allot and issue to Mr. KONG, Ms. ZHANG and Ms. JIANG, a total of 8,604,513 Shares at par value. As a result, the total issued share capital of our Company increased from RMB173,890,257 to RMB182,584,770, and such increase in share capital was registered with Beijing Tongzhou Market Supervision and Management Bureau on May 25, 2022; and
- (e) pursuant to an investment agreement dated June 16, 2022 entered into by our Company with, among others, (i) Tianjin Huapu Biopharmaceutical Technology Partnership (Limited Partnership) (天津華普生物醫藥科技合夥企業(有限合夥)); (ii) Beijing Xinyin Xinghong Equity Investment Partnership (Limited Partnership) (北京信銀興弘股權投資合夥企業(有限合夥)); (iii) Zibo Runxin Xinchuang Investment Partnership (Limited Partnership) (淄博潤信芯創投資合夥企業(有限合夥)); (iv) Zibo Runwen Kangju Equity Investment Partnership (Limited Partnership) (淄博潤文康聚股權投資合夥企業(有限合夥)); (v) Beijing Yizhuang II; and (vi) Hengji Rongyu (collectively as the “**Series C Investors**”), the Series C Investors subscribed for the increased share capital of our Company of RMB9,478,262 at a consideration of RMB218.0 million. As a result of such subscription, the total issued share capital of our Company increased from RMB182,584,770 to RMB192,063,032 and such increase in share capital was registered with Beijing Tongzhou Market Supervision and Management Bureau on June 17, 2022.

Assuming the [REDACTED] is not exercised, upon completion of the [REDACTED], our share capital will be increased to RMB[REDACTED], made up of [REDACTED] Domestic Shares and [REDACTED] H Shares fully paid up or credited as fully paid up, representing approximately [REDACTED]% and [REDACTED]% of our share capital, respectively. For more details, see “History, Development and Corporate Structure — Our corporate developments” in this document.

Save as disclosed above, there has been no alteration in our total issued share capital within the two years immediately preceding the date of publication of this document.



## APPENDIX VII

## STATUTORY AND GENERAL INFORMATION

### 3. Changes in the Share Capital of Our Subsidiaries

A summary of the corporate information and the particulars of our subsidiaries are set out in Note 36 to the Accountants’ Report as set out in Appendix I to this document.

Save as disclosed below, there has been no alteration in the total issued share capital of our subsidiaries within two years immediately preceding the date of this document.

In April 2022, the registered capital of Zhuhai Luzhu, our wholly-owned subsidiary, was increased from RMB100.0 million to RMB200.0 million.

### 4. Resolutions of Shareholders of our Company

Pursuant to the resolutions passed at a duly convened general meeting of our Shareholders on June 18, 2022, it was resolved, among others:

- (a) our H Shares to be [REDACTED] on the Stock Exchange be issued; and
- (b) authorizing our Board to handle all relevant matters relating to, among other things, the implementation of issuance of H Shares and the [REDACTED].

Pursuant to the resolutions passed at a duly convened general meeting of our Shareholders on April 10, 2023, the Articles of Association was approved and adopted and shall become effective upon the [REDACTED].

### 5. Restrictions on Repurchase

See Appendices IV and V to this document for details.

## APPENDIX VII

## STATUTORY AND GENERAL INFORMATION

### B. FURTHER INFORMATION ABOUT THE BUSINESS OF OUR COMPANY

#### 1. Summary of Material Contracts

The following contracts (not being contract entered into in the ordinary course of business) were entered into by our Company within the two years preceding the date of this document and are or may be material:

- (a) an investment agreement (投資協議) dated August 30, 2021 entered into among (i) CCB International Capital Management (Tianjin) Ltd. (建銀國際資本管理(天津)有限公司); (ii) Jinjiang Zhenrui Equity Investment Partnership (Limited Partnership) (晉江禎睿股權投資合夥企業(有限合夥)); (iii) Zhuhai Livzon Pharmaceutical Equity Investment Management Co., Ltd. (珠海市麗珠醫藥股權投資管理有限公司); (iv) Hangzhou Taikun Equity Investment Fund Partnership (Limited Partnership) (杭州泰鯤股權投資基金合夥企業(有限合夥)); (v) Haikou Hengji Rongyu Investment Center (Limited Partnership) (海口恒基榮域投資中心(有限合夥)); (vi) Beijing Xinchuang Technology Phase I Venture Capital Center (Limited Partnership) (北京芯創科技一期創業投資中心(有限合夥)) (collectively, the “**Series B Investors**”); (vii) Beijing Yizhuang Biological Medicine Investment Center (Limited Partnership) (北京亦莊生物醫藥併購投資中心(有限合夥)); (viii) Beijing Science Sun Pharmaceutical Co., Ltd. (北京賽升藥業股份有限公司); (ix) Beijing Yizhuang II Biological Medical Industry Investment Fund (Limited Partnership) (北京亦莊二期生物醫藥產業投資基金(有限合夥)); (x) KONG Jian (孔健); (xi) ZHANG Yanping (張琰平); (xii) Beijing Luzhu Biotechnology Co., Ltd. (北京綠竹生物技術股份有限公司); (xiii) Zhuhai Hengqin Luzhu Enterprise Management Partnership (Limited Partnership) (珠海橫琴綠竹企業管理合夥企業(有限合夥)); (xiv) JIANG Xianmin (蔣先敏); (xv) KONG Xi (孔茜); (xvi) ZHOU Peng (周朋); (xvii) HUANG Ying (黃穎); (xviii) ZHONG Siyu (鍾思雨); and (xix) CHEN Qingyun (陳清雲), pursuant to which the Series B Investors agreed to subscribe for registered capital of Beijing Luzhu Biotechnology Co., Ltd. (北京綠竹生物技術股份有限公司) in the amount of RMB27,216,175 (which correspond with 27,216,175 shares of Beijing Luzhu Biotechnology Co., Ltd. (北京綠竹生物技術股份有限公司)) at a total consideration of RMB350,000,000;
- (b) an investment agreement (投資協議) dated December 31, 2021 entered into among (i) Hainan Zhaoan Private Equity Fund Management Partnership (Limited Partnership) (海南兆安私募基金管理合夥企業(有限合夥)); (ii) Haikou Hengji Rongyu Investment Center (Limited Partnership) (海口恒基榮域投資中心(有限合夥)); (iii) Gongqingcheng Zhenrui Equity Investment Partnership (Limited Partnership) (共青城臻銳股權投資合夥企業(有限合夥)); (iv) Jinjiang Xuanhong No.1 Equity Investment Partnership (Limited Partnership) (晉江軒弘壹號股權投資合夥企業(有限合夥)); (v) Shaanxi Jinou Investment Fund Partnership (Limited Partnership) (陝西金甌投資基金合夥企業(有限合夥)) (collectively, the “**Series B+ Investors**”); (vi) CCB International Capital Management (Tianjin) Ltd. (建銀國際資本管理(天津)有限公司); (vii) Jinjiang Zhenrui Equity Investment Partnership (Limited Partnership) (晉江禎睿股權投資合夥企業(有限合夥)); (viii) Zhuhai Livzon Pharmaceutical Equity Investment Management Co., Ltd. (珠海市麗珠醫藥股權投資管理有限公司); (ix) Hangzhou Taikun Equity Investment Fund Partnership (Limited Partnership) (杭州泰鯤股權投資基金合夥企業(有限合夥)); (x) Haikou Hengji Rongyu Investment Center (Limited Partnership) (海口恒基榮域投資中心(有限合夥)); (xi)

APPENDIX VII

STATUTORY AND GENERAL INFORMATION

- Beijing Xinchuang Technology Phase I Venture Capital Center (Limited Partnership) (北京芯創科技一期創業投資中心(有限合夥)); (xii) Beijing Yizhuang Biological Medicine Investment Center (Limited Partnership) (北京亦莊生物醫藥併購投資中心(有限合夥)); (xiii) Beijing Science Sun Pharmaceutical Co., Ltd. (北京賽升藥業股份有限公司); (xiv) Beijing Yizhuang II Biological Medical Industry Investment Fund (Limited Partnership) (北京亦莊二期生物醫藥產業投資基金(有限合夥)); (xv) KONG Jian (孔健); (xvi) ZHANG Yanping (張琰平); (xvii) Beijing Luzhu Biotechnology Co., Ltd. (北京綠竹生物技術股份有限公司); (xviii) Zhuhai Hengqin Luzhu Enterprise Management Partnership (Limited Partnership) (珠海橫琴綠竹企業管理合夥企業(有限合夥)); (xix) JIANG Xianmin (蔣先敏); (xx) KONG Xi (孔茜); (xxi) ZHOU Peng (周朋); (xxii) ZHONG Siyu (鍾思雨); and (xxiii) CHEN Qingyun (陳清雲), pursuant to which the Series B+ Investors agreed to subscribe for registered capital of Beijing Luzhu Biotechnology Co., Ltd. (北京綠竹生物技術股份有限公司) in the amount of RMB6,674,082 (which correspond with 6,674,082 shares of Beijing Luzhu Biotechnology Co., Ltd. (北京綠竹生物技術股份有限公司)) at a total consideration of RMB120,000,000;
- (c) an investment agreement (投資協議) dated June 16, 2022 entered into among (i) Tianjin Huapu Biopharmaceutical Technology Partnership (Limited Partnership) (天津華普生物醫藥科技合夥企業(有限合夥)); (ii) Beijing Yizhuang II Biological Medical Industry Investment Fund (Limited Partnership) (北京亦莊二期生物醫藥產業投資基金(有限合夥)); (iii) Beijing Xinyin Xinghong Equity Investment Partnership (Limited Partnership) (北京信銀興弘股權投資合夥企業(有限合夥)); (iv) Haikou Hengji Rongyu Investment Center (Limited Partnership) (海口恒基榮域投資中心(有限合夥)); (v) Zibo Runxin Xinchuang Investment Partnership (Limited Partnership) (淄博潤信芯創投資合夥企業(有限合夥)); (vi) Zibo Runwen Kangju Equity Investment Partnership (Limited Partnership) (淄博潤文康聚股權投資合夥企業(有限合夥)) (collectively, the “**Series C Investors**”); (vii) Hainan Zhaoan Private Equity Fund Management Partnership (Limited Partnership) (海南兆安私募基金管理合夥企業(有限合夥)); (viii) Haikou Hengji Rongyu Investment Center (Limited Partnership) (海口恒基榮域投資中心(有限合夥)); (ix) Gongqingcheng Zhenrui Equity Investment Partnership (Limited Partnership) (共青城臻銳股權投資合夥企業(有限合夥)); (x) Jinjiang Xuanhong No.1 Equity Investment Partnership (Limited Partnership) (晉江軒弘壹號股權投資合夥企業(有限合夥)); (xi) Shaanxi Jinou Investment Fund Partnership (Limited Partnership) (陝西金甌投資基金合夥企業(有限合夥)); (xii) CCB International Capital Management (Tianjin) Ltd. (建銀國際資本管理(天津)有限公司); (xiii) Jinjiang Zhenrui Equity Investment Partnership (Limited Partnership) (晉江禎睿股權投資合夥企業(有限合夥)); (xiv) Zhuhai Livzon Pharmaceutical Equity Investment Management Co., Ltd. (珠海市麗珠醫藥股權投資管理有限公司); (xv) Hangzhou Taikun Equity Investment Fund Partnership (Limited Partnership) (杭州泰鯤股權投資基金合夥企業(有限合夥)); (xvi) Haikou Hengji Rongyu Investment Center (Limited Partnership) (海口恒基榮域投資中心(有限合夥)); (xvii) Beijing Xinchuang Technology Phase I Venture Capital Center (Limited Partnership) (北京芯創科技一期創業投資中心(有限合夥)); (xviii) Beijing Yizhuang II Biological Medical Industry Investment Fund (Limited Partnership) (北京亦莊二期生物醫藥產業投資基金(有限合夥)); (xix) Beijing Yizhuang Biological Medicine Investment Center (Limited Partnership) (北京亦莊生物醫藥併購投資中心(有限合夥)); (xx) Beijing Science Sun Pharmaceutical Co., Ltd. (北京賽升藥業股份有限公司); (xxi) KONG Jian (孔健); (xxii) ZHANG Yanping (張琰平); (xxiii) Beijing Luzhu Biotechnology Co., Ltd. (北京綠竹生物技術股份有限公司); (xxiv) Zhuhai Hengqin Luzhu Enterprise Management Partnership (Limited Partnership) (珠海橫琴綠竹企業管理合夥企業(有限合夥)); (xxv) JIANG Xianmin (蔣先敏); (xxvi) KONG Xi

**APPENDIX VII**

**STATUTORY AND GENERAL INFORMATION**

- (孔茜); (xxvii) ZHOU Peng (周朋); (xxviii) ZHONG Siyu (鍾思雨); and (xxix) CHEN Qingyun (陳清雲), pursuant to which the Series C Investors agreed to subscribe for registered capital of Beijing Luzhu Biotechnology Co., Ltd. (北京綠竹生物技術股份有限公司) in the amount of RMB9,478,262 (which correspond with 9,478,262 shares of Beijing Luzhu Biotechnology Co., Ltd. (北京綠竹生物技術股份有限公司)) at a total consideration of RMB218,000,000;
- (d) a non-competition undertaking dated March 30, 2023 entered into among KONG Jian (孔健), ZHANG Yanping (張琰平), Zhuhai Hengqin Luzhu Enterprise Management Partnership (Limited Partnership) (珠海橫琴綠竹企業管理合夥企業(有限合夥)) and Beijing Luzhu Biotechnology Co., Ltd. (北京綠竹生物技術股份有限公司) (for itself and on behalf of its subsidiaries from time to time), details of which are set out in “Relationship with Controlling Shareholders — Non-Competition Undertaking” in this document; and
- (e) the [REDACTED].

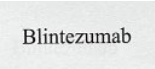
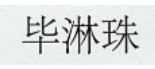

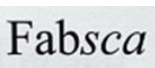



APPENDIX VII

STATUTORY AND GENERAL INFORMATION

2. Our Material Intellectual Property Rights

(a) Trademarks

As of the Latest Practicable Date, we had registered the following trademarks which we consider to be or may be material to our business:

No.	Trademark	Registration Number	Registrant	Class	Place of registration	Expiry date
1		38211621	Luzhu Biotechnology	5	PRC	February 27, 2030
2		38209032	Luzhu Biotechnology	5	PRC	January 13, 2030
3		38202087	Luzhu Biotechnology	42	PRC	February 27, 2030
4		38205838	Luzhu Biotechnology	42	PRC	February 27, 2030
5		59101383	Luzhu Biotechnology	5	PRC	March 27, 2032
6		59072989	Luzhu Biotechnology	35	PRC	March 27, 2032
7		59090541	Luzhu Biotechnology	5	PRC	February 20, 2032
8		59090566	Luzhu Biotechnology	35	PRC	February 20, 2032
9		305828121	Luzhu Biotechnology	5, 42	Hong Kong	December 9, 2031

APPENDIX VII

STATUTORY AND GENERAL INFORMATION

As of the Latest Practicable Date, we had applied for the registration of the following trademarks, which we consider to be or may be material to our business:

No.	Trademark	Application Number	Applicant	Class	Place of application	Date of application
1	 绿竹生物 LUZHU BIOTECH	59093789	Luzhu Biotechnology	5	PRC	September 8, 2021
2	 绿竹生物 LUZHU BIOTECH	59081922	Luzhu Biotechnology	35	PRC	September 8, 2021
3	<b>ForgEvax</b>	59075461	Luzhu Biotechnology	5	PRC	September 8, 2021
4	<b>ForgEvax</b>	59088974	Luzhu Biotechnology	35	PRC	September 8, 2021
5	<b>QuagEvax</b>	59093763	Luzhu Biotechnology	5	PRC	September 8, 2021
6	<b>QuagEvax</b>	59090579	Luzhu Biotechnology	35	PRC	September 8, 2021
7	<b>TetragEvax</b>	59078653	Luzhu Biotechnology	5	PRC	September 8, 2021
8	<b>TetragEvax</b>	59101682	Luzhu Biotechnology	35	PRC	September 8, 2021
9	<b>Zostervax</b>	59089892	Luzhu Biotechnology	5	PRC	September 8, 2021
10	<b>Zostervax</b>	59072970	Luzhu Biotechnology	35	PRC	September 8, 2021
11.	<b>维可兴</b>	68999108	Luzhu Biotechnology	5	PRC	December 26, 2022
12.	<b>维可兴</b>	68997753	Luzhu Biotechnology	35	PRC	December 26, 2022
13.	<b>维可兴</b>	68999962	Luzhu Biotechnology	42	PRC	December 26, 2022

**APPENDIX VII**

**STATUTORY AND GENERAL INFORMATION**

<u>No.</u>	<u>Trademark</u>	<u>Application Number</u>	<u>Applicant</u>	<u>Class</u>	<u>Place of application</u>	<u>Date of application</u>
14.	<b>唯可幸</b>	68995220	Luzhu Biotechnology	5	PRC	December 26, 2022
15.	<b>唯可幸</b>	69002104	Luzhu Biotechnology	35	PRC	December 26, 2022
16.	<b>唯可幸</b>	68997774	Luzhu Biotechnology	42	PRC	December 26, 2022
17.	<b>威必信</b>	68994824	Luzhu Biotechnology	5	PRC	December 26, 2022
18.	<b>威必信</b>	68995239	Luzhu Biotechnology	35	PRC	December 26, 2022
19.	<b>威必信</b>	68994067	Luzhu Biotechnology	42	PRC	December 26, 2022
20.	<b>新格康</b>	69002978	Luzhu Biotechnology	5	PRC	December 26, 2022
21.	<b>新格康</b>	68994025	Luzhu Biotechnology	35	PRC	December 26, 2022
22.	<b>新格康</b>	68991232	Luzhu Biotechnology	42	PRC	December 26, 2022

**(b) Patents**

For a discussion of the details of the material patents and material patent applications by our Company, see “Business — Intellectual Property Rights” in this document.

**(c) Domain Names**

As of the Latest Practicable Date, we owned the following domain name which we consider to be material to or may be material to our business:

<u>No.</u>	<u>Owner</u>	<u>Domain Name</u>	<u>Date of registration</u>	<u>Expiry Date</u>
1.	Luzhu Biotechnology	luzhubiotech.com	June 10, 2010	June 10, 2026

Save as disclosed above, as of the Latest Practicable Date, there were no other trade or service marks, patents, copyrights, intellectual or industrial property rights which were material in relation to our business.

## APPENDIX VII

## STATUTORY AND GENERAL INFORMATION

### 3. Employee Incentive Scheme

The following is a summary of the principal terms of the employee incentive scheme (“**Employee Incentive Scheme**”) approved and adopted by our Company on December 15, 2021 for the purpose of attracting and retaining talents for our Group. Under the Employee Incentive Scheme, eligible participants are granted interests in Hengqin Luzhu LP (“**Restricted Shares**”), our employee incentive platform. As of the Latest Practicable Date, Hengqin Luzhu LP held approximately 6.41% of our total issued Shares. The Employee Incentive Scheme does not involve the grant of options by our Company to subscribe for new Shares.

#### (a) *Purpose*

The purpose of the Employee Incentive Scheme is to attract and retain talents for our Group. The Employee Incentive Scheme fosters shared interests between shareholders of our Company and our management team, thereby furthering our Company’s focus on long-term development.

#### (b) *Eligible participants*

Persons eligible to participate in the Employee Incentive Scheme are the employees and consultants of our Group, and any other person whom the scheme administrator considers appropriate.

#### (c) *Term*

Subject to any early termination due to, among others, the liquidation or cessation of business of the Company, the Employee Incentive Scheme shall be valid and effective for five years commencing on the adoption date of the scheme.

#### (d) *Scheme administration*

Mr. KONG has been authorized by the Board to act as the scheme administrator, and has the authority to, among others, determine the eligible participants of the scheme, the number of Restricted Shares to be granted, the grant price, when the Restricted Shares granted may vest, and the repurchase of Restricted Shares from grantees. Mr. KONG shall abstain from deciding on matters that he has conflict of interest in, and such matters shall be decided by the Board instead.

#### (e) *Vesting of Restricted Shares*

The vesting of the Restricted Shares granted is conditional upon the completion of a qualified [REDACTED] and the expiry of the lock-up period as required by the CSRC (where applicable). In the event that the corresponding employment contract or consultancy agreement of the grantee is terminated (otherwise than due to fault of the grantee) prior to the vesting of the Restricted Shares, such Restricted Shares shall be unconditionally repurchased by persons or entities designated by the scheme administrator at the original grant price (if already paid by the grantee), or nil consideration.



*(f) Realization of economic benefits attached to the Restricted Shares*

Grantees may realize the economic benefits attached to the Restricted Shares by making an application with the general partner of Hengqin Luzhu LP, who shall then sell the underlying Shares held by Hengqin Luzhu LP in the open market and distribute the sale proceeds to the relevant grantees after deducting relevant expenses and taxes. The corresponding Restricted Shares shall then be transferred to the general partner of Hengqin Luzhu LP, or be canceled by way of capital reduction.

*(g) No repurchase of Restricted Shares by our Group*

No members of the Group are required to repurchase any Restricted Shares under the scheme.

APPENDIX VII

STATUTORY AND GENERAL INFORMATION

C. FURTHER INFORMATION ABOUT OUR DIRECTORS, SUPERVISORS AND SUBSTANTIAL SHAREHOLDERS

1. Disclosure of Interests

(a) *Disclosure of Interests of Directors and Supervisors in the share capital of our Company and its associated corporations following completion of the [REDACTED]*

Immediately following the completion of the [REDACTED] and assuming no exercise of the [REDACTED], the interests and/or short positions (as applicable) of our Directors, Supervisors and chief executive of our Company in the shares, underlying shares or debentures of our Company or any associated corporation (within the meaning of Part XV of the SFO) which (a) will have to be notified to our Company and the Stock Exchange pursuant to Divisions 7 and 8 of Part XV of the SFO or (b) will be required, pursuant to section 352 of the SFO, to be entered in the register referred to therein, or (c) will be required, pursuant to the Model Code for Securities Transactions by Directors of Listed Issuers as set out in Appendix 10 to the Listing Rules to be notified to our Company and the Stock Exchange once our H Shares are [REDACTED], will be as follows:

(i) *Interests in our Company*

Name of Shareholder	Nature of interest	As of the Latest Practicable Date		Immediately following the completion of the [REDACTED] (assuming no exercise of the [REDACTED])			
		Number of Domestic Shares <sup>(1)</sup>	Approximate percentage of shareholding in the total issued share capital of our Company	Number of Shares <sup>(1)</sup>	Description of Shares <sup>(6)</sup>	Approximate percentage of shareholding in our Domestic Shares / H Shares (as appropriate) <sup>(6)</sup>	Approximate percentage of shareholding in the total issued share capital of our Company
Mr. KONG	Beneficial interest	58,294,513	30.35%	[REDACTED]	Domestic Shares	[REDACTED]%	[REDACTED]%
	Interest of spouse <sup>(2)</sup>	20,200,000	10.52%	[REDACTED]	H Shares	[REDACTED]%	[REDACTED]%
	Interest in controlled corporation <sup>(3)</sup>	12,307,500	6.41%	[REDACTED]	H Shares	[REDACTED]%	[REDACTED]%
Ms. ZHANG	Beneficial interest	20,200,000	10.52%	[REDACTED]	H Shares	[REDACTED]%	[REDACTED]%
	Interest of spouse <sup>(2)</sup>	58,294,513	30.35%	[REDACTED]	Domestic Shares	[REDACTED]%	[REDACTED]%
	Interest of spouse <sup>(2)</sup>	12,307,500	6.41%	[REDACTED]	H Shares	[REDACTED]%	[REDACTED]%
Ms. JIANG	Beneficial interest	4,000,000	2.08%	[REDACTED]	H Shares	[REDACTED]%	[REDACTED]%
Mr. MA Biao (馬曩)	Interest in controlled corporation <sup>(4)</sup>	51,721,196	26.93%	[REDACTED]	H Shares	[REDACTED]%	[REDACTED]%
Ms. KONG Xi (孔茜)	Beneficial interest	550,000	0.29%	[REDACTED]	H Shares	[REDACTED]%	[REDACTED]%
Ms. PENG Ling (彭玲)	Interest in controlled corporation <sup>(5)</sup>	12,307,500	6.41%	[REDACTED]	H Shares	[REDACTED]%	[REDACTED]%

## APPENDIX VII

## STATUTORY AND GENERAL INFORMATION

*Notes:*

- (1) All interests stated are long positions.
- (2) Mr. KONG and Ms. ZHANG are the spouse of each other. Accordingly, they are deemed to be interested in the same number of Shares that the other person is interested in for the purpose of the SFO.
- (3) These Shares are held by Hengqin Luzhu LP. As of the Latest Practicable Date, Mr. KONG was the sole general partner of Hengqin Luzhu LP. Therefore, Mr. KONG is deemed to be interested in the Shares held by Hengqin Luzhu LP under the SFO. For details, see “Substantial Shareholders” in this document.
- (4) These Shares are held by Beijing Yizhuang, Beijing Yizhuang II and Beijing Science Sun, in which Mr. MA Biao is deemed to be interested under the SFO. For details, see “Substantial Shareholders” in this document.
- (5) These Shares are held by Hengqin Luzhu LP in which Ms. PENG Ling (彭玲) is deemed to be interested in under the SFO. As of the Latest Practicable Date, Hengqin Luzhu LP was owned as to 40.67% by Beijing Luzhu Kangrui, and Ms. PENG Ling (彭玲) was the general partner of Beijing Luzhu Kangrui. For details, see “Substantial Shareholders” in this document.
- (6) For the avoidance of doubt, both Domestic Shares and H Shares are ordinary Shares in the share capital of our Company, and are considered as one class of Shares.

*(ii) Interests in associated corporations of our Company*

To the best knowledge of the Directors, none of our Directors, Supervisors or chief executive of our Company has interests or short positions in the shares, underlying shares or debentures of the associated corporations of our Company.

***(b) Disclosure of Interests of Substantial Shareholders***

Same as disclosed in “Substantial Shareholders” in this document, immediately following the completion of the [REDACTED] and assuming that the [REDACTED] is not exercised, our Directors are not aware of any person (not being a Director or chief executive of our Company) who will have interests or short positions in our Shares or underlying Shares which would be required to be disclosed to us and the Stock Exchange under the provisions of Divisions 2 and 3 of Part XV of the SFO, or, directly or indirectly, be interested in 10% or more of the nominal value of any class of share capital carrying the rights to vote in all circumstances at general meetings of our Company or any other members of our Group.

### **2. Particulars of Directors’ and Supervisors’ Service Contracts**

Pursuant to Rules 19A.54 and 19A.55 of the Listing Rules, we [have] entered into a contract with each of our Directors and Supervisors in respect of, among other things, (i) compliance with relevant laws of regulations, (ii) observance of the Articles of Association, and (iii) provisions on arbitration.

Save as disclosed in this document, none of the Directors or Supervisors has or is proposed to have a service contract with any member of our Group (other than contracts expiring or determinable by the relevant employer within one year without the payment of compensation other than statutory compensation).

## APPENDIX VII

## STATUTORY AND GENERAL INFORMATION

### 3. Remuneration of Directors and Supervisors

The aggregate amount of remuneration paid or payable to our Directors and Supervisors (including salaries, remuneration, pension, discretionary bonus, share-based payments and other welfares) for the two years ended December 31, 2021 and 2022 were approximately RMB47.6 million and RMB85.3 million, respectively.

It is estimated that, under the arrangements currently in force, the aggregate amount of remuneration payable to our Directors and Supervisors for the year ending December 31, 2023 will be approximately RMB51.8 million (excluding any discretionary bonus but including historical share-based payment expenses).

The aggregate amount of remuneration which were paid or payable by our Group to our five highest paid individuals for the two years ended December 31, 2021 and 2022 were approximately RMB67.1 million and RMB87.6 million, respectively.

During the Track Record Period, no fees were paid by our Group to any of our Directors, Supervisors or the five highest paid individuals as an inducement to join us or as compensation for loss of office, and there has been no arrangement under which a Director or Supervisor has waived or agreed to waive any emoluments.

### 4. Disclaimers

Save as disclosed in this document,

- (a) none of our Directors, Supervisors or our chief executive has any interest or short position in the shares, underlying shares or debentures of us or any of our associated corporations (within the meaning of Part XV the SFO) which will have to be notified to us and the Stock Exchange pursuant to Divisions 7 and 8 of Part XV of the SFO, or which will be required, pursuant to section 352 of the SFO, to be entered in the register referred to therein, or which will be required to be notified to us and the Stock Exchange pursuant to Model Code for Securities Transactions by Directors of Listed Issuers as set out in the Appendix 10 to the Listing Rules once the H Shares are [REDACTED] on the Stock Exchange;
- (b) none of our Directors or Supervisors is aware of any person (not being a Director or chief executive of our Company) who will, immediately following completion of the [REDACTED] (without taking into account any H Shares which may be allotted and issued pursuant to the exercise of the [REDACTED]), have an interest or short position in the Shares or underlying Shares which would fall to be disclosed to us under the provisions of Divisions 2 and 3 of Part XV of the SFO or who is interested, directly or indirectly, in 10% or more of the nominal value of any class of share capital carrying the rights to vote in all circumstances at general meetings of our Company or any other member of our Group; and

## APPENDIX VII

## STATUTORY AND GENERAL INFORMATION

- (c) so far as is known to our Directors, none of our Directors, Supervisors, their respective close associates (as defined under the Listing Rules) or Shareholders who own more than 5% of the number of issued Shares have any interests in the five largest customers or the five largest suppliers of our Group;
- (d) save as disclosed in this document, none of our Directors, Supervisors or any of the parties listed in “— 8. Qualifications of Experts” in this section is:
  - (i) interested in our promotion, or in any assets which have been, within two years immediately preceding the date of this document, acquired or disposed of by or leased to us, or are proposed to be acquired or disposed of by or leased to any member of our Group; or
  - (ii) materially interested in any contract or arrangement subsisting at the date of this document which is significant in relation to our business.

### D. OTHER INFORMATION

#### 1. Estate Duty

Our Directors have been advised that no material liability for estate duty is likely to fall on our Company or any of our subsidiaries under the laws of the PRC.

#### 2. Litigation

Except as disclosed in this document, as of the Latest Practicable Date, we were not engaged in any litigation, arbitration or claim of material importance and no litigation, arbitration or claim of material importance is known to our Directors to be pending or threatened by or against any member of our Group, that would have a material adverse effect on our Group’s results of operations or financial condition, taken as a whole.

#### 3. Preliminary Expenses

As of the Latest Practicable Date, our Company had not incurred material preliminary expenses.

#### 4. Promoter

The promoters of our Company comprised Mr. KONG, Ms. ZHANG and Ms. JIANG. Save as disclosed in this document, within the two years preceding the date of this document, no cash, securities or other benefit has been paid, allotted or given or is proposed to be paid, allotted or given to any promoter in connection with the [REDACTED] and the related transactions described in this document.

#### 5. Taxation of Holders of H Shares

The sale, purchase and transfer of H Shares are subject to Hong Kong stamp duty if such sale, purchase and transfer are effected on the H Share register of members of our Company, including in circumstances where such transactions are effected on the Stock Exchange. The current rate of Hong Kong stamp duty for such sale, purchase and transfer is 0.13% of the consideration or, if higher, the fair value of the H Shares being sold or transferred.

## APPENDIX VII

## STATUTORY AND GENERAL INFORMATION

### 6. Application for [REDACTED]

The Sole Sponsor has made an application on behalf of our Company to the [REDACTED] Committee for the [REDACTED] of, and permission to [REDACTED], the H Shares in issue and to be issued as mentioned in this document. All necessary arrangements have been made to enable the securities to be admitted into [REDACTED].

### 7. No Material Adverse Change

Save as disclosed in this document, our Directors has confirmed that there has been no material adverse change in the financial or trading position of our Group since December 31, 2022 (being the date to which our Company’s latest consolidated audited financial results were prepared).

### 8. Qualification of Experts

The qualifications of the experts (as defined under the Listing Rules and the Companies (Winding Up and Miscellaneous Provisions) Ordinance) who have given their opinion and/or advice in this document are as follows:

<u>Name</u>	<u>Qualification</u>
China International Capital Corporation Hong Kong Securities Limited	A licensed corporation under the SFO for type 1 (dealing in securities), type 2 (dealing in futures contracts), type 4 (advising on securities), type 5 (advising on futures contracts) and type 6 (advising on corporate finance) of the regulated activities as defined under the SFO
Deloitte Touche Tohmatsu	Certified Public Accountants under Professional Accountant Ordinance (Chapter 50 of the Laws of Hong Kong) and Registered Public Interest Entity Auditor under Accounting and Financial Reporting Council Ordinance (Chapter 588 of the Laws of Hong Kong)
Commerce & Finance Law Offices	Legal advisor to our Company as to PRC law
Frost & Sullivan (Beijing) Inc., Shanghai Branch Co.	Independent industry consultant
Hiways Law Firm	Legal advisor to our Company as to PRC intellectual property related law
Savills Valuation and Professional Services (China) Limited	Independent property valuer

## APPENDIX VII

## STATUTORY AND GENERAL INFORMATION

### 9. Consents of Experts

Each of the experts as referred to in the paragraph headed “— 8. Qualification of Experts” in this section has given, and has not withdrawn their written consents to the issue of this document with the inclusion of their reports and/or letters and/or opinions and/or the references to their names included herein in the form and context in which they are respectively included.

None of the experts named above has any shareholding interests in our Company or the right (whether legally enforceable or not) to subscribe for or to nominate persons to subscribe for securities in our Company.

### 10. Sole Sponsor’s Independence

The Sole Sponsor satisfies the independence criteria applicable to sponsors set out in Rule 3A.07 of the Listing Rules.

The Sole Sponsor’s fees payable by us in respect of the Sole Sponsor’s services as sponsor for the [REDACTED] are US\$1,300,000.

### 11. Binding Effect

This document shall have the effect, if an application is made in pursuance hereof, of rendering all persons concerned bound by all the provisions (other than the penal provisions) of sections 44A and 44B of the Companies (Winding Up and Miscellaneous Provisions) Ordinance so far as applicable.

### 12. Bilingual Document

The English language and Chinese language versions of this document are being published separately in reliance upon the exemption provided by section 4 of the Companies (Exemption of Companies and Prospectuses from Compliance with Provisions) Notice (Chapter 32L of the Laws of Hong Kong).

This document is written in the English language and contains a Chinese translation for information purposes only. Should there be any discrepancy between the English language of this document and the Chinese translation, the English language version of this document shall prevail.

### 13. Miscellaneous

Save as disclosed in this document:

- (a) within the two years preceding the date of this document, our Company has not issued nor agreed to issue any share or loan capital fully or partly paid either for cash or for a consideration other than cash;
- (b) no share or loan capital of our Company is under option or is agreed conditionally or unconditionally to be put under option;

**APPENDIX VII**

**STATUTORY AND GENERAL INFORMATION**

---

- (c) our Company has not issued nor agreed to issue founder, management or deferred shares or any deferred debentures;
- (d) our Company has no outstanding convertible debt securities;
- (e) within the two years immediately preceding the date of this document, no commission, discount, brokerage or other special term has been granted or agreed to be granted in connection with the issue or sale of any capital of our Company any of our subsidiaries;
- (f) there is no arrangement under which future dividends are waived or agreed to be waived;
- (g) there has been no interruption in our business which may have or have had a significant effect on the financial position in the last 12 months;
- (h) our Company is not presently listed on any stock exchange or traded on any trading system;  
and
- (i) our Company currently does not intend to apply for the status of a sino-foreign investment joint stock limited company and does not expect to be subject to the Sino-Foreign Joint Venture Law of the PRC.



## APPENDIX VIII DOCUMENTS DELIVERED TO THE REGISTRAR OF COMPANIES AND AVAILABLE ON DISPLAY

### DOCUMENTS DELIVERED TO THE REGISTRAR OF COMPANIES

The documents attached to a copy of this document and delivered to the Registrar of Companies in Hong Kong for registration were (i) a copy of the [REDACTED]; (ii) a copy of each of the material contracts referred to in the paragraph headed “B. Further Information about the Business of our Company — 1. Summary of Material Contracts” in Appendix VII to this document; and (iii) the written consents issued by each of the experts and referred to in paragraph headed “D. Other information — 8. Qualifications of Experts” in Appendix VII to this document.

### DOCUMENTS AVAILABLE ON DISPLAY

Copies of the following documents will be available on display on the website of the Stock Exchange at [www.hkexnews.hk](http://www.hkexnews.hk) and our website at [www.luzhubiotech.com](http://www.luzhubiotech.com) during a period of 14 days from the date of this document:

- (a) the Articles of Association;
- (b) the Accountants’ Report prepared by Deloitte Touche Tohmatsu, the text of which is set out in Appendix I to this document;
- (c) the audited consolidated financial statements of our Group for the two years ended December 31, 2021 and 2022;
- (d) the report received from Deloitte Touche Tohmatsu on the unaudited [REDACTED] financial information of our Group, the text of which is set out in Appendix II to this document;
- (e) the letter, summary of values and valuation report relating to our property interests prepared by Savills Valuation and Professional Services (China) Limited, the text of which is set out in Appendix III to this document;
- (f) the industry report prepared by Frost & Sullivan (Beijing) Inc., Shanghai Branch Co.;
- (g) the PRC legal opinions issued by Commerce & Finance Law Offices, our legal advisors as to PRC law, in respect of certain aspects and the property interests of our Group;
- (h) the material contracts referred to in the paragraph headed “B. Further Information about the Business of our Company — 1. Summary of Material Contract” in Appendix VII to this document;
- (i) the service agreements and letters of appointment referred to in “C. Further Information about Directors and Substantial Shareholders — 2. Particulars of Directors’ and Supervisors’ Service Contracts” in Appendix VII to this document;
- (j) the written consents referred to in the paragraph headed “D. Other Information — 9. Consents of Experts” in Appendix VII to this document; and
- (k) the PRC Company Law and the Trial Administrative Measures of Overseas Securities Offering and Listing by Domestic Companies, together with unofficial English translations thereof.