

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 ⁽¹⁾	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 ⁽²⁾	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- α 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[®], 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 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[®], indicating that the immunogenicity of LZ901 is not inferior to that of Shingrix[®].

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

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[®] 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. 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[®], 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[®], and four herpes zoster vaccines under development in the U.S. In November 2020, Zostavax[®] 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.⁽¹⁾ 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[®] 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[®], indicating that the immunogenicity of LZ901 is not inferior to that of Shingrix[®].

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[®] 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- α 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- α inhibitor marketed by AbbVie Inc. under the brand name Humira[®]. Humira[®] 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[®] expired in Europe in October 2018, and is expected to expire in the U.S. in 2023. The launch of biosimilars of Humira[®] led to the declined sales of Humira[®] in Europe since 2019. Humira[®] 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[®] 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[®] (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. 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[®]. 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[®]; (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 2.6×10^{-9} 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 ⁽²⁾
					Before Track Record Period	During Track Record Period ⁽¹⁾	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 ⁽³⁾	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 ⁽⁴⁾	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[®] 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:

	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)
Loss before tax	(539,357)	(725,180)
Loss and total comprehensive expense for the year	(539,357)	(725,180)

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>
Total non-current assets	151,602	469,166
Total current assets	574,293	601,004
Total assets	725,895	1,070,170
Total non-current liabilities	1,286,998	38,590
Total current liabilities	23,422	94,114
Net current assets	550,871	506,890
Total liabilities	1,310,420	132,704
Net (liabilities) assets	(584,525)	937,466

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
Cash and cash equivalents at end of the year	32,030	68,976

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 ⁽¹⁾	24.5	6.4
Quick ratio ⁽²⁾	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[®] 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] ⁽¹⁾	HK\$[REDACTED]	HK\$[REDACTED]
Unaudited [REDACTED] adjusted consolidated net tangible assets per Share ⁽²⁾	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.