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Post Hearing Information Pack of



Qyuns Therapeutics Co., Ltd.

江蘇荃信生物醫藥股份有限公司

(the “Company”)

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

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Qyuns Therapeutics Co., Ltd. 江蘇荃信生物醫藥股份有限公司

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

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Number of [REDACTED] under : [REDACTED] H Shares
the [REDACTED]
Number of [REDACTED] : [REDACTED] H Shares (subject to
[REDACTED])
Number of [REDACTED] : [REDACTED] H Shares (subject to
[REDACTED])
Maximum [REDACTED] : HK\$[REDACTED] per [REDACTED],
plus brokerage of 1.0%, SFC
transaction levy of 0.0027%, Stock
Exchange trading fee of 0.00565% and
AFRC transaction levy of 0.00015%
(payable in full on application in Hong
Kong dollars and subject to refund)
Nominal Value : RMB1.00 per H Share
[REDACTED] : [REDACTED]

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[REDACTED]

EXPECTED TIMETABLE⁽¹⁾

[REDACTED]

EXPECTED TIMETABLE⁽¹⁾

[REDACTED]

EXPECTED TIMETABLE⁽¹⁾

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SUMMARY

This summary aims to give you an overview of the information contained in this document. As this is a summary, it does not contain all the information that may be important to you. You should read this document in its entirety before you decide to invest in the [REDACTED]. There are risks associated with any investment. Some of the particular risks in investing in the [REDACTED] are set out in “Risk Factors” of this document. You should read that section carefully before you decide to invest in the [REDACTED]. In particular, we are a biotech company [REDACTED] on the Main Board of the Stock Exchange under Chapter 18A of the Listing Rules on the basis that we are unable to meet the requirements under Rule 8.05(1), (2) or (3) of the Listing Rules. There are unique challenges, risks and uncertainties associated with investing in companies such as ours. Your investment decision should be made in light of these considerations.

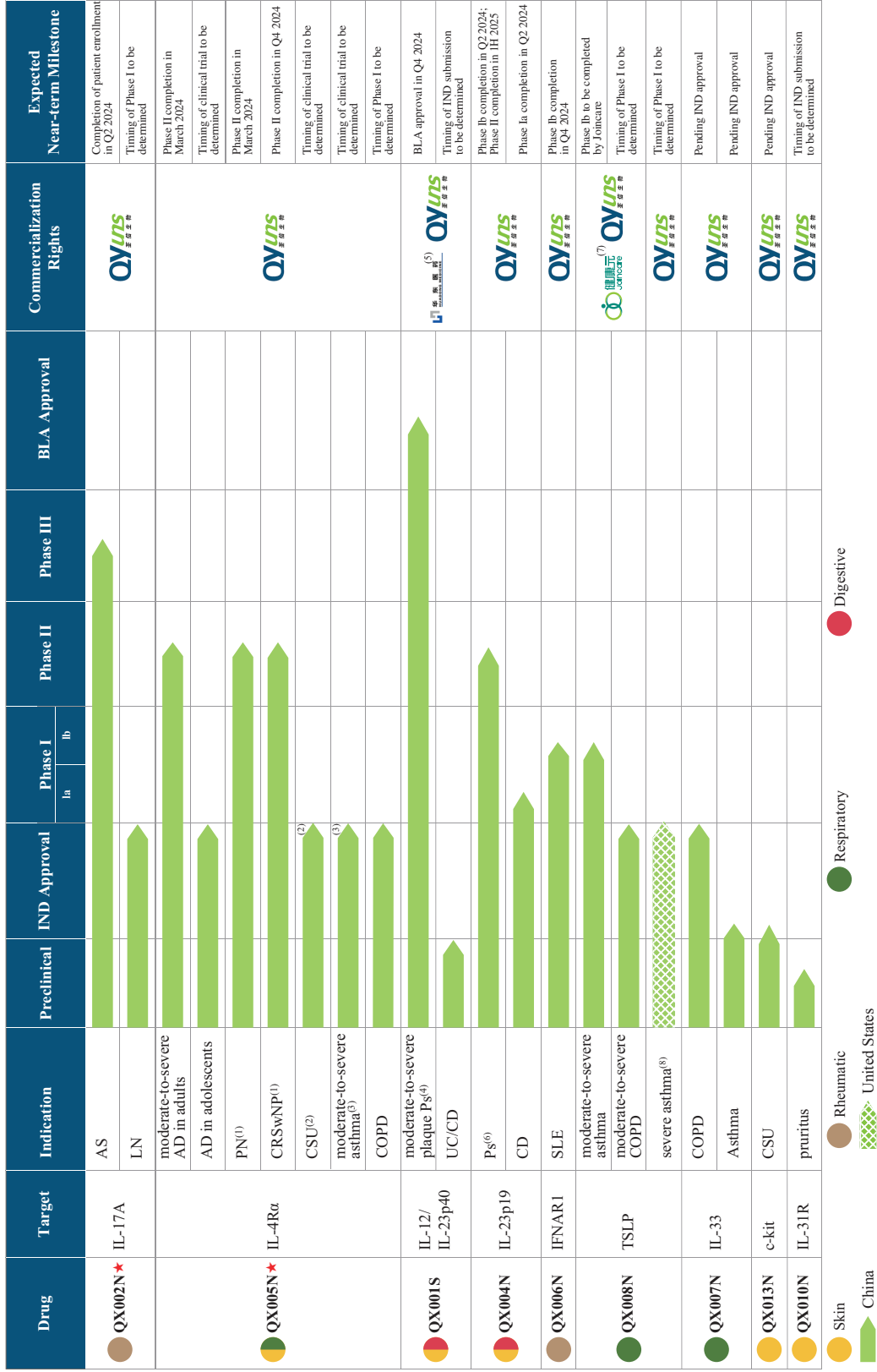
OVERVIEW

Founded in 2015, we are a clinical-stage biotech company exclusively focused on biologic therapies for autoimmune and allergic diseases. We have two Core Products, QX002N and QX005N, both of which are self-developed. QX002N is an IL-17A inhibitor and we have initiated a Phase III clinical trial for ankylosing spondylitis (AS) in China. QX005N is a monoclonal antibody (mAb) blocking IL-4R α and we have initiated Phase II clinical trials for atopic dermatitis (AD), prurigo nodularis (PN) and chronic rhinosinusitis with nasal polyps (CRSwNP) in China. As of the Latest Practicable Date, we had seven other pipeline drug candidates in addition to our Core Products, four of which were in the clinical stage. Our pipeline covers four major areas in the autoimmune and allergic disease field, namely, skin, rheumatic, respiratory and digestive diseases.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET OUR CORE PRODUCTS AND OTHER PIPELINE PRODUCTS SUCCESSFULLY.

SUMMARY

The following chart summarizes our portfolio of drug candidates as of February 20, 2024.



SUMMARY

★ Core Product

AD: atopic dermatitis

AS: ankylosing spondylitis

CD: Crohn’s disease

COPD: chronic obstructive pulmonary disease

CRSwNP: chronic rhinosinusitis with nasal polyps

CSU: chronic spontaneous urticaria

LN: lupus nephritis

PN: prurigo nodularis

Ps: psoriasis

SLE: systemic lupus erythematosus

UC: ulcerative colitis

IFNAR1: interferon-alpha/beta receptor subunit 1

IL-4R α : interleukin-4 receptor subunit α

IL-12/IL-23p40: interleukin-12/interleukin-23

subunit p40

IL-17A: interleukin-17A

IL-23p19: interleukin-23 subunit p19

IL-31R: interleukin-31 receptor

IL-33: interleukin-33

TSLP: thymic stromal lymphopoietin

Notes:

- (1) We directly commenced a Phase II clinical trial of QX005N for PN and a Phase II clinical trial of QX005N for CRSwNP by leveraging the Phase Ia clinical trial results of QX005N in healthy subjects and the Phase Ib clinical trial results of QX005N for moderate-to-severe AD in adults.
- (2) We plan to consult with the NMPA about directly initiating a Phase III clinical trial of QX005N for CSU by leveraging the Phase I clinical trial results of QX005N for moderate-to-severe AD in adults as well as the Phase II clinical trial results of QX005N for moderate-to-severe AD in adults and/or PN.
- (3) We plan to consult with the NMPA about directly initiating a Phase III clinical trial of QX005N for asthma by leveraging the Phase I clinical trial results of QX005N for moderate-to-severe AD in adults as well as the Phase II clinical trial results of QX005N for CRSwNP.
- (4) Zhongmei Huadong and we directly commenced the Phase III clinical trial of QX001S for Ps after completion of the Phase I clinical trial as Phase II clinical trials are not required for biosimilars.
- (5) In August 2020, we entered into a collaboration agreement with Zhongmei Huadong, a subsidiary of Huadong Medicine, with respect to the joint development and exclusive commercialization of QX001S in China. We retain the exclusive development and commercialization rights of QX001S outside China. For further details, please refer to “Business—Collaboration with Zhongmei Huadong.”
- (6) As of February 20, 2024, we had completed subject enrollment for both the Phase Ib clinical trial and the Phase II clinical trial of QX004N for Ps. We expect to complete the Phase Ib clinical trial in the second quarter of 2024.
- (7) In January 2024, we entered into a technology transfer agreement with Joincare Pharmaceutical Group Industry Co., Ltd. (“Joincare”), to grant Joincare an exclusive license to develop, manufacture and commercialize QX008N in mainland China, Hong Kong and Macau. Joincare will be responsible for the BLA application and will be the MAH of QX008N in the licensed territory, once approved. We retain the exclusive rights to develop, manufacture and commercialize QX008N outside the licensed territory. See “Business—Our Other Key Product Candidates—QX008N—Licenses, Rights and Obligations” for details.
- (8) We obtained an IND approval of QX008N for the treatment of severe asthma from the FDA in September 2022 and intend to formulate a clinical development plan for QX008N in the United States depending on the data from our Phase Ia and Phase Ib clinical trials in China.

SUMMARY

Our Core Products

QX002N

One of our Core Products, QX002N, is a high-affinity monoclonal antibody (mAb) targeting IL-17A, a key player in the pathological mechanism of various autoimmune diseases. IL-17A inhibitors are recommended by prevailing clinical guidelines as second-line standalone treatment (the same designation as TNF inhibitors) for AS patients with high disease activity after receiving first-line traditional treatments. Between the two classes of biologics (*i.e.*, TNF inhibitors and IL-17A inhibitors), IL-17A inhibitors have shown clear clinical benefit in patients who are intolerant to or fail to achieve adequate disease control with TNF- α inhibitors.

We have obtained IND approval for QX002N for AS and LN and plan to prioritize the development of the former indication. QX002N demonstrated promising efficacy in our Phase Ib and Phase II clinical trials for AS. In our Phase Ib clinical trial, 62.5% and 37.5% of subjects receiving QX002N (160 mg) once every 2 weeks achieved Assessment of Spondyloarthritis International Society 20 (ASAS20, defined as 20% improvement from baseline in the ASAS score) and ASAS40 (defined as 40% improvement from baseline in the ASAS score) responses at week 16, respectively. In our Phase II clinical trial, the ASAS20 and ASAS40 response rates of subjects receiving QX002N (160 mg) once every 4 weeks reached 60.0% and 40.0% at week 16, respectively. ASAS20 and ASAS40 indicate 20% and 40% improvement, respectively, from baseline in the ASAS score, a widely used measurement of symptom improvement for AS patients. We conducted a pre-Phase III consultation with the NMPA, which raised no material questions and confirmed that it had no objections to the commencement of such trial in its official response in July 2023. We commenced the Phase III clinical trial in September 2023 and expect to complete it in the second half of 2025.

Addressable Market and Competitive Landscape

According to Frost & Sullivan, the prevalence of AS in China was 3.9 million in 2022, and is estimated to reach 4.0 million in 2030. The AS drug market in China was US\$1.8 billion in 2022, and is estimated to reach US\$6.5 billion in 2030, at a CAGR of 17.4%. Upon its approval and commercialization, we expect QX002N to face intense competition from approved biologic drugs from multinational pharmaceutical companies as well as potential competition from drug candidates in clinical development in China for AS. As of the Latest Practicable Date, such drugs and drug candidates were exclusively TNF inhibitors and IL-17 inhibitors. The TNF inhibitors include adalimumab and numerous adalimumab biosimilars and proposed biosimilars. As of the Latest Practicable Date, there were two IL-17A antibody drugs approved for AS treatment in China, namely, secukinumab and ixekizumab, both of which had also been approved by the FDA. As of the same date, in addition to our QX002N, there were ten IL-17-targeting biologic drug candidates indicated for AS in the clinical stage in China. The following table sets forth details of QX002N and IL-17 antibody drugs or drug candidates for AS in the clinical stage in China as of the Latest Practicable Date.

SUMMARY

Marketed IL-17A Inhibitors for AS in China

Target	Brand Name	INN	Company	NMPA Approval Time	Median Price ⁽¹⁾	NRDL Inclusion	Expected Patent Expiration ⁽²⁾
IL-17A	Cosentyx	Secukinumab	Novartis	2020	1,188.0	Yes	2025
	Taltz	Ixekizumab	Eli Lilly	2022	1,218.0	Yes	2026

Clinical-Stage IL-17A Inhibitor Candidates for AS in China

Target	Drug Code	Company	Status	First Posted Date
IL-17A	GR1501	GenrixBio	BLA submission	2024-01-04
	SHR-1314	Hengrui	BLA submission	2024-02-08
	Netakimab	Biocad	Phase III	2022-09-30
	QX002N	the Company	Phase III	2023-08-31
	AK111	Akeso	Phase III	2023-10-08
	JS005	Junshi Bioscience	Phase II	2021-09-30
	HB0017	Huabo	Phase II	2023-04-12
	SSGJ-608	SunShine Guojian	Phase II	2024-01-29
	Secukinumab-CMAB015	MabPharm	Phase I	2023-01-18
IL-17A, IL-17F	Bimekizumab	UCB Pharma	BLA submission	2023-07-20
	LZM012	Livzon	Phase III	2023-07-28

Source: Frost & Sullivan Report (based on annual reports of relevant companies and information published by the NMPA)

Notes:

- (1) Reflects the NRDL median price for minimum formulation unit in 2022 in RMB.
- (2) Reflects the present anticipated expiration time of the relevant amino acid sequence patent in the PRC.

QX005N

Our other Core Product, QX005N, is designed to inhibit IL-4R α , a validated target investigated for a wide range of indications. Because IL-4R α controls the signaling of both IL-4 and IL-13, which is critical in the initiation of type 2 inflammation (an overactive immune response driven by certain type 2 immune cells), it has emerged as a key target for new drug development in related indications. According to Frost & Sullivan, IL-4R α inhibitors had been approved or were under development for 20 indications globally as of the Latest Practicable Date. Dupilumab, the first FDA-approved IL-4R α inhibitor, is one of the best-selling biologic drugs globally for allergic diseases, with annual sales of US\$8.7 billion in 2022.

As of the Latest Practicable Date, we had obtained seven IND approvals for QX005N (namely, AD in adults, AD in adolescents, PN, CRSwNP, CSU, asthma and COPD). QX005N demonstrated favorable safety and efficacy results in our Phase Ia and Phase Ib clinical trials for AD. In the Phase Ib clinical trial in patients with moderate-to-severe AD, in each of the 300 mg and 600 mg groups, 75.0% of subjects achieved Eczema Area and Severity Index-75 (EASI-75) responses (defined as $\geq 75\%$ improvement from baseline in the EASI score) and 50.0% of subjects reached Investigator’s Global Assessment (IGA) scores (0 or 1) at week 12 without significantly increased safety risks. We have started a Phase II clinical trial for AD and completed patient enrollment in February 2023. In September 2023, we conducted a formal consultation with the CDE of the NMPA inquiring whether the NMPA had any objections to or additional requirements on our conduct of the Phase Ib/Phase II clinical trial, and the NMPA

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did not raise any objections or additional requirements. In addition, we commenced a Phase II clinical trial for PN in February 2023. According to Frost & Sullivan, QX005N was the first biologic drug candidate developed by a Chinese domestic company to start a clinical trial for PN in China. In January 2024, the CDE granted QX005N the breakthrough therapy designation for the treatment of PN, signifying its superior clinical benefits compared to current treatment methods. The designation is designed to expedite the development and regulatory review of innovative drugs demonstrating substantial potential in addressing serious conditions. We also commenced a Phase II clinical trial of QX005N for CRSwNP in April 2023.

Addressable Market and Competitive Landscape

Upon approval and commercialization of QX005N, we expect it to face intense competition from approved biologic drug as well as potential competition from drug candidates in clinical development in China for the same indication. The industry landscapes of the major indications in China are as follows:

- **AD.** According to Frost & Sullivan, the prevalence of AD in China was 70.3 million in 2022, and is expected to reach 78.5 million in 2030. The AD drug market in China was US\$1.0 billion in 2022, and is estimated to grow rapidly to reach US\$7.1 billion in 2030, at a CAGR of 23.3%. As of the Latest Practicable Date, dupilumab was the only biologic drug approved in China for AD, which had also been admitted to the NRDL. As of the same date, there were 21 biologic drug candidates for AD in the clinical stage in China, among which 10 were IL-4R α inhibitors. Biologics targeting IL-13, TSLP, IL-33, ST2, CD200R, OX40, IL-2R and IL-17RB are also being developed for AD. The following table sets forth details of QX005N as well as approved biologic drugs and drug candidates for AD in the clinical stage in China that target IL-4R α as of the Latest Practicable Date.

Marketed Anti-IL-4R α Biologics for AD in China								
Target	Brand Name	INN	Company	NMPA Approval Time	Branded or Biosimilar	Availability of biosimilar	2022 NRDL covered	NRDL Median price in 2022 ⁽¹⁾ (RMB)
IL-4R α	Dupilixent	Dupilumab	Sanofi / Regeneron	2020	Branded	—	Yes	3,160.0

Clinical-Stage Anti-IL-4R α Biologic Drug Candidates for AD in China				
Target	Drug Code	Company	Status	First posted Date
IL-4R α	CM310	Keymed Bioscience	BLA submission	2023-12-07
	CBP-201	Connect Biopharmaceuticals	Phase II	2020-11-20
	TQH2722	Chia Tai-tianqing	Phase II	2023-03-27
	QX005N	the Company	Phase II	2022-07-14
	MG-K10	Mabgeek	Phase III	2023-11-29
	SSGJ-611	Sunshine Guojian	Phase III	2023-12-18
	SHR-1819	Hengrui	Phase II	2022-09-27
	GR1802	Genrix Bio	Phase III	2023-12-14
	AK120	Akeso	Phase I / II	2021-08-20
	BA2101	Boan Bio	Phase I	2023-01-16

Source: NMPA, CDE, Frost & Sullivan Report

Note:

- (1) Reflects the median price for a drug’s minimum formulation unit as included in the NRDL.

SUMMARY

- PN.** According to Frost & Sullivan, the prevalence of PN in China was 2.0 million in 2022, and is estimated to reach 2.1 million in 2030. Development of the PN drug market in China is still at an early stage with dupilumab being the only biologic drug approved in China as of the Latest Practicable Date. As of the same date, there were only two biologic drug candidates for PN in the clinical stage in China, both of which were IL-4R α inhibitors, as set out below.

Marketed Targeted Biologics for PN in China				
Brand Name	INN	Company	Target	NMPA Approval Time
Dupilixent	Dupilumab	Sanofi	IL-4R α	2023

Clinical-Stage Biologic Drug Candidates for PN in China				
Target	Drug Code	Company	Status	First posted Date
IL-4R α	QX005N	the Company	Phase II	2022-12-16
	BA2101	Boan Biotech	Phase I	2023-01-16

Source: NMPA, Frost & Sullivan Report

- CRSwNP.** According to Frost & Sullivan, the prevalence of CRSwNP in China was 20.4 million in 2022, and is estimated to reach 22.3 million in 2030. The CRSwNP drug market in China was US\$141.7 million in 2022, and is expected to reach US\$633.4 million in 2030, at a CAGR of 20.6%. As of the Latest Practicable Date, no biologic drug had been approved for the treatment of CRSwNP in China. As of the same date, there were 13 biologic drug candidates for CRSwNP in the clinical stage in China, including six IL-4R inhibitors. Biologics targeting IL-5 and TSLP are also being developed for CRSwNP. The following table sets forth details of QX005N as well as the biologic drug candidates for CRSwNP in the clinical stage in China as of the Latest Practicable Date.

Clinical-Stage Biologic Drug Candidates for CRSwNP in China				
Target	Drug Code	Company	Status	First posted Date
IL-4R α	CM310	Keymed Bioscience	Phase III	2022-06-20
	Dupilumab	Sanofi	Phase III	2023-03-24
	GR1802	Genrix Bio	Phase II	2023-01-03
	QX005N	the Company	Phase II	2023-01-06
	SSGJ-611	Sunshine Guojian	Phase II	2023-04-27
IL-5	Mepolizumab	GSK	Phase III	2021-04-12
	Depemokimab	GSK	Phase III	2022-05-20
	Mepolizumab-BAT2606	Biothera	Phase I	2022-07-27
TSLP	Tezepelumab	Amgen/AstraZeneca	Phase III	2021-03-25
	SHR-1905	Hengrui	Phase II	2023-05-29
	TQC2731	Chia Tai Tianqing	Phase II	2023-08-01
	CM326	Keymed Bioscience	Phase I / II	2022-03-14
IL-5R α	Benralizumab	AstraZeneca	Phase III	2020-06-02

Source: Frost & Sullivan Report (based on annual reports of relevant companies and information published by the NMPA)

Our Other Key Drug Candidates

- QX001S:** QX001S is our first expected commercial drug, the first domestically developed ustekinumab biosimilar with BLA submitted in China and potentially one of the first ustekinumab biosimilars to be approved in China, which targets IL-12/IL-23p40 and has

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been widely regarded as one of the major treatments for Ps worldwide. In our Phase I clinical trial for Ps, QX001S demonstrated a safety and PK profile comparable to that of ustekinumab. In our Phase III clinical trial for Ps, QX001S demonstrated clinical equivalence to ustekinumab in terms of efficacy, safety, immunogenicity and PK profile. Zhongmei Huadong, a subsidiary of Huadong Medicine and our commercialization partner for QX001S, submitted a BLA in China in July 2023, which was accepted by the NMPA in August 2023 and under review as of the Latest Practicable Date. We expect QX001S to face fierce competition upon its commercialization, especially considering that the other two ustekinumab biosimilar candidates in China commenced their Phase III clinical trials at a similar time as our Phase III trial. See “Risk Factors—Our drug candidates will be subject to intense competition with biologics drugs and other drugs for autoimmune and allergic diseases after commercialization and may fail to compete effectively against competitors” for details.




- QX004N: We are developing QX004N, an IL-23p19 inhibitor, for Ps and CD. We completed a Phase Ia clinical trial of QX004N in healthy subjects for the Ps indication in China in September 2023 and QX004N showed a good safety profile. As of September 30, 2023, we had also commenced a Phase Ib clinical trial and a Phase II clinical trial in China to evaluate QX004N for this indication and expect to complete them in the second quarter of 2024 and the first half of 2025, respectively. We also commenced a Phase Ia clinical trial for CD in China in February 2023.
- QX006N: We are developing QX006N, an IFNAR1-targeting mAb, for the treatment of SLE, a difficult indication for new drug development. The first-in-class IFNAR1 inhibitor, SAPHNELO (anifrolumab), was approved by the FDA in 2021, making it the only new SLE treatment in more than 10 years. As of the Latest Practicable Date, our QX006N was one of the only two IFNAR1 inhibitors developed by Chinese domestic companies that had entered the clinical stage for SLE in China. QX006N showed a good safety profile in our Phase Ia clinical trial, and promising potency and affinity comparable to those of an internally prepared anifrolumab analog in our preclinical studies. We initiated a Phase Ib clinical trial in SLE patients in March 2023 and expect to complete such trial in the fourth quarter of 2024.
- QX008N: QX008N is a humanized IgG1 mAb targeting TSLP, designed for the treatment of moderate-to-severe asthma and moderate-to-severe COPD. TSLP-targeting therapy is the only class of biologic drugs globally approved for asthma that can slow disease progression for asthma patients with low-level or no expression of type 2 biomarkers. QX008N demonstrated a potency superior to an internally prepared tezepelumab analog and exhibited a good safety profile in our Phase Ia clinical trial. We commenced a Phase Ib clinical trial in adult patients with moderate-to-severe asthma in August 2023, the remainder of which will be completed by Joincare, our licensing partner.

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Our Disease Area Coverage and Product Matrix

Our pipeline covers the four major disease areas in the autoimmune and allergic disease field, namely, skin, rheumatic, respiratory and digestive diseases. In this field, there are often complex relationships between and among various targets and indications across disease areas. For a drug developer, product positioning is key to the potential clinical and commercial value of its pipeline. We illustrate in the chart below the positioning of our product matrix in context, and further set out our pipeline design for each of the major disease areas.

	Skin					Rheumatic			Respiratory			Digestive	
	 Ps	 AD	 PN	 CSU	 Pruritus	 AS	 SLE	 LN	 CRSwNP	 Asthma	 COPD	 CD	 UC
QX002N★ IL-17A						●		●					
QX005N★ IL-4Rα		●	●	●					●	●	●		
QX001S IL-12/IL-23p40	●											○	○
QX004N IL-23p19	●											●	
QX006N IFNAR1						●							
QX008N TSLP										●	●		
QX007N IL-33										○	●		
QX013N c-kit				○									
QX010N IL-31R				○									

 IND approved  Preclinical
 Core Product

The Autoimmune and Allergic Disease Drug Market

Autoimmune and allergic diseases represent the second-largest therapeutic area globally, only after oncology, and have witnessed a succession of blockbuster drugs. According to Frost & Sullivan, the market size of autoimmune and allergic disease drugs amounted to US\$187.5 billion in 2022, which was 12.5% for all drugs combined. Among the 100 top-selling drugs in 2022, around one fifth were autoimmune or allergic drugs, including two—Humira (adalimumab, a TNF inhibitor) (No. 2; US\$21.2 billion) and Stelara (ustekinumab, an IL-12/IL-23 inhibitor) (No. 9; US\$9.7 billion)—in the top 10. Humira, in particular, was the world’s best-selling drug for the last ten years (2013-2022), with the exception of the years 2021 and 2022, when it ranked second only to COVID-19 vaccines. In contrast, market development in China has lagged significantly behind. According to Frost & Sullivan, the total patient population of autoimmune and allergic diseases in China exceeded 420 million as compared to 100 million in the United States in 2020. However, China’s autoimmune and

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allergic drug market was only US\$7.2 billion in 2020, approximately 7.5% of the U.S. market of US\$95.6 billion. Specifically, biologic drugs dominate developed markets, but their penetration in China remains low. In 2020, biologic drugs made up over 60% of the autoimmune and allergic disease drug market in the United States, but only about 10% of the China market.

The underdevelopment of the China market has historical reasons. Due to an innovation gap, most of the innovative biologic drugs available in China have been expensive blockbuster drugs developed by multinational corporations, or MNCs, typically not covered by public medical insurance. This has had two effects. On the one hand, since autoimmune and allergic diseases are often not fatal, Chinese patients, when they have limited ability to pay and are price-sensitive, are less inclined to address them with significant economic resources as committedly as they might with fatal diseases such as cancer, leading to discontinued treatment, ineffective traditional treatment or no treatment at all. In addition, due to limited returns, the MNCs have not invested extensively in physician and patient education in China, which has perpetuated poor awareness. As a result, diagnosis and treatment rates for many diseases in this field have been low. The *status quo* indicates a deep structural misalignment with the unmet medical need. Autoimmune and allergic diseases are serious diseases. They can severely affect patients’ quality of life in various manifestations, including great pain, persistent itchiness, disfigurement, disability, severe psychological pressure and social exclusion. They impose profound disease burden on patients and society and require safe and effective treatment.

Despite the historical underdevelopment, China’s autoimmune and allergic disease drug market has been changing in recent years, especially since 2021. Several important factors have driven the industry toward more alignment with global trends and more certainty in market prospect:

- *Approvals, NRDL admissions and accelerated sales ramp-up of blockbuster drugs.* A number of blockbuster drugs developed by MNCs were approved in China and admitted to the NRDL. While unit prices dropped, sales increased. For example, Cosentyx (secukinumab, an IL-17A inhibitor) was approved in China for moderate-to-severe plaque Ps in March 2019 and admitted to the NRDL in March 2021. While its unit price (150 mg) decreased from RMB2,998 in 2020 to RMB1,188 in 2022, its China sales increased from US\$72.5 million in 2020 to US\$279.0 million in 2021 and US\$601.4 million in 2022. Dupixent (dupilumab, an IL-4R α inhibitor) was approved for moderate-to-severe AD in June 2020 and admitted to the NRDL in January 2021. While its unit price (300 mg) decreased from RMB6,666 in 2020 to RMB3,160 in 2022, its China sales increased from US\$13.7 million in 2020 to US\$87.4 million in 2021 and US\$248.1 million in 2022.* Apart from the expansion in sales volume, there has also been an evident acceleration in such expansion. According to Frost & Sullivan, it took seven years for Humira (adalimumab) to achieve annual sales of US\$100.0 million in China since its approval in the country in 2010, whereas it took Cosentyx only two years to reach the same milestone.

* Future China sales of Cosentyx and Dupixent, after the initial years following NMPA approval and NRDL admission, may not sustain similar growth rates.

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- *Evolution of treatment paradigm from traditional anti-inflammatory agents to biologics.* Traditional anti-inflammatory agents are commonly used treatment options for autoimmune diseases, particularly during the initial stages of the diseases. However, traditional anti-inflammatory agents are also noted with limited efficacy in patients with more severe symptoms and there remain concerns over the potential side effects from long-term use of some of these agents. Therefore, over the past decades, biologic drugs with superior efficacy and safety have been increasingly accepted by physicians and patients globally. The evolution of treatment paradigm from traditional anti-inflammatory agents to biologics is also accompanied by continuous upgrades in classes of biologic drugs. For example, compared to first-generation TNF- α inhibitors, which have relatively high risk of serious infections, certain biologics targeting interleukins (*e.g.*, IL-17 and IL-23) have demonstrated better efficacy and/or safety for certain indications and are under extensive investigation with more drugs potentially to be approved. The same trend is also found and followed in China, and drives an increasing demand for novel biologic drugs.
- *Rise of domestic developers.* Recognizing the great potential of the therapeutic area, a growing number of Chinese pharmaceutical companies have begun to conduct R&D on autoimmune and allergic disease drugs. Drugs developed by Chinese domestic companies are expected to have a price advantage. Domestic companies may also leverage their in-depth understanding and extensive coverage of local patients and hospitals to, together with MNCs, improve awareness of autoimmune and allergic diseases and biologic therapies through more precise and effective marketing activities and patient education.

Due to these favorable changes, the autoimmune and allergic disease drug market in China expanded from US\$7.2 billion in 2020 to US\$9.0 billion in 2022, representing a CAGR of 11.8%, with the proportion of biologic drugs increased to 20.4% in 2022. The market is expected to continue to develop. According to Frost & Sullivan, it is expected to grow to US\$41.5 billion in 2030, at a CAGR of 21.1% from 2022, and with the proportion of biologic drugs increased to about 60%. The market has significant further, long-term growth potential. On the demand side, although usually not fatal, autoimmune and allergic diseases are also usually incurable, and are classic chronic diseases that require long-term or even life-long care. For example, while allergy desensitization, a therapy that aims to weaken a patient’s allergic reactions by exposing them to gradually increasing doses of allergens, is widely used for treatment of allergies of pollen, mites, animal dander and certain medications, it is barely effective for systemic allergic diseases without a specific allergen, such as AD, PN, CRSwNP, asthma and COPD. Accordingly, patients have stable need for medication over long periods of time, resulting in high lifetime value (LTV). In addition, long-term medication causes drug resistance and adherence issues, creating a need for alternative therapies. Furthermore, the pathogenic mechanisms of many autoimmune and allergic diseases are not fully understood. One drug is often used for multiple indications, with varying response rates, indicating that the development of precision medicine and individualized treatment is still at a very early stage. On the supply side, compared with oncology, which is crowded with many international and

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domestic pharmaceutical companies, competition in the autoimmune and allergic drug market is relatively less intense. As indicated in the 2022 Drug Evaluation Report released by the NMPA, among 769 IND approvals granted in 2022, fewer than 140 were in the autoimmune and allergic field, compared with more than 430 in oncology.

We are well positioned to take advantage of this market opportunity. Since our establishment in 2015, we have exclusively focused on the autoimmune and allergic field and built a pipeline covering the four major disease areas in the field, namely, skin, rheumatic, respiratory and digestive diseases.

- *Skin diseases.* Inflammatory skin diseases have large patient populations in China. According to Frost & Sullivan, there are expected to be 6.8 million psoriasis (Ps) patients in China by 2030, 20% to 30% of whom having moderate-to-severe disease, indicating an estimated drug market of US\$9.9 billion. In the same year, there are expected to be 78.5 million atopic dermatitis (AD) patients, 30% of whom having moderate-to-severe disease, indicating an estimated drug market of US\$7.1 billion, and 2.1 million prurigo nodularis (PN) patients with no approved biologic therapies, indicating a market with substantial unmet medical needs.
- *Rheumatic diseases.* Inflammatory rheumatic diseases are multiple immune diseases, such as ankylosing spondylitis (AS), systemic lupus erythematosus (SLE) and lupus nephritis (LN). In addition to persistent and mysterious pain, rheumatic conditions can cause patients to develop deformities so severe that daily tasks like walking or getting dressed feel impossible. In 2030, there are expected to be 4.0 million AS patients in China, with an estimated drug market of US\$6.5 billion, and 1.1 million SLE patients, with an estimated drug market of US\$3.4 billion.
- *Respiratory diseases.* Inflammatory respiratory diseases, such as asthma, chronic rhinosinusitis with nasal polyps (CRSwNP) and chronic obstructive pulmonary disease (COPD), have large patient populations in China. In 2030, there are expected to be 78.1 million asthma patients in China, about 10% of whom having severe disease, indicating an estimated drug market of US\$10.6 billion. In the same year, there are expected to be 22.3 million CRSwNP patients, with an estimated drug market of US\$0.6 billion, and 110.7 million COPD patients, with an estimated drug market of US\$6.3 billion.
- *Digestive diseases.* Inflammatory digestive diseases, such as ulcerative colitis (UC) and Crohn’s disease (CD), are conditions characterized by chronic inflammation of the gastrointestinal tract, which can be aggressive and significantly impact the patient’s quality of life. In 2030, there are expected to be 1.2 million UC and CD patients in China, with an estimated drug market of US\$5.5 billion.

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COMPETITION

The development and commercialization of innovative biologic drugs are highly competitive and subject to rapid and significant changes. We face potential competition from many different sources working to develop therapies targeting the same indications for which we develop our drug candidates, in particular in the autoimmune and allergic disease areas. These include major pharmaceutical companies as well as specialty pharmaceutical companies of various sizes. Our Core Products and key drug candidates face competition from approved and clinical-stage drug candidates, including biologics and small-molecule targeted drugs, that focus on similar indications and target patient population with us, and these competing products may have significant competitive strengths and advantages when compared to our drug candidates. In addition, as biologics are a relatively new class of drugs, prevailing clinical guidelines have not yet recommended biologics as a main treatment option for LN, PN, CRSwNP, asthma, COPD and pruritus, some of which are indications being investigated for our Core Products QX002N and QX005N. For the competitive landscape of our Core Products and other product candidates, see “Business—Our Drug Candidates—Our Core Products” and “Industry Overview” in this document.

OUR STRENGTHS

We believe our strengths are:

- Exclusive focus on autoimmune and allergic diseases, covering four major disease areas and key therapeutic pathways;
- Broad pipeline of biologics in autoimmune and allergic diseases, with Core Products in late-stage clinical development for the most advanced indications;
- Commercial-scale in-house manufacturing capacity ensuring stable and cost-controllable supply of our products;
- Practical commercialization model leveraging strategic partnership to secure early product launch; and
- Seasoned management team with extensive industry experience and successful entrepreneurial track records.

OUR STRATEGIES

We plan to pursue the following strategies:

- Build leadership in dermatology, advance other drug candidates and strategically expand our pipeline;

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- Continue to optimize CMC quality management system and improve production efficiency and enhance manufacturing capacity utilization;
- Cooperate with established pharmaceutical companies in commercialization;
- Explore international expansion opportunities; and
- Continue to recruit and develop talent.

RESEARCH AND DEVELOPMENT

We are a clinical-stage biotech company exclusively focused on biologic therapies for autoimmune and allergic diseases, with a self-developed drug pipeline. We believe research and development is critical to our ability to grow into a biopharmaceutical company and remain competitive in the industry. We have established an integrated R&D platform as the foundation for our continuous innovation. The platform comprises five R&D components, including (i) mAb screening and function verification; (ii) analytical method development; (iii) cell line screening and process development; (iv) drug formulation development; and (v) preclinical and clinical sample analysis and testing. We also have established a commercial-scale in-house manufacturing facility which supports our R&D activities from preclinical and clinical trial drug manufacturing to future commercial manufacturing. As a result, we are able to conduct our R&D with high efficiency, having obtained 18 IND approvals (17 from the NMPA and 1 from the FDA) over the past 8 years. We have developed all of our biologic drug candidates in-house and received a number of awards recognizing our R&D capabilities. We have set up two clinical development centers in Beijing and Shanghai and conduct our R&D activities through an in-house team, as well as engagement of external CROs, as is in line with industry practice. As of the Latest Practicable Date, our in-house R&D team comprised 122 members, approximately 60% of which had a master’s degree or above in biology or pharmacy-related field.

For the years ended December 31, 2021 and 2022 and the nine months ended September 30, 2023, our research and development expenses amounted to RMB151.9 million, RMB257.2 million and RMB263.3 million, respectively, accounting for 75.7%, 77.1% and 68.1% of our operating expenses in the same periods, respectively. In particular, the R&D expenses attributable to our Core Products, QX002N and QX005N, accounted for 11.9% and 24.7% of our total R&D expenses in 2021, 19.3% and 25.7% of our total R&D expenses in 2022, and 21.7% and 33.6% of our total R&D expenses in the nine months ended September 30, 2023, respectively. During the Track Record Period, our R&D expenses increased significantly, primarily as a result of the advancement and expansion of preclinical and clinical studies of our drug candidates.

In line with industry practice, we also engage reputable CROs to support our preclinical and clinical studies from time to time. On December 20, 2022, we entered into a five-year collaboration framework agreement with Hangzhou Tigermed Consulting Co., Ltd. (“Tigermed”) for the future development of our drug candidates, including QX002N, QX005N

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and others, in China. Tigermed is one of the industry-leading CROs in China, whose business covers the development and registration of innovative pharmaceutical candidates. As of the Latest Practicable Date, we had entered into service contracts with Tigermed with respect to the Phase III clinical trial of QX002N for AS and the Phase II clinical trials of QX005N for PN and CRSwNP.

MANUFACTURING

We are one of only a few Chinese biotech companies that are focused on autoimmune and allergic diseases and have an established commercial-scale in-house manufacturing capability, according to Frost & Sullivan. Our manufacturing facility was established according to the cGMP standards of China, the United States and the EU (although not GMP-certified due to the termination of the certification mechanism by relevant government agencies in China since 2019). Our manufacturing facility is located at our headquarters in Taizhou, Jiangsu and occupies 57,977 sq.m. of land. Our drug substance manufacturing site has four 2,000L single-use bioreactors and one downstream purification/production line with an annual manufacturing capacity of approximately 300 kg therapeutic antibodies. Our drug product manufacturing site has one vial fill-finish and packaging production line for 2 ml, 10 ml and 30 ml vials, with a manufacturing capacity of 18,000 vials/hour, and one prefilled syringe production line for 1 ml and 2 ml syringes, with a manufacturing capacity of 9,000 syringes/hour. We have completed the manufacturing of multiple batches of drug substance and drug products (including QX001S and our Core Products, QX002N and QX005N) for various clinical trials, scale-up research and/or BLA-required process validation. We produced 11 batches of drug substances in each of 2021 and 2022 and successfully released 8 batches in 2021 and 10 batches in 2022 (with the remaining batches being 200L pilot scale batches dedicated for process optimization and therefore not qualified to be released for clinical use). During the same time, we also produced over 20 batches of drug products, all of which were released successfully. In the nine months ended September 30, 2023, we produced 11 batches of drug substances and 18 batches of drug products, among which 10 batches and 18 batches were released successfully, respectively. The expected maximum number of drug substance and drug product batches that can be released annually are 40 and 120, respectively. We believe that our self-owned cGMP-standard manufacturing capability, coupled with our strong R&D capability, will allow us to achieve reliable cost control and ensure stable clinical and commercial drug supply to weather any supply chain disruptions.

COMMERCIALIZATION

In order to ensure the successful launch of our first expected commercial drug, QX001S, we entered into a strategic collaboration agreement with Zhongmei Huadong, a subsidiary of Huadong Medicine, in August 2020, with respect to the joint development and exclusive commercialization of QX001S in China. Huadong Medicine is experienced in chronic disease management and has strong sales networks for autoimmune and allergic drugs. As we are at an early stage of preparation for future commercialization of our drug candidates, building a large commercialization team would be time-consuming and expensive, which would increase our commercial risk and distract us from our R&D efforts. To address this conundrum, we

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strategically choose to cooperate with established pharmaceutical companies to quickly and cost-effectively commercialize selected products. We believe that the strategic cooperation with Huadong Medicine will help ensure effective and efficient commercialization of QX001S. Going forward, we also plan to leverage the strong physician resources and networks of established pharmaceutical companies to build connections with participants in the drug sales and distribution chain, to prepare us for future commercial launches of our other drug candidates. In the future, we plan to build a relatively small, indication-specialized in-house commercialization team, beginning with indications with relatively limited patient populations treated in a small number of key hospitals, leveraging our deep understanding of these indications and physician resources.

COLLABORATION WITH ZHONGMEI HUADONG

On August 14, 2020, we entered into a collaboration agreement (as supplemented on December 7, 2023, the “QX001S Framework Agreement,” and together with the QX001S Production Quality Agreement and the QX001S Supply Agreement (as defined below), the “QX001S Agreements”) with Zhongmei Huadong, a subsidiary of Huadong Medicine, with respect to the joint development and exclusive commercialization of QX001S in China. As of the Latest Practicable Date, Zhongmei Huadong and Cellularforce had also entered into the QX001S Production Quality Agreement and the QX001S Supply Agreement for the Product Supply (as defined below) as individual agreements under the QX001S Framework Agreement based on the principles provided in the QX001S Framework Agreement. Huadong Medicine is a leading PRC pharmaceutical company listed on the Shenzhen Stock Exchange, whose business covers the whole pharmaceutical industrial chain, integrating R&D, manufacturing and sales of medicine. While Huadong Medicine (including Zhongmei Huadong) is a large comprehensive pharmaceutical company with strong sales networks for autoimmune and allergic drugs, we do not consider it to be our competitor primarily because (i) for the same skin disease indications, such as Ps and AD, Huadong Medicine’s focus is primarily on developing systematic topical drugs that are more commonly used for mild diseases, which would not directly compete with our biologic drug candidates that are intended for more severe cases and instead are complementary to our business; (ii) while Zhongmei Huadong had a biologic drug candidate for SLE in the clinical trial stage as of the Latest Practicable Date, we do not consider it to be a direct competitor to QX006N as these two drug candidates have different mechanisms of action and both are still in early clinical trial stage with considerable time before their commercialization (if at all); and (iii) in 2022, Huadong Medicine obtained the commercialization right of etanercept (a TNF inhibitor) and tofacitinib (a JAK inhibitor), both developed by Pfizer, for the treatment of AS in China, but we believe they will primarily cover a different patient population from QX002N as QX002N targets IL-17A, a promising target that has shown clear clinical benefit in AS patients who are intolerant to or fail to achieve adequate disease control with TNF- α inhibitors and there still remain concerns over the safety profile of JAK inhibitors.

Pursuant to the QX001S Framework Agreement, we agree to grant Zhongmei Huadong joint clinical development, manufacturing and exclusive commercialization rights of QX001S in China. We retain the full development and commercialization rights of QX001S outside

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China. Zhongmei Huadong and we agree to establish a joint development committee (the “JDC”) to manage the joint clinical development of QX001S, which shall be responsible for overseeing the development, clinical trials and registrational matters of QX001S before its commercial launch. In addition, we were responsible for and completed the preclinical studies and the Phase I clinical trial of QX001S for the treatment of Ps which were ongoing before the date of execution of the QX001S Framework Agreement at our cost. Zhongmei Huadong and we also agree to establish a joint sales committee (the “JSC”) for the commercialization of QX001S, which shall be responsible for overseeing the commercialization, manufacturing and marketing expense proposal of QX001S and other commercialization-related work. In particular, Zhongmei Huadong shall be the Marketing Authorization Holder (“MAH”) of QX001S in China to exclusively conduct marketing activities and commercialization of QX001S, who shall make commercially reasonable efforts to promote such commercialization. Jiangsu Cellularforce Biopharma Co., Ltd. (“Cellularforce”), our CMC-focused subsidiary, shall be solely responsible for the commercial production of QX001S in the PRC (the “Product Supply”), at a unit supply price which will be determined by taking into account our actual costs expected to be incurred for manufacturing of QX001S and a cost-plus margin of 25% for such manufacturing (the “Markup”).

We are the sole owner of all intellectual property (including trade secrets) associated with QX001S that were developed by us independently before the date of the QX001S Framework Agreement. We and Zhongmei Huadong shall be the co-owners of any intellectual property (including trade secrets) (the “Co-Developed IP rights”) associated with QX001S that are developed since the date of the QX001S Framework Agreement. Any of the aforementioned intellectual property (including trade secrets) may be used at no cost by both parties in China and solely by us outside China. With respect to the Co-Developed IP rights, Zhongmei Huadong shall be primarily responsible for the relevant application and registrational matters in China while we shall be responsible for such application and registrational matters outside China. If a party decides to abandon any intellectual property (including trade secrets) mentioned therein, the other party shall be entitled to a priority transfer.

Zhongmei Huadong made an upfront payment of RMB30 million to us within ten days upon the execution of the QX001S Framework Agreement and also made a milestone payment of RMB20 million to us within ten days after we completed the sample production of QX001S for a Phase III clinical trial and have obtained consent to proceed with such trial. Both the upfront payment and milestone payment are non-refundable. As of the Latest Practicable Date, we had received the upfront payment and milestone payment in a total of RMB50 million from Zhongmei Huadong under the QX001S Framework Agreement. In addition, during the joint development, Zhongmei Huadong shall be responsible for any expenses related to the clinical trials and regulatory communication and registration for QX001S; we shall be responsible for expenses related to the sample production and process development and optimization prior to the commercialization of QX001S. The accumulative pre-tax profit generated from sales of QX001S in China (as calculated pursuant to the QX001S Framework Agreement), after setting off the accumulative losses attributable to the commercialization of QX001S incurred in prior

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years (if any), shall be shared by Zhongmei Huadong and us on a 50:50 basis, provided that 50% of the Markup for the manufacturing of QX001S will be further deducted from our portion of the pre-tax profit receivable and attributed to Zhongmei Huadong’s portion instead.

To ensure that the Product Supply is in compliance with the relevant regulations and technical specifications, Zhongmei Huadong and Cellularforce entered into a production quality agreement on June 16, 2022 (as amended on October 25, 2022, March 16, 2023 and April 26, 2023, the “QX001S Production Quality Agreement”), which provides that Cellularforce’s production of QX001S shall follow the detailed requirements as specified in this agreement and each party shall be responsible for carrying out respective duties as required by the relevant law or regulation. On September 28, 2022, Zhongmei Huadong and Cellularforce further entered into a supply agreement (the “QX001S Supply Agreement”) with respect to the Product Supply. Pursuant to the QX001S Supply Agreement, Zhongmei Huadong may place production orders of QX001S with Cellularforce after Zhongmei Huadong completes the onsite assessment and verification of Cellularforce’s manufacturing facility and obtains approval for the commissioned production as required by the relevant regulatory authorities, and Cellularforce is entitled to commission fees per orders completed, the calculation and settlement of which shall be determined in subsequent supplemental agreements. As of the Latest Practicable Date, Zhongmei Huadong had completed the onsite assessment and verification of the manufacturing facility.

We believe this collaboration with Huadong Medicine (including Zhongmei Huadong) will enable us to leverage its market access, nationwide sales and marketing network targeting the autoimmune and allergic disease field as well as its extensive experience in chronic disease management, which will be crucial to support rapid commercialization of QX001S. For further details, please refer to “Business—Collaboration with Zhongmei Huadong.”

INTELLECTUAL PROPERTY

As of the Latest Practicable Date, we held 37 patents in China, including 31 invention patents and 6 utility models, as well as 9 patents overseas. As of the same date, we also had 44 patent applications pending in China and overseas. In particular, with respect to our Core Products, we had eight registered patents and two pending patent applications for QX002N and five registered patents and four pending patent applications for QX005N. All of our patents and patent applications as of the Latest Practicable Date are self-owned. See “Business—Intellectual Property” for key information of our material patents and patent applications. As of the Latest Practicable Date, we had registered 83 trademarks in the PRC and Hong Kong. As of the same date, we were also the registered owner of 21 domain names in the PRC. During the Track Record Period and up to the Latest Practicable Date, we had not been involved in any material proceeding in respect of, and we had not received notice of any material claim of infringement of, any intellectual property rights that may be threatened or pending, in which we may be a claimant or a respondent that may have a material adverse impact on us.

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RAW MATERIALS AND SUPPLIERS

During the Track Record Period, we primarily procured raw materials and consumables for the development and manufacture of our drug candidates from reputable domestic and overseas suppliers. Our purchases mainly include third-party contracting services for preclinical and clinical studies of our drug candidates (including patient recruitment, services from hospitals as trial sites and typical CRO services in line with market practice, such as toxicity or PK/PD studies, the daily management of a clinical study, record keeping and report preparation) as well as raw materials, consumables and equipment. In each of the years ended December 31, 2021 and 2022 and the nine months ended September 30, 2023, our purchases from our five largest suppliers in the aggregate accounted for 26.3%, 27.4% and 25.2% of our total purchases in the same periods, respectively, while purchases from our largest supplier accounted for 8.3%, 12.1% and 11.9% of our total purchases in the same periods, respectively. See “Business—Raw Materials and Suppliers” for further details.

OUR CONTROLLING SHAREHOLDERS AND CONTINUING CONNECTED TRANSACTIONS

Immediately upon completion of the [REDACTED], Mr. Qiu Jiwan (裘霽宛) will, directly or through Hangzhou Quanyi, Shanghai Quanyou and Xinfu Tongxin, control the voting rights of approximately [REDACTED]% of the total share capital of our Company.

Hangzhou Quanyi is an investment holding general partnership owned as to 50% by Mr. Qiu and 50% by Mr. Yu Guo’an (余國安) as its general partners. Mr. Qiu and Mr. Yu Guo’an first became acquainted in February 2004 when Mr. Qiu joined Hangzhou Epitomics as its deputy general manager and Mr. Yu Guo’an served as the general manager of Hangzhou Epitomics at that time. Pursuant to the supplemental partnership agreement of Hangzhou Quanyi entered into between Mr. Qiu and Mr. Yu Guo’an on February 5, 2022, Mr. Qiu and Mr. Yu Guo’an agreed and confirmed, among others, that since the date of establishment of our Company, they have been and would continue to be parties acting in concert and they have agreed to consult with each other and reach a consensus between themselves before making the decisions and exercising their voting rights through Hangzhou Quanyi at the Board and Shareholders’ meetings and in the event that they are unable to reach consensus on any matter presented, the decisions of Mr. Qiu shall prevail. Shanghai Quanyou is an investment holding limited partnership whose general partner is Mr. Qiu. Xinfu Tongxin is one of our employee share incentive platforms whose general partner is Mr. Qiu. Accordingly, Mr. Qiu, Mr. Yu Guo’an, Hangzhou Quanyi, Shanghai Quanyou and Xinfu Tongxin constitute a group of our Controlling Shareholders under the Listing Rules.

We have entered into certain agreements with Zhongmei Huadong, one of our substantial shareholders, who will become a connected person of our Company upon [REDACTED] and the transactions contemplated under such agreements will constitute connected transactions of our Company under Chapter 14A of the Listing Rules upon [REDACTED]. For details, see “Connected Transactions.”

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[REDACTED] INVESTMENTS

We have concluded several rounds of [REDACTED] Investments and raised a total of RMB1,261.5 million. According to the PRC Company Law, all current Shareholders (including the [REDACTED] Investors) are subject to a lock-up period of 12 months following the [REDACTED]. We have a broad and diverse base of [REDACTED] Investors. Among our [REDACTED] Investors, each of Zhongmei Huadong, Hongtai Aplus, Taizhou Huayin, Matrix Partners China, Triwise Capital and Shenzhen Lucky-source is a [REDACTED] who has made meaningful investment in our Company in accordance with Chapter 2.3 of the Guide. Upon completion of the [REDACTED], (i) Zhongmei Huadong will be interested in approximately [REDACTED]% of the total issued share capital of our Company; (ii) Hongtai Aplus will be interested in approximately [REDACTED]% of the total issued share capital of our Company; (iii) Taizhou Huayin will be interested in approximately [REDACTED]% of the total issued share capital of our Company; (iv) Matrix Partners China will be interested in approximately [REDACTED]% of the total issued share capital of our Company; (v) Triwise Capital will be interested in approximately [REDACTED]% of the total issued share capital of our Company; and (vi) Shenzhen Lucky-source will be interested in approximately [REDACTED]% of the total issued share capital of our Company. For details, see “History and Corporate Structure—[REDACTED] Investments.”

RISK FACTORS

There are certain risks and uncertainties involved in investing in our H Shares, some of which are beyond our control. These risks are set out in “Risk Factors” in this document. Some of the major risks we face include:

- our drug candidates will be subject to intense competition with biologic drugs and other drugs for autoimmune and allergic diseases after commercialization and may fail to compete effectively against their competitors;
- we depend substantially on the success of our drug candidates, all of which are undergoing preclinical or clinical development and if we are unable to successfully complete clinical development of our drug candidates, or experience significant delays in doing so, our business prospects will be significantly impacted;
- we have incurred significant operating losses since our inception and anticipate that we will continue to incur operating losses for the foreseeable future and may never become profitable;
- we have no track record in commercializing our drug candidates and our collaboration with pharmaceutical companies to market our drug candidate and our plan to establish an indication-specialized in-house commercialization team may not materialize as we expected; and

SUMMARY

- if we are unable to obtain and maintain patent protection for our drug candidates through intellectual property rights, third parties could develop and commercialize products and technologies similar or identical to ours and compete directly against us, and the commercial prospects of our drug candidates would be materially and adversely affected.

SUMMARY OF KEY FINANCIAL INFORMATION

This summary historical financial information set forth below is derived from, and should be read in conjunction with, our consolidated financial information, together with the accompanying notes, set forth in “Appendix I—Accountants’ Report” to this document, as well as the information set forth in “Financial Information” of this document. Our consolidated financial information has been prepared in accordance with IFRS.

Summary of Consolidated Statements of Profit or Loss and Other Comprehensive Income

	Year ended December 31,		Nine months ended September 30,	
	2021	2022	2022	2023
			<i>(unaudited)</i>	
			<i>(Renminbi in thousands)</i>	
Administrative expenses	(48,804)	(76,603)	(33,237)	(123,247)
Research and development expenses	(151,887)	(257,214)	(189,749)	(263,270)
Loss from operations	(168,622)	(293,689)	(191,993)	(373,313)
Loss before taxation	(426,544)	(312,381)	(205,980)	(385,559)
Loss for the year/period	(426,471)	(312,308)	(205,925)	(385,504)
Loss attributable to:				
Equity shareholders of the Company	(411,039)	(298,191)	(196,649)	(373,978)
Non-controlling interests	(15,432)	(14,117)	(9,276)	(11,526)

Our net loss decreased from RMB426.5 million to RMB312.3 million from 2021 to 2022, primarily because we did not recognize any changes in the carrying amount of financial liabilities associated with certain preferred rights granted to certain [REDACTED] Investors in 2022 as such preferred rights were waived by our [REDACTED] Investors in July 2021, partially offset by an increase in our research and development expenses from RMB151.9 million in 2021 to RMB257.2 million in 2022, primarily attributable to an increase in engagement costs of CROs and trial sites and our R&D staff costs. Our net loss increased from RMB205.9 million in the nine months ended September 30, 2022 to RMB385.5 million in the nine months ended September 30, 2023, primarily attributable to (i) an increase in our staff costs as we amortized the additional equity incentives granted in October 2022 in the nine months ended September 30, 2023 and (ii) an increase in our engagement costs of CROs and trials sites as we advance our drug development pipeline.

SUMMARY

Summary of Consolidated Statements of Financial Position

	As of December 31,		As of September 30,
	2021	2022	2023
	<i>(Renminbi in thousands)</i>		
Total non-current assets	419,232	399,152	382,017
Total current assets	648,261	635,948	459,180
Total current liabilities	69,673	122,190	178,742
Net current assets	578,588	513,758	280,438
Total assets less current liabilities	997,820	912,910	662,455
Total non-current liabilities	293,654	251,497	257,558
Net assets	704,166	661,413	404,897
Total equity attributable to equity shareholders of the Company	670,351	641,715	396,725
Non-controlling interests	33,815	19,698	8,172

The decrease in our net current assets from RMB578.6 million as of December 31, 2021 to RMB513.8 million as of December 31, 2022 was primarily due to an increase of RMB45.6 million in interest-bearing borrowings, primarily attributable to (i) a reclassification of RMB29.7 million from the non-current portion to the current portion of our secured bank loan of RMB300.0 million obtained in 2020 and (ii) short-term bank loans of RMB15.9 million obtained by one of our subsidiaries to fund working capital needs. The decrease in our net current assets from RMB513.8 million as of December 31, 2022 to RMB280.4 million as of September 30, 2023 was primarily attributable to a decrease of RMB250.7 million in our financial assets at fair value through profit or loss as we reduced purchasing of wealth management products in the nine months ended September 30, 2023, which outpaced the increase in cash and cash equivalents of only RMB44.5 million, as we spent cash to support our daily operations in the nine months ended September 30, 2023.

The decrease in our net assets from RMB704.2 million as of December 31, 2021 to RMB661.4 million as of December 31, 2022 was primarily attributable to our net loss of RMB312.3 million in 2022, partially offset by issuance of ordinary shares in the Series C Financing of RMB227.5 million and an increase in share-based payment reserve of RMB41.6 million. The decrease in our net assets from RMB661.4 million as of December 31, 2022 to RMB404.9 million as of September 30, 2023 was primarily attributable to our net loss of RMB385.5 million in the nine months ended September 30, 2023, partially offset by an increase in share-based payment reserve of RMB99.5 million and proceeds from shares issued under the Original Share Option Scheme and the Employee Share Incentive Scheme of RMB29.5 million.

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Summary of Consolidated Statements of Cash Flows

	Year ended		Nine months ended	
	December 31,		September 30,	
	2021	2022	2022	2023
	<i>(unaudited)</i>			
	<i>(Renminbi in thousands)</i>			
Net cash used in operating activities	(122,576)	(225,212)	(158,030)	(252,157)
Net cash (used in)/generated from investing activities	(247,416)	(5,704)	(103,929)	252,705
Net cash generated from financing activities	281,482	211,494	222,970	44,063
Net (decrease)/increase in cash and cash equivalents	(88,510)	(19,422)	(38,989)	44,611
Cash and cash equivalents at beginning of the year/period	309,287	218,055	218,055	213,090
Effect of foreign exchange rate changes	(2,722)	14,457	17,249	(66)
Cash and cash equivalents at ending of the year/period	<u>218,055</u>	<u>213,090</u>	<u>196,315</u>	<u>257,635</u>

We had net cash outflows from our operating activities during the Track Record Period. Substantially all of our operating cash outflows resulted from research and development expenses and general and administrative expenses. Our primary uses of cash during the Track Record Period were funding our research and development of our biologic drug candidates, purchase of raw materials, settlement of construction fees of our manufacturing facility in Taizhou, as well as other working capital needs. During the Track Record Period, we primarily funded our working capital requirement through equity financing. We monitor and maintain a level of cash and cash equivalents we consider adequate to finance our operations and mitigate the effects of fluctuations in cash flows. Going forward, we believe our liquidity requirements will be satisfied by using funds from a combination of bank balances, [REDACTED] from the [REDACTED], bank and other borrowings and cash generated from our operations.

Our Directors are of the opinion that, taking into account the financial resources available to our Group, including cash and cash equivalents, short-maturity financial products we purchased, unutilized bank facilities and the estimated [REDACTED] from the [REDACTED], we have sufficient working capital to cover at least 125% of our costs, including general, administrative and operating costs and research and development costs, for at least the next 12 months from the date of this document.

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Our cash burn rate refers to our average monthly (i) net cash used in operating activities, which includes research and development expenses, and (ii) capital expenditures. Taking into account our cash and cash equivalents and short-maturity financial products we purchased, and assuming average monthly net cash used in operating activities and capital expenditures going forward of 1.5 times the average level in 2021 and 2022, we estimate we will be able to maintain our financial viability for 12.9 months from the date of this document without considering [REDACTED] from the [REDACTED]; or, if we also take into account the [REDACTED] from [REDACTED], assuming an [REDACTED] of HK\$[REDACTED] per [REDACTED] (being the low-end of the indicative [REDACTED] range), 19.9 months from the date of this document. Our Directors and our management team will continue to monitor our working capital, cash flows and our business development status.

KEY FINANCIAL RATIO

Our current ratio, which equals current assets divided by current liabilities, was 9.3, 5.2 and 2.6 as of December 31, 2021 and 2022 and September 30, 2023, respectively. See “Financial Information—Key Financial Ratio” for details.

UNAUDITED PRELIMINARY FINANCIAL INFORMATION FOR THE YEAR ENDED DECEMBER 31, 2023

The unaudited preliminary financial information as of and for the year ended December 31, 2023 as set out in Appendix III to this document was agreed by the Company’s reporting accountant to the amounts set out in the Group’s unaudited consolidated financial statements for the year ended December 31, 2023 in accordance with Practice Note 730 (Revised) “Guidance for Auditors Regarding Preliminary Announcements of Annual Results” issued by the Hong Kong Institute of Certified Public Accountants. Since such preliminary financial information has not been audited by our reporting accountants or any other independent auditor, such financial information should not be relied upon to provide the same quality of information associated with information that has been subject to an audit by an independent auditor.

THE [REDACTED]

The [REDACTED] by us consists of:

- the [REDACTED] by us of initially [REDACTED] H Shares, or [REDACTED], for [REDACTED] by the public in Hong Kong, referred to in this document as the [REDACTED]; and
- the [REDACTED] by us of initially [REDACTED] H Shares, or [REDACTED], outside the U.S. (including to professional, institutional and other investors within Hong Kong) in offshore transactions in reliance on Regulation S referred to in this document as the [REDACTED].

SUMMARY

The number of [REDACTED] and [REDACTED], or together, [REDACTED], is subject to [REDACTED] as described in the section headed “[REDACTED]” in this document.

[REDACTED] STATISTICS

	<u>Based on the [REDACTED] of HK\$[REDACTED]</u> (HK\$)	<u>Based on the [REDACTED] of HK\$[REDACTED]</u> (HK\$)
Market capitalization of our Shares (approximation) ⁽¹⁾	[REDACTED]	[REDACTED]
Unaudited <i>pro forma</i> adjusted consolidated net tangible assets per Share	[REDACTED]	[REDACTED]

Notes:

- (1) The calculation of market capitalization is based on [REDACTED] Shares expected to be in issue immediately after completion of the [REDACTED].
- (2) The unaudited pro forma adjusted consolidated net tangible assets per Share is calculated after making the adjustments referred to in “Financial Information—Unaudited Pro Forma Adjusted Consolidated Net Tangible Assets” in this document.
- (3) No adjustment has been made to the unaudited pro forma statement of adjusted consolidated net tangible assets to reflect any trading results or other transactions we entered into subsequent to 30 September 2023.

FUTURE PLANS AND [REDACTED]

We estimate that we will receive [REDACTED] of approximately HK\$[REDACTED] after deducting the [REDACTED] and expenses payable by us in the [REDACTED], assuming an [REDACTED] of HK\$[REDACTED] per [REDACTED], being the mid-point of the indicative [REDACTED] range of HK\$[REDACTED] to HK\$[REDACTED] per [REDACTED] set out in this document. We intend to use the [REDACTED] from the [REDACTED] for the following purposes:

- approximately [REDACTED]%, or HK\$[REDACTED], will be allocated for the development and registration of our Core Product, QX002N, of which:
 - approximately [REDACTED]%, or HK\$[REDACTED], will be allocated to the Phase III clinical trial for the treatment of AS; and
 - approximately [REDACTED]%, or HK\$[REDACTED], will be allocated for the CMC costs and the preparation of requisite registration filings of QX002N;

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- approximately [REDACTED]%, or HK\$[REDACTED], will be allocated for the development and registration of our other Core Product, QX005N, of which:
 - approximately [REDACTED]%, or HK\$[REDACTED], will be allocated to QX005N for the treatment of AD, of which approximately [REDACTED]%, or HK\$[REDACTED], will be allocated to the Phase II clinical trial; and approximately [REDACTED]%, or HK\$[REDACTED], will be allocated to the Phase III clinical trial;
 - approximately [REDACTED]%, or HK\$[REDACTED], will be allocated to QX005N for the treatment of PN, of which approximately [REDACTED]%, or HK\$[REDACTED], will be allocated to the Phase II clinical trial; and approximately [REDACTED]%, or HK\$[REDACTED], will be allocated to the Phase III clinical trial;
 - approximately [REDACTED]%, or HK\$[REDACTED], will be allocated for the Phase II clinical trials of QX005N for the treatment of CRSwNP; and
 - approximately [REDACTED]%, or HK\$[REDACTED], will be allocated for the CMC costs and the preparation of requisite registration filings of QX005N;
- approximately [REDACTED]%, or HK\$[REDACTED], will be allocated for the development and registration of QX004N;
- approximately [REDACTED]%, or HK\$[REDACTED], will be allocated for clinical development of QX006N; and
- approximately [REDACTED]%, or HK\$[REDACTED], will be allocated for the research and development of certain of our other assets, including QX007N, QX010N and QX013N, and drug discovery.

[REDACTED] EXPENSES

Our [REDACTED] expenses include [REDACTED], professional fees and other fees incurred in connection to the [REDACTED] and the [REDACTED]. [REDACTED] expenses to be borne by us are estimated to be approximately RMB[REDACTED] (HK\$[REDACTED]), constituting approximately [REDACTED]% of the gross [REDACTED] from the [REDACTED]. The [REDACTED] expenses include fees and expenses of the Sole Sponsor and [REDACTED] (assuming an [REDACTED] of HK\$[REDACTED] per [REDACTED], being the mid-point of the indicative [REDACTED] range of HK\$[REDACTED] to HK\$[REDACTED] per [REDACTED]) of approximately RMB[REDACTED], fees and expenses of legal advisors and accountants of approximately RMB[REDACTED] and other fees and expenses of approximately RMB[REDACTED], primarily including fees and expenses of internal control consultant, financial printer, industry consultant and background search agent. During the Track Record Period, we incurred a total

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of RMB[REDACTED] (HK\$[REDACTED]) in [REDACTED] expenses, among which RMB[REDACTED] (HK\$[REDACTED]) was recognized in our consolidated statement of profit or loss, and RMB[REDACTED] (HK\$[REDACTED]) was directly attributable to the issue of our Shares to the public and will be deducted from equity upon the [REDACTED]. We estimate that we will incur additional [REDACTED] expenses of approximately RMB[REDACTED] (HK\$[REDACTED]), of which approximately RMB[REDACTED] (HK\$[REDACTED]) is expected to be charged to our consolidated statements of profit or loss, and approximately RMB[REDACTED] (HK\$[REDACTED]) is directly attributable to the issue of our shares to the public and will be deducted from equity upon the [REDACTED]. The [REDACTED] expenses above are the latest practicable estimate for reference only, and the actual amount may differ from this estimate.

RECENT DEVELOPMENTS

Breakthrough Therapy Designation of QX005N for PN

In January 2024, the CDE granted QX005N the breakthrough therapy designation for the treatment of PN, signifying its superior clinical benefits compared to current treatment methods. The designation is designed to expedite the development and regulatory review of innovative drugs demonstrating substantial potential in addressing serious conditions.

Outlicensing of QX008N

In January 2024, we entered into a technology transfer agreement with Joincare Pharmaceutical Group Industry Co., Ltd. (“Joincare”), to grant Joincare an exclusive license to develop, manufacture and commercialize QX008N in mainland China, Hong Kong and Macau. Joincare will be responsible for the BLA application and will be the MAH of QX008N in the licensed territory, once approved. See “Business—Our Other Key Product Candidates—QX008N—Licenses, Rights and Obligations” for details.

IND Approval of QX005N for AD in Adolescents

We obtained an IND approval of QX005N for the treatment of AD in adolescents aged between 12 and 17 years from the NMPA in October 2023. See “Business—Our Drug Candidates—Our Core Products—QX005N—Atopic Dermatitis” for details.

Impact of the COVID-19 Outbreak

We have not experienced any material disruption since the outbreak of the COVID-19 pandemic for our clinical activities, such as patient recruitment and clinical trials. The COVID-19 outbreak has caused some delays in certain clinical trials of QX002N, QX004N, QX005N, QX006N and QX008N in China. For example, our Phase II clinical trial of QX002N for AS, which commenced in January 2022, experienced delay in the completion of patient enrollment for approximately two months (from the expected completion in July 2022 to

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September 2022) and interruption in follow-up visits of some patients due to COVID-19-related lockdown measures in cities where our clinical trial sites/patients were located. In the Phase Ib clinical trial of QX005N for AD, due to COVID-19-related lockdown measures, one patient was lost to follow-up, whose data were considered invalid. However, the COVID-19 pandemic has not had a material impact on our overall clinical activities and development timeline. As of the Latest Practicable Date, the outbreak of COVID-19 had not caused any early termination of our clinical trials. We have employed various measures to mitigate any impact of the COVID-19 pandemic on our ongoing clinical trials and patient participation, including engaging new clinical trial sites to diversify the geographical location of clinical trials, adopting a variety of remote working tools in clinical trials, including remote monitoring, video and/or phone call visits, electronic consent and electronic health records, engaging in frequent communications with our CROs and principal investigators to identify and address any issues that may arise and suggesting the investigators to encourage enrolled patients to visit qualified local hospitals for follow-up evaluations if necessary. For instance, in response to the endemic outbreak of COVID-19 in various cities in 2022, in an effort to reduce the risk of being impacted by local outbreak of COVID-19 and related prevention and control policies, we engaged over 29 trial sites in over 16 provinces or municipalities in 2022 for our Phase II clinical trial of QX005N in adult patients with PN to diversify the geographic locations of our trial sites. Accordingly, such trial was not materially impacted by the COVID-19 pandemic. The trial sites of our ongoing clinical trials scatter in cities around China, including Beijing, Tianjin, Changsha, Hangzhou, Guangzhou, Changchun and Xi’an, among others. Given that the PRC government has substantially lifted its COVID-19 prevention and control policies since December 2022, our Directors are of the view that it is unlikely that the COVID-19 pandemic will have a material adverse effect on our business going forward.

During the Track Record Period and up to the Latest Practicable Date, the COVID-19 pandemic did not have any material adverse effect on our results of operations and financial position. However, we cannot assure you that the COVID-19 pandemic will not further escalate or have material adverse effect on our performance in the future. Please see “Risk Factors—Risks Relating to Our Operations—We may experience additional challenges related to the COVID-19 pandemic” for details.

Certain Management Estimate

We expect to incur a net loss in 2024, primarily because we expect to incur (i) significant research and development expenses as we continue to advance our drug development pipeline and (ii) significant equity-settled share-based payment expenses as we need to amortize granted equity incentives over the related vesting period, while we do not expect to generate substantial revenue in 2024 as we only plan to begin commercializing QX001S, our most advanced drug candidate, in the fourth quarter of 2024.

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No Material Adverse Change

Our Directors confirm that, as of the date of this document, there has been no material adverse change in our financial or trading position, indebtedness, mortgage, contingent liabilities, guarantees or prospects since September 30, 2023, the end of the period reported on in the Accountants’ Report set out in Appendix I to this document.

CSRC FILING

We submitted a filing to the CSRC for application of [REDACTED] of the H Shares on the Stock Exchange and the [REDACTED] on April 6, 2023. The CSRC confirmed our completion of filing on July 19, 2023. As advised by our PRC Legal Advisors, the Company has completed all necessary filings with the CSRC for the [REDACTED] of the H Shares on the Stock Exchange.

DEFINITIONS AND ACRONYMS

In this document, unless the context otherwise requires, the following terms shall have the meanings set out below. Certain other terms are explained in the section headed “Glossary of Technical Terms” in this document.

DEFINITIONS

“Accountants’ Report”	the accountants’ report for the Track Record Period prepared by KPMG, the text of which is set out in Appendix I to this document;
“Articles of Association” or “Articles”	the articles of association of our Company adopted on March 23, 2023 which shall become effective as of the date on which the H Shares are [REDACTED] on the Stock Exchange, as amended from time to time, a summary of which is set out in “Appendix VII—Summary of Articles of Association” to this document;
“associate(s)”	has the meaning ascribed to it under the Listing Rules;
“Audit Committee”	the audit committee of our Board;
“Board” or “Board of Directors”	the board of Directors;
“business day”	a day on which banks in Hong Kong are generally open for normal banking business to the public and which is not a Saturday, Sunday or public holiday in Hong Kong;

[REDACTED]

DEFINITIONS AND ACRONYMS

[REDACTED]

“Cellularforce”	Jiangsu Cellularforce Biotechnology Co., Ltd. (江蘇賽孚士生物技術有限公司), a company established in the PRC with limited liability on August 2, 2018 and an indirect non-wholly owned subsidiary of our Company which is owned as to 66% by Saifu Juli and 34% by Taizhou Huacheng;
“China” or “PRC”	The People’s Republic of China, but for the purpose of this document and for geographical reference only and except where the context requires otherwise, references in this document to “China” and the “PRC” do not apply to Hong Kong, the Macau Special Administrative Region and Taiwan;
“close associate(s)”	has the meaning ascribed to it under the Listing Rules;
“Companies Ordinance”	the Companies Ordinance (Chapter 622 of the Laws of Hong Kong) as amended, supplemented or otherwise modified from time to time;
“Companies (Winding Up and Miscellaneous Provisions) Ordinance”	the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Chapter 32 of the Laws of Hong Kong), as amended, supplemented or otherwise modified from time to time;
“Company”	Qyuns Therapeutics Co., Ltd. (江蘇荃信生物醫藥股份有限公司) (formerly known as Qyuns Therapeutics Co., Ltd. (江蘇荃信生物醫藥有限公司)), a limited liability company established in the PRC on June 16, 2015 which was converted into a joint stock company with limited liability on September 30, 2021;
“Company Law” or “PRC Company Law”	the Company Law of the PRC (中華人民共和國公司法), as amended, supplemented or otherwise modified from time to time;

DEFINITIONS AND ACRONYMS

“connected person(s)”	has the meaning ascribed to it under the Listing Rules;
“connected transaction(s)”	has the meaning ascribed to it under the Listing Rules;
“Controlling Shareholder(s)”	has the meaning ascribed to it under the Listing Rules and, unless the context requires otherwise, refers to Mr. Qiu, Mr. Yu Guo’an, Hangzhou Quanyi, Shanghai Quanyou and Xinfu Tongxin; and a Controlling Shareholder shall mean each or any of them;
	[REDACTED]
“Director(s)”	the director(s) of our Company;
“EIT Law”	the PRC Enterprise Income Tax Law (中華人民共和國企業所得稅法), as enacted by the NPC on March 16, 2007 and effective on January 1, 2008, as amended, supplemented or otherwise modified from time to time;
“Employee Share Incentive Scheme”	the restricted share scheme approved and adopted by our Company on September 15, 2022, a summary of the principal terms of which is set forth in “Appendix VIII—Statutory and General Information—D. Employee Share Incentive Scheme” to this document;
“Extreme Conditions”	the occurrence of “extreme conditions” as announced by any government authority of Hong Kong due to serious disruption of public transport services, extensive flooding, major landslides, large-scale power outage or any other adverse conditions before Typhoon Signal No. 8 or above is replaced with Typhoon Signal No. 3 or below;
“Frost & Sullivan”	Frost & Sullivan (Beijing) Inc., Shanghai Branch Co., a global market research and consulting company, which is an Independent Third Party;
“Frost & Sullivan Report”	an independent market research report commissioned by us and prepared by Frost & Sullivan for the purpose of this document;

[REDACTED]

DEFINITIONS AND ACRONYMS

- “Group” our Company and all of our subsidiaries or, where the context so requires, in respect of the period before our Company became the holding company of our present subsidiaries, the business operated by such subsidiaries or their predecessors (as the case may be);
- “Guide” The Guide for New Listing Applicants, as published by the Stock Exchange on November 29, 2023 and effective on January 1, 2024, as amended or supplemented or otherwise modified from time to time;
- “H Share(s)” shares of our Company for which an application has been made for [REDACTED] and permission to [REDACTED] on the Stock Exchange;
- [REDACTED]
- “Hangzhou Quanli” Hangzhou Quanli Investment Management Partnership (Limited Partnership) (杭州荃厲投資管理合夥企業(有限合夥)), a limited partnership established in the PRC on May 15, 2015 and one of our original employee incentive platforms, which was owned as to 1% by Mr. Qiu as its general partner and 99% by Mr. Yu Guo’an as its limited partner and was deregistered on March 21, 2022;
- “Hangzhou Quanyi” Hangzhou Quanyi Investment Management Partnership (General Partnership) (杭州荃毅投資管理合夥企業(普通合夥)), a general partnership established in the PRC on May 15, 2015 and one of our Controlling Shareholders, which is owned as to 50% by Mr. Qiu and 50% by Mr. Yu Guo’an, both as its general partners acting in concert;
- “HK\$” Hong Kong dollars, the lawful currency of Hong Kong;

[REDACTED]

DEFINITIONS AND ACRONYMS

[REDACTED]

“Hong Kong” or “HK”

the Hong Kong Special Administrative Region of the PRC;

[REDACTED]

DEFINITIONS AND ACRONYMS

[REDACTED]

“Huadong Medicine”	Huadong Medicine Co., Ltd. (華東醫藥股份有限公司), a pharmaceutical company whose shares are listed on the Shenzhen Stock Exchange (stock code: 000963);
“Independent Third Party(ies)”	individuals or company(ies), who or which, to the best of our Directors’ knowledge, information and belief, having made all reasonable enquiries, is not a connected person of our Company within the meaning of the Listing Rules;

[REDACTED]

DEFINITIONS AND ACRONYMS

[REDACTED]

“Jiayin Lucky-source”

Gongqingcheng Jiayin Lucky-source Equity Investment Partnership (Limited Partnership) (共青城佳銀瑞享源股權投資合夥企業(有限合夥)), a limited partnership established in the PRC on March 2, 2020 and one of our [REDACTED] Investors. For its background information, see “History and Corporate Structure—[REDACTED] Investments” in this document;

[REDACTED]

“Latest Practicable Date”

February 17, 2024, being the latest practicable date for the purpose of ascertaining certain information contained in this document prior to its publication;

“LEI”

Legal Entity Identifier, a 20-character alpha-numeric code under the Global LEI System adopted by the Financial Stability Board to uniquely identify distinct legal entities which participate in financial transactions;

[REDACTED]

“Listing Rules”

the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited, as amended or supplemented or otherwise modified from time to time;

DEFINITIONS AND ACRONYMS

“Main Board”	the stock exchange (excluding the option market) operated by the Stock Exchange which is independent from and operated in parallel with the Growth Enterprise Market of the Stock Exchange;
“Matrix Partners China”	Matrix Partners China VI, L.P. and Matrix Partners China VI-A, L.P., both being limited partnerships incorporated under the laws of the Cayman Islands and our [REDACTED] Investors. For their background information, see “History and Corporate Structure—[REDACTED] Investments” in this document;
“Mr. Qiu”	Mr. Qiu Jiwan (裘霽宛), our founder, executive Director, chairman of our Board, our chief executive officer and general manager, and one of our Controlling Shareholders;
“Nomination Committee”	the nomination committee of our Board;

[REDACTED]

DEFINITIONS AND ACRONYMS

“PRC government”	the central government of the PRC and all governmental subdivisions (including provincial, municipal and other regional or local government entities) and organizations of such government or, as the context requires, any of them;
“PRC Legal Advisors”	JunHe LLP, our legal advisors as to PRC laws in connection with the [REDACTED];
“[REDACTED] Investment(s)”	the [REDACTED] investment(s) in our Company, details of which are set out in “History and Corporate Structure—[REDACTED] Investments” in this document;
“[REDACTED] Investor(s)”	the investor(s) of the [REDACTED] Investments;

[REDACTED]

“Regulation S”	Regulation S under the U.S. Securities Act;
“Remuneration and Appraisal Committee”	the remuneration and appraisal committee of our Board;
“Saifu Juli”	Taizhou Saifu Juli Biomedical Co., Ltd. (泰州市賽孚聚力生物醫藥有限公司), a company established in the PRC with limited liability on July 6, 2018 and a direct wholly owned subsidiary of our Company;

DEFINITIONS AND ACRONYMS

“Shanghai Quanyou”	Shanghai Quanyou Fanyue Investment Management Partnership (Limited Partnership) (上海荃友凡悅投資管理合夥企業(有限合夥)), a limited partnership established in the PRC on November 2, 2015 and one of our Controlling Shareholders, which is owned as to approximately 45.71% by Mr. Qiu as its general partner, 8.57% by Ms. Xu Qiu (許秋), the spouse of Mr. Qiu, as one of its limited partners, and 45.72% by three Independent Third Parties as its other limited partners;
“Share(s)”	ordinary share(s) with par value RMB1.00 each in the share capital of the Company;
“Shareholder(s)”	holder(s) of our Share(s);
“Sole Sponsor” and “[REDACTED]”	China International Capital Corporation Hong Kong Securities Limited;
	[REDACTED]
“State Council”	the State Council of the PRC (中華人民共和國國務院);
“Stock Exchange”	The Stock Exchange of Hong Kong Limited, a wholly owned subsidiary of Hong Kong Exchange and Clearing Limited;
“Strategy and Development Committee”	the strategy and development committee of our Board;
“subsidiary(ies)”	has the meaning ascribed to it under the Listing Rules;
“substantial shareholder(s)”	has the meaning ascribed to it under the Listing Rules;
“Supervisor(s)”	the supervisor(s) of our Company;
“Supervisory Committee”	the supervisory committee of our Company;

DEFINITIONS AND ACRONYMS

“Taizhou Quanli” Taizhou Quanli Enterprise Management Partnership (Limited Partnership) (泰州荃勵企業管理合夥企業(有限合夥)), a limited partnership established in the PRC on August 17, 2018 and one of our original employee incentive platforms, which was owned as to 1% by Mr. Qiu as its general partner and 99% by Mr. Wu Yiliang (吳亦亮), our executive Director and executive deputy general manager of Cellularforce, and deregistered on February 18, 2022;

“Track Record Period” the two years ended December 31, 2021 and 2022 and the nine months ended September 30, 2023;

[REDACTED]

“[REDACTED] Share(s)” ordinary Share(s) issued by our Company with a nominal value of RMB1.00 each which is/are not listed on any stock exchange;

“U.S.” or “United States” the United States of America, its territories, its possessions and all areas subject to its jurisdiction;

“U.S. persons” U.S. persons as defined in Regulation S;

“U.S. Securities Act” United States Securities Act of 1933, as amended, supplemented or otherwise modified from time to time;

“we,” “us” or “our” the Company or the Group, as the context requires;

“Xinfu Quanxin” Taizhou Xinfu Quanxin Enterprise Management Partnership (Limited Partnership) (泰州信孚全心企業管理合夥企業(有限合夥)), a limited partnership established in the PRC on February 27, 2023, which is owned as to approximately 0.56% by Mr. Wu Yiliang, our executive Director and executive deputy general manager of Cellularforce as its general partner and approximately 99.44% by 28 employees of our Group as its limited partners, and is one of our employee share incentive platforms;

DEFINITIONS AND ACRONYMS

“Xinfu Tongxin”	Taizhou Xinfu Tongxin Enterprise Management Partnership (Limited Partnership) (泰州信孚同心企業管理合夥企業(有限合夥)), a limited partnership established in the PRC on August 19, 2021, which is owned as to approximately 7.20% by Mr. Qiu as its general partner, approximately 11.38% by Xinfu Quanxin as one of its limited partners and approximately 81.42% by 39 employees of our Group as its limited partners, and is one of our employee share incentive platforms and one of our Controlling Shareholders;
“Zhongmei Huadong”	Hangzhou Zhongmei Huadong Pharmaceutical Co., Ltd. (杭州中美華東製藥有限公司), a company established in the PRC with limited liability on December 31, 1992 and one of our [REDACTED] Investors. For its background information, see “History and Corporate Structure—[REDACTED] Investments” in this document;

DEFINITIONS AND ACRONYMS

ACRONYMS

“AFRC” the Accounting and Financial Reporting Council of Hong Kong;

“CAGR” compounded annual growth rate, which is calculated by dividing the amount at the end of the period by the amount of the beginning of that period, raising the result to an exponent of one divided by the number of years in the period, and subtracting one from the subsequent result;

[REDACTED]

“CDE” Center for Drug Evaluation (國家藥品監督管理局藥品審評中心), a division of the NMPA responsible for acceptance and technical review of applications for drug clinical trials and drug marketing authorization;

“CNIPA” National Intellectual Property Administration of the PRC (國家知識產權局);

“CSRC” China Securities Regulatory Commission (中國證券監督管理委員會);

“EMA” European Medicines Agency;

“FDA” the United States Food and Drug Administration;

[REDACTED]

“IASB” International Accounting Standards Board;

“IDMC” independent data monitoring committee;

“IFRS” International Financial Reporting Standards;

DEFINITIONS AND ACRONYMS

“MAH”	Marketing Authorization Holder;
“MOFCOM” or “Ministry of Commerce”	the Ministry of Commerce of the PRC (中華人民共和國商務部);
“NASDAQ”	the Nasdaq Global Select Market in the United States;
“NMPA”	the National Medical Products Administration of the PRC (國家藥品監督管理局) and its predecessor, the China Food and Drug Administration (國家食品藥品監督管理總局);
“PBOC”	the People’s Bank of China (中國人民銀行), the central bank of the PRC;
“PCT”	the Patent Cooperation Treaty;
“Renminbi” or “RMB”	the lawful currency of the PRC;
“SAFE”	the State Administration of Foreign Exchange of the PRC (中華人民共和國國家外匯管理局);
“SAMR”	the State Administration for Market Regulation (國家市場監督管理總局);
“Securities and Futures Commission” or “SFC”	the Securities and Futures Commission of Hong Kong;
“SFO”	the Securities and Futures Ordinance, Chapter 571 of the Laws of Hong Kong, as amended, supplemented or otherwise modified from time to time;
“STA”	the State Taxation Administration of the PRC (中華人民共和國國家稅務總局); and
“VAT”	value-added tax.

DEFINITIONS AND ACRONYMS

For ease of reference, the names of Chinese laws and regulations, governmental authorities, institutions, natural persons or other entities (including certain of our subsidiaries) have been included in the document in both the Chinese and English languages and in the event of any inconsistency, the Chinese versions shall prevail. English translations of company names and other terms from the Chinese language are provided for identification purposes only.

Certain amounts and percentage figures included in this document were subjected to rounding adjustments. Accordingly, figures shown as totals in certain tables may not be arithmetic aggregation of the figures preceding them.

For the purpose of this document, references to “provinces” of China include provinces, municipalities under direct administration of the central government and provincial-level autonomous regions.

GLOSSARY OF TECHNICAL TERMS

In this document, unless the context otherwise requires, explanations and definitions of certain terms used in this document in connection with our Group and our business shall have the meanings set out below. The terms and their meanings may not correspond to standard industry meaning or usage of these terms.

“adverse event” or “AE”	any untoward medical occurrence in a patient or clinical investigation subject administered a drug or other pharmaceutical product during clinical trials, which does not necessarily have a causal relationship with the treatment
“agonist”	a chemical that binds to and activates a receptor or other membrane protein to produce a biological response
“ankylosing spondylitis” or “AS”	a chronic progressive inflammatory disease that is primarily characterized by inflammation of the spinal joints, leading to reduced flexibility of the joints and stiffness in the spine over time
“antagonist”	a type of drug that blocks or decreases a biological response by binding to and blocking a receptor or a ligand without activating it
“antibiotic”	a drug or medicine that kills or inhibits the growth of bacteria. Antibiotics are the chief antibacterial agents for fighting bacterial infections, and antibiotic medications are widely used in the treatment and prevention of those infections
“antibody”	a protein produced in response to and counteracting a specific antigen. Antibodies combine chemically with substances which the body recognizes as alien, such as bacteria, viruses and foreign substances in the blood

GLOSSARY OF TECHNICAL TERMS

“ASAS20”	Assessment of Spondyloarthritis International Society 20, a widely used measurement of symptom improvement in AS patients, defined as (i) an improvement of no less than 20% from baseline (and absolute improvement from baseline of at least 1 on a 0-to-10 scale) in at least three of the following four domains: patient global assessment of disease, total back pain, function (as assessed by the Bath Ankylosing Spondylitis Functional Index) and inflammation, and (ii) an absence of deterioration from baseline (meaning a worsening of no less than 20% and absolute worsening of at least 1 on a 0-to-10 scale) in the remaining domain
“ASAS40”	Assessment of Spondyloarthritis International Society 40, defined as an improvement of no less than 40% in at least three of the four domains (same as ASAS20) with an absolute improvement of at least 2 on a 0-to-10 scale, and no worsening in the remaining domain
“atopic dermatitis” or “AD”	an immune-mediated inflammatory skin disease that causes dry, itchy and inflamed skin
“AUC”	area under curve, a parameter of systemic exposure
“AUC _{0-inf} ” or “AUC _{inf} ”	area under the curve over a period of time from administration (0) to the time that the drug is no longer present in the body (infinity)
“AUC _{0-last} ” or “AUC _{last} ”	area under the concentration-time curve from the first time point measured (0) to the time of the last measurable concentration
“AUC _{0-t} ”	area under the concentration-time curve from the first time point measured (0) to the last time point measured (t)
“autoimmune”	with respect to any disorder or disease, an abnormal immune response of the body against substances and tissues normally present in the body
“bioavailability”	the fraction of an administered dose of drug that reaches systemic circulation, which is one of the principal pharmacokinetic properties of drugs

GLOSSARY OF TECHNICAL TERMS

“biologics”	drug products derived from a variety of natural sources—human, animal, or microorganism—that may be produced by biotechnology methods and other cutting-edge technologies (in contrast to small-molecule drugs, which are chemically synthesized). Biologics can be composed of sugars, proteins or nucleic acids or complex combinations of these substances, or may be living entities, such as cells and tissues
“biosimilar”	a follow-on version of innovator biopharmaceuticals which are separately developed after patents protecting the innovator biopharmaceuticals have expired and have similar quality, safety and efficacy as the innovator biopharmaceuticals
“BLA”	biologics license application
“bronchodilators”	a type of medication that makes breathing easier by relaxing the muscles in the lungs and widening the airways
“Crohn’s disease” or “CD”	a chronic, incurable inflammatory bowel disease that affects the lining of the digestive tract and can sometimes cause life-threatening complications. CD symptoms can include abdominal pain, diarrhea, weight loss, anemia and fatigue
“CDMO”	a contract development and manufacturing organization, which provides support to the pharmaceutical industry by providing development and manufacturing services outsourced on a contract basis
“cell line”	a population of cells that descend from a single cell and contain the same genetic makeup, and can be propagated repeatedly
“cGMP”	current good manufacturing practice, regulations and procedures that provide for proper design, monitoring, and control of manufacturing processes and facilities
“clinical trial”	a research study for validating or finding the therapeutic effects and side effects of test drugs in order to determine the therapeutic value and safety of such drugs

GLOSSARY OF TECHNICAL TERMS

“C _{max} ”	maximum concentration, a parameter of systemic exposure
“CMC”	the chemistry, manufacturing and controls processes in the development, licensure, manufacturing and ongoing marketing of pharmaceutical products
“chronic obstructive pulmonary disease” or “COPD”	a chronic inflammatory lung disease that causes obstructed airflow from the lungs, symptoms including breathing difficulty, cough and mucus production
“corticosteroids”	class of steroid hormones drug that lower inflammation in the body and reduce immune system activity
“CRO”	a contract research organization, which provides support to the pharmaceutical industry by providing research and development services outsourced on a contract basis
“chronic rhinosinusitis with nasal polyps” or “CRSwNP”	a subgroup of chronic rhinosinusitis characterized by the presence of fleshy swellings (nasal polyps) that develop in the lining of the nose and paranasal sinuses
“chronic spontaneous urticaria” or “CSU”	the occurrence of urticaria for six weeks or longer without identifiable specific triggers
“cytokine”	proteins secreted by cells in both innate and adaptive immune responses, which can regulate diverse functions in the immune response
“double blind”	with respect to a clinical trial or study, one in which neither the participants nor the persons or entities conducting the same know who is receiving a particular treatment. This procedure is utilized to prevent bias in research results
“EASI”	the Eczema Area and Severity Index, a standardized evaluation tool for severity of AD signs in clinical studies that integrates body surface and the intensity of lesional skin into one composite score
“endpoint”	with respect to a clinical study or trial, the outcome that is measured
“eosinophil”	a type of disease-fighting white blood cell

GLOSSARY OF TECHNICAL TERMS

“gastrointestinal”	relating to or affecting the stomach and intestines, which comprise the digestive system
“half-life” or “ $T_{1/2}$ ”	the time it takes for the concentration of a drug in the plasma or the total amount in the body to be reduced by 50%
“immunoglobulin” or “Ig”	also known as antibody, a glycoprotein molecule produced by plasma cell (white blood cell)
“inflammatory bowel disease” or “IBD”	ongoing inflammation of all or part of the digestive tract, including CD and UC
“IGA”	the Investigator’s Global Assessment, a five-point scale that provides a global clinical assessment of AD severity ranging from 0 to 4 (clear, mild, moderate and severe disease)
“IgE”	immunoglobulin E, a type of antibody that has only been found in mammals and initiates an allergic reaction, and its level is typically elevated in allergic disorders
“IgG”	human immunoglobulin G, the most common antibody type found in blood circulation that plays an important role in antibody-based immunity against invading pathogens
“IL”	interleukin, a type of cytokine-signaling molecule in the immune system to provoke an immune response in the body of a human and other animals
“immune system”	a system of biological structures and processes within an organism that protects against disease. In order to function properly, an immune system must detect a wide variety of agents, from viruses to parasitic worms, and distinguish them from the organism’s own healthy tissue
“immunogenicity”	the ability of a particular substance, such as an antigen or epitope, to provoke an immune response in the body of a human and other animal
“immunosuppressants”	drugs or medicines that depress or prevent activity of the immune system

GLOSSARY OF TECHNICAL TERMS

“IND”	investigational new drug
“inhibitor”	a substance added or applied to another substance to slow down a reaction or to prevent an unwanted chemical change
“ <i>in vitro</i> ”	a medical study or experiment which is done in the laboratory within the confines of a test tube or laboratory dish
“ <i>in vivo</i> ”	a medical test, experiment or procedure that is done on (or in) a living organism, such as a laboratory animal or human
“lupus nephritis” or “LN”	a common complication of SLE, where the immune system mistakenly attacks the kidneys, leading to inflammation and possible organ damage
“lymphocyte”	a sub-type of white blood cells, such as T cells and B cells
“mast cell”	a type of white blood cell that is found in connective tissues all through the body, especially under the skin, near blood vessels and lymph vessels, in nerves and in the lungs and intestines
“monoclonal antibody” or “mAb”	antibody generated by identical immune cells that are all clones of the same parent cell
“MTD”	maximum tolerated dose, the highest dose of a drug or treatment that does not cause unacceptable side effects. The maximum tolerated dose is determined in clinical trials by testing increasing doses on different groups of people until the highest dose with acceptable side effects is found
“NK cell”	natural killer cell, a type of white blood cell that has granules with enzymes that can kill tumor cells or cells infected with a virus

GLOSSARY OF TECHNICAL TERMS

“NOAEL”	no-observed-adverse-effect level, the level of exposure of an organism, found by experiment or observation, at which there is no biologically or statistically significant increase in the frequency or severity of any adverse effects (<i>e.g.</i> , alteration of morphology, functional capacity, growth, development or life span) in the exposed population when compared to its appropriate control
“NRDL”	National Reimbursement Drug List of China
“OD”	Optical Density
“pharmacodynamics” or “PD”	the study of how a drug affects an organism, which, together with pharmacokinetics, influences dosing, benefit and adverse effects of the drug
“pharmacokinetics” or “PK”	the study of the bodily absorption, distribution, metabolism and excretion of drugs, which, together with pharmacodynamics, influences dosing, benefit and adverse effects of the drug
“pharmacology”	a branch of medicine and pharmaceutical sciences which is concerned with the study of drug or medication action, where a drug can be broadly or narrowly defined as any man-made, natural or endogenous molecule which exerts a biochemical or physiological effect on the cell, tissue, organ or organism
“Phase I clinical trial”	study in which a drug is introduced into healthy human subjects or patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion and, if possible, an early indication of its effectiveness. Phase I clinical trial can be further divided into the Phase Ia clinical trial, which is often a single ascending dose study, and the Phase Ib clinical trial, which is often a multiple ascending dose study
“Phase II clinical trial”	study in which a drug is administered to a limited patient population to identify possible adverse effects and safety risks, preliminarily evaluate the efficacy of the product for specific targeted diseases and determine dosage tolerance and optimal dosage

GLOSSARY OF TECHNICAL TERMS

“Phase III clinical trial”	study in which a drug is administered to an expanded patient population generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to statistically evaluate the efficacy and safety of the product for approval and to provide adequate information for the labeling of the product
“phototherapy”	a form of treatment that uses ultraviolet light to treat skin conditions
“placebo”	any dummy medical treatment administered to the control group in a controlled clinical trial in order that the specific and non-specific effects of the experimental treatment can be distinguished
“preclinical studies”	studies testing a drug on non-human subjects, to gather efficacy, toxicity, pharmacokinetic and safety information and to decide whether the drug is ready for clinical trials
“prurigo nodularis” or “PN”	a chronic skin disorder characterized by the presence of hard and extremely itchy bumps known as nodules, which tend to be found in easy-to-scratch areas, such as the arms, legs, the upper back and abdomen
“pruritus”	itchy skin, which is an uncomfortable, irritating sensation that makes the patient want to scratch
“psoriasis” or “Ps”	a skin disease associated with dysregulation of the immune systems that causes a rash with itchy and scaly patches, most commonly on the knees, elbows, trunk and scalp
“Q2W”	every two weeks
“Q4W”	every four weeks
“receptor”	a region of tissue, or a molecule in a cell membrane, which responds specifically to a particular signal, that is any of a neurotransmitter, hormone, antigen or other substance
“rheumatoid arthritis” or “RA”	a chronic autoimmune disorder primarily characterized by inflammation in the joints

GLOSSARY OF TECHNICAL TERMS

“serious adverse event” or “SAE”	any AE in a patient or participant during clinical trials that results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, or is a congenital anomaly/birth defect
“systemic lupus erythematosus” or “SLE”	an autoimmune disease primarily characterized by widespread inflammation and tissue damage in various organs, such as the skin, brain, lungs, kidneys and blood vessels
“TARC”	thymus and activation-regulated chemokine, a type of disease-specific biomarkers for AD
“TEAE”	treatment-emergent adverse event, an undesirable event not present prior to the medical treatment or an already present adverse event that worsens following the treatment in terms of intensity or frequency
“TESAE”	treatment-emergent serious adverse event, a serious adverse event occurring or worsening following the treatment in terms of intensity or frequency
“T helper cells” or “Th cells”	a type of immune cells that activates other immune cells by releasing cytokines and play an important role in the adaptive immune system, which is also known as CD4 ⁺ T cells
“T _{max} ”	the time it takes for a drug to reach C _{max} after administration, a PK parameter
“TNF”	tumor necrosis factor, a group of cell signaling proteins (cytokines) that regulate immune cells and mediate the inflammatory responses
“TNF-α”	a prominent member of the TNF family and one of the cytokines that make up the acute phase reaction, a series of physiological process occurring soon after the onset of inflammatory processes

GLOSSARY OF TECHNICAL TERMS

“tolerability”	the degree to which overt adverse events of a drug can be tolerated by a patient, as defined by International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
“toxicity”	the degree to which a substance or a mixture of substances can harm humans or animals
“TSLP”	thymic stromal lymphopoietin, a protein belonging to the cytokine family, which plays an important role in the maturation of T cell populations through activation of antigen presenting cells (APCs)
“type 2 inflammation”	a specific type of immune response pattern driven by certain type 2 immune cells, which produce the type 2 cytokines (including IL-4, IL-5 and IL-13) and other inflammatory mediators. Diseases that can be caused by dysregulated type 2 inflammation include atopic dermatitis, asthma and chronic rhinosinusitis, etc.
“ulcerative colitis” or “UC”	a chronic, inflammatory bowel disease that causes inflammation in the digestive tract
“urticaria”	a type of skin disease characterized by itchy swelling on the skin surface

FORWARD-LOOKING STATEMENTS

We have included in this document forward-looking statements. Statements that are not historical facts, including statements about our intentions, beliefs, expectations or predictions for the future, are forward-looking statements.

This document contains certain forward-looking statements and information relating to our Company and our subsidiaries that are based on the beliefs of our management as well as assumptions made by and information currently available to our management. When used in this document, the words “aim,” “anticipate,” “believe,” “could,” “expect,” “going forward,” “intend,” “may,” “ought to,” “plan,” “project,” “seek,” “should,” “will,” “would” and the negative of these words and other similar expressions, as they relate to our Group or our management, are intended to identify forward-looking statements. Such statements reflect the current views of our management with respect to future events, operations, liquidity and capital resources, some of which may not materialize or may change. These statements are subject to certain risks, uncertainties and assumptions, including the other risk factors as described in this document. You are strongly cautioned that reliance on any forward-looking statements involves known and unknown risks and uncertainties. The risks and uncertainties facing our company which could affect the accuracy of forward-looking statements include, but are not limited to, the following:

- the timing of initiation and completion and the progress of our research and development programs and clinical trials;
- the timing and likelihood of regulatory filings and approvals, and pricing of our drug candidates;
- the commercialization of our drug candidates;
- the market opportunities and competitive landscape of our drug candidates;
- estimates of our costs, expenses, future revenues, capital expenditures and our needs for additional financing;
- our ability to attract and retain senior management and key employees;
- our operations and business prospects;
- future developments, trends, conditions and competitive landscape in the industry and markets in which we operate;
- changes to regulatory and operating conditions in the industry and markets in which we operate;

FORWARD-LOOKING STATEMENTS

- our strategies, plans, objectives and goals and our ability to successfully implement them;
- our financial condition and operating results and performance;
- industry trends and competition; and
- general political and economic conditions;

Subject to the requirements of applicable laws, rules and regulations, we do not have any and undertake no obligation to update or otherwise revise the forward-looking statements in this document, whether as a result of new information, future events or otherwise. As a result of these and other risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this document might not occur in the way we expect or at all. Accordingly, you should not place undue reliance on any forward-looking information. All forward-looking statements in this document are qualified by reference to the cautionary statements in this section.

In this document, statements of or references to our intentions or those of our Directors are made as of the date of this document. Any such information may change in light of future developments.

RISK FACTORS

An investment in our H Shares involves significant risks. You should carefully consider all of the information in this document, including the risks and uncertainties described below, as well as our financial statements and the related notes, and the “Financial Information” section, before making an investment in our H Shares. Particularly, we are a biotech company [REDACTED] on the Main Board of the Stock Exchange under Chapter 18A of the Listing Rules. The following is a description of what we consider to be our material risks. Any of the following risks could have a material adverse effect on our business, financial condition and results of operations. In any such case, the market price of our H Shares could decline, and you may lose all or part of your investment given the nature of biotech industry.

These factors are contingencies that may or may not occur, and we are not in a position to express a view on the likelihood of any such contingency occurring. The information given will not be updated after the date hereof, and is subject to the cautionary statements in “Forward-looking Statements” in this document.

We believe there are certain risks and uncertainties involved in an investment in our H Shares, some of which are beyond our control. We have categorized these risks and uncertainties into: (i) risks relating to the development of our drug candidates; (ii) risks relating to the manufacturing and commercialization of our drug candidates; (iii) risks relating to our financial position and need for additional capital; (iv) risks relating to extensive government regulation; (v) risks relating to our intellectual property rights; (vi) risks relating to our operations; (vii) risks relating to the [REDACTED].

Additional risks and uncertainties that are presently not known to us or that we currently deem immaterial could also harm our business, financial condition and operating results. You should consider our business and prospects in light of the challenges we face, including the ones discussed in this section.

RISKS RELATING TO THE DEVELOPMENT OF OUR DRUG CANDIDATES

Our drug candidates will be subject to intense competition with biologic drugs and other drugs for autoimmune and allergic diseases after commercialization and may fail to compete effectively against competitors.

The pharmaceutical industry is subject to intense competition. In particular, according to Frost & Sullivan, competition within China’s biologic drug market for autoimmune and allergic diseases is expected to continue to intensify in the following years, primarily due to growing efforts among pharmaceutical companies to address the vast underserved medical needs in the field, favorable government policies and expansion of approved biologic drugs and indications. As a result, we will face intense competition with respect to any drug candidates that we may seek to develop or commercialize in the future.

RISK FACTORS

Many of our drug candidates will face competition from biologic drugs developed by major international and domestic pharmaceutical companies with the same targets as ours. For example, QX001S, our most advanced and only biosimilar drug candidate, is a proposed biosimilar to ustekinumab, one of the major biologic treatments and best-selling drugs for the treatment of Ps worldwide. If and when we obtain regulatory approval for QX001S, it will compete not only with the originator drug, Stelara, but also with other biosimilars of ustekinumab and biologics of the same target in China. As of the Latest Practicable Date, Stelara had been approved for the treatment of Ps in China and three other biologic drug candidates with the same target as QX001S were in the clinical stage. In particular, we expect QX001S to face intense competition upon its commercialization considering that the other two ustekinumab biosimilar candidates in China commenced their Phase III clinical trials at a similar time as our Phase III trial. Similarly, we also expect our Core Products, QX002N and QX005N, to face (i) intense competition from approved drugs from multinational pharmaceutical companies, such as secukinumab and ixekizumab for QX002N and dupilumab for QX005N; and (ii) potential competition from drug candidates under clinical development in China. Specifically, as of the Latest Practicable Date, there were 10 IL-17-targeting biologic drug candidates in addition to QX002N indicated for AS in the clinical stage in China and 20 biologic drug candidates in addition to QX005N for AD in the clinical stage in China, among which 9 were IL-4R α inhibitors. Some of the drug candidates in the clinical stage were in the same or a more advanced stage of development than our QX002N or QX005N.

The ability of our drug candidates to successfully compete with other drugs of the same targets and gain market share against the originator drug and other biosimilars will depend on various factors, including the timing of regulatory approval, the efficacy and safety profile of our drug candidates in comparison to other drugs, convenience of our dosing regimens, pricing and market coverage of our or our commercialization partner's sales and distribution channels. However, we cannot guarantee you that we will be able to successfully compete on all or any of the aforementioned aspects against major pharmaceutical companies that operate on a global or national level, which may have stronger medical and technological capabilities, greater pricing flexibility, better track records, greater brand name recognition or greater financial, marketing and public relations resources than we do.

Furthermore, our drug candidates will also face competition from biologic drugs with different targets developed for the same indication. For example, in addition to IL12/IL23 inhibitors, QX001S will also compete with, among others, TNF- α inhibitors and IL-17A inhibitors which are or will be approved by the NMPA for the treatment of Ps in China. In addition, traditional non-biologic medications are widely prescribed for autoimmune and allergic disease in China. We cannot guarantee you that biologic drugs will successfully replace these traditional therapies for the relevant patient population. Furthermore, newer generations of drugs, including biologics and small-molecule targeted drugs, may be developed that compete with our drugs. For example, tyrosine kinase 2 (TYK2) inhibitors, a newer family of small-molecule targeted drugs, have demonstrated in clinical studies promising efficacy profiles and improvements on traditional limitations of JAK-related toxicities. These newer-generation drugs may have advantages such as ease of administration.

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If any or all of our drug candidates fail to compete effectively in one or more of the aforementioned fronts, our competitors may be able to establish a strong market position and render our drug candidates non-competitive or even obsolete before we can recover the expenses of developing and commercializing any of our drug candidates. Our efforts to compete may compel us to reduce prices for our drug, or take other measures that may adversely affect our profitability. Such inability to compete effectively could erode our profit margins and market share, which may in turn materially and adversely affect our business, financial position, results of operations and growth potential.

We depend substantially on the success of our drug candidates, all of which are undergoing preclinical or clinical development. If we are unable to successfully complete clinical development of our drug candidates, or experience significant delays in doing so, our business prospects will be significantly impacted.

Our business will depend on the successful development of our existing drug candidates and new drug candidates that we may identify and develop. As of the Latest Practicable Date, our pipeline consisted of eight drug candidates in various phases of preclinical or clinical development and we had one drug candidate, QX001S, at the BLA filing stage in China. We cannot guarantee you that we can successfully complete the preclinical and clinical development of any of our existing drug candidates in a timely manner, or at all. Most of our drug candidates will require further preclinical and/or clinical development before they could obtain regulatory approval in China and potentially other jurisdictions.

All of our drug candidates are biologic drugs indicated for the treatment of autoimmune or allergic diseases. The development for such drugs is a complex and challenging process due to various factors, including but not limited to: (i) complicated mechanisms of autoimmune and allergic diseases, which are multifactorial disorders that may involve dysregulated immune responses, genetic and environmental factors and interactions between different cell types and signaling pathways; (ii) limited understanding of the relevant pathogenesis despite significant advances in the research of autoimmune and allergic diseases in recent years; (iii) heterogeneous patient populations with varying symptoms, disease severity and responses to a specific therapy; (iv) complex standards for drug evaluation, which requires the use of multiple endpoints, including clinical, biochemical, and immunological measures; and (v) safety concerns, including infections, allergic reactions, and immune-related toxicities. Therefore, the development of biological drugs for autoimmune and allergic diseases is a complex and challenging process that requires a deep understanding of disease pathogenesis, careful selection of patient populations and rigorous evaluation of drug safety and efficacy.

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We have invested a significant portion of our efforts and financial resources in the discovery and development of our drug candidates. For the years ended December 31, 2021 and 2022 and the nine months ended September 30, 2023, our research and development expenses amounted to RMB151.9 million, RMB257.2 million and RMB263.3 million, respectively. We expect to continue to incur substantial and increasing expenditures through the projected commercialization of our drug candidates. The success of our drug candidates in terms of preclinical or clinical development will depend on a number of factors, including:

- successful completion of preclinical studies;
- receipt of regulatory approvals for our clinical trials;
- successful enrollment of patients in, and completion of, clinical trials;
- favorable safety and efficacy data from our clinical trials and other studies;
- maintaining sufficient manufacturing capabilities to ensure supply of our drug candidates for clinical use;
- our ability to effectively and simultaneously design, manage and supervise a significant number and range of clinical trials;
- our ability to reach agreements on acceptable terms with prospective CROs and trial sites, the terms of which can be subject to negotiation and may vary among different CROs and trial sites;
- the performance by CROs, or other third parties we may retain to conduct clinical trials, of their duties to us in a manner that complies with our protocols and applicable laws and that protects the integrity of the resulting data;
- our ability to control clinical trial-related costs;
- our ability to obtain sufficient supplies of competitor drugs or originator drugs that may be necessary for use in clinical trials for evaluation of our drug candidates;
- obtaining and maintaining patent, trade secret and other intellectual property protection and regulatory exclusivity; and
- ensuring that we do not infringe upon, misappropriate or otherwise violate the patents, trade secrets or other intellectual property rights of third parties, and successfully defending against any claims by third parties against us on these fronts;

If we do not achieve one or more of these factors in a timely manner, or at all, we could experience significant delays in completing or be unable to complete the preclinical or clinical development of our drug candidates, resulting in our inability to obtain regulatory approval for

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our drug candidate. As a result, we may fail to generate sufficient revenue or cash flow from product sales to continue our operations, in which event our financial condition, results of operations and business prospects will be materially and adversely affected.

Clinical development of our drug candidates involves a lengthy and expensive process with uncertain outcomes, and the results of preclinical studies and clinical trials may not be indicative of the final results.

Clinical trials are expensive, difficult to design and implement, and may take years to complete. At the same time, their outcomes are inherently uncertain. Failure can occur at any time during clinical development. Moreover, the results of preclinical studies and early-stage clinical trials may not be indicative of the results of later clinical trials. Drug candidates during later stages of clinical trials may fail to show the desired outcomes in safety and efficacy in spite of having progressed through the earlier stages of clinical trials. In some instances, there can be significant variability in the safety and/or efficacy results among different trials of the same drug candidates due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the subject pools, such as genetic differences, patient compliance with the dosing regimen and other trial protocol elements, and the rate of dropout among clinical trial participants. We cannot guarantee that our future clinical trial results will be favorable based on the current available preclinical and clinical data.

As a result, we may not be able to control the timing and expenses related to completing our clinical trials or obtaining regulatory approval. Unfavorable clinical trial results may force us to restructure our clinical trials, increase our drug development cost and delay our receipt of regulatory approval for our drug candidates. Therefore, it may take us longer to begin commercializing our drug candidates and navigate the path to profitability, while other companies who are developing drugs for the same indications may be able to gain a competitive advantage if they commercialize their drugs first, potentially affecting our ability to gain market share and acceptance, which may have a material adverse effect on our business, financial position and our results of operations.

If our drug candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we may incur additional costs or be subject to unfavorable circumstances during the development and commercialization of our drug candidates.

Before obtaining regulatory approval for the commercial sale of our drug candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of our drug candidates for their proposed indications. Results of our clinical trials could reveal limited efficacy or unacceptable severity or prevalence of adverse events. In such an event, our clinical trials could be suspended or terminated and the NMPA may order us to cease further development of, or deny approval of, our drug candidates for any or all targeted indications.

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Even if we could obtain regulatory approval for our drug candidates, in the event that the results of our clinical trials are only modestly positive, or if they raise safety concerns regarding our drug candidates, we may still be subject to unfavorable circumstances, including:

- obtain approval for indications that are not as broad as intended;
- be required to market our drugs under more restrictive labels, such as adding additional warnings and cautionary statements;
- be required to suspend the sales and marketing of our drugs if they had been approved and commercialized;
- be subject to additional post-marketing testing requirements;
- be held liable for harm caused to our patients and be subject to litigation and product liability claims; and
- be unable to obtain adequate insurance coverage or reimbursement for our drugs from the government or commercial insurers.

If we experience any of the above undesirable conditions, our business may be materially harmed, and we may not be able to generate sufficient revenues and cash flows to continue our operations and may experience a decline in the market price of our H Shares.

We may encounter difficulties in enrolling subjects in our clinical trials, which may delay our clinical development activities or lead to higher development costs for our drug candidates.

The timely completion of clinical trials depends on, among others, our ability to enroll a sufficient number of subjects who will remain in the clinical trials until their conclusion. We may not be able to initiate or continue clinical trials for our drug candidates if we are unable to locate and enroll a sufficient number of eligible subjects, or if there are delays in the enrollment of eligible subjects. We may encounter challenges with enrolling subjects in our clinical trials for various reasons beyond our control, such as:

- difficulties with recruiting a sufficient number of subjects that possess the traits and characteristics we seek;
- the subjects' perceptions as to the potential advantages and risks of the drug candidates being studied in relation to other available drugs or drug candidates;
- the resources we have to facilitate timely subject enrollment in our clinical trials;
- the efforts made by trial executing personnel, including our CROs, to screen and recruit eligible subjects; and
- the proximity and availability of clinical trial sites for prospective subjects.

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Our clinical trials will likely compete with other clinical trials for drug candidates that are in the same therapeutic areas as our drug candidates. This competition will reduce the number and types of patients available to us as some patients might choose to enroll in a trial being conducted by one of our competitors instead of ours.

Even if we are able to enroll a sufficient number of patients in our clinical trials, patient enrollment may also be delayed as a result of public events, epidemics or similar incidences which are out of our control, such as the COVID-19 pandemic. During the Track Record Period, COVID-19 outbreak caused delays in our ongoing clinical trials for various drug candidates. Such delays in patient enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent timely completion of these trials and adversely affect our ability to advance the development, regulatory approval and commercialization of our drug candidates.

We rely on third parties to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our drug candidates and our business could be substantially harmed.

We may rely on third-party organizations, such as CROs, hospitals and clinics, to monitor, support and execute preclinical studies and/or clinical trials for our drug candidates. In 2021, 2022 and the nine months ended September 30, 2023, we engaged 28, 37 and 31 CROs, respectively. In particular, We engaged CROs to conduct preclinical PK, PD and toxicity studies and all completed and ongoing clinical trials of both QX002N and QX005N. We have limited control over the operations of such third parties, and may have less control over the timing, quality and cost of the relevant preclinical and clinical studies than if we conducted these studies by ourselves. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities.

Our CROs are not our employees and, except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our ongoing clinical and preclinical programs. Our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our drug candidates if (i) CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines; (ii) they need to be replaced; or (iii) the quality or accuracy of the clinical data that they or our clinical investigators obtain is compromised due to failure to adhere to our clinical protocols and regulatory requirements. For example, the third parties on which we rely to execute our preclinical studies are required to conduct such studies in accordance with the good laboratory practice (GLP) and the Regulations for the Administration of Affairs Concerning Experimental Animals (《實驗動物管理條例》). We, our CROs and our clinical investigators are also required to comply with the good clinical practice (GCP), which are regulations and guidelines enforced by the NMPA and other relevant authorities, during the clinical development of our drug candidates. Our pivotal

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clinical trials must be conducted with products produced in accordance with the cGMP standards. If any of our CROs or clinical investigators fail to comply with these regulations, the clinical data generated in our clinical trials may be deemed unreliable and the NMPA or other regulatory authorities may require us to perform additional or repeat clinical trials before approving our marketing applications, which would delay the regulatory approval process.

Furthermore, if any of our relationships with our third-party CROs is terminated, we may not be able to enter into arrangements with alternative CROs in a timely manner or on commercially reasonable terms, if at all, and we may not be able to meet our desired clinical development timelines. Even if we could successfully replace the original CROs in a timely manner, it is possible that the type and quality of services the new CROs provide do not conform to our original standards. Replacing or engaging new CROs could be time-consuming and expensive and may divert management's time and focus. To the extent that we are unable to identify, retain and successfully manage the performance of third-party service providers in the future, our business may be adversely affected. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter any challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

The data we gather in our research and development may be affected by factors unrelated to our drug candidates or out of our control, which could adversely affect the reliability of our clinical results or analyses.

We collect, aggregate, process and analyze data when we identify a promising drug candidate and while conducting preclinical studies and clinical trials. During the process, the overall quality of data collected or accessed may be affected by many factors that are unrelated to the tested drug candidates and out of our control. For example, we cannot assure the trial subjects' full compliance with the trial protocols. Additionally, we cannot guarantee that all of our employees or staff of our CROs would strictly comply with the good clinical practice (GCP) standards or other related guidelines and regulations when collecting or accessing preclinical and/or clinical data. We may not be able to discover every data issue and error when monitoring and auditing our data.

Such factors may negatively affect the reliability of our trial results and analyses and the NMPA or other regulatory authorities may require us to perform additional or repeat clinical trials before approving our marketing applications. Major issues in data integrity could also subject us to questions or claims from the NMPA or other relevant authorities, and may expose us to liability relating to our storage, handling, submission, delivery or display of clinical data. Although we maintain insurance coverage for clinical trials, this coverage may prove to be inadequate or could cease to be available to us on acceptable terms, if at all. Even unsuccessful claims could result in substantial costs and diversion of management time, attention and resources. A claim brought against us that is uninsured or under-insured could harm our business, financial condition and results of operations. Any such claims or proceedings brought against us may negatively impact our business, prospects and reputation.

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We may not be able to discover or develop suitable novel drug candidates.

We plan to continue building our pipeline through our internal discovery and development platforms by identifying new therapeutic targets and drug candidates and pursuing the development of our drug candidates for additional indications. During the process, we may require additional technical, financial or other resources to enhance our existing research and development capabilities.

The successful discovery of new therapeutic targets or drug candidates depend, to a large extent, on factors out of our control, such as the emergence of new scientific methodologies in the medical industry, initial safety and efficacy results of potential candidates and the availability of technical, financial or other resources to support our discovery effort. We cannot assure you that we will ever be able to identify additional therapeutic opportunities for our drug candidates or develop suitable potential drug candidates through internal research programs, any of which could materially and adversely affect our future growth and prospects. Even if we do identify initially promising drug candidates, there is no guarantee that we will obtain favorable results in later clinical development of such candidates. Failure to successfully identify or develop novel and suitable drug candidates may materially and adversely affect our ability to expand our pipeline and grow our business.

We may not be successful in adapting to new technologies and methodologies.

Our continued competitiveness depends on our ability to adapt to evolving technological developments and methodologies in the biotech and pharmaceutical industry. However, adapting to the latest technological developments and methodologies may require us to invest significant resources to enhance our own research and development, testing and manufacturing capabilities. There is no assurance that we will be able to secure such resources, or that we will succeed in making the necessary improvements. We also cannot guarantee that we will be successful in our attempts to adapt our drug candidates to emerging technologies and methodologies in a way that will gain market acceptance. Should we fail to respond in a timely or effective manner, we may be unable to improve and maintain our competitive position and materially and adversely affect our business and prospects.

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RISKS RELATING TO THE MANUFACTURING AND COMMERCIALIZATION OF OUR DRUG CANDIDATES

We have no track record in commercializing our drug candidates. Our collaboration with pharmaceutical companies to market our drug candidate and our plan to establish an indication-specialized in-house commercialization team may not materialize as we expected.

We do not have any track record of successfully launching and commercializing drugs. We intend to seek opportunities of strategic cooperation with well-known pharmaceutical companies with extensive experience in the sales and marketing of drugs for autoimmune and allergic diseases in China. For example, in August 2020, we entered into a collaboration agreement with Zhongmei Huadong, a subsidiary of Huadong Medicine, with respect to the joint development and exclusive commercialization of QX001S in China. For details, see “Business—Collaboration with Zhongmei Huadong” in this document.

We believe collaboration with pharmaceutical companies such as Zhongmei Huadong will enable us to leverage their market access and sales and marketing network targeting the autoimmune or allergic diseases to execute our commercialization strategy for future approved drugs. However, there is no assurance that we will be able to establish or maintain such collaborative arrangements or, even if we are able to do so, that such arrangements will facilitate the commercialization of our drugs as expected. Once we enter into such collaboration agreements, the sales and marketing of our drugs will depend, to varying degrees, on the efforts of our partners, over whom we have limited influence or control and our revenue from product sales may be lower than if we had commercialized our drug candidates ourselves. Collaborations involving our drug candidates are subject to various risks, for further discussion, see “—Risks Relating to Our Operations—We have entered into collaborations agreements, and may form or seek other collaborations or strategic alliances or enter into licensing arrangements in the future, and we may not realize the benefits of such alliances or licensing arrangements.”

We also intend to build an indication-specialized in-house commercialization team, beginning with indications with relatively limited patient populations treated in a small number of key hospitals. However, establishing an in-house sales and marketing team requires significant expenditures, management resources and time. We would potentially have to compete with other drug companies to recruit, hire, train and retain marketing and sales personnel. Additionally, given the relatively small scale of our future in-house team, we cannot guarantee that we will succeed in establishing sufficient sales coverage and penetration to hospitals, pharmacies and other medical institutions across China, which could adversely affect the commercial opportunities of our drug candidates.

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We may face extra obstacles in the commercialization of our biosimilar drug candidate, due to the uncertainty in approval pathway for biosimilars in China and heightened risks relating to potential patent litigation.

The approval pathway for biosimilars in China remains fluid, which may adversely affect the regulatory approval of our biosimilar drug candidate. The NMPA issued the Technical Guideline for the Research, Development and Evaluation of Biosimilars (Tentative) (the “Biosimilars Guideline”) on February 28, 2015. The Biosimilars Guideline outlines the regulatory framework for biosimilars, aiming to move toward a clear industry structure for the development of biosimilars. On June 29, 2020, the NMPA issued the Requirements for Registration Classification and Application Dossiers of Biological Products (the “Registration Requirements”), which specifies Class 3.3 as the registration classification for biosimilars. However, various uncertainties surrounding the application and interpretation of the Biosimilars Guideline and the Registration Requirements could adversely affect the regulatory approval of our existing biosimilar drug candidate, namely, QX001S, our most advanced drug candidate. Uncertainties surrounding the approval process for biosimilars in China include:

- both the Biosimilars Guideline and the Registration Requirements remained unclear on certain fundamental issues for the administration of biosimilars, such as the evaluation criteria for interchangeability with reference products;
- although the Biosimilars Guideline adopted a stepwise comparability approach, it does not contain sufficient details to be regarded as overarching guidelines and it is also not clear whether the NMPA will take further steps to develop product-specific guidelines;
- while under the Registration Requirements biosimilars are subject to a separate approval pathway under Class 3.3, it remains unclear if the time to market for biosimilars will be reduced compared with the lengthy review process for innovative biologics; and
- the regulatory policies and guidelines may change in the future, and it is unpredictable whether the NMPA and other regulatory authorities will issue updated policies or guidelines to replace or supplement the Biosimilar Guidelines, or whether such updated policies or guidelines will bring additional compliance costs or substantial impediments for our biosimilar candidates to obtain regulatory approvals.

Additionally, biosimilar products may also be subject to extensive patent clearances and patent infringement litigation, which may delay or prevent the commercial launch of a drug candidate. Many pharmaceutical companies, including the ones that developed the reference drugs for which we are developing biosimilars, have developed worldwide patent portfolios of varying sizes and breadth. Many patents may cover a marketed product, including but not limited to the composition of the product, methods of use, formulations, cell line constructions, vectors, growth media, production processes and purification processes. Not all such patents

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have expired globally, including potentially in the jurisdictions where we intend to commercialize our biosimilar drug candidate. Relevant parties may submit applications for patent term extensions in jurisdictions where extensions are available, seeking to extend patent protection. If approved, such extension may interfere with or delay the launch of our biosimilar product. As such, we cannot assure you that our QX001S will be approved under the Biosimilars Guideline, in a timely manner or at all, and we may not ultimately be able to develop and market it successfully if we are subject to related intellectual property infringement or misappropriation claims.

Our drug candidates may fail to achieve market acceptance and commercial success.

Even if we receive the requisite regulatory approvals for our drug candidates, there is no guarantee that our drug candidates will gain sufficient market acceptance across the medical community and among patients. The degree of market acceptance of our drug candidates will depend on, among other things, the following factors:

- the clinical indications for which our drugs are approved and patient demand for the drugs that treat those clinical indications;
- the potential and perceived advantages of our drugs over alternative treatments, including as to cost, effectiveness, safety and convenience;
- the time required to manufacture and launch our drugs, and to make them publicly available;
- the availability of adequate insurance coverage and reimbursement by the government and emerging commercial insurers;
- the willingness and ability of patients to pay out of pocket without the above-mentioned insurance coverage and reimbursement;
- reliance on and preference for current therapies by physicians, healthcare providers and clinics, and patients;
- drugs commercialized by our competitors, particularly if they are launched before, at or around the same time as our own drugs;
- the prevalence and severity of any side effects;
- labeling requirements imposed by the NMPA or other relevant authorities, particularly in relation to warnings as to health and safety risks or limitations on effectiveness;
- the effectiveness of our and our commercialization partner's sales and marketing efforts;

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- adverse publicity about our drugs or favorable publicity about competitive products; and
- potential product liability claims.

Additionally, biologic therapies have relatively limited track record in the treatment of autoimmune and allergic diseases in China, and extensive market education will be needed for the marketing our future approved drugs. We cannot assure you that such education efforts will generate sufficient acceptance for our drug candidates among patients with autoimmune and allergic diseases. Even if our drugs achieve market acceptance, we may not be able to maintain such market acceptance if new drugs or treatments that are more favorably received or cost effective than ours are introduced. Failure to achieve or maintain market acceptance of our drugs could adversely affect our business, prospects and results of operations.

We have no track record in manufacturing drugs for commercial sale.

We currently produce drug candidates for clinical use at our manufacturing facility in Taizhou and intend to manufacture drugs for future commercial sales at the same facility once our drug candidates obtain regulatory approval. We have no proven track record in manufacturing biologics for commercial sale. The manufacturing of biologic drugs is highly exacting and complex, due in part to strict regulatory requirements and medical and other scientific specifications. Should problems arise in the course of producing our drug candidates, we may need to dispose of batches and incur additional unexpected expenses in connection with replacement and disposal. Such incidents could, among other things, lead to increase in manufacturing costs and decline in our profit margin. We may also need to invest additional time and human resources to investigate the causes of the problems and formulate appropriate solutions. In cases where problems are discovered after our drugs reach the market, we may also be forced to issue recalls and be subjected to product liability claims.

Other challenges we may face during manufacturing include, but are not limited to:

- inability to obtain or maintain requisite approval to utilize manufacturing premises and/or operate manufacturing facilities;
- inability to procure consumables and/or raw materials of sufficient quantity and satisfactory quality in a timely manner, or at all;
- shortage of qualified manufacturing, quality control or quality assurance personnel to carry out and oversee the manufacturing process in accordance with relevant regulations;
- longer than expected periods of time necessary to commence or ramp up production; and
- delay in our development or approval timeline, which could lead to delay in our manufacturing schedule and low utilization rate of our manufacturing facilities.

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Secondary to our own manufacturing needs, we are also providing CDMO services to third parties through our manufacturing facility in Taizhou, which may lead to additional risks in the manufacturing process, such as inability to manufacture multiple biologic drugs in the same production line while conforming to applicable manufacturing standards, or failure to obtain sufficient numbers of orders to efficiently utilize our full manufacturing capacity and achieve economies of scale.

In the event that we encounter such issues, there is no guarantee that we will be able to timely or effectively resolve them. Given our limited experience with manufacturing biologics for commercial sale, we may be less adept at handling manufacturing issues or managing our manufacturing operations than our competitors. Additionally, should factors beyond our control affect our manufacturing processes such that we are unable to achieve or maintain cGMP or other required standards, regulators may issue warnings, withdraw regulatory approvals or take other actions such as recalls, seizures, totally or partially suspend our production, suspend ongoing clinical trials, refuse to approve pending applications or supplemental applications, halt production and distribution or impose civil and criminal penalties.

Furthermore, due to the complex nature of our drugs, we may not be able to manufacture them in a timely manner, at a price or in sufficient quantities necessary to be profitable. As our drug portfolio grows and matures, we will also need to expand our commercial manufacturing capacity in parallel. However, doing so may require significant capital expenditures and time. Failure to expand in a timely and cost-effective manner may affect our ability to manufacture sufficient quantities of drugs for sale and drug candidates for our development purposes. Should we be unable to maintain the efficiency of our manufacturing procedures or control our manufacturing costs, we may experience material adverse effects on our prospects, business and results of operations.

Scarcity of available raw materials or increases in our raw material costs may negatively impact our business, financial condition and results of operations.

We procure raw materials from both domestic and overseas suppliers according to our drug development plans. For certain raw materials with limited number of suppliers, should our suppliers temporarily suspend production, raise or be forced to raise their prices, or fail to supply such raw materials to us for other reasons such as logistical issues, we cannot guarantee that we will be able to find alternative suppliers who can provide the required raw materials and product components on reasonable terms, at sufficient amounts or in accordance with our desired quality standards in a timely manner, or at all. Certain raw materials necessary for the development and manufacturing our drug candidates are provided by third-party suppliers that are based outside of China, in which case they may need to maintain export or import licenses to continue providing us with required raw materials. We have no control over whether they will obtain and maintain, or be able to obtain and maintain, such export and import licenses or other permits and approvals necessary for their operations.

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Furthermore, we expect that our need for stable supply of raw materials will grow as we continue to expand our business and begin manufacturing drugs for commercial sale after we obtain regulatory approval. As more drug candidates progress into advanced stages of clinical trials, we will also require larger amounts of comparison drugs. Any significant delay in obtaining such raw materials or comparison drugs in the quantity and quality required may delay our preclinical studies and clinical trials, the regulatory approval for our drug candidates or the manufacturing of our future approved drugs.

Raw materials used in our manufacturing may be subject to price volatility caused by external conditions, such as fluctuations in transportation costs, changes in government policies and natural disasters. As a result, our raw materials costs may also fluctuate from time to time or increase substantially going forward, which could adversely affect our profitability. The search for replacement for our suppliers or raw materials may result in reduction in production volume and delay in our manufacturing, sales and marketing or other business operations, and may divert management attention and financial resources so as to materially and adversely affect our business, financial condition, results of operations and prospects.

Failure to maintain effective quality control over our drugs, particularly undetected errors or defects in our manufacturing, may harm our reputation or expose us to product liability claims.

The effectiveness of our quality control procedures depends on various factors, such as the procedures governing our manufacturing processes, the quality and reliability of our manufacturing facility and equipment, the qualification and experience of our manufacturing and quality control staff and our ability to ensure that the relevant personnel adhere to our quality control procedures. However, we cannot assure you that our internal policies and procedures will be effective in consistently preventing and resolving deviations from our quality standards. Any significant failure of our quality control procedures could render our drugs unsuitable for use, adversely affect our ability to comply with applicable cGMP requirements, jeopardize our manufacturing permits and/or harm our market reputation and relationship with business partners. Any such events may have a material adverse effect on our business, financial condition and results of operations.

Guidelines, recommendations and studies published by various organizations may disfavor our drug candidates.

Government agencies, professional societies, practice management groups, private health and science foundations and organizations focused on various diseases may publish guidelines, recommendations or studies that affect demand for our drugs candidates. Any such guidelines, recommendations or studies that reflect negatively on our drug candidates, either directly or relative to drugs offered by our competitors, could diminish demand for our drug candidates and adversely impact our future sales revenues. Furthermore, the sales of our future approved drugs depends in part on our ability to educate patients and members of the medical community

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(including healthcare providers) about our drugs and drug candidates. Our ability to convey our messages effectively may be negatively impacted by the publication of guidelines, recommendations or studies on our drug candidates.

There may be fewer market opportunities for our drug candidates than we originally anticipated, and our drug candidates may be ultimately unprofitable even if commercialized.

We estimate the extent of market opportunities for our drug candidates by analyzing information from various third-party sources, such as scientific literature and industry reports. We also use such estimates to make decisions regarding our drug development strategies, including whether or not to prioritize the development of a particular drug candidate. However, these estimates may be based on imprecise or inaccurate data, leading us to over- or under-estimate market opportunities for certain drugs, which will affect our resource allocation decisions.

The market opportunities available will depend on, among others, the degree of acceptance for our drugs by the medical community, patient access, drug pricing and availability of government or commercial insurance and reimbursement. From time to time, we may discover that demand for our drugs is lower than anticipated due to the smaller-than-expected target patient population, availability of other more effective or accessible therapies and difficulty in identifying or approaching new patients. Such unfavorable developments may materially and adversely affect our prospects, business and results of operations.

Medical insurance coverage and reimbursement may be limited or unavailable in certain market segments for our drugs, which may adversely affect their sales prospects.

Successful sales of our future approved drugs partly depend on the availability of adequate insurance coverage and reimbursement from the government and commercial insurers, as patients often rely on such reimbursement for all or part of the costs associated with their medical treatment. Government authorities and commercial medical insurance providers will decide on the coverage of drugs and the amount of reimbursement, based on their consideration of factors such as:

- whether the drug and/or treatment is safe, effective and medically necessary;
- whether the drug and/or treatment is appropriate for specific diseases and/or patients;
- whether the drug and/or treatment is considered experimental or investigational; and
- whether the drug and/or treatment is cost-effective given their budgets or profit margins.

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We cannot guarantee that reimbursement will be available for our future approved drugs and, if available, the level of reimbursement. In China, the amounts reimbursable to program participants for their drug purchases depend on the inclusion of the drugs in the NRDL or other government-sponsored medical insurance programs, as well as the tiers under which the drugs are classified in such programs. The Ministry of Human Resources and Social Security (MOHRSS) of the PRC, the National Healthcare Security Administration (NHSA), together with provincial or local human resources and social security authorities, regularly review the inclusion of or removal of drugs from the NRDL, as well as the tier under which a drug will be classified. Even though the number of innovative drugs included in the NRDL is expected to increase in the future, there can be no assurance that any of our future approved drugs will be included in the NRDL or other government-sponsored medical insurance programs.

Even if reimbursement is available, we may need to significantly concede on prices for our future approved drugs in China, which could adversely affect our profitability.

For any of our future approved drugs seeking inclusion into the NRDL, we may need to engage in price negotiation with the NHSA or other relevant regulatory authorities, which may lead to a reduction in our prices. Even if the NHSA or any of its local counterparts includes any of our future approved drugs in the NRDL or the PRDL, which may increase the demand for such drugs, our potential revenue or profitability from the sales of such drugs may still decrease as a result of lowered prices. Additionally, eligibility for reimbursement in China does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sales and distribution expenses.

Moreover, the prices we may offer to the NHSA and its local counterparts may be used as benchmarks and further reduced by discounts required by private hospitals. The centralized tender process in China may also create pricing pressure among substitute products or products that are perceived to be substitute products, and we cannot assure you that our future approved drugs would not be adversely affected.

We may explore opportunities to commercialize our drugs globally, which may expose us to risks associated with conducting business in international markets.

As we grow our business, we intend to cooperate with MNCs or pharmaceutical companies with established local sales networks to conduct clinical trials and/or sell our drugs outside of China. Should we succeed in doing so, our business is subject to risks associated with doing business globally, including (i) changes in a country or region’s political and cultural climate or general economic conditions, (ii) unexpected changes in or high costs associated with complying with laws and regulatory requirements, (iii) difficulties with enforcing contractual provisions in unfamiliar jurisdictions, (iv) potential disputes with foreign partners that may be protracted or more difficult to resolve due to distance and time differences, (v) exposure to litigation or third-party product liability claims outside of China, (vi) concerns voiced by local governments and regulators on arrangements pertaining to our research and clinical trial sites, (vii) inadequate intellectual property protection in other countries, (viii) the possibility of economic sanctions, trade restrictions, discrimination,

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protectionism or unfavorable policies against foreign drug companies, including those from China, (ix) the effects of applicable local tax regimes, royalties and other payment obligations owed to local governments, and (x) fluctuations in local currency exchange rates. Any of such occurrences could negatively affect our expansion plan.

Our operation may be adversely affected by changes in the relationship between China and other nations.

Changes in the political relationship between China and other nations may adversely affect various aspects of our business operation. For example, there have been significant uncertainties over the past few years about the relationship between the United States and China with respect to a range of important issues. It is unclear whether these uncertainties could be resolved effectively. They may continue to escalate going forward and result in certain types of goods, such as advanced R&D and manufacturing equipment and raw materials, becoming significantly more expensive to procure from overseas suppliers or even becoming illegal to export. Furthermore, if we decide to explore opportunities to conduct clinical trials and/or seek regulatory approval for our drug candidates in the U.S., such undesirable changes in the relationship between China and the U.S. may adversely affect our expansion plan, including our ability to effectively engage local service providers or collaboration partners and our prospect of receiving fair treatment from relevant regulatory authorities. Therefore, tensions and political concerns between China and other nations may therefore adversely affect our business, financial conditions, results of operations and prospects.

RISKS RELATING TO OUR FINANCIAL POSITION AND NEED FOR ADDITIONAL CAPITAL

We have incurred significant operating losses since our inception and anticipate that we will continue to incur operating losses for the foreseeable future and may never become profitable. As a result, you may lose all or part of your investment in us.

We are a pre-revenue biotech company and have not successfully commercialized any drug candidates. Investments in the development of innovative drugs such as ours are highly speculative. It entails substantial upfront capital expenditure and significant risks that a drug candidate may fail to gain regulatory approval or become commercially viable. As a result, you may lose all or part of your investment in us given the high risks involved in our business and associated with the biotech industry. During the Track Record Period, we did not generate any revenue from our drug candidates under development, and we will continue to incur significant research and development and other expenses related to our ongoing operations. Our ability to generate revenue will depend primarily on the success of the clinical trials, regulatory approval and commercialization of our drug candidates, which is subject to significant uncertainty. Even if we successfully complete clinical trials and obtain regulatory approval to market our drug candidates, our future revenue will depend upon other factors such as the market size for the proposed applications of our approved drugs, and our ability to achieve sufficient market acceptance.

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We have incurred significant expenses related to the research and development of our drug candidates in the past. For the years ended December 31, 2021 and 2022 and the nine months ended September 30, 2023, our research and development expenses amounted to RMB151.9 million, RMB257.2 million and RMB263.3 million, respectively, which contributed significantly to our net losses of RMB426.5 million, RMB312.3 million and RMB385.5 million in the same periods, respectively.

We expect to continue to incur net losses in the near future, and the losses may increase as we further our research and development efforts, seek regulatory approvals for our drug candidates and expand our collaboration with third parties for the commercialization of future approved drugs. The size of our future net losses will depend, in part, on the number and scope of our drug development programs and the associated costs of those programs, the cost of manufacturing and commercializing any approved drugs and our ability to generate revenues.

We may never become profitable. Even if we achieve profitability in the future, we may not be able to maintain profitability in subsequent periods. Our failure to become or remain profitable would decrease the value of our Company and could impair our ability to raise capital, maintain our R&D efforts, expand our business and/or continue our operations. Failure to become or remain profitable may adversely affect the market price of our H Shares. A decline in the market price of our H Shares could cause you to lose all or part of your investments in our business.

We had net operating cash outflows during the Track Record Period and we may need to obtain additional financing to fund our operations.

We recorded net cash outflow from operating activities of RMB122.6 million, RMB225.2 million and RMB252.2 million for the years ended December 31, 2021 and 2022 and the nine months ended September 30, 2023, respectively. We cannot assure you that we will be able to generate cash flows from operating activities in the future. Net operating cash outflow may impair our ability to make necessary capital expenditures and meet our liquidity requirements, thereby constraining our operational flexibility. If we are unable to maintain adequate working capital, we may default in our payment obligations and may not be able to meet our capital expenditure requirements, which may have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, our existing cash and cash equivalents may not be sufficient to enable us to complete all development or commercially launch all of our current pipeline products for the anticipated characteristics and to invest in additional programs. Accordingly, we may require further funding through public or private offerings, debt financing, collaboration and licensing arrangements or other sources. If we resort to other financing activities to generate additional cash, we will incur financing costs and we cannot guarantee that the financing may be available when we need them, on terms that are favorable to us, or at all.

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Fair value changes in our wealth management products and related valuation uncertainty due to the use of unobservable inputs may adversely affect our financial condition and results of operations.

During the Track Record Period, we acquired certain wealth management products to improve the utilization of our cash on hand on a short-term basis. We classified these wealth management products as financial assets at fair value through profit or loss (“FVTPL”). As of December 31, 2021 and 2022 and September 30, 2023, we recorded financial assets at FVTPL of RMB402.4 million, RMB401.1 million and RMB150.4 million, respectively. We recorded net realized and unrealized gains on financial assets at FVTPL of RMB6.5 million, RMB11.9 million and RMB4.6 million for the years ended December 31, 2021 and 2022 and the nine months ended September 30, 2023, respectively. However, we may incur fair value losses on such financial assets in the future, which will adversely affect our financial condition and results of operations.

Additionally, the fair value of these financial assets was established using significant unobservable inputs, including the expected interest return rate, which cannot be supported by observable market prices or rates and may involve management judgment and be inherently uncertain. See note 28(e) in the Accountants’ Report set out in Appendix I to this document for details. Any change in the judgment or the use of unobservable inputs may lead to different valuation results and, in turn, changes in the fair value of these financial assets and may adversely affect our financial condition and results of operations.

We may need to obtain substantial additional financing to fund our operations and may be forced to accept unfavorable terms or limitations on our operation during the process. If financing is not available on terms acceptable to us, or at all, we may be unable to complete the development and commercialization of our drug candidates.

We need to make substantial investments to complete preclinical and clinical development, obtain regulatory approvals, manufacture sufficient quantities of drug candidates for clinical and future commercial use and coordinate marketing activities in relation to our drug candidates as a condition to generating revenue. We also envisage significant funds to be expended on our post-approval commitments such as monitoring the efficacy and safety of our drugs on the market, if and when they are approved and commercialized. In doing so, we must expend substantial financial resources to fund our continuing and future operations.

During the Track Record Period, we funded our operations primarily through equity financing and the construction of our manufacturing facility primarily through bank borrowings. We may continue to rely on such methods, as well as debt financing, collaboration and licensing arrangements or other sources to raise additional capital. If we resort to other financing activities, we will incur financing costs and we cannot guarantee you that the financing may be available when we need them, on terms that are favorable to us, or at all. In the event we enter into collaborations or licensing arrangements in order to raise capital, we may be required to accept unfavorable terms, including relinquishing or licensing to a third

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party on unfavorable terms our rights to technologies or drug candidates that we otherwise would seek to develop or commercialize ourselves or potentially reserve for future potential arrangements when we might be able to achieve more favorable terms.

Furthermore, our ability to raise funds will also depend on financial, economic and market conditions and other factors, many of which are beyond our control. If adequate funding is not available to us on a timely manner, we may have to delay, limit, reduce or terminate preclinical studies, clinical trials or other research and development activities or the manufacturing and commercialization for one or more of our drug candidates, which in turn will adversely affect our business prospects.

The discontinuation of any government grants or preferential tax treatment currently available to us may adversely affect our business, financial condition and results of operations.

We benefited from government grants and preferential tax treatment during the Track Record Period. We recorded government grants of RMB20.0 million, RMB9.2 million and RMB4.3 million for the years ended December 31, 2021 and 2022 and the nine months ended September 30, 2023, respectively. Such government grants primarily included subsidies to encourage research and development activities, subsidy for interest expenses of bank loans, reimbursement for capital expenditure incurred for the construction of our manufacturing facility and subsidies for talent recruitment. Additionally, Our Company obtained the certificate of high-technology enterprise in November 2021 and is subject to a preferential income tax rate of 15% for a three-year period. We also enjoyed deductible allowances for our research and development expenses during the Track Record Period.

We cannot assure you that we will continue to receive government grants or preferential tax treatment at the existing levels, or at all. The relevant authorities may issue administrative decisions or modify government policies that reduce the amount of government grants and preferential tax treatment that has been available to us, or end our eligibility to receive such financial subsidies. The discontinuation of government grants or preferential tax treatment currently available to us may adversely affect our results of operations and prospects. Further, prospective investors should note that should there be any changes in the amounts of our government grants and preferential tax treatment in a given year, our financial performance for that period may not be directly comparable to our historical financial results.

We may be subject to penalties from the PBOC or adverse judicial rulings as a result of providing loan financings.

In January 2021, we provided a short-term loan of RMB100.0 million to Taizhou Huawei Investment Ltd. (泰州華威投資有限公司) (“Taizhou Huawei”) with an expected yield at 7.0% per annum. The loan was fully settled in July 2021. We derived an interest income of RMB3.6 million from providing the loan in 2021. For further details, please refer to “Financial Information—Material Transactions with Related Parties” in this document.

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According to the General Lending Provisions (貸款通則) promulgated by the PBOC, only financial institutions may legally engage in the business of extending loans, and loans between companies that are not financial institutions are prohibited. The PBOC may impose a fine of one to five times of the income generated (being interests charged) from the loan advancing activities between enterprises. By providing the loan to Taizhou Huawei, we recognized an interest income of RMB3.6 million. Therefore, we may be subject to penalties by PBOC of up to RMB18.0 million under a strict reading of the General Lending Provisions. However, according to the Provisions of the Supreme People’s Court on Several Issues concerning the Application of Law in the Trial of Private Lending Cases (最高人民法院關於審理民間借貸案件適用法律若干問題的規定) (the “Private Lending Interpretations”), which became effective on September 1, 2015 and was latest amended on December 29, 2020, the Supreme People’s Court recognizes the validity and legality of financing arrangements and lending transactions between non-financial institutions so long as certain requirements, such as the interest rates charged, are satisfied and there is no violation of relevant provisions of laws and regulations.

As of the Latest Practicable Date, no administrative action, fine or penalty had been imposed by the PBOC on us regarding the loan. As advised by our PRC Legal Advisors, under the Private Lending Interpretations, PRC courts will support a company’s claim for interest from the date of engagement of contract to August 19, 2020 with relevant judicial interpretation at the time. PRC courts will also support such claim from August 20, 2020 to the date of repayment of the loan as long as (i) the annual interest rate does not exceed four times the prime rate for one-year loans published by the National Interbank Funding Center when the related lawsuit is brought; and (ii) the lending contract is valid under the PRC Civil Code and satisfies certain requirements of the Private Lending Interpretations. Based on the above, our PRC Legal Advisors is of the view that the risk that we would be subject to any penalty with respect to such interest-bearing loan pursuant to the General Lending Provisions by the relevant regulatory authorities is remote. However, the final determination of the relevant regulatory authorities could be different, and we may be subject to penalties from the PBOC or adverse judicial rulings as a result of our provision of loan financing to Taizhou Huawei Investment Ltd. during the Track Record Period or any prior periods. Any of these penalties or adverse judicial rulings could have a material adverse effect on our business, financial position and results of operations.

We have incurred and may continue to incur share-based payments. The issuance of share-based payment awards may cause dilution to our existing Shareholders and may affect the market price of our H Shares.

For the years ended December 31, 2021 and 2022 and the nine months ended September 30, 2023, we recognized equity-settled share-based payment expenses of RMB11.7 million, RMB41.6 million and RMB99.5 million, respectively. We only granted shares to our certain key employees during the Track Record Period. In the future, we may issue options and shares to our Directors, senior management and/or key employees to incentivize their performance and align their interests with ours. As a result, we may incur equity-settled share-based

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payments, which could have a material adverse effect on our net profits. Furthermore, the grant of equity-accounted share-based payments may result in an immediate and potentially substantial dilution to our existing Shareholders and could result in a decline in the value of our H Shares.

We have a limited operating history, which may make it difficult to evaluate our current business and predict our future performance.

We are a biotech company with a relatively short operating history. Our operations to date have focused on business planning, raising capital, establishing our drug portfolio and conducting clinical trials of our drug candidates. Most of our drug candidates were still at various stages of development and we had not commercialized any of our drug candidates as of the Latest Practicable Date. Our limited operating history, particularly in the rapidly evolving pharmaceutical industry, may make it difficult to evaluate our current business and reliably predict our future performance. Our future financial performance will depend, in part, on our ability to effectively manage our recent growth and any future growth. We might not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, operational inefficiencies, loss of business opportunities, loss of employees and reduced productivity among remaining employees. We may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. If we do not address these risks and difficulties successfully, our business will suffer. These risks may cause potential investors to lose substantially all of their investment in us.

RISKS RELATING TO EXTENSIVE GOVERNMENT REGULATION

The drug industry in China is highly regulated and such regulations are subject to change, which may adversely affect multiple aspects of our operation.

We conduct our research, development and commercialization activities in China, which regulate such activities in great depth and detail. Biotech companies in China are subject to comprehensive government regulation and supervision encompassing the approval, registration, manufacturing, packaging, licensing and marketing of new drugs. The process of obtaining regulatory approvals and compliance with appropriate laws and regulations require substantial time and financial resources. Failure to comply with the applicable requirements at any time during the product development, approval, manufacturing, sales and marketing or post-approval approval process, may subject an applicant to administrative or judicial sanctions. These sanctions could include a regulator’s refusal to approve pending applications, withdrawal of an approval, license revocation, a clinical hold, voluntary or mandatory product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. The failure to comply with these regulations could have a material adverse effect on our business, financial condition and prospects.

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In recent years, the regulatory framework in China regarding the drug industry has undergone significant changes, and we expect that it will continue to evolve. Any such changes may increase compliance costs related to our business, cause delays in or prevent the successful development or commercialization of our drug candidates and reduce the current benefits we believe are available to us from developing and manufacturing drugs in China. PRC governmental authorities have become increasingly vigilant in enforcing laws in the pharmaceutical industry and any failure by us or our third-party contractors to maintain compliance with applicable laws and regulations may materially and adversely affect our business activities.

The process of obtaining regulatory approval for our drug candidates is lengthy, expensive and inherently uncertain.

The process required to obtain approval from the NMPA or other relevant authorities is a lengthy, expensive and uncertain process, and approval is never guaranteed. When we submit a registration application to the regulatory authorities, the regulatory authorities will decide whether to accept or reject the registration application. We cannot be certain that all of our submissions will be accepted for filing and review by the regulatory authorities. In addition, the time required to obtain approval from the regulatory authorities is unpredictable and could take years following the commencement of preclinical studies and clinical trials. Results of such applications depend upon numerous factors and are subject to substantial discretion of the regulatory authorities. As of the Latest Practicable Date, we had not received marketing approval for any of our drug candidates, and it is possible that none of our drug candidates or any drug candidates we may discover and seek to develop in the future will ever obtain such approval.

Our drug candidates could fail to obtain regulatory approval for many reasons, including uncertainties associated with, or as a result of, our clinical trials results and procedures. See “—Risks Relating to the Development of Our Drug Candidates—We depend substantially on the success of our drug candidates, all of which are undergoing preclinical or clinical development. If we are unable to successfully complete clinical development of our drug candidates, or experience significant delays in doing so, our business prospects will be significantly impacted.” However, even if we successfully complete all preclinical studies and clinical trials for our drug candidates in compliance with the current regulations of the NMPA or other relevant authorities, we may still face risks of failure to obtain regulatory approval due to factors beyond our control, such as changes in approval policies or regulations that render our preclinical and clinical data insufficient or require us to amend our clinical trial protocols, regulatory requests for additional analysis, or questions regarding interpretations of data and results and the emergence of new information regarding our drug candidates or other drugs. Any of these occurrences may materially and adversely affect our approval and commercialization timeline and therefore harm our business, financial condition and prospects significantly.

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Our failure to maintain or renew our drug manufacturing license, or other licenses, permits and certificates required for our business may materially and adversely affect our business, financial condition and results of operations.

Pursuant to relevant laws and regulations, we are required to obtain and maintain various licenses, permits and certificates from relevant authorities to operate our business. For example, Cellularforce, our CMC-focused subsidiary, holds the Drug Manufacturing Certificate (藥品生產許可證) issued by Jiangsu Medical Products Administration, which is necessary for the operation of our manufacturing facility in Taizhou, Jiangsu. Some of these licenses, permits and certificates are subject to periodic renewal and/or reassessment by the relevant authorities, and the standards of such renewal and/or reassessment may change from time to time. Any failure to obtain or renew any licenses, permits and certificates necessary for our operations may result in enforcement actions thereunder, including orders issued by the relevant regulatory authorities suspending our operations, and corrective measures requiring capital expenditure or remedial actions, which in the future could materially and adversely affect our business, financial condition and results of operations.

Furthermore, if the interpretation or implementation of existing laws and regulations changes, or new laws or regulations come into effect, requiring us to obtain any additional licenses, permits and certificates that were previously not required to operate our existing businesses, we cannot assure you that we will successfully obtain such licenses, permits and certificates. Our failure to obtain the additional licenses, permits and certificates may restrict the conduct of our business, decrease our revenues and/or increase our costs, which could materially reduce our profitability and prospects.

Even after obtaining regulatory approval for marketing, our drug candidates will continue to remain subject to ongoing or additional regulatory requirements and review, which may result in significant additional expenses, or penalties if we fail to comply with such requirements.

Once approved, our drugs may be subject to ongoing or additional regulatory requirements related to manufacturing, labeling, packaging, storing, advertising, promoting, sampling, record-keeping, post-marketing clinical trials and submission of information related to safety, efficacy and other post-marketing clinical data.

Drug manufacturers are required to comply with rules promulgated by the NMPA to ensure that quality control and manufacturing procedures conform to current good manufacturing practices (cGMP) regulations. As such, we will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made to regulatory authorities, such as in any NDA or BLA, marketing applications or responses to queries and observations from relevant authorities. We expect to expend considerable time and resources to meet our various regulatory compliance obligations in relation to manufacturing, production and quality control.

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Furthermore, the regulatory approvals we may obtain for our drug candidates may be subject to conditions that affect the commercial potential of our drugs, or require that we conduct costly post-marketing clinical trials or other measures to monitor their safety and efficacy. The NMPA may also require us to follow a risk evaluation and mitigation program. Such conditions and requirements may lead to substantial increase in our compliance costs and any failure to comply with such conditions and requirements may cause the regulatory authorities to impose sanctions or penalties that could adversely affect our business operations.

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

If we begin commercializing our drugs in China, our operations would be subject to various anti-kickback, false claims, medical staff payment transparency, fraud and abuse laws or similar healthcare laws and regulations in China, including, without limitation, the PRC Anti-Unfair Competition Law (《中華人民共和國反不正當競爭法》) and the PRC Drug Administration Law (《中華人民共和國藥品管理法》). These laws and regulations may impact, among other things, our proposed sales and marketing programs. Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including penalties, fines and/or exclusion or suspension from governmental healthcare programs and debarment from contracting with the PRC government.

Although we have put in place policies and procedures that ensure that we and our employees comply with fraud and abuse and other healthcare laws and regulations, we cannot guarantee that our employees, as well as third parties that we collaborate with such as CROs, hospitals, physicians and other medical professionals will fully comply with such laws and regulations at all times. In the event that our employees or other third party collaborators do not adhere to fraud and abuse and other healthcare laws and regulations, we may be subject to investigations, civil, criminal and administrative penalties and contractual damages that generate negative publicity and substantially harm our reputation, business and prospects.

Off-label use of our products after their approval could lead to adverse drug reactions and negative results that may materially harm the reputation of our company and of the relevant drugs, while off-label use of our competitor drugs could adversely affect the market potential for our products, which in turn could affect our financial condition.

Products distributed or sold in the pharmaceutical market may be subject to off-label drug use. Off-label drug use is prescribing a product for an indication, dosage or in a dosage form that have not been approved by the relevant authorities. Considering that many pathogenic pathways and therapeutical targets could apply to multiple indications within the field of autoimmune and allergic diseases, there remains the risk that our drug candidates and the drugs and drug candidates of our competitors could be subject to off-label drug use after obtaining

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regulatory approval and are prescribed for indications or in dosages or dosage forms that have not been approved by competent authorities, even though the NMPA and other relevant authorities actively enforce the laws and regulations prohibiting the promotion of off-label use.

On the one hand, in off-label use, our drug candidates may be less effective or entirely ineffective in the unintended patient population and may cause adverse drug reactions. Any of these occurrences can create negative publicity and significantly harm the reputation of our company and of the relevant drugs, our commercial operations and our financial condition. These occurrences may also expose us to product liability claims, or lead to a delay in the progress of our clinical trials, and may also ultimately result in failure to obtain regulatory approval for our drug candidates. On the other hand, off-label use of our competitor drugs could in effect intensify the competition that our products face and result in unlawful erosion of our market share, which could also adversely affect our business prospects.

RISKS RELATING TO OUR INTELLECTUAL PROPERTY RIGHTS

If we are unable to obtain and maintain patent protection for our drug candidates, third parties could develop and commercialize products and technologies similar or identical to ours and compete directly against us, and the commercial prospects of our drug candidates would be materially and adversely affected.

We view the proprietary protection of our drugs as integral to our entire operation. Throughout the Track Record Period, we sought to protect the drug candidates and technologies that we consider commercially important by filing patent applications in China, the United States and other countries, relying on trade secrets or pharmaceutical regulatory protection or employing a combination of these methods. Any failure by us to obtain or maintain patent protection with respect to our drug candidates and technologies could materially adversely affect our business, financial condition, results of operations and prospects.

The patent application and prosecution processes are expensive, time-consuming and complex, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patents and patent applications at a reasonable cost or in a timely manner in all desirable territories. For example, in China, the China National Intellectual Property Administration (CNIPA) may require us to amend our patent applications after substantive examinations, including reducing the patentable coverage, and if we fail to respond within a specified period, our applications will be deemed to be withdrawn. As a result, we may not be able to prevent competitors from developing and commercializing competitive drugs in all such fields and territories. Furthermore, the patent positions of biotech and pharmaceutical companies are generally highly uncertain, involve complex legal and factual questions, and have been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are uncertain.

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Patents may be invalidated and patent applications may not be granted for a number of reasons, including known or unknown prior art, deficiencies in the patent application or the lack of novelty of the underlying invention or technology. For example, in making any patent application, there is no guarantee that we will have been the first to develop our drug candidates or other proprietary technologies through independent means. In such cases, it is possible that our patent applications will be rejected. It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, consultants, advisors and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to obtain patent protection.

In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in certain jurisdictions are typically not published until 18 months after filing, or in some cases, not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions.

Furthermore, China and the U.S. have adopted the “first-to-file” system under which whoever first files a patent application will be awarded the patent if all other patentability requirements are met and no objection are raised by other parties. Under the first-to-file system, if third parties file first, they may be granted a patent relating to a technology which we invented. In addition, under the PRC patent law, any organization or individual that applies for a patent in a foreign country for an invention or utility model accomplished in China is required to report to the CNIPA for confidential examination. Otherwise, if an application is later filed in China, the patent right will not be granted.

The scope of patent protection is uncertain and our current or any future patents may be challenged and invalidated even after issuance, which would materially and adversely affect our ability to successfully commercialize any drug candidates.

The scope of patent protection in various jurisdictions is uncertain. Changes in patent laws or their interpretation in China or other jurisdictions may increase the uncertainties and costs surrounding the prosecution of our patents, diminish our ability to protect our innovations, affect the value of our intellectual property, jeopardize ongoing patent applications and/or narrow the scope of our patent rights. We cannot predict whether the patent applications we are currently pursuing, and may pursue going forward, will be granted, or, if granted, whether they could continue to provide sufficient protection from competitors.

The coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we currently own or may own in the future are granted as patents, they may not be issued in

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a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents that we hold may be challenged, narrowed, circumvented or invalidated by third parties.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patent rights may be challenged in the courts or patent offices in China, the U.S. and other countries. An adverse determination from such challenges could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or drug candidates and compete directly with us without payment to us, or result in our inability to manufacture or commercialize drug candidates without infringing, misappropriating or otherwise violating third-party patent rights. Such challenges also may result in substantial costs and require significant time from our scientists and management, even if the eventual outcome is favorable to us.

Furthermore, there is no guarantee that we will be granted patent extensions. On October 17, 2020, the Patent Law of the PRC was amended with effect from June 1, 2021, according to which the patent administration department under the State Council may, upon request, extend terms for invention patents relating to new drugs that have obtained regulatory approvals for no more than five years, and the total term of the patent right may not exceed 14 years after the regulatory approval for the marketing of a new drug. Similarly in the United States, we may apply for a patent term extension of up to five years as compensation for the patent term lost during clinical trials and the FDA regulatory review process under the Drug Price Competition and Patent Term Restoration Act of 1984. The exact duration of the extension depends on the time we spend in clinical studies, as well as getting an NDA approval from the FDA. However, a patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of approval, only one patent may be extended, and only those claims covering the approved drug, a method for use, or a method for manufacturing may be extended. Following the expiration of our patents, it is possible that our competitors may develop and market generic version of such drugs, thereby materially and adversely affecting our ability to compete.

Our drugs may become subject to intellectual property infringement or misappropriation claims or other legal challenges and such litigation could be costly and time-consuming and could prevent or delay us from developing or commercializing our drug candidates.

Our commercial prospect depends partly upon our ability to develop, manufacture, market and sell our drug candidates without infringing, misappropriating or otherwise violating the intellectual property rights of others. Many drug companies maintain worldwide patent portfolios. Their patents may cover various aspects of a single drug, including but not limited to composition, administration method, cell line constructions, vectors, growth media, manufacturing processes and purification measures. Such patents may be valid globally, including in jurisdictions where we intend to commercialize our drugs. As the drug industry

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continues to expand and more patents are applied for and granted, we are subject to higher risks of unknowingly violating the patents of third parties. Furthermore, our competitors may also obtain patents that restrict or preclude our ability to lawfully manufacture and market our drugs.

We cannot guarantee that our drug candidates or any uses of our drug candidates do not and will not in the future infringe third-party patents or other intellectual property rights. It is also possible that we failed to identify, or may in the future fail to identify, relevant patents or patent applications held by third parties that cover our drug candidates. Additionally, pending patent applications which have been published can, subject to certain limitations, be later amended in a manner that could cover our drug candidates or their use.

Third parties might allege that we are infringing their patent rights or that we have misappropriated their trade secrets, or that we are otherwise violating their intellectual property rights, whether with respect to the manner in which we have conducted our research, use or manufacture of the biologics we have developed or are developing. Such third parties might resort to litigation against us. Any patent or trademark infringement, trade secret misappropriation or other intellectual property claims or legal proceedings brought against us could result in substantial costs and divert capital resources and management attention. In the event that we are unsuccessful in defending such claims or legal proceedings, we may be compelled to accept one or more of the following solutions:

- pay substantial damages, court costs, and attorneys' fees;
- obtain licenses or pay ongoing royalties on unfavorable terms;
- cease developing, manufacturing or selling drugs that incorporate the intellectual property in dispute;
- cease using and registering certain domain names, brands or trademarks in connection with some or all of our drugs and business activities in some or all jurisdictions in which we operate;
- redesign or reengineer drugs; and
- change our business processes.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. Thus, even if we ultimately prevail, or settle at an early stage, such litigation could burden us with substantial unanticipated costs.

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As the legal threshold for bringing intellectual property claims and proceedings against us is low, we may be subject to intellectual property claims and proceedings regardless of the merit and probability of success of such claims. Any intellectual property–related disputes or litigation, regardless of outcome or merit, could result in substantial costs and expenses, negative publicity and diversion of management resources. During the course of any intellectual property claims or proceedings, there could be public announcements of the results of hearings, rulings on motions and other interim proceedings in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our drug candidates, future drug candidates, programs or intellectual property could be diminished. Accordingly, the market price of our H Shares may decline. Such announcements could also harm our reputation or the market for our drug candidates, which could have a material adverse effect on our business. An adverse outcome in such litigation or proceedings may expose us or any future strategic partners to loss of our proprietary position, expose us to significant liability or require us to seek licenses that may not be available on commercially acceptable terms, if at all, which could have a material adverse effect on our business.

We may face challenges associated with protecting our intellectual property rights in other jurisdictions.

As of the Latest Practicable Date, we held 37 patents in China as well as 9 patents overseas. As of the same date, we also had 44 patent applications pending in China and overseas.

In the event that we are able to commercialize our drugs on an international scale, we may face challenges associated with protecting our intellectual property rights in other jurisdictions. Filing, prosecuting, maintaining and defending patents in all other countries throughout the world requires significant financial resources and management attention. Moreover, our intellectual property rights in other jurisdictions may be of different scope and strength as compared to those in our target markets. Consequently, we may not be able to entirely prevent third parties from using our intellectual property to produce, sell or import drugs in other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own drugs, and may also export otherwise infringing drugs to jurisdictions where we do not have patent protection or strong patent enforcement rights. Such occurrences may diminish our competitive advantages, prospects and market share.

RISK FACTORS

Intellectual property rights do not necessarily protect us from all potential threats in competition.

As intellectual property rights have limitations, they do not necessarily protect us from all potential threats in our competition with other biotech companies. Some of such limitations include:

- others may be able to manufacture drugs that are similar to our drug candidates or apply similar technology that is not covered by the patents we own or license, now or in the future;
- others may independently develop similar drugs through methods or means that do not technically infringe, misappropriate or otherwise violate our intellectual property rights, particularly if the scope of protection afforded by our intellectual property rights is limited by the laws and regulations of certain jurisdictions or pursuant to court judgments or other legal proceedings;
- we might not have been the first to file patent applications covering certain of our inventions;
- it is possible that our pending licensed patent applications or those that we may own in the future will not lead to issued patents;
- we may not develop additional proprietary technologies that are patentable;
- we may choose not to file a patent for certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property
- our patents may be rendered invalid or unenforceable as a result of legal challenges by our competitors; and
- our competitors might conduct research and development activities in countries where we do not have patent rights and use the information learned to develop competitive drugs for sale in our major markets.

Failure to protect our know-how, trade secrets and other confidential proprietary information may adversely affect our competitiveness.

In addition to patents and pending patent applications, we rely on know-how, trade secrets and other confidential proprietary information that cannot be patented to maintain our competitive position. To protect such intellectual property, we generally enter into non-disclosure and confidentiality agreements with employees, business partners, consultants, advisors and other third parties. Our standard employment contract contains a confidentiality clause and an assignment clause, under which we own all the rights to all inventions, technologies, know-how and trade secrets derived during the course of our employee’s work.

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We also enter into standard non-compete agreements with our key personnel. Additionally, we require our collaborating research institutions or other individuals to sign contracts with provisions that limit their ability to disclose certain data and other information obtained during the course of their research. However, we cannot assure you that our employees or other third parties will not intentionally or inadvertently make unauthorized disclosures or uses of our know-how, trade secrets and other confidential proprietary information. We also cannot guarantee the physical and cyber security of our information technology systems from data breaches and malicious attacks. Despite measures taken to protect our intellectual property, unauthorized parties may attempt to or successfully gain access to, obtain or use information that we regard as proprietary without our consent. Moreover, there may not be adequate remedies readily available to mitigate their unauthorized use or disclosure of our confidential proprietary information. We may hence be unable to sufficiently protect our trade secrets and proprietary information and other parties may attempt to or successfully make use of our know-how, trade secrets and other confidential proprietary information to produce drugs that erode our competitive position. Any enforcement and/or remedial measures that we take may be expensive and time-consuming, and the eventual outcomes may be unfavorable.

In addition, while we typically require our employees who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Furthermore, the assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, each of which may result in claims by or against us related to the ownership of such intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our management and scientific personnel. Any of the foregoing could materially adversely affect our business, financial condition, results of operations and prospects.

We may be subject to claims that our employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of their former employers or claims asserting ownership of what we regard as our own intellectual property.

Many of our employees, consultants and advisors, including our senior management, were previously employed at other pharmaceutical or biotech companies, including our competitors or potential competitors. Some of these employees, consultants and advisers executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's former employer, or that third parties have an interest in our patents as an inventor or co-inventor. We are not aware of any threatened or pending claims related to these matters or concerning the agreements with our senior management, but such claims may rise in the future. If we fail in defending any such claims,

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in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

Failure to adequately protect our trade names, trademarks and other intellectual property may affect our ability to build brand recognition.

We conduct our business under the brand name of “Qyuns (荃信).” As of the Latest Practicable Date, we had registered 83 trademarks in the PRC and Hong Kong. As of the same date, we were the registered owner of 21 domain names in the PRC. However, our measures to protect intellectual property rights afford limited protection and policing unauthorized use of our intellectual property may be difficult and expensive. In addition, the enforceability, scope and validity of laws governing intellectual property rights in China are uncertain and still evolving. We cannot guarantee that we will be able to detect unauthorized use of our intellectual property rights or take appropriate steps to enforce them in a timely and effective manner. Moreover, attempts to protect our intellectual property rights through litigation could result in substantial costs and divert resources and management attention.

Furthermore, our registered and unregistered trade names or trademarks may be challenged, infringed, circumvented or declared generic or infringing on other marks. We may not be able to protect our rights to these trade names and trademarks, which we need to build brand recognition among potential partners or customers in our markets of interest. As our products mature, our reliance on our trademarks to differentiate us from our competitors will increase, and as a result, if we are unable to prevent third parties from adopting, registering or using trademarks and trade dress that infringe, dilute or otherwise violate our trademark rights, or engaging in conduct that constitutes unfair competition, defamation or other violation of our rights, our business could be materially adversely affected.

Additionally, there is no guarantee that we will always be able to successfully register our trade names and trademarks. Failure to do so may prevent us from using our trade names and trademarks under the protection of the relevant laws and regulations, and we risk being accused of infringing other intellectual property rights. In addition, at times, competitors may adopt trade names or trademarks similar to our own and impede our ability to build brand recognition. Over the long term, failure to establish brand recognition based on our trade names and trademarks may prevent us from competing effectively and diminish our future prospects.

RISK FACTORS

RISKS RELATING TO OUR OPERATIONS

We may fail to successfully manage our growth and expand our operations.

Since our inception, we have sought to expand our business through organic growth. As we advance our drug candidates through clinical trials and prepare for potential commercial launch for multiple drug candidates in the future, we will need to expand our development and manufacturing capabilities and seek cooperation opportunities for the sales and marketing of our future approved drugs.

Our recent growth and any future growth will impose significant added responsibilities on members of management, including (i) identifying, recruiting and integrating additional employees in accordance with our development plan; (ii) managing our internal development efforts effectively, including the clinical and regulatory authority review process for our drug candidates, while complying with our contractual obligations to contractors and other third parties; and (iii) improving our operational, financial and management controls, reporting systems and procedures. We would also need to secure and manage additional collaborative relationships with various strategic partners, such as Zhongmei Huadong, suppliers, CROs and other third parties.

However, we cannot guarantee that we will be able to successfully execute our development strategies. To a certain extent, our future growth may be affected by changes in regulatory, economic or political conditions beyond our control, such as changes in China’s general economic conditions, the biotech industry and relevant government regulations.

It is difficult to predict our future growth based on our historical and operating data. We also cannot assure you that our future development plan will materialize. Investors should not rely solely on our historical results of operations to predict our future performance. Additionally, our expansion plans are based on our forward-looking assessment of market prospects. We cannot assure you that our assessments will prove correct.

We may be unable to attract and retain senior management and qualified clinical or research and development personnel.

Our operation depends in part on our continued ability to attract, retain and motivate senior management and qualified management, clinical and scientific personnel. We believe their efforts, connections and industry expertise are key to our business development.

The loss of services of any of our key management personnel may impede the achievement of our research, development and commercialization objectives. We cannot guarantee that we will be able to promptly hire and integrate qualified replacements. Replacing executive officers or senior management personnel may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize biologic drugs like those we develop. Competition to hire from this limited pool

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is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotech companies for similar personnel.

In addition, the future growth of our business will depend partly on our ability to attract and retain qualified personnel on reasonable terms, particularly those involved in our clinical and research and development operations. We may need to compete with other drug companies for employees with the relevant qualifications and experience. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. Our consultants and advisers may be employed by others entities and may have commitments under consulting or advisory contracts with employers that may limit their availability to us. Although we have not historically experienced unique difficulties attracting and retaining qualified employees, we could experience such problems in the future. If we are unable to continue to attract and retain high-quality personnel, our ability to pursue our growth strategy will be limited. Any inability to hire and retain personnel with the talent and technical skill that we need to conduct our business could materially adversely affect our business, financial condition, results of operations and prospects.

We have entered into collaborations agreements, and may form or seek other collaborations or strategic alliances or enter into licensing arrangements in the future, and we may not realize the benefits of such alliances or licensing arrangements.

We have entered into a collaboration agreement with Zhongmei Huadong, a subsidiary of Huadong Medicine, with respect to the joint development and exclusive commercialization of QX001S in China. See “Business—Collaboration with Zhongmei Huadong” for further details. We may continue to explore a variety of possible strategic collaborations or license opportunities in an effort to gain access to additional drug candidates, technologies or commercialization resources.

We face significant competition in seeking appropriate strategic partners and the negotiation process, which is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our drug candidates, because a majority of them may be deemed to be at too early of a stage of development for collaborative effort and potential partners may not view our drug candidates as having the requisite potential to demonstrate safety and efficacy or commercial viability.

In addition, collaborations involving our drug candidates are subject to various risks, including, but not limited to:

- collaboration partners have significant discretion in determining the development or commercialization strategy for our drug candidate during collaboration, which may be different from what we expected and may be ineffective;

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- the development or commercialization capabilities of our partners may not be as strong as we expected;
- collaboration partners may not pursue development and commercialization of our drug candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in their strategic focus, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaboration partners may not commit sufficient resources to the development or sales and marketing of one or more of our drug candidates;
- we could grant exclusive rights to our collaboration partners that would prevent us from collaborating with others;
- collaboration partners may not properly obtain, protect, maintain, defend or enforce our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- collaboration partners may not aggressively or adequately pursue litigation against generic filers or may settle such litigation on unfavorable terms, as they may have different economic interests than ours, and such decisions could negatively impact any royalties we may receive under our license agreements;
- we may encounter material disputes with collaboration partners regarding the terms of our collaboration, which could lead to disruption of the development or commercialization of our drug candidates and litigations that could be time-consuming and expensive; and
- collaborations may be terminated and, if terminated, may result in a need for additional time and capital to pursue alternative partners for the development or commercialization of the applicable drug candidates;

Therefore, we may not be able to realize the benefit of current or future collaborations, if we are unable to successfully integrate such collaborations with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or other financial benefits that justify such transaction. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail or delay the development or commercialization of one or more of our drug candidates, reduce the scope of any sales or marketing activities, or increase our expenditures

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and undertake such development or commercialization activities at our own expense. As a result, we may not be able to further develop our drug candidates or bring them to market and generate product sales revenue, which would harm our business prospects, financial condition and results of operations.

Our employees, CROs, collaboration partners and others with whom we deal may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements, which could harm our reputation and subject us to penalties and significant expenses that have a material adverse effect on our business, financial condition and results of operations.

We are exposed to the risk of fraud, misconduct or other illegal activity by our employees, CROs, collaboration partners and others with whom we deal. Misconduct by these parties could include intentional, reckless and negligent conduct that fails to: (i) comply with the laws of the NMPA and other regulatory authorities; (ii) provide true, complete and accurate information to the NMPA and other regulatory authorities; (iii) comply with healthcare fraud and abuse laws in China; or (iv) report financial information or data accurately or to disclose unauthorized activities to us. If we obtain NMPA approval for any of our drug candidates and begin commercializing those drugs in China, our potential exposure under relevant laws will increase significantly and our costs associated with compliance with such laws are also likely to increase. These laws may impact, among other things, our current activities with principal investigators of our clinical trials and our use of information obtained in the course of patient recruitment for clinical trials.

It is not always possible to identify and deter misconduct by employees and other parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses, or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

We may be required to pay late payment fines or other penalties in connection with our failure to contribute to social insurance and housing provident funds.

In accordance with applicable PRC laws and regulations, we are obliged to contribute to social insurance and housing provident funds for our employees. During the Track Record Period, we did not fully contribute to social insurance and housing provident funds for some of our employees and engaged third-party agents to make the payment of social insurance and housing provident fund on behalf of us for certain employees. We made full provisions for the total amount of such shortfall of RMB3.8 million, RMB5.4 million and RMB3.9 million to our consolidated statement of profit or loss and other comprehensive income for the years ended December 31, 2021 and 2022 and the nine months ended September 30, 2023, respectively. Our PRC Legal Advisors have advised us that, under the Regulations on Administration of Housing Provident Fund (《住房公積金管理條例》), if we fail to pay housing provident fund

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contributions within the prescribed deadlines, we may be subject to an order by the relevant people's court to make such payments. According to the Social Insurance Law of the PRC (《中華人民共和國社會保險法》), for outstanding social insurance fund contributions that we did not fully pay within the prescribed deadlines, the relevant PRC authorities may demand that we pay the outstanding social insurance contributions within a stipulated deadline and we may be liable for a late payment fee equal to 0.05% of the outstanding contribution amount for each day of delay. If we fail to repay the outstanding social insurance contributions within the stipulated period, we may be liable to a fine of one to three times the outstanding contribution amount. As of September 30, 2023, the outstanding balance of our shortfall in contribution amounted to RMB4.5 million for social insurance and RMB8.2 million for housing provident fund. Therefore, as advised by our PRC Legal Advisors, we could be subject to fines of up to RMB13.5 million in relation to the shortfall in our contribution to social insurance and a late fee of 0.05% of the outstanding amount for each day of delay. As advised by our PRC Legal Advisors, the risk of us being penalized for such shortfall is remote, provided that we rectify such shortfall in a timely manner after receiving notices from the relevant PRC authorities. As of the Latest Practicable Date, we had not received any order of correction from the competent authority, or any complaint or labor arbitration application from any of our employees, as a result of any such arrangement. However, we cannot assure you that the competent authority will not require us to rectify any non-compliance or to pay any penalty related thereto.

We may be required to pay administrative fines for our failure to register some of our lease agreements with housing administration authorities.

As of the Latest Practicable Date, we had not completed the administrative filings of the lease agreements relating to seven properties we leased for business purposes, with an aggregate GFA of 1,229 sq.m. As registration of the lease agreement will require the cooperation of the landlord, we cannot assure you that we can complete the registration of such lease agreement in a timely manner or at all. According to applicable PRC administrative regulations, the lessor and the lessee of a lease agreement are required to file the lease agreement with relevant governmental authorities within 30 days after the execution of the lease agreement. If the filing is not made, the governmental authorities may require that the filing be made within a stated period of time, failing which they may impose a fine ranging from RMB1,000 to RMB10,000 for each agreement that has not been properly filed. It is not clear under applicable PRC laws if the fine will be borne by the lessor or lessee. According to applicable PRC administrative regulations, lessors of the related leases need to provide us with certain documents (such as their business licenses or identification information) in order to complete the administrative filing. There can be no assurance that the lessors of our leased properties will be cooperative in the process of completing the filings. If we fail to complete the administrative filings within the period required by the relevant governmental authorities and the relevant authorities determine that we shall be liable for failing to complete the administrative filings of all the relevant lease agreements, we may be subject to a fine of up to RMB10,000 for each such lease agreement or such other fine which may be determined by relevant government authorities.

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

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures, manufacturing facilities and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials, and may produce hazardous waste products. We may contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain statutory employees’ social insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of or exposure to hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage, use or disposal of biological or hazardous materials.

In addition, we may be required to incur substantial costs to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions. Any of the foregoing could materially adversely affect our business, financial condition, results of operations and prospects.

Changes in social trends and political policies related to environmental, social, and governance issues may adversely affect our business operation.

As a biotech company, we are subject to potential risks arising from changes in social trends and political policies related to environmental, social, and governance (ESG) issues, such as public perception with respect to animal testing for the R&D of biologic drugs. Changes in social trends and political policies related to ESG issues could impact our business model in several ways. For example, if there is a shift towards more stringent regulations on environmental protection or animal welfare, we may face increased compliance costs and operational challenges. Similarly, if there is a growing demand for biologic drugs that are developed and manufactured using environmentally friendly process, we may need to adapt our pipeline and invest in new technologies and process to reduce our environmental footprint. Moreover, changes in political policies related to ESG issues may impact our access to funding and other resources that are critical to our growth and success. For instance, if there is a change in government policies that restricts funding for biotech companies that do not meet certain ESG criteria, we may face challenges in securing financing for our business activities.

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Should we fail to detect or prevent violations of applicable anti-bribery laws by our employees, researchers, marketing and sales personnel and other business partners, we may experience material adverse effects on our business and be subject to significant penalties.

We are subject to anti-bribery laws in China that generally prohibit companies and their intermediaries from making payments to government officials to obtain or retain business or secure any other improper advantages. Within the healthcare industry, violations of anti-bribery and anti-corruption laws may include improper payments that facilitate outcomes in research studies and/or drug supply negotiations or opportunities to sell drugs or other healthcare products at hospitals and other medical institutions. Although we have put in place policies and procedures that ensure that we and our employees comply with anti-bribery laws, we cannot guarantee that our research and development staff, sales and marketing personnel and other employees, as well as third parties that we collaborate with such as CROs, hospitals and medical professionals will fully comply with anti-bribery and anti-corruption regulations at all times. We also cannot assure you that we will be able to detect and prevent all instances of improper practices with respect to our clinical trials and other aspects of our business. In the event that our employees or other third party collaborators such as our research and development staff, sales and marketing personnel and other employees do not adhere to anti-bribery and anti-corruption laws, we may be subject to investigations, sanctions or fines that generate negative publicity and substantially harm our reputation, business and prospects.

Negative publicity about us, our Shareholders and affiliates, our brand and management may materially and adversely affect our business, reputation and trading price of our H Shares.

We believe that market awareness and recognition of our brand image is important to our commercial prospect. Despite our efforts to promote our brand image, we may not be successful in doing so. Over the long term, negative publicity may materially and adversely affect our business and brand so as to reduce the trading price of our H Shares and diminish our competitive position.

As we continue to grow our business, we may find it necessary to expand our network of collaborators to enhance our marketing and branding efforts. Since we have limited control over such parties, we cannot guarantee that our efforts will be successful, nor that they will perform according to the standards expected. Any actions on their part that reflect negatively on our business or generate negative publicity for us may impede our efforts to establish our industry reputation.

Furthermore, negative publicity about us, our Shareholders and affiliates, alleged misconduct or improper activities or negative rumors relating to us, our management, employees, business partners or affiliates may arise from time to time in the internet and other media sources. They may harm our business and results of operations even if they are unsubstantiated. There is no guarantee that our efforts to defend ourselves against such negative publicity or rumors, or to address them internally, will be successful. Any regulatory inquiries or investigations against our directors and senior management, business partners or

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other affiliates regarding any perceived unethical, fraudulent or other inappropriate conduct may be particularly harmful to our reputation regardless of the merits or final outcome. In turn, this may affect our ability to grow our business and attract customers, suppliers and talented employees.

We are also particularly susceptible to negative media about the drug industry in general or particular drugs or services. Such negative media may result from the actions of competitors or other industry players, over whom we have no control. It is possible that the PRC government may promulgate laws and regulations that seek to address the source and reasons for such negative media. We cannot guarantee that we will be able to adapt to such laws and regulations in a timely and effective manner, including adequate management of the related compliance costs.

We may be involved in product liability claims or other disputes, litigation, arbitration and legal proceedings in the ordinary course of our business.

From time to time, we may be directly or indirectly involved in legal proceedings and claims that arise in the ordinary course of business or pursuant to governmental or regulatory enforcement activity. In particular, we face an inherent risk of product liability as a result of the clinical testing and any future commercialization of our drug candidates. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the drug, negligence, strict liability or a breach of warranties. Claims could also be asserted under applicable consumer protection laws. If we cannot successfully defend ourselves against or obtain indemnification from our collaboration partners for product liability claims, we may incur substantial liabilities or be required to limit commercialization of our drug candidates. Even a successful defense would require significant financial and management resources. Regardless of the merits or the eventual outcome of such product liability claims, we may be subject to the following consequences:

- less interest in our drug candidates and reduced demand for our drugs;
- reputational damage;
- withdrawal of clinical trial participants;
- inability to commercialize drug candidates;
- loss of revenue;
- costs incurred to defend legal proceedings;
- substantial monetary damages payable to trial subjects or customers; and
- product recalls, withdrawals or the imposition of labeling, marketing or promotional restrictions that limit our ability to commercialize our drug candidates.

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If we are unable to defend ourselves against such claims, we may be subject to, among other things, civil liability for adverse events or other losses caused by our products and to criminal liability and the potential revocation of our business licenses if our products are found to be defective.

In addition to product liability claims, our employees may also sue us for labor-related disputes or occupational injuries, and we are subject to risks associated with having limited control over the behavior of employees or other business partners who may intentionally or unintentionally harm the interests of our customers. Any claims, disputes and legal proceedings brought against us could result in substantial costs and divert capital resources and management attention, even if we should mount a successful defense. We may suffer damage to our reputation regardless of the merits or outcome, leading to material adverse effects on our business, financial position and brand value.

Existing PRC laws and administrative regulations require us to maintain liability insurance to cover product liability claims on clinical trials. Any product liability insurance for clinical trials, when obtained, may be prohibitively expensive, or may not fully cover our potential liabilities. Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of drug candidates we develop. Moreover, claims that may be brought against us could result in a court judgment or settlement for such amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

We are exposed to risks in connection with failing to detect and prevent fraud, negligence or other misconduct committed by third parties.

Our information management system and internal control procedures are designed to monitor our operations and overall compliance. However, we cannot guarantee that they will always enable us to detect, prevent and take remedial measures in relation to fraud, negligence or other misconduct (accidental or otherwise) committed by our employees, business partners, suppliers, customers or other third parties in a timely and effective manner. There will therefore continue to be risks that fraud, negligence and other misconduct (accidental or otherwise) may occur and cause negative publicity, which may have an adverse effect on our brand and reputation. Although we have limited control over the behavior of any of these parties, we may be viewed as at least partially responsible for their conduct. We may become, or be joined as, a defendant in litigation or other administrative or investigative proceedings and be held accountable for injuries or damages sustained by our employees, business partners, suppliers,

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customers or other third parties from time to time. To the extent that we cannot recover related costs from the employees, business partners, suppliers, customers or other third parties involved, we may experience material adverse effects on our business, financial position and results of operations.

We may experience additional challenges related to the COVID-19 pandemic.

The outbreak of COVID-19, a highly contagious disease known to cause respiratory illness, had caused an adverse impact on the economy and social conditions in China and other affected countries since late 2019, and had an impact on our industry and caused temporary suspension of some of our clinical trials. Many countries imposed unprecedented measures to halt the spread of the COVID-19 pandemic, including city lockdowns and travel restrictions. The Chinese government had implemented emergency measures in various key cities or regions across the country, including Taizhou, in response to the outbreak of the Delta variant since July 2021 and the Omicron variant since November 2021, including travel restrictions, mandatory cessations of business operations, mandatory quarantines, and limitations on social and public gatherings. These measures affected our research and development and manufacturing activities. In particular, we experienced varying extents of delay in our clinical trials in 2022 when the research institution we engaged were under lockdown. For example, our Phase II clinical trial of QX002N for AS, which commenced in January 2022, experienced delay in patient enrollment for approximately two months and interruption in follow-up visits of some patients due to COVID-19-related lockdown measures in cities where our clinical trial sites/patients were located. In the Phase Ib clinical trial of QX005N for AD, due to COVID-19-related lockdown measures, one patient was lost to follow-up, whose data were considered invalid.

Since December 2022, the Chinese government has taken measures to lift the pandemic-related restrictions on social and economic activities to facilitate people’s return to normalcy. However, there is still uncertainty as to the future development of the COVID-19 pandemic. There could be a resurgence of the disease and infections could increase again across the country. The continuation or any future recurrence of COVID-19 may adversely affect our business operations, such as causing temporary delay of our existing and future clinical trials and reducing working capacity of our employees. Such occurrences may have the effect of increasing our drug development costs and affect our ability to conduct our business operations.

Although we constantly monitor the status of the COVID-19 pandemic, it is affected by factors beyond our control. We cannot guarantee that any mitigation measures we may take will be sufficient against the effects of a global pandemic. In the event that we are unable to minimize the negative effects of any future recurrence of COVID-19 on our business, we may experience material adverse effects on our financial statements and results of operations.

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Our insurance coverage may not sufficiently cover the risks related to our business operations.

We maintain insurance policies that we believe are customary with standard commercial practice in the drug industry and as required under the relevant PRC laws and regulations. However, we cannot guarantee you that our insurance policies will provide adequate coverage for all the risks in connection with our business operations. For example, although we maintain liability insurance covering our clinical trials as required under PRC laws and regulations, our coverage may be insufficient to cover any amounts payable under court judgments or settlements. Should we incur substantial amounts in product liability claims, and be unable to cover these with our existing insurance policies or internal resources, we may be forced to suspend other key operations, such as the conduct of clinical trials, to divert funds from other aspects of our business.

Moreover, there are certain losses for which insurance is not available in China on commercially practicable terms, such as losses suffered due to business interruptions, earthquakes, typhoons, flooding, war or civil disorder. We may be required to bear our losses to the extent that they are not covered by insurance, or that our insurance coverage is insufficient, and such amounts could be substantial. We could suffer significant costs and diversion of our resources as a result.

Our information technology systems, or those of our CROs or other service providers or consultants, may fail or suffer security breaches.

Despite the implementation of security measures, our internal computer systems and those of our CROs, service providers or consultants are vulnerable to damage or interruption caused by, among others, power outages, computer viruses, phishing attacks, ransomware, worms, unauthorized access, telecommunication failures, cyber-attacks, natural disasters, terrorism and war. Should such events occur and interrupt our operations, we may experience a material disruption to our business operations.

In our ordinary course of business, we collect and store sensitive information, including the personal information of our employees, various intellectual property (including trade secrets), research and development information, sales and marketing strategies and key business and financial data. We manage and maintain our information and data through on-site systems and third-party vendors. Because information systems, networks and other technologies are critical to many of our operating activities, shutdowns or service disruptions at our sites or third-party vendors may materially and adversely affect our business operations by damaging key data and equipment. Such disruptions may be caused by events such as computer hacking, phishing attacks, ransomware, dissemination of computer viruses, worms and other destructive or disruptive software, denial of service attacks and other malicious activity, as well as power outages, natural disasters (including extreme weather), terrorist attacks or other similar events. There is no guarantee that our disaster recovery and automatic

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recovery systems will be able to retain and recover all the equipment or data affected by shutdowns or service disruptions. In addition, we may not have adequate insurance coverage to compensate for losses associated with such events.

Furthermore, we are vulnerable to risks caused by misappropriation, misuse, leakage, falsification, or intentional or accidental release or loss of sensitive information maintained in our information systems and those of our vendors, including confidential data on our employees, customers, suppliers and clinical trial subjects. Outside parties may attempt to penetrate our information systems or those of our vendors, or fraudulently induce our employees or our vendors’ employees to disclose sensitive information through means such as viruses, phishing and cyber-attacks. The number and complexity of these threats continue to increase over time. In the event of a material breach of our information technology systems or those of our vendors, our business partners, customers or other industry players may have a negative perception of the effectiveness of our security measures, and we may experience harm to our reputation and credibility. We may also be compelled to expend substantial financial resources to repair or replace our information systems. In addition, we may be subjected to collective actions and/or claims from individuals respecting issues related to data privacy laws and regulations, such as misuse or inappropriate disclosure of data and unfair or deceptive practices.

We cannot guarantee that our internal control procedures will always be sufficient to identify and mitigate threats to our information systems. The development and maintenance of our information systems is costly and requires ongoing monitoring and updating as technologies change and efforts to overcome security measures become increasingly sophisticated. We may not always be able to adapt our internal control procedures and update our information systems in a sufficiently timely or effective manner to eliminate all such risks. Additionally, the more we outsource protection and upgrading of our information systems to vendors, engage in electronic transactions and rely on cloud-based information systems, the less control we have over the risks to our information systems. To the extent that disruptions or security breaches of our information systems or those of our vendors, CROs, service providers or other consultants compel us to temporarily suspend our business operations, we may experience delays to the development and commercialization of our drug candidates.

Failure to comply with existing or future laws and regulations related to privacy or data security could lead to government enforcement actions, which could include civil or criminal fines or penalties, private litigation, other liabilities, and/or adverse publicity.

The regulatory framework for the collection, use, safeguarding, sharing, transfer and other processing of personal information in China is rapidly evolving and is likely to remain uncertain for the foreseeable future. There are numerous laws that protect the confidentiality of individually identifiable patient health information, including patient records, and restricting the use and disclosure of that protected information. Regulatory authorities may continue to introduce additional legislative and regulatory proposals concerning personal data protection.

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Measures for the Security Assessment for Cross-border Transfer of Personal Information (Draft for Comment) (《個人信息出境安全評估辦法(徵求意見稿)》) was published by the Cyberspace Administration of China in 2019, which may, upon enactment in current form, require security assessment before transferring personal information collected in China abroad. Moreover, the Standing Committee of the NPC promulgated the Personal Information Protection Law of the PRC (《中華人民共和國個人信息保護法》), which became effective on November 1, 2021, sets forth detailed rules on handling personal information and legal responsibilities and also strengthen the punishment for illegal process of personal information. Under the Personal Information Protection Law of the PRC, healthcare relevant personal information, including the information collected during clinical trials, shall be deemed as “sensitive personal information” and shall be under strict protection. Furthermore, GCP requires that the privacy of trial subjects and the confidentiality of the relevant information shall be protected.

Moreover, the Data Security Law of the PRC (《中華人民共和國數據安全法》) which has taken effect on September 1, 2021, provides that relevant authorities will establish the measures for the cross-border transfer of import data, if any company violates the Data Security Law of the PRC to provide important data outside China, such company may be punished by administration sanctions, including penalties, fines, and/or may suspension of relevant business or revocation of the business license. The Cyberspace Administration of China published Measures for the Security Assessment for Cross-border Transfer of Personal Information (Draft for Comment) (《個人信息出境安全評估辦法(徵求意見稿)》) in 2019, which may, upon enactment in current form, require security assessment before transferring personal information collected in China abroad. Moreover, the Outbound Data Transfer Security Assessment Measures (the “Outbound Data Transfer Security Assessment Measures”) (《數據出境安全評估辦法》) was published on July 7, 2022 and became effective on September 1, 2022, which specifies that data processors who intend to provide important data and personal information that are collected and generated in the operation within the territory of the PRC to overseas shall be subject to security assessment. The Outbound Data Transfer Security Assessment Measures further stipulate the process and requirements for the security assessment. However, it remains uncertain how the PRC government authorities will regulate companies under such circumstances if the Outbound Data Transfer Security Assessment Measures are fully implemented as-is. These bring more uncertainties with respect to the application and enforcement of the newly published measures, and we may be subject to such outbound data security assessment. We will closely monitor and assess any relevant legislative and regulatory development and prepare for a security assessment when necessary.

Compliance with these and any other applicable laws, regulations, standards and obligations relating to data privacy, security and transfers is a rigorous and time-intensive process and may cause us to incur additional operational costs or require us to modify our data processing practices and processes. If we or our third-party vendors, collaborators, contractors and consultants fail to comply with any such laws or regulations, we may face proceedings against us by data protection authorities and governmental entities, which could subject us to significant fines, penalties, judgments, negative publicity and reputational damage, and may otherwise materially and adversely affect our business, financial condition and results of operations.

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We may be subject to natural disasters, acts of war or terrorism or other factors beyond our control.

Natural disasters, acts of war, terrorism or other factors beyond our control may adversely affect the economy, infrastructure and livelihood of the people in the regions where we conduct our business. Our operations may be under the threat of floods, earthquakes, sandstorms, snowstorms, fire or drought, power, water or fuel shortages, failures, malfunction and breakdown of information management systems, unexpected maintenance or technical problems, or are susceptible to potential wars or terrorist attacks. Serious natural disasters may result in loss of lives, injury, destruction of assets and disruption of our business and operations. Acts of war or terrorism may also injure our employees, cause loss of lives, disrupt our business network and destroy our markets. Any of these factors and other factors beyond our control could have an adverse effect on the overall business sentiment and environment, cause uncertainties in the regions where we conduct business, cause our business to suffer in ways that we cannot predict and materially and adversely impact our business, financial conditions and results of operations.

RISKS RELATING TO THE [REDACTED]

There has been no prior public market for our H Shares and an active [REDACTED] market for our H Shares may not develop.

No public market currently exists for our H Shares. The initial [REDACTED] for our H Shares to the public will be the result of negotiations between our Company and [REDACTED] (on behalf of themselves and the [REDACTED]), and the [REDACTED] may differ significantly from the [REDACTED] of the H Shares following the [REDACTED]. We have applied to the Stock Exchange for the [REDACTED] of, and permission to [REDACTED], the H Shares. A [REDACTED] on the Stock Exchange, however, does not guarantee that an active and liquid [REDACTED] market for our H Shares will develop, or if it does develop, that it will be sustained following the [REDACTED], or that the market price of the H Shares will rise following the [REDACTED].

The [REDACTED] and [REDACTED] of our H Shares may be volatile, which could result in substantial losses for investors who [REDACTED] our H Shares in the [REDACTED].

The [REDACTED] and [REDACTED] of our H Shares may be highly volatile. Several factors beyond our control such as variations in our revenue, earnings and cash flow, strategic alliances, the addition or departure of key personnel, litigation, the removal of the restrictions on H share transactions or volatility in [REDACTED] and changes in demand for our products may cause significant and sudden changes to the [REDACTED] and [REDACTED] of our H Shares. Furthermore, the [REDACTED] of our H Shares could also decline as a result of future sales of a substantial number of our H Shares or other securities relating to our H Shares in the public market, or the issuance of new shares or other securities, or the perception that such sales or issuances may occur. New shares or share-linked securities issued by our Company may also confer rights and privileges that take priority over those conferred by the H Shares.

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The Stock Exchange and other securities markets have, from time to time, experienced significant price and trading volume volatility that are not related to the operating performance of any particular company. This volatility may also materially and adversely affect the [REDACTED] of our H Shares.

Since there will be a gap between the [REDACTED] and [REDACTED] of our H Shares, holders of our H Shares are subject to the risk that the [REDACTED] of our H Shares may fall during the period before [REDACTED] of our H Shares begin.

The [REDACTED] of our H Shares sold in the [REDACTED] is expected to be determined on the [REDACTED]. However, the H Shares will not commence [REDACTED] on the Stock Exchange until they are delivered, which is expected to be on a later date than the [REDACTED]. As a result, investors may not be able to sell or otherwise [REDACTED] the H Shares during that period. Accordingly, Shareholders are subject to the risk that the [REDACTED] of the H Shares could be lower than the [REDACTED] when [REDACTED] begins as a result of adverse market conditions or adverse developments that may occur between the time of [REDACTED] and the time of initial [REDACTED].

Potential investors will experience immediate and substantial dilution as a result of the [REDACTED].

Potential investors will pay a price per H Share in the [REDACTED] that substantially exceeds the per H Share value of our tangible assets after subtracting our total liabilities as of September 30, 2023. Therefore, purchasers of our H Shares in the [REDACTED] will experience a substantial immediate dilution in *pro forma* net tangible assets, and our existing Shareholders will receive an increase in the *pro forma* adjusted net tangible assets per Share on their Shares. As a result, if we were to distribute our net tangible assets to the Shareholders immediately following the [REDACTED], potential investors would receive less than the amount they paid for their H Shares. For more information, see “Appendix II—Unaudited Pro Forma Financial Information” to this document.

Any possible conversion of our [REDACTED] Shares into H Shares in the future could increase the supply of our H Shares in the market and negatively impact the [REDACTED] of our H Shares.

All of our [REDACTED] Shares may be converted into H Shares and such converted Shares may be [REDACTED] or [REDACTED] on an overseas stock exchange. Any [REDACTED] or [REDACTED] of the converted Shares on an overseas stock exchange shall also comply with the regulatory procedures, rules and requirements of such stock exchange. However, the PRC Company Law provides that in relation to the [REDACTED] of a company, the shares of that company which are issued prior to the [REDACTED] shall not be transferred within one year from the date of the [REDACTED]. Therefore, upon the completion of the relevant filing procedure, shares currently held on our [REDACTED] Share register may be [REDACTED], after the conversion, in the form of H Shares on the Stock Exchange after one year of the [REDACTED], which could further increase the supply of our H Shares in the market and could negatively impact the [REDACTED] of our H Shares.

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We cannot guarantee the accuracy of facts, forecasts and other statistics obtained from official government sources or other sources contained in this document.

Certain facts, statistics and data contained in this document relating to the pharmaceutical industry in and outside China have been derived from various official government publications, industry associations, independent research institutions, third party reports and/or other publicly available sources we generally believe to be reliable, as well as a report prepared by Frost & Sullivan that we commissioned. We believe that the sources of such information are appropriate sources for such information, but the information has not been independently verified by us or any other party involved in the [REDACTED] and no representation is given as to its accuracy.

There is no assurance whether and when we will pay dividends, which is subject to restrictions under PRC law.

No dividend had been paid or declared by our Company during the Track Record Period. Under the applicable PRC laws, the payment of dividends may be subject to certain limitations. The calculation of our profit under applicable accounting standards differs in certain respects from the calculation under IFRS. As a result, we may not be able to pay a dividend in a given year even if we were profitable as determined under IFRS. Our Board may declare dividends in the future after taking into account our results of operations, financial condition, cash requirements and availability and other factors as it may deem relevant at such time. Any declaration and payment as well as the amount of dividends will be subject to our constitutional documents and the PRC laws and regulations and requires approval at our shareholders' meeting. No dividend shall be declared or payable except out of our profits and reserves lawfully available for distribution.

Dividends payable to investors and gains on the [REDACTED] of our H Shares may be subject to PRC income taxes.

Under applicable PRC tax laws, regulations and statutory documents, non-PRC resident individuals and enterprises are subject to different tax obligations with respect to dividends received from us or gains realized upon the [REDACTED] or other disposition of our H Shares. Non-PRC individuals are generally subject to PRC individual income tax under the Individual Income Tax Law of the PRC (《中華人民共和國個人所得稅法》) with respect to PRC source income or gains at a rate of 20% unless specifically exempted by the tax authority of the State Council or reduced or eliminated by an applicable tax treaty. We are required to withhold related tax from dividend payments. Pursuant to applicable regulations, domestic non-foreign-invested enterprises issuing shares in Hong Kong may generally, when distributing dividends, withhold individual income tax at the rate of 10%. However, withholding tax on distributions paid by us to non-PRC individuals may be imposed at other rates pursuant to applicable tax treaties (and up to 20% if no tax treaty is applicable) if the identity of the individual holder of H shares and the tax rate applicable thereto are known to us. There is uncertainty as to whether gains realized upon disposition of H shares by non-PRC individuals are subject to PRC individual income tax.

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Non-PRC resident enterprises that do not have establishments or premises in the PRC, or that have establishments or premises in the PRC but their income is not related to such establishments or premises are subject to PRC EIT at the rate of 10% on dividends received from PRC companies and gains realized upon disposition of equity interests in the PRC companies pursuant to the EIT Law and other applicable PRC tax regulations and statutory documents, which may be reduced or eliminated under special arrangements or applicable treaties between the PRC and the jurisdiction where the non-resident enterprise resides.

Pursuant to applicable regulations, we intend to withhold tax at a rate of 10% from dividends paid to non-PRC resident enterprise holders of our H Shares (including HKSCC Nominees). Non-PRC resident enterprises that are entitled to be taxed at a reduced rate under an applicable income tax treaty will be required to apply to the PRC tax authorities for a refund of any amount withheld in excess of the applicable treaty rate, and payment of such refund will be subject to the PRC tax authorities' verification. As of the Latest Practicable Date, there were no specific rules on how to levy tax on gains realized by non-resident enterprise holders of H shares through the sale or transfer by other means of H shares.

There remains significant uncertainty as to the interpretation and application of the relevant PRC tax laws by the PRC tax authorities, including whether and how individual income tax or EIT on gains derived by holders of our H Shares from their disposition of our H Shares may be collected. If any such tax is collected, the value of our H Shares may be materially and adversely affected.

Fluctuations in Renminbi exchange rates may lead to foreign exchange losses and materially and adversely affect our ability to pay dividends to holders of our H Shares.

We expect that a substantial majority of our revenue will be denominated in Renminbi. A portion of our revenues may be converted into other currencies in order to meet our foreign currency obligations. For example, we need to obtain foreign currency to make payments of declared dividends, if any, on our H Shares. Shortages in availability of foreign currency may then restrict our ability to remit sufficient foreign currency to pay dividends or make other payments or otherwise to satisfy our foreign currency denominated obligations.

The [REDACTED] from the [REDACTED] will be denominated in Hong Kong dollars. As a result, any appreciation of the Renminbi against the U.S. dollar, the Hong Kong dollar or any other foreign currencies may result in the decrease in the value of our [REDACTED] from the [REDACTED]. Conversely, any depreciation of the Renminbi may adversely affect the value of, and any dividends payable on, our H Shares in foreign currency. In addition, there are limited instruments available for us to reduce our foreign currency risk exposure at reasonable costs. Any of these factors could materially and adversely affect our business, financial condition, results of operations and prospects, and could reduce the value of, and dividends payable on, our H Shares in foreign currency terms.

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Forward-looking statements contained in this document are subject to risks and uncertainties.

This document contains certain forward-looking statements and information relating to us that are based on the beliefs of our management as well as assumptions made by and information currently available to our management. When used in this document, the words “aim,” “anticipate,” “believe,” “can,” “continue,” “could,” “estimate,” “expect,” “going forward,” “intend,” “ought to,” “may,” “might,” “plan,” “potential,” “predict,” “project,” “seek,” “should,” “will,” “would” and similar expressions, as they relate to us or our business, are intended to identify forward-looking statements. Such statements reflect the current views of our management with respect to future events, business operations, liquidity and capital resources, some of which may not materialize or may change. These statements are subject to certain risks, uncertainties and assumptions, including the other risk factors as described in this document. Should one or more of these risks or uncertainties materialize, or if any of the underlying assumptions prove incorrect, actual results may diverge significantly from the forward-looking statements in this document. Whether actual results will conform to our expectations and predictions is subject to a number of risks and uncertainties, many of which are beyond our control, and reflect future business decisions that are subject to change. In light of these and other uncertainties, the inclusion of forward-looking statements in this document should not be regarded as representations that our plans or objectives will be achieved, and investors should not place undue reliance on such forward-looking statements. All forward-looking statements contained in this document are qualified by reference to the cautionary statements set out in this section. Subject to the ongoing disclosure obligations of the Listing Rules or other requirements of the Stock Exchange, we do not intend publicly to update or otherwise revise the forward-looking statements in this document, whether as a result of new information, future events or otherwise.

You should read this entire document carefully and should not consider or rely on any particular statements in published media reports without carefully considering the risks and other information contained in this document.

Prior to the publication of this document, and subsequent to the date of this document but prior to the completion of the [REDACTED], there may have been or may be press and media coverage regarding us, our business, our industry and the [REDACTED]. Such press and media coverage may include references to information that do not appear in this document or is inaccurate. We have not authorized the publication of any such information contained in such press and media coverage. Therefore, we make no representation as to the appropriateness, accuracy, completeness or reliability of any information disseminated in the press or media and do not accept any responsibility for the accuracy or completeness of any financial information or forward-looking statements contained therein. To the extent that any of such information is inconsistent or conflicts with the contents of this document, we expressly disclaim responsibility for them. Accordingly, prospective investors should only rely on information included in this document and not on any of the information in press articles or other media coverage in deciding whether or not to invest in our [REDACTED]. By applying to purchase our H Shares in the [REDACTED], you will be deemed to have agreed that you have not and will not rely on any information other than that contained in this document, the [REDACTED], and any formal announcements made by us in Hong Kong in relation to our [REDACTED].

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

In preparation for the [REDACTED], our Group has sought the following waivers from strict compliance with the relevant provisions of the Listing Rules and exemption from strict compliance with the relevant provisions of the Companies (Winding Up and Miscellaneous Provisions) Ordinance:

MANAGEMENT PRESENCE IN HONG KONG

Pursuant to Rules 8.12 and 19A.15 of the Listing Rules, an issuer must have sufficient management presence in Hong Kong and, in normal circumstances, at least two of the issuer’s executive directors must be ordinarily resident in Hong Kong.

Currently, all of our executive Directors reside in the PRC and for the foreseeable future will not be ordinarily resident in Hong Kong. Our Group’s business operations, management headquarter, senior management and assets are primarily conducted and located in the PRC, and it would be practically difficult and commercially unnecessary for us to relocate two of our executive Directors to Hong Kong, or to appoint additional executive Directors solely for the purpose of satisfying Rules 8.12 and 19A.15 of the Listing Rules, primarily on the basis that, as our headquarters, business operations, senior management and assets are located in the PRC, our management is best able to attend to its function by being based in the PRC.

Accordingly, we have applied to the Stock Exchange for, and the Stock Exchange [has granted] us, a waiver from compliance with Rules 8.12 and 19A.15 of the Listing Rules subject to, among others, the following conditions:

- (a) pursuant to Rule 3.05 of the Listing Rules, we have appointed two authorized representatives, Mr. Qiu, our executive Director, chairman of our Board, our chief executive officer and general manager, and Ms. Tang King Yin (鄧景賢) (“Ms. Tang”), one of our joint company secretaries, who will act as our Company’s principal channel of communication with the Stock Exchange. Ms. Tang is ordinarily resident in Hong Kong. Although Mr. Qiu resides in the PRC, he possesses valid travel documents and is able to renew such travel documents when they expire to travel to Hong Kong. Each of our authorized representatives will be available to meet with the Stock Exchange in Hong Kong within a reasonable time frame upon the request of the Stock Exchange and will be readily contactable by telephone, facsimile and/or email (where available). Each of our authorized representatives is authorized to communicate on our behalf with the Stock Exchange. Our Company has been registered as a non-Hong Kong company under Part 16 of the Companies Ordinance and Ms. Tang has also been authorized to accept service of legal process and notices in Hong Kong on behalf of our Company;

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- (b) both of our authorized representatives have means to contact all our Directors (including our independent non-executive Directors) promptly at all times as and when the Stock Exchange wishes to contact our Directors for any matters. Our Directors who are not ordinarily resident in Hong Kong possess or can apply for valid travel documents to visit Hong Kong and will be able to meet with the Stock Exchange within a reasonable period of time, when required. Each of our Directors has provided his/her respective mobile phone numbers, office phone numbers, fax numbers and/or email addresses (where available) to our authorized representatives. In the event that a Director expects to travel, he/she will endeavor to provide the phone number of the place of his/her accommodation to our authorized representatives or maintain an open line of communication via his/her mobile phone. Each of our Directors and authorized representatives has provided his/her mobile phone numbers, office phone numbers, fax numbers and/or email addresses (where available) to the Stock Exchange;
- (c) pursuant to Rule 3A.19 of the Listing Rules, we have appointed Somerley Capital Limited as our compliance advisor (the “Compliance Advisor”), which shall have access at all times to our authorized representatives, Directors, senior management and other officers of our Company, and will act as an additional channel of communication between the Stock Exchange and us; and
- (d) meetings between the Stock Exchange and our Directors could be arranged through our authorized representatives or the Compliance Advisor, or directly with our Directors within a reasonable time frame. We will promptly inform the Stock Exchange of any changes of our authorized representatives and/or the Compliance Advisor.

JOINT COMPANY SECRETARIES

According to Rules 3.28 and 8.17 of the Listing Rules and Chapter 3.10 of the Guide issued by the Stock Exchange, the secretary of an issuer must be a person who has the requisite knowledge and experience to discharge the functions of the company secretary and is either (i) a member of the Hong Kong Chartered Governance Institute, a solicitor or barrister as defined in the Legal Practitioners Ordinance (Chapter 159 of the Laws of Hong Kong) or a certified public accountant as defined in the Professional Accountants Ordinance (Chapter 50 of the Laws of Hong Kong); or (ii) an individual who, by virtue of his/her academic or professional qualifications or relevant experience, is, in the opinion of the Stock Exchange, capable of discharging the functions of a company secretary.

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According to Chapter 3.10 of the Guide, the waiver under Rule 3.28 of the Listing Rules will be granted for a fixed period of time, but in any case, will not exceed three years from the [REDACTED] (the “Waiver Period”) and on the conditions that (i) the company secretary in question must be assisted by a person who possesses the qualifications or experience as required under Rule 3.28 and is appointed as a joint company secretary throughout the Waiver Period; and (ii) the waiver can be revoked if there are material breaches of the Listing Rules by our Company.

We have appointed Mr. Hu Yanbao (胡衍保) (“Mr. Hu”) and Ms. Tang as our joint company secretaries. Mr. Hu joined our Group as a senior manager in November 2020 and was appointed as our Board secretary in August 2022, where he has been primarily responsible for business development, financing and corporate governance of our Group. Our Directors are of the view that, having regard to Mr. Hu’s thorough understanding of the overall business operations and corporate governance matters of our Group, he is considered as a suitable person to act as a company secretary of our Company. In addition, as our headquarters and principal business operations are substantially based and conducted in the PRC, our Directors believe that it is necessary to appoint Mr. Hu as a company secretary whose presence in the headquarters of our Group enables him to attend the day-to-day corporate secretarial matters of our Group and to take the necessary actions in an effective and efficient manner.

However, given that Mr. Hu does not possess a qualification stipulated in Rule 3.28(1) of the Listing Rules nor the “relevant experience” set out in Rule 3.28(2) of the Listing Rules, he is not able to solely fulfill the requirements as a company secretary of a listed issuer stipulated under Rules 3.28 and 8.17 of the Listing Rules. In order to provide support to Mr. Hu, we have appointed Ms. Tang, an associate member of both The Hong Kong Chartered Governance Institute and The Chartered Governance Institute in the United Kingdom, who is qualified under Rule 3.28 of the Listing Rules, to act as the other joint company secretary to closely work with and provide support to Mr. Hu during the Waiver Period so as to enable Mr. Hu to acquire the relevant experience (as required under Rule 3.28(2) of the Listing Rules) to duly discharge his duties as a company secretary of a listed issuer.

Accordingly, we have applied to the Stock Exchange for, and the Stock Exchange [has granted] us, a waiver from strict compliance with the requirements under Rules 3.28 and 8.17 of the Listing Rules in relation to the appointment of Mr. Hu as our joint company secretary on the condition that Mr. Hu will be assisted by Ms. Tang as our joint company secretary throughout the Waiver Period. Being a senior manager of corporate services of Tricor Services Limited and by virtue of her experience in corporate secretarial practice, Ms. Tang is, in our Directors’ opinion, a qualified and suitable person to render assistance to Mr. Hu so as to enable him to acquire the relevant experience (as required under Rule 3.28(2) of the Listing Rules) to duly discharge his duties. In addition, Mr. Hu will comply with the annual professional training requirement under Rule 3.29 of the Listing Rules and will enhance his

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knowledge of the Listing Rules during the Waiver Period. Our Company will further ensure that Mr. Hu has access to the relevant training and support that would enhance his understanding of the Listing Rules and the duties of a company secretary of an issuer listed on the Stock Exchange.

Such waiver will be revoked immediately if and when Ms. Tang ceases to provide such assistance or our Company commits any material breaches of the Listing Rules during the Waiver Period. Before the expiry of such three-year period, we will liaise with the Stock Exchange to enable it to assess the then experience of Mr. Hu, having had the benefit of Ms. Tang’s assistance for three years, will have acquired the relevant experience within the meaning of Rule 3.28 of the Listing Rules so that a further waiver will not be necessary.

See “Directors, Supervisors and Senior Management” in this document for the biographical information of Mr. Hu and Ms. Tang.

CONTINUING CONNECTED TRANSACTIONS

We have entered into certain transactions with Zhongmei Huadong, our substantial shareholder, which will constitute continuing connected transactions for our Company under Chapter 14A of the Listing Rules upon [REDACTED]. We have applied to the Stock Exchange for, and the Stock Exchange [has granted] us, a waiver from strict compliance with the announcement, circular and independent shareholders’ approval requirements under Rule 14A.105 of the Listing Rules in respect of the continuing connected transactions as disclosed in “Connected Transactions—(B) Continuing Connected Transactions subject to the Reporting, Annual Review and Announcement Requirements but exempt from the Circular and Independent Shareholders’ Approval Requirements”. For further information, see “Connected Transactions” in this document.

EXEMPTION FROM STRICT COMPLIANCE WITH SECTION 342(1) OF THE COMPANIES (WINDING UP AND MISCELLANEOUS PROVISIONS) ORDINANCE IN RELATION TO PARAGRAPH 27 OF PART I AND PARAGRAPH 31 OF PART II OF THE THIRD SCHEDULE TO THE COMPANIES (WINDING UP AND MISCELLANEOUS PROVISIONS) ORDINANCE

According to section 342(1)(b) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance, the document shall include the matters specified in Part I of the Third Schedule thereto and the reports specified in Part II of the Third Schedule thereto.

According to paragraph 27 of Part I of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance, our Company is required to include in the document a statement as to the gross trading income or sales turnover (as the case may be) of our

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

Company during each of the three financial years immediately preceding the issue of the document as well as an explanation of the method used for the computation of such income or turnover and a reasonable breakdown of the more important trading activities.

According to paragraph 31 of Part II of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance, our Company is required to include in the document a report prepared by our Company’s auditor with respect to the profits and losses and assets and liabilities of our Company for each of the three financial years immediately preceding the issue of the document.

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

According to Rule 4.04(1) of the Listing Rules, the accountants’ report contained in the document must include, among others, the results of the company in respect of each of the three financial years immediately preceding the issue of the document or such shorter period as may be acceptable to the Stock Exchange.

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

Accordingly, we have applied to the SFC for, and the SFC [has granted], a certificate of exemption from strict compliance with the requirements under section 342(1) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance in relation to paragraph 27 of Part I and paragraph 31 of Part II of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance, on the conditions that the particulars of the exemption are set forth in this document and this document will be issued on or before [REDACTED], on the following grounds:

- (a) we are a clinical-stage biotech company exclusively focused on biologic therapies for autoimmune and allergic diseases, and falls within the scope of biotech company as defined under Chapter 18A of the Listing Rules;

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

- (b) the Accountants’ Report for each of the two financial years ended December 31, 2022 and the nine months ended September 30, 2023 has been prepared and is set out in Appendix I to this document in accordance with Rule 18A.06 of the Listing Rules;
- (c) we are a pre-revenue biotech company and we did not generate any revenue or incur any cost of revenue during the Track Record Period. The details of our major activities have been fully disclosed in “Business” in the document;
- (d) the unaudited preliminary financial information for the year ended December 31, 2023 and a commentary on the results for the year have been set out in Appendix III to this document, which have been prepared in compliance with the content requirements as for a preliminary results announcements under Rule 13.49 of the Listing Rules and have been agreed with our reporting accountants following their review under Practice Note 730 “Guidance for Auditors Regarding Preliminary Announcements of Annual Results” issued by the Hong Kong Institute of Certified Public Accountants;
- (e) notwithstanding that the financial results set out in this document are only for the two years ended December 31, 2022 and the nine months ended September 30, 2023, other information required to be disclosed under the Listing Rules and the Companies (Winding Up and Miscellaneous Provisions) Ordinance has been adequately disclosed in this document pursuant to the relevant requirements;
- (f) given that Chapter 18A of the Listing Rules provides that the minimum track record period for biotech companies in terms of financial disclosure is two years, strict compliance with the requirements of section 342(1) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance and paragraph 27 of Part I and paragraph 31 of Part II of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance would be unduly burdensome for our Company;
- (g) our Directors and the Sole Sponsor confirm that after performing all due diligence work which they consider appropriate, up to the date of this document, there has been no material adverse change to the financial and trading positions or prospects of our Company since September 30, 2023 (immediately following the date of the latest audited statement of financial position in the Accountants’ Report set out in Appendix I to this document) to the date of this document and there has been no event which would materially affect the information shown in the Accountants’ Report as set out in Appendix I and the unaudited preliminary financial information for the year ended December 31, 2023 as set out in Appendix III to this document and the section headed “Financial Information” in this document and other parts of the document; and

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

- (h) our Directors are of the view that the Accountants’ Report covering the two years ended December 31, 2022 and the nine months ended September 30, 2023 and the unaudited preliminary financial information for the year ended December 31, 2023 included in this document, together with other disclosure in this document, have already provided the potential investors with adequate and reasonably up-to-date information in the circumstances to form a view on the track record of our Company, and our Directors confirm that all information which is necessary for the investing public to make an informed assessment of our Group’s business, assets and liabilities, financial position, trading position, management and prospects has been included in this document. Further, our Company shall publish an announcement stating that the relevant financial information has been included in this document within the time prescribed under Rule 13.49(1) of the Listing Rules and shall publish the annual report for the year ended December 31, 2023 within the time prescribed under Rule 13.46(2) of the Listing Rules, respectively. Therefore, the exemption would not prejudice the interest of the investing public.

WAIVER FROM STRICT COMPLIANCE WITH RULE 4.04(1) OF THE LISTING RULES AND EXEMPTION FROM STRICT COMPLIANCE WITH SECTION 342(1) IN RELATION TO PARAGRAPH 27 OF PART I AND PARAGRAPH 31 OF PART II OF THE THIRD SCHEDULE TO THE COMPANIES (WINDING UP AND MISCELLANEOUS PROVISIONS) ORDINANCE

According to Rule 4.04(1) of the Listing Rules, the accountants’ report contained in the document must include, among others, the results of the company in respect of each of the three financial years immediately preceding the issue of the document or such shorter period as may be acceptable to the Stock Exchange.

Chapter 1.1A of the Guide issued by the Stock Exchange provides that where an applicant issues its listing document in the third month after the latest year end, a Rule 4.04(1) waiver would be subject to the following conditions: (i) the applicant must list on the Stock Exchange within three months after the latest year end; (ii) the applicant must obtain a certificate of exemption from the SFC on compliance with the Companies (Winding Up and Miscellaneous Provisions) Ordinance requirements; and (iii) the listing document must include the financial information for the latest financial year and a commentary on the results for that financial year. The financial information to be included in the listing document must (a) follow the same content requirements as for a preliminary results announcement under Rule 13.49 of the Listing Rules; and (b) be agreed with the reporting accountants following their review under Practice Note 730 “Guidance for Auditors Regarding Preliminary Announcements of Annual Results” issued by the Hong Kong Institute of Certified Public Accountants.

According to section 342(1)(b) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance, the document shall include the matters specified in Part I of the Third Schedule thereto and the reports specified in Part II of the Third Schedule thereto.

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

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

According to paragraph 31 of Part II of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance, our Company is required to include in the document a report prepared by our Company’s auditor with respect to the profits and losses and assets and liabilities of our Company for each of the three financial years immediately preceding the issue of the document.

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

We have applied to the Stock Exchange for a waiver from strict compliance with Rule 4.04(1) of the Listing Rules not to include in this document the results of our Company in respect of the financial year immediately preceding the issue of this document, and such waiver [has been] granted by the Stock Exchange on the conditions that:

- (a) this document must be issued on or before [REDACTED] and the H Shares of our Company will be [REDACTED] on the Stock Exchange on or before [REDACTED];
- (b) our Company obtains a certificate of exemption from the SFC on strict compliance with section 342(1)(b) in relation to paragraph 27 of Part I and paragraph 31 of Part II of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance;
- (c) this document contains the preliminary unaudited financial information for the year ended December 31, 2023 and a commentary on the results for the year. The financial information (a) follows the same content requirements as for a preliminary results announcement under Rule 13.49 of the Listing Rules; and (b) is agreed with our reporting accountants following their review under Practice Note 730 “Guidance for Auditors Regarding Preliminary Announcements of Annual Results” issued by the Hong Kong Institute of Certified Public Accountants; and

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

- (d) our Company will not be in breach of our constitutional documents or laws and regulations of the PRC or other regulatory requirements as a result of not publishing our preliminary results announcements for the year ended December 31, 2023.

Accordingly, we have also applied to the SFC for, and the SFC [has granted], a certificate of exemption under section 342A(1) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance, exempting our Company from strict compliance with the requirements of paragraph 27 of part I and paragraph 31 of part II of the Third Schedule of the Companies (Winding Up and Miscellaneous Provisions) Ordinance on the conditions that (i) the particulars of the exemption are set forth in this document; and (ii) this document will be issued on or before [REDACTED]. See “—Exemption from Strict Compliance with Section 342(1) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance in relation to Paragraph 27 of Part I and Paragraph 31 of Part II of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance” in this section for further details.

The application to the Stock Exchange for a waiver from strict compliance with Rule 4.04(1) of the Listing Rules was made on the grounds, among others, that strict compliance with the above requirements would be unduly burdensome and the waiver would not prejudice the interests of the investing public as:

- (a) there would not be sufficient time for our Company and our reporting accountants to finalize the audited financial statements for the year ended December 31, 2023 for inclusion in this document. If the financial information for the year ended December 31, 2023 is required to be audited, our Company and our reporting accountants would have to carry out substantial work to prepare, update and finalize the Accountants’ Report and this document, and the relevant sections of this document will need to be updated to cover such additional period;
- (b) the Accountants’ Report for each of the two financial years ended December 31, 2022 and the nine months ended September 30, 2023 has been prepared and is set out in Appendix I to this document;
- (c) the unaudited preliminary financial information for the year ended December 31, 2023 and a commentary on the results for the year have been set out in Appendix III to this document, which have been prepared in compliance with the content requirements as for a preliminary results announcements under Rule 13.49 of the Listing Rules and have been agreed with our reporting accountants following their review under Practice Note 730 “Guidance for Auditors Regarding Preliminary Announcements of Annual Results” issued by the Hong Kong Institute of Certified Public Accountants;

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

- (d) notwithstanding that the financial results set out in this document are only for the two years ended December 31, 2022 and the nine months ended September 30, 2023, other information required to be disclosed under the Listing Rules and the Companies (Winding Up and Miscellaneous Provisions) Ordinance has been adequately disclosed in this document pursuant to the relevant requirements;
- (e) our Directors and the Sole Sponsor confirm that after performing all due diligence work which they consider appropriate, up to the date of this document, there has been no material adverse change to the financial and trading positions or prospects of our Company since September 30, 2023 (immediately following the date of the latest audited statement of financial position in the Accountants' Report set out in Appendix I to this document) to the date of this document and there has been no event which would materially affect the information shown in the Accountants' Report as set out in Appendix I and the unaudited preliminary financial information for the year ended December 31, 2023 as set out in Appendix III to this document and the section headed "Financial Information" in this document and other parts of the document;
- (f) our Directors are of the view that the Accountants' Report covering the two years ended December 31, 2022 and the nine months ended September 30, 2023 and the unaudited preliminary financial information for the year ended December 31, 2023 included in this document, together with other disclosure in this document, have already provided the potential investors with adequate and reasonably up-to-date information in the circumstances to form a view on the track record of our Company, and our Directors confirm that all information which is necessary for the investing public to make an informed assessment of our Group's business, assets and liabilities, financial position, trading position, management and prospects has been included in this document. Further, our Company shall publish an announcement stating that the relevant financial information has been included in this document within the time prescribed under Rule 13.49(1) of the Listing Rules and shall publish the annual report for the year ended December 31, 2023 within the time prescribed under Rule 13.46(2) of the Listing Rules, respectively. Therefore, the waiver would not prejudice the interest of the investing public.

INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]

[REDACTED]

INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]

[REDACTED]

INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]

[REDACTED]

INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]

[REDACTED]

INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]

[REDACTED]

INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]

[REDACTED]

DIRECTORS, SUPERVISORS AND PARTIES INVOLVED IN THE [REDACTED]

DIRECTORS

Name	Address	Nationality
Executive Directors		
Mr. Qiu Jiwan (裘霽宛)	Room 501, Building 3 Zhu Yuan, Yijing Yuan Xihu District Hangzhou, Zhejiang PRC	Chinese
Mr. Wu Yiliang (吳亦亮)	Room 701, Building 18 Xiangxie Wan No. 99 Huizhan Road Medical New and High-tech Zone Taizhou, Jiangsu PRC	Chinese
Mr. Lin Weidong (林偉棟)	Room 501, No. 142 Lane 3088, Jinxiu Road Pudong New District Shanghai PRC	Chinese
Non-executive Directors		
Mr. Yu Xi (余熹)	No. 47, Lane 199 Jianghua Road Minhang District Shanghai PRC	Chinese
Mr. Wu Zhiqiang (吳志強)	Room 401, Building 18 Jintong Taohuayuan Community No. 66 Yinfeng Road Medical New and High-tech Zone Taizhou, Jiangsu PRC	Chinese
Dr. Xue Mingyu (薛明宇)	Room 21D, Building 1, No. 8 Baishida Garden No. 213 Tai'an Road Luohu District Shenzhen, Guangdong PRC	Chinese

DIRECTORS, SUPERVISORS AND PARTIES INVOLVED IN THE [REDACTED]

Name	Address	Nationality
Independent non-executive Directors		
Dr. Zou Zhongmei (鄒忠梅)	Room 601, Unit 1 Building 8, Baicao Yuan Haidian District Beijing PRC	Chinese
Dr. Ling Jianqun (凌建群)	Room 1301, Unit 1 Block 1, Guanlan Yuan No. 69 West Songhua River Street Nanjing, Jiangsu PRC	Chinese
Mr. Fung Che Wai, Anthony (馮志偉)	Flat G, 11/F Hong Yan Court Healthy Street Central North Point Hong Kong	Chinese

SUPERVISORS

Name	Address	Nationality
Mr. Ye Xiang (葉翔)	Room 303, No. 3 Lane 1518, Chongxin Road Jiading District Shanghai PRC	Chinese
Dr. Ding Chao (丁超)	1-2/F No. 150 East Jiuxiangling Nanshan District Shenzhen, Guangdong PRC	Chinese
Ms. Wang Yujiao (王玉姣)	Room 502, Unit 2 Building 7, Xuzhong Junyuefu Chengxiang Street Xiaoshan District Hangzhou, Zhejiang PRC	Chinese

For further information regarding our Directors and Supervisors, see “Directors, Supervisors and Senior Management” in this document.

DIRECTORS, SUPERVISORS AND PARTIES INVOLVED IN THE [REDACTED]

PARTIES INVOLVED IN THE [REDACTED]

**Sole Sponsor [REDACTED] China International Capital Corporation Hong Kong
Securities Limited**
29/F One International Finance Centre
1 Harbour View Street
Central
Hong Kong

[REDACTED]

DIRECTORS, SUPERVISORS AND PARTIES INVOLVED IN THE [REDACTED]

[REDACTED]

DIRECTORS, SUPERVISORS AND PARTIES INVOLVED IN THE [REDACTED]

**Legal advisors to
our Company**

As to Hong Kong and United States laws:
Sidley Austin
Level 39, Two International Finance Centre
8 Finance Street
Central
Hong Kong

As to PRC laws:
JunHe LLP
26/F, HKRI Centre One
HKRI Taikoo Hui
288 Shimen Road (No. 1)
Shanghai
PRC

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

As to Hong Kong and United States laws:
O'Melveny & Myers
31/F, AIA Central
1 Connaught Road Central
Hong Kong

As to PRC laws:
Jingtian & Gongcheng
34/F, Tower 3
China Central Place
77 Jianguo Road
Chaoyang District
Beijing
PRC

**Auditors and reporting
accountants**

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

Industry consultant

Frost & Sullivan (Beijing) Inc., Shanghai Branch Co.
2504 Wheelock Square
1717 West Nanjing Road
Jingan District
Shanghai
PRC

DIRECTORS, SUPERVISORS AND PARTIES INVOLVED IN THE [REDACTED]

Independent property valuer **Asia-Pacific Consulting and Appraisal Limited**
Flat/Rm A, 12/F
Kiu Fu Commercial Building
300 Lockhart Road, Wanchai
Hong Kong

[REDACTED]

CORPORATE INFORMATION

Headquarters and registered office in the PRC	Room 1310, Building 1 No. 907 Yaocheng Avenue Taizhou, Jiangsu PRC
Principal place of business in Hong Kong	5/F, Manulife Place 348 Kwun Tong Road Kowloon Hong Kong
Company’s website	<u>www.qyuns.net</u> <i>(information on this website does not form part of this document)</i>
Joint company secretaries	Mr. Hu Yanbao (胡衍保) Room 206, Building 13 Dahua Jinxiuhuacheng No. 195 South Hailing Road Gaogang District Taizhou, Jiangsu PRC Ms. Tang King Yin (鄧景賢) <i>(Associate of both The Hong Kong Chartered Governance Institute and The Chartered Governance Institute in the United Kingdom)</i> 5/F, Manulife Place 348 Kwun Tong Road Kowloon Hong Kong
Authorized representatives	Mr. Qiu Jiwan (裘霽宛) Room 501, Building 3 Zhu Yuan, Yijing Yuan Xihu District Hangzhou, Zhejiang PRC Ms. Tang King Yin (鄧景賢) 5/F, Manulife Place 348 Kwun Tong Road Kowloon Hong Kong

CORPORATE INFORMATION

Audit Committee

Mr. Fung Che Wai, Anthony (馮志偉)
(Chairman)
Mr. Wu Zhiqiang (吳志強)
Dr. Ling Jianqun (凌建群)

Remuneration and Appraisal Committee

Dr. Ling Jianqun (凌建群) (Chairman)
Dr. Zou Zhongmei (鄒忠梅)
Mr. Qiu Jiwan (裘霽宛)

Nomination Committee

Mr. Qiu Jiwan (裘霽宛) (Chairman)
Dr. Zou Zhongmei (鄒忠梅)
Dr. Ling Jianqun (凌建群)

Strategy and Development Committee

Mr. Qiu Jiwan (裘霽宛) (Chairman)
Mr. Yu Xi (余熹)
Dr. Xue Mingyu (薛明宇)

Compliance advisor

Somerley Capital Limited
20/F, China Building
29 Queen’s Road Central
Hong Kong

[REDACTED]

Principal banks

**Shanghai Pudong Development Bank
Taizhou Branch**
No. 215 North Youth Road
Taizhou, Jiangsu
PRC

**Shanghai Pudong Development Bank
High-tech Zone Branch**
1/F, Data Building
Medical New and High-tech Zone
Taizhou, Jiangsu
PRC

China Merchants Bank Taizhou Branch
No. 293-10 South Gulou Road
Hailing District
Taizhou, Jiangsu
PRC

INDUSTRY OVERVIEW

Certain information and statistics set out in this section have been extracted from various official government publications, market data providers and a report commissioned by us and prepared by an independent third party, Frost & Sullivan. The information from official government sources has not been independently verified by us, the Sole Sponsor, the [REDACTED], the [REDACTED], the [REDACTED], the [REDACTED], the [REDACTED], the [REDACTED] or any of their respective directors, officers, employees, advisers or agents or any other parties involved in the [REDACTED], and no representation is given as to its accuracy, fairness and completeness.

OVERVIEW OF THE BIOLOGIC DRUG MARKET FOR AUTOIMMUNE AND ALLERGIC DISEASES

Biologic drugs are large-molecule drugs, which include monoclonal antibodies (mAbs), recombinant proteins, vaccines and other emerging categories. China’s biologics market expanded from US\$32.3 billion in 2017 to US\$63.5 billion in 2021, at a CAGR of 18.4% and is estimated to reach US\$185.9 billion in 2030, at a CAGR of 12.7% from 2021 to 2030. Biologics accounted for approximately 15.3% and 25.8% of China’s overall pharmaceuticals market in 2017 and 2021, respectively, and the market share is estimated to rise further to 43.8% in 2030. The rapid growth in China’s biologics market is primarily attributable to better diagnosis with enhanced accuracy, more treatment options and improved drug affordability, which trends are expected to continue and drive further growth in the market.

Autoimmune diseases are associated with disorders that lead to abnormally high activity of the immune system, causing the body to mistakenly attack and damage its own tissues. There are over 100 different types of autoimmune diseases, which can affect almost any part of the body, *e.g.*, the skin, joints, muscles, bones and digestive system. Allergic diseases are conditions caused by hypersensitivity of the immune system due to contact with allergens in the external environment, such as pollen, certain food, medication and insect stings, which can also affect multiple organs. Autoimmune and allergic diseases can trigger serious symptoms such as acute pain, persistent itchiness and disfigurement and, in some cases, may even lead to life-threatening complications and be fatal. In addition, despite their non-contagious nature, the social stigma often associated with these diseases due to the visibility of the lesions and inadequate understanding in the general public may further affect patients’ mental well-being and reduce their quality of life, posing a significant socioeconomic burden on both the patients and society. Most autoimmune and allergic diseases are chronic diseases and require long-term care at high costs. It has been challenging to develop effective treatments of these diseases for long-term use because their pathogeneses are yet to be fully understood. In recent years, the emergence of targeted biologic therapies has brought profound changes to the treatment paradigm for these diseases with improved efficacy and safety profiles.

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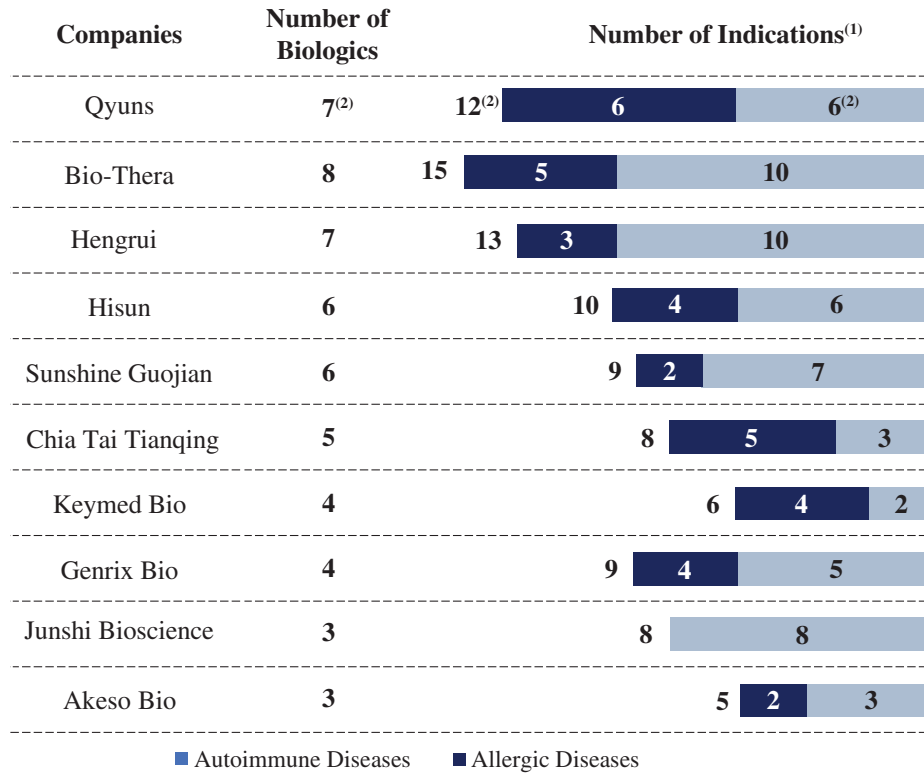
Biologic Drug Market for Autoimmune and Allergic Diseases in China

Although autoimmune and allergic diseases represent the second-largest therapeutic area globally, market development in China has lagged significantly behind. While the total patient population of autoimmune and allergic diseases in China exceeded 420 million as compared to 100 million in the United States in 2020. China’s autoimmune and allergic drug market was 7.5% of that of the United States in 2020. The global market size of autoimmune and allergic disease drugs amounted to US\$187.5 billion while China’s autoimmune and allergic drug market was only US\$9.0 billion in 2022. In addition, biologic drugs dominate developed markets, but their penetration in China remains low. In 2020, biologic drugs accounted for more than 60% of the autoimmune and allergic drug market in the United States, but only about 10% of the China market. The China’s autoimmune and allergic disease drug market is estimated to grow to US\$41.5 billion in 2030, at a CAGR of 21.1% from 2022, and with the proportion of biologic drugs increased to about 60%.

Despite the historical underdevelopment, the China autoimmune and allergic disease drug market has been changing in recent years. A number of blockbuster drugs developed by MNCs were approved in China and admitted to the NRDL. While unit prices dropped, sales soared. As a result, there remains significant market potential for biologic drugs for autoimmune and allergic diseases in China. Recognizing the great market potential, an increasing number of Chinese pharmaceutical companies have begun to conduct R&D on autoimmune and allergic disease drugs and achieved noticeable progress. For example, the number of IND approvals of biologic drugs in China for major inflammatory skin diseases* increased from nil in 2017 to 22 in 2022. The chart below sets forth the details of major domestic biopharmaceutical companies targeting autoimmune and allergic diseases in China, including the number of biologic drugs and candidates which have obtained IND approval as of the Latest Practicable Date, as well as the indication coverage of each company.

* including psoriasis, atopic dermatitis, prurigo nodularis and chronic spontaneous urticaria.

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Source: Frost & Sullivan Report (based on annual reports of relevant companies and information published by the NMPA)

Notes:

- (1) Different subtypes or severities of same indication or different product candidates with same indication are only counted once for the purpose of indication coverage.
- (2) Include one IND-approved drug candidate that the Company had put on hold.

Market Drivers and Future Trends

The primary drivers and future trends of the biologic drug market for autoimmune and allergic diseases in China include:

- *Vast underserved medical needs.* Although the superior efficacy and safety profile of biologics has resulted in growing acceptance among patients and doctors globally, the penetration rate of biologics in China remains low. There is still great potential for biologic drugs to capture more market share in China in competition with other pharmaceutical products for the same indications.
- *Favorable government policies in China.* China is striving to establish clear regulatory pathways to assure market access for quality biologic drugs. For example, in October 2023, the NMPA provided a response to the Suggestions on Further Accelerating the Review and Approval of Domestic Innovative Drugs (“關於進一步加快國產創新藥審評審批的建議”) on its website, which states that a series of

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measures to encourage drug R&D and innovation has been implemented, including (i) reforming the clinical trial management process to promote drug innovation and research; (ii) improving the expedited marketing registration process for drugs; (iii) including drugs that are for urgent clinical needs and in short supply, for children, for rare diseases, for major contagious diseases and certain vaccines listed in the Drug Administration Law (《藥品管理法》), the Vaccine Administration Law (《疫苗管理法》) and other relevant State Council documents into the scope of the expedited marketing registration program to promote R&D and registration by the relevant R&D institutions; (iv) optimizing the review and approval process; (v) supporting the research, manufacturing and registration of innovative drugs; and (vi) establishing an early resolution mechanism for drug patent disputes. In particular, the CDE issued the CDE’s Standards for Accelerating the Review Work for Marketing Approval Applications of Innovative Drugs (Trial) (《藥審中心加快創新藥上市許可申請審評工作規範(試行)》) in April 2023, which is intended for innovative drugs that are (i) included in the breakthrough therapy drug program, (ii) for children and (iii) for rare diseases, and is expected to expedite the marketing process of these drugs to meet relevant patients’ medication needs. Additionally, in May 2022, the PRC State Council issued the 14th Five-Year Plan for National Health (《“十四五”國民健康規劃》), which is designed to accelerate the review and approval process of innovative drugs, drugs and medical devices with urgent clinical needs and in short supply, and drugs for rare diseases. In April 2023, the PRC State Council further issued the 14th Five-Year Plan for Modernization of Market Supervision (《“十四五”市場監管現代化規劃》), which is designed to steadily improve drug safety, efficacy and accessibility and expedite the marketing process of innovative drugs through optimizing the review process. In particular, it is expected to improve the rapid review and approval mechanism for innovative drugs and strengthen guidelines on the R&D of major innovative drugs by establishing a national drug and medical device innovation collaboration mechanism, and it encourages simultaneous R&D and regulatory approval applications of innovative drugs in the PRC and overseas. Furthermore, the CDE issued the Guidelines for Biosimilar Similarity Evaluation and Indication Extrapolation Techniques (《生物類似藥相似性評價和適應症外推技術指導原則》) in 2021, which is designed to further regulate and guide the development as well as evaluation of biosimilar drugs and to promote the development of the biomedical industry. Later in 2022, the CDE also issued the Technical Guidelines for Clinical Pharmacological Studies of Biosimilars (《生物類似藥臨床藥理學研究技術指導原則》) and provided technical guidance on the clinical pharmacological research of biosimilars to further promote R&D of biosimilars in China.

- *Expansion of approved biologic drugs and indications.* In the past, the number of approved biologic drugs and indications in China was relatively limited. Until 2022, there had been only 51 approved mAbs cumulatively in China, compared with 126 in the U.S. Particularly, among the approved innovative mAbs in China, only nine were developed by Chinese domestic companies and the rest were developed by MNCs, suggesting room for further participation from Chinese domestic companies

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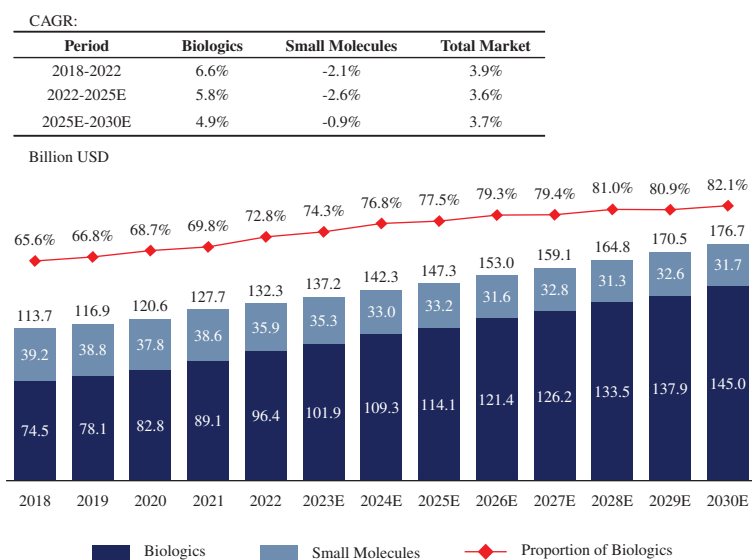
in the China biologic drug market. In addition, dupilumab, an anti-IL-4R α antibody, has been approved by the FDA for five indications since 2017 but only received NMPA approval for one indication since 2020. It is expected that more innovative biologic drugs for a wider spectrum of indications will be available in the China market in light of favorable government policies as well as increasing R&D investment in biologic drugs from Chinese domestic drug developers to seize the market opportunities.

- Improved affordability.* The high costs associated with current biologic therapies have imposed significant socioeconomic burden on both the patients and society and discouraged wide application of biologic drugs as first-line treatments for autoimmune and allergic diseases. In recent years, the inclusion of innovative biologic drugs in the NRDL has led to significant price cuts. Additionally, advancement in science and improvement of manufacturing technology are expected to further reduce the costs associated with biologic drugs in China, which in turn could improve their affordability and accessibility.

OVERVIEW OF THE AUTOIMMUNE DISEASE DRUG MARKET

The global autoimmune disease drug market increased from US\$113.7 billion in 2018 to US\$132.3 billion in 2022, at a CAGR of 3.9%. It is estimated to reach US\$147.3 billion in 2025, at a CAGR of 3.6% from 2022 to 2025, and US\$176.7 billion in 2030, at a CAGR of 3.7% from 2025 to 2030. The biologic drug market for autoimmune diseases amounted to US\$96.4 billion in 2022 and is estimated to increase to US\$145.0 billion in 2030, accounting for 72.8% and 82.1% of the global market in 2022 and 2030, respectively. The following chart sets forth the historical and estimated global autoimmune disease drug market for the periods indicated.

Global Autoimmune Disease Drug Market, 2018-2030E

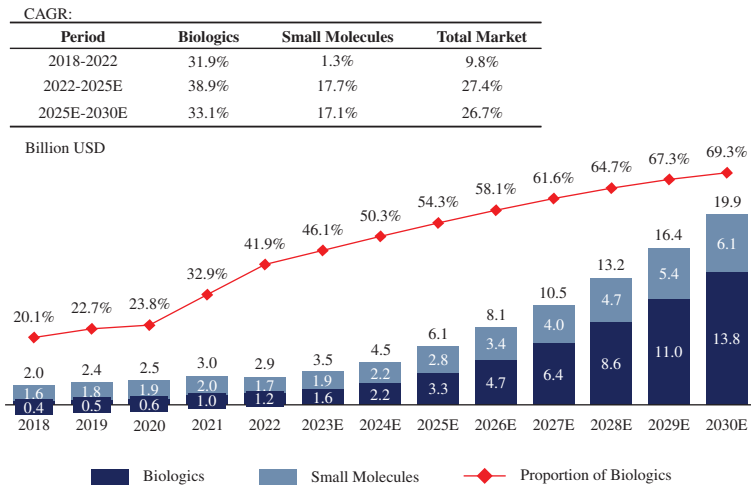


Source: Frost & Sullivan Report (based on annual reports of relevant companies, literature review and expert interviews)

INDUSTRY OVERVIEW

Given the large patient pool in China and the advancement of innovative therapies for autoimmune diseases, China’s autoimmune disease drug market is expected to grow rapidly. It increased from US\$2.0 billion in 2018 to US\$2.9 billion in 2022, at a CAGR of 9.8%. It is estimated to reach US\$6.1 billion in 2025, at a CAGR of 27.4% from 2022 to 2025, and US\$19.9 billion in 2030, at a CAGR of 26.7% from 2025 to 2030. Biologic drugs’ share of China’s autoimmune disease drug market is estimated to increase from 41.9% in 2022 to 69.3% in 2030. The following chart sets forth the historical and estimated autoimmune disease drug market in China for the periods indicated.

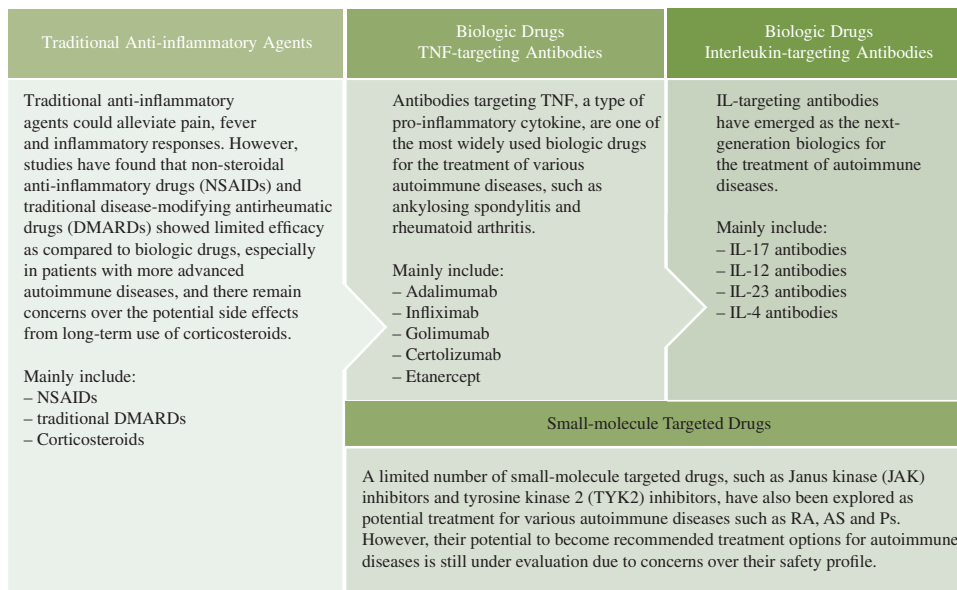
China Autoimmune Disease Drug Market, 2018-2030E



Source: Frost & Sullivan Report (based on annual reports of relevant companies, literature review and expert interviews)

Evolution of Autoimmune Disease Treatments

There are several major types of treatments that target autoimmune diseases. The following diagram illustrates the evolution of the autoimmune disease treatments.



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Traditional anti-inflammatory agents are commonly used treatment options for patients with autoimmune diseases, particularly during the initial stages of disease. They have shown the potential to rapidly improve symptoms by alleviating pain, reducing fever and mitigating inflammatory responses. However, traditional anti-inflammatory agents are also noted with limited efficacy in patients with more severe symptoms and there remain concerns over the potential side effects from long-term use of some of these agents. For example, NSAID therapy may lead to side effects such as nausea, allergy and high blood pressure in long-term use. Biologic drugs have emerged as effective innovative therapies for many autoimmune diseases over the past decades. Biologic drugs have revolutionized autoimmune disease treatment by targeting specific factors driving disease progression, instead of suppressing the immune system indiscriminately, thereby reducing the serious side effects that can result. Antibodies targeting TNF, a type of pro-inflammatory cytokine, are one of the most widely used biologic drugs for the treatment of various autoimmune diseases, such as ankylosing spondylitis (AS) and rheumatoid arthritis (RA). TNF inhibitors have shown potential to control disease activity and provide substantial improvements in patients’ daily function, with durable treatment effect. However, there remain substantial limitations associated with TNF inhibitors. Studies have shown that up to 40% of patients become intolerant or fail to achieve adequate disease control with anti-TNF therapies.

In recent years, studies have demonstrated that interleukins, a type of cytokines, play essential roles in modulating the growth, differentiation and activation of various immune cells, including T cells, during inflammatory and immune responses. Therefore, IL inhibitors have emerged as the next-generation biologic drugs for autoimmune diseases. The IL family include a variety of cytokines, among which those related to T helper cells 17 and T helper cells 2 (Th17 and Th2), such as IL-17A and IL-23, are the most studied.

- *IL-17A antibodies.* As of the Latest Practicable Date, there were two anti-IL-17A antibodies approved globally, namely, secukinumab and ixekizumab, both of which were also approved in China. Secukinumab is currently approved in over 90 countries worldwide, including the U.S., the EU, Japan and China. In China, secukinumab is approved for the treatment of AS and moderate-to-severe plaque psoriasis. In 2022, secukinumab recorded sales of US\$4.8 billion and US\$601.4 million globally and in China, respectively. IL-17A antibodies are expected to experience rapid increase in their market shares, primarily driven by improving drug affordability and fast expansion of approved indications. As of the Latest Practicable Date, there were 16 IL-17A antibodies in clinical development in China.
- *IL-23 antibodies.* As of the Latest Practicable Date, there were five IL-23 antibodies approved globally, namely, ustekinumab, Wezlana (ustekinumab-auub, a biosimilar to ustekinumab), guselkumab, tildrakizumab and risankizumab. Among them, guselkumab and tildrakizumab had been approved in China. As of the Latest Practicable Date, there were six antibody candidates targeting IL-23 in the clinical stage in China.

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Other promising innovative biologic treatments for autoimmune diseases include interferon (IFN) inhibitors and B cell–related therapies. IFNs are a family of cytokines that help enhance antiviral responses and immune activation, and have been found to play important roles in autoimmune and chronic inflammatory responses. B cell–related therapies aim to inhibit autoreactive B cell activation and autoantibody production. Popular B cell–related targets include, among others, B lymphocyte stimulator (BLyS), also known as B cell activating factor (BAFF), a member of the TNF cytokine family and a key factor in the differentiation and survival of B cells; a proliferation inducing ligand (APRIL); and various membrane protein present on B cells, such as CD20, CD40 and CD80. IFN inhibitors and B cell–related therapies have been approved by the FDA (B cell–related therapies were also approved by the NMPA) as treatment for SLE and are under investigation as potential treatment options for other autoimmune diseases such as RA and lupus nephritis (LN).

However, drug accessibility and treatment compliance for biologic drugs in the treatment of autoimmune diseases have historically been relatively low in China, primarily due to limited number of approved biologic drugs, high treatment cost associated with the MNC-developed blockbuster drugs and lack of awareness and education regarding autoimmune diseases. For example, according to a study conducted from 2010 to 2012, the penetration rate of biologic drugs in RA patients in the U.S. was approximately 50.7%, compared to 8.3% for China in a study conducted several years later, from 2016 to 2017.

In addition, small-molecule targeted therapies, such as Janus kinase (JAK) inhibitors, have also been explored as potential treatment for autoimmune diseases such as psoriasis, RA and AS. JAK is a family of signaling molecules involved in the intracellular transduction of immune signaling of various cytokine receptor cells. JAK inhibitors have shown clear clinical benefit in patients with certain autoimmune diseases in terms of symptom relief and reduction of inflammation. However, the FDA and the EMA required warning for several first-generation JAK inhibitors with respect to the increased risks of major cardiovascular events and malignancies in patients and the long-term safety profile of later-generation candidates is still under evaluation. Other small-molecule drugs under investigation for the treatment of autoimmune diseases also include TYK2 inhibitors and PDE-4 inhibitors.

Major Autoimmune Diseases

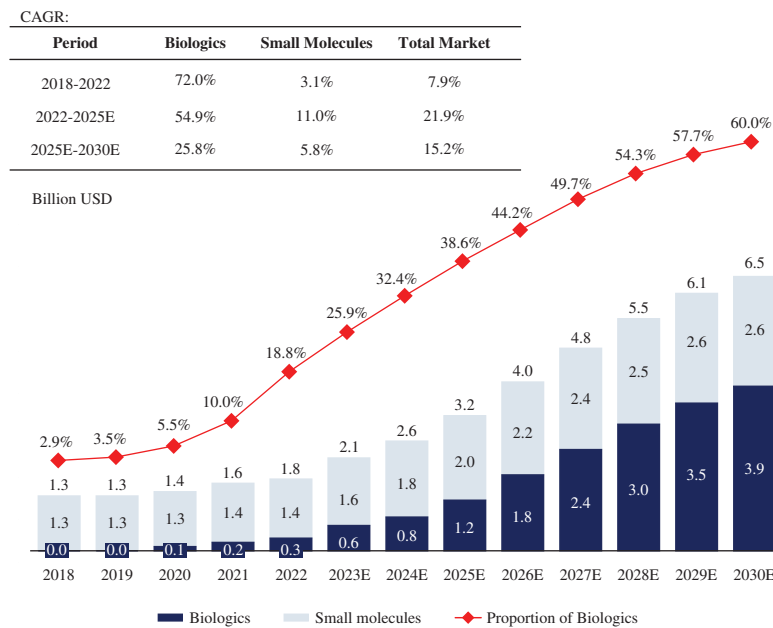
Ankylosing Spondylitis

Ankylosing spondylitis (AS) is a chronic progressive inflammatory disease that is primarily characterized by inflammation of the spinal joints, leading to reduced flexibility of the joints and stiffness in the spine over time. The prevalence of AS in China reached 3.9 million in 2022, and is expected to remain relatively stable over the next decade. A considerable proportion of AS patients first develop symptoms in their early adulthood or adolescence, and require long-term treatment to control disease progression.

INDUSTRY OVERVIEW

The AS drug market in China increased from US\$1.3 billion in 2018 to US\$1.8 billion in 2022, at a CAGR of 7.9%. It is estimated to reach US\$3.2 billion in 2025, at a CAGR of 21.9% from 2022 to 2025, and US\$6.5 billion in 2030, representing a CAGR of 15.2% from 2025 to 2030. The market for biologic drugs indicated for AS in China is estimated to increase from US\$0.3 billion in 2022 to US\$3.9 billion in 2030, representing 18.8% and 60.0% of China’s AS drug market in 2022 and 2030, respectively. The significant growth of China’s AS drug market despite a relatively stable patient population has been, and is expected to continue to be, primarily driven the quickly expanding biologic drug market for AS, benefiting from the improving awareness and acceptance by AS patients for biologic therapies, as well as the reduced treatment costs of such therapies after their admission into the NRDL. The historical and expected growth of China’s AS biologic drug market is primarily attributable to the sales of biologics that have been successfully commercialized, such as secukinumab and adalimumab (a TNF inhibitor), and the number of biologic drugs expected to be approved in the near future based on the progress of their clinical trials. The following chart sets forth the historical and estimated AS drug market in China for the periods indicated.

AS Drug Market in China, 2018-2030E



Source: Frost & Sullivan Report (based on annual reports of relevant companies, literature review and expert interviews)

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Treatment Paradigms for AS in China

There is currently no cure for AS and available treatments aim to control inflammation, prevent joint damage and provide symptom relief. Medications indicated for AS mainly include NSAIDs, traditional DMARDs and corticosteroids. NSAIDs are recommended as the first-line treatment and standard of care for AS in China. NSAID therapies can quickly improve patients’ lower back pain and stiffness, as well as reduce joint swelling and pain. However, they are noted with limited efficacy in patients with more severe disease and their effectiveness in suppressing bone erosion and remodeling associated with AS remains unclear. Corticosteroids are often recommended for the treatment of AS in combination with NSAIDs or traditional DMARDs for patients with severe symptoms. However, there are safety risks associated with long-term systemic use of corticosteroids. Maintenance treatment with systemic use of corticosteroids can cause a series of severe adverse effects, such as osteoporosis, adrenal suppression and hyperglycemia (high blood sugar), and dose-dependent growth suppression in children and adolescents. In the past decades, biologic drugs have emerged as effective innovative therapies for AS. The diagram below illustrates the recommended treatment paradigm for AS in China.

Treatment Diagram of AS in China

	NSAIDs Therapy	Traditional DMARDs* Therapy	Corticosteroids Therapy	Biologics Therapy
Drugs	Traditional NSAIDs*	Sulfasalazine	Corticosteroids	TNF inhibitors; IL inhibitors
Pharmacology	Quickly improve patients’ lower back pain and stiffness, reduce joint swelling and pain	Relieve joint pain, swelling and stiffness; reduce serum IgA levels; relieve peripheral arthritis symptoms	Anti-inflammatory; Anti-allergic and immunosuppressive; inhibit inflammatory mediators, like TNF- α	Support the immune system to block TNF and reduce inflammation caused by too much TNF/IL
Dosage	The same NSAIDs should be used for at least 2 weeks; change to another NSAIDs if ineffective after 2-4 weeks	This medicine takes effect slowly; increase 0.25g per week from 2.0g and use for 4-6 weeks, or even 1-3 years	Internal injection in the joint cavity; oral and intravenous application are not recommended; apply less than 2-3 times a year	The TNF- α inhibitor treatment is recommended for 6-12 weeks, or even 2 years. Change to IL inhibitors or another inhibitor if ineffective
Side Effects	Stomach pain; heartburn; nausea; allergy; high blood pressure, etc.	Digestive symptoms; rash; blood cell reduction; headache; dizziness, etc.	Long-term large-dose use can cause osteoporosis and muscular atrophy, etc.	Nausea; headache; itchiness; dizziness; difficulty breathing; chest pain, etc.

*: NSAIDs (Nonsteroidal Anti-inflammatory Drugs) include aspirin, acetaminophen, indomethacin, naproxen, etc. Commonly used traditional DMARDs (disease-modifying anti-rheumatic drugs) include methotrexate, leflunomide, sulfasalazine, hydroxychloroquine, azathioprine, cyclophosphamide, etc.

Source: *Diagnosis and Treatment of Ankylosing Spondylitis in China (2020)* and Frost & Sullivan analysis

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There are two classes of approved biologic drugs in China for the treatment of AS, namely, TNF inhibitors and IL-17 inhibitors. TNF, most prominently TNF- α , is a type of pro-inflammatory cytokine produced by certain types of white blood cells during acute inflammation and plays a role in the regulation of the immune system. Dysregulation of TNF may lead to excessive inflammation, which in turn may cause various autoimmune and immune-mediated disorders. TNF inhibitors block the binding of TNF to TNF receptors, thereby suppressing their biological effects. TNF inhibitors are recommended as second-line treatment for AS patients by prevailing clinical guidelines and currently one of the most commonly used biologic drugs for AS in China. However, studies have shown that up to 40% of patients with AS become intolerant or fail to achieve adequate disease control with anti-TNF therapies, indicating significant heterogeneity in treatment response. Thus, there remains an unmet medical need for novel treatments with a different mechanism of action.

With recent scientific advancements demonstrating the role of IL-17A in AS pathogenesis, IL-17A antibodies have emerged as a new class of biologic drugs for AS and have been recommended by prevailing clinical guidelines as second-line standalone treatment (the same designation as TNF inhibitors) for AS patients with high disease activity after receiving first-line traditional treatments. Therefore, either IL-17A inhibitors or TNF inhibitors could be recommended for AS patients failing first-line treatments, while between the two classes of biologics, IL-17A inhibitors have also shown clear clinical benefit in patients who are intolerant to or fail to achieve adequate disease control with TNF inhibitors. In addition, the dosing regimens for certain IL-17A inhibitors are more convenient than those of many TNF inhibitors. For example, secukinumab could be administered once every four weeks, while adalimumab, one of the best-selling TNF inhibitors, requires a dosing regimen of once every two weeks. As a result, there has been an increasing acceptance of IL-17A inhibitors as a new class of biologic therapy for AS by medical practitioners and patients, as evidenced by the quickly increasing sales of secukinumab, which achieved sales of US\$601.4 million in China in 2022 (with sales for AS treatment accounting for a significant portion). Consequently, the market share of IL-17A inhibitors in AS biologic drug market in China surpassed that of TNF inhibitors in 2022. We believe that QX002N will primarily compete with anti-IL-17 drugs and other biologic drugs, primarily TNF inhibitors, in China.

In addition to traditional treatments and targeted biologics, tofacitinib by Pfizer, a small molecule Janus kinase (JAK) inhibitor, has been approved for AS treatment by the FDA and the NMPA. However, tofacitinib is recommended by the FDA only for AS patients who are intolerant or non-responsive to one or more TNF inhibitors as there still remain concerns over the safety profile of JAK inhibitors.

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As of the Latest Practicable Date, there were 20 biologic drugs approved for AS treatment in China, comprising 18 TNF inhibitors (including Humira (adalimumab) and 7 adalimumab biosimilars) and 2 IL-17A antibody drugs, namely, secukinumab and ixekizumab, both of which had also been approved by the FDA. No biosimilar or generic of secukinumab or ixekizumab had been approved for the treatment of AS in China as of the Latest Practicable Date. As of the same date, in addition to QX002N, there were 21 biologic drug candidates indicated for AS in the clinical stage in China, comprising 11 TNF inhibitors (including 8 proposed adalimumab biosimilars) and 10 IL-17 inhibitors.

The following table sets forth details of QX002N and IL-17 antibody drugs or drug candidates for AS in the clinical stage in China as of the Latest Practicable Date.

Marketed IL-17A Inhibitors for AS in China							
Target	Brand Name	INN	Company	NMPA Approval Time	Median Price ⁽¹⁾	NRDL Inclusion	Expected Patent Expiration ⁽²⁾
IL-17A	Cosentyx	Secukinumab	Novartis	2020	1,188.0	Yes	2025
	Taltz	Ixekizumab	Eli Lilly	2022	1,218.0	Yes	2026

Clinical-Stage IL-17A Inhibitor Candidates for AS in China				
Target	Drug Code	Company	Status	First Posted Date
IL-17A	GR1501	GenrixBio	BLA submission	2024-01-04
	SHR-1314	Hengrui	BLA submission	2024-02-08
	Netakimab	Biocad	Phase III	2022-09-30
	QX002N	the Company	Phase III	2023-08-31
	AK111	Akeso	Phase III	2023-10-08
	JS005	Junshi Bioscience	Phase II	2021-09-30
	HB0017	Huabo	Phase II	2023-04-12
	SSGJ-608	SunShine Guojian	Phase II	2024-01-29
	Secukinumab-CMAB015	MabPharm	Phase I	2023-01-18
IL-17A, IL-17F	Bimekizumab	UCB Pharma	BLA submission	2023-07-20
	LZM012	Livzon	Phase III	2023-07-28

Source: Frost & Sullivan Report (based on annual reports of relevant companies and information published by the NMPA)

Notes:

- (1) Reflects the NRDL median price for minimum formulation unit in 2022 in RMB.
- (2) Reflects the present anticipated expiration time of the relevant amino acid sequence patent in the PRC.

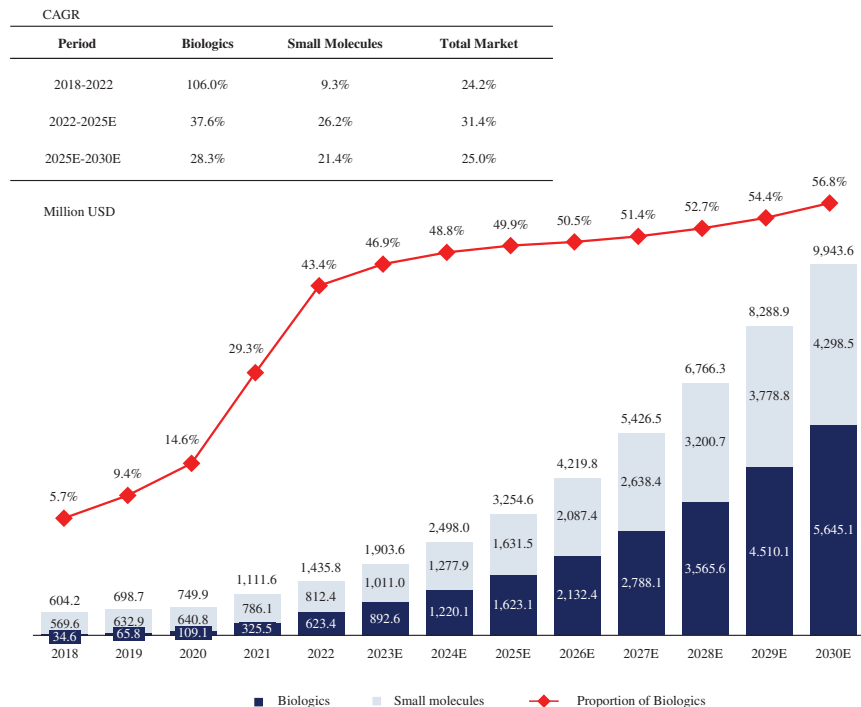
Psoriasis

Psoriasis (Ps) is a common chronic skin disease with no cure, with plaque Ps being the most common type. The prevalence of Ps in China has generally remained stable, which increased from 6.5 million in 2017 to 6.7 million in 2022, and is anticipated to reach 6.8 million in 2030. 20% to 30% of the patients have moderate-to-severe Ps.

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The Ps drug market in China grew rapidly from US\$604.2 million in 2018 to US\$1,435.8 million in 2022, at a CAGR of 24.2%, and is estimated to increase to US\$3,254.6 million in 2025, at a CAGR of 31.4% from 2022 to 2025, and further increase to US\$9,943.6 million in 2030, at a CAGR of 25.0% from 2025 to 2030. The significant growth of the Ps drug market in China is primarily attributable to (i) a higher penetration rate of biologics in the Ps drug market in China with a rapid growth rate, which is expected to reach 56.8% in 2030, mainly driven by the sales of biologics that have been successfully commercialized (*e.g.*, secukinumab, ustekinumab and ixekizumab) and a higher demand for biologics as Ps patients need treatments with better efficacy and a complete or near-to-complete elimination of symptoms has gradually become the requirement for Ps treatments by prevailing guidelines; (ii) major Ps biologics have been gradually included in the NRDL and experienced a decrease in their prices, which has improved the affordability of these drugs and is expected to further drive the growth of the Ps drug market in China; (iii) the increasing prevalence of Ps in China and the number of Ps patients in China is expected to reach 6.8 million in 2030, which also contributes to the growth of the Ps drug market in China; and (iv) there have been increasing marketing efforts to further expand the coverage of biologics in the Ps drug market in China. Biologic drugs accounted for 43.4% of the market in 2022, which is estimated to increase to 56.8% in 2030. The following table sets forth the size of the Ps drug market in China for the periods indicated.

Psoriasis Drug Market in China, 2018-2030E



Source: Frost & Sullivan Report (based on annual reports of relevant companies, literature review and expert interviews)

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Treatment Paradigms for Ps in China

Because Ps is incurable, the goal of treatment is to control disease progression and maintain long-term efficacy. Treatment paradigms are based on the patients’ conditions, including the type of Ps, the severity of the conditions and any co-morbidities. Topical drugs are usually used to treat patients with mild Ps but can cause local adverse reactions if used long term. It may be inconvenient for patients with extensive rashes and there is significant variation in patient compliance. Non-steroidal anti-inflammatory drugs (NSAIDs) and disease-modifying anti-rheumatic drugs (DMARDs) are also commonly used to control Ps and alleviate symptoms such as pain, stiffness and swelling. However, studies have found that NSAIDs and conventional DMARDs showed limited efficacy as compared to targeted biologic drugs, which has become a main treatment option for moderate-to-severe plaque Ps in China.

Small-molecule targeted drugs are a relatively new class of medications as a potentially promising treatment option for Ps patients. For example, JAK inhibitors have shown promising clinical results but may lead to more severe side effects and higher toxicity, causing the FDA to advise that they should be used with caution for patients with certain risk factors. PDE-4 inhibitors, another family of small-molecule drugs, have shown good safety profile but with limited efficacy. As a result, their use as a recommended long-term treatment option for a broad section of Ps patients remains under evaluation. Recently, tyrosine kinase 2 (TYK2) inhibitors, a newer family of small-molecule targeted drugs, have demonstrated in clinical studies promising efficacy profiles for treating Ps and improvements on traditional limitations of JAK-related toxicities.

Since the first biologic drug for Ps treatment, namely, an anti-IL-8 humanized mAb, was approved in China in 2003, there have been over ten biologic drugs approved for Ps in China in recent years. They belong to two main types, namely, TNF inhibitors and IL inhibitors, which are considered first-generation and second-generation drugs. TNF, most prominently TNF- α , is a type of pro-inflammatory cytokine produced by certain types of white blood cells during acute inflammation and plays a role in the regulation of the immune system. TNF inhibitors block the binding of TNF to TNF receptors, thereby suppressing their biological effects. Adalimumab, a TNF- α inhibitor and sold under the brand name Humira, was the world’s best-selling drug for eight years in the last ten (2013-2022). As TNF inhibitors have significant limitations, including multiple adverse effects and a high rate of non-responsiveness, IL inhibitors present a promising treatment for Ps. Common IL targets under investigation include IL-17A and IL-23. Among IL inhibitors, IL-23 is expected to be one of the mainstream targets for Ps treatment given its key role in alleviation of inflammation and its superior efficacy and safety profile in comparison with IL-17A inhibitors in clinical studies. For example, risankizumab, an IL-23p19 inhibitor, demonstrated superior efficacy and similar safety with less frequent dosing compared with secukinumab, an IL-17 inhibitor, in a Phase III clinical trial in patients with chronic, moderate-to-severe plaque Ps (the IMMerge study), as measured by PASI 90 at week 52. The chart below sets forth the global sales of marketed biologics targeting IL-23 and IL-17A in 2022.

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Target	Drug	Global sales 2022 (million USD)	SUM – Global sales 2022 (million USD)
IL-23	Ustekinumab	9,723	17,556
	Guselkumab	2,668	
	Tildrakizumab-asmn	Undisclosed	
	Risankizumab-rzaa	5,165	
IL-17A	Secukinumab	4,788	7,270
	Ixekizumab	2,482	

Source: Frost & Sullivan Report (based on annual reports of relevant companies)

Competitive Landscape of Biologics for Ps Treatment in China

As of the Latest Practicable Date, there were 21 biologic drugs for Ps approved in China, including 13 TNF inhibitors (including Humira (adalimumab) and 6 adalimumab biosimilars) and 8 IL inhibitors, among which ustekinumab was the only approved IL-12/IL-23 inhibitor while guselkumab and tildrakizumab were the only approved IL-23 inhibitors. As of the same date, besides QX001S and QX004N, there were 32 biologic drug candidates for Ps in the clinical stage in China, including 15 IL-17 inhibitors, 8 TNF- α inhibitors (including 7 proposed adalimumab biosimilars), 3 targeting IL-23, 3 targeting IL-12/IL-23 (including 2 proposed ustekinumab biosimilars) and 3 targeting IL-36R. Due to the aforementioned limitations of TNF inhibitors, we believe that QX001S and QX004N will primarily compete with other IL inhibitors. The following table sets forth details of QX001S and QX004N as well as approved biologic drugs and drug candidates in the clinical stage for Ps in China that are IL inhibitors as of the Latest Practicable Date.

Marketed IL Inhibitors for Psoriasis in China

Target	Brand Name	International Nonproprietary Name (INN)	Company	NMPA Approval Time	Branded or Biosimilar	Availability of biosimilar	2022 NRDL covered	NRDL Median price in 2022 ⁽¹⁾ (RMB)
IL-23	Tremfya	Guselkumab	Janssen (J&J)	2019	Branded	—	No	—
	益路取	Tildrakizumab-asmn	Sun Pharma; Kangzhe Biotech	2023	Branded	—	No	—
IL-12, IL-23	Stelara	Ustekinumab	Janssen (J&J)	2017	Branded	—	Yes	4,318.0
IL-17A	Cosentyx	Secukinumab	Novartis	2019	Branded	—	Yes	1,188.0
	TALTZ	Ixekizumab	Eli Lilly	2019	Branded	—	Yes	1,218.0
IL-17RA	LUMICEF	Brodalumab	Kyowa Kirin	2020	Branded	—	No	—
IL-8	Enboke (恩博克)	—	ASIA SPACE	2003	Branded	—	Yes	270.0
IL-36R	Spevigo	Spesolimab	Boehringer Ingelheim	2022	Branded	—	No	—

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Clinical-Stage IL Inhibitor Candidates for Psoriasis in China				
Target	Drug Code	Company	Status	First Posted Date
IL-23	IBI112	Innovent	Phase III	2022-12-26
	QX004N	the Company	Phase II	2023-01-06
	Risankizumab	Boehringer Ingelheim	Phase I	2019-07-18
	NBL-012	NovaRock	Phase I	2021-06-03
IL-12, IL-23	Ustekinumab-QX001S	the Company	BLA submission	2023-08-12
	Ustekinumab-BAT2206	Bio-Thera	Phase III	2021-06-25
	AK101	Akeso	BLA submission	2023-08-23
	Ustekinumab-SYSA1902	CSPC	Phase III	2023-01-29
IL-17A	GR1501	GenrixBio	BLA submission	2023-03-25
	SHR-1314	Henrui	BLA submission	2023-04-27
	JS005	Junshi Bioscience	Phase III	2023-07-12
	Secukinumab-BAT2306	Bio-Thera	Phase III	2022-07-25
	SSGJ-608	Sunshine Guojian	Phase III	2022-11-10
	AK111	Akeso	Phase III	2023-02-15
	HB0017	Huaota Biopharm; Huabo Bio	Phase II	2022-08-22
	SYS6012	CSPC	Phase I	2023-12-05
	BR201	BioRay	Phase I	2023-11-16
	Netakimab	BIOCAD	Phase I	2022-10-19
	Secukinumab-CMAB015	Mabpharm	Phase I	2023-01-18
	NVS451	National Vaccine & Serum Institute	Phase I	2023-05-08
	FTC001/CNTO6785	Shandong Fontacea	Phase I	2023-06-26
	IL-17A, IL-17F	Bimekizumab	UCB Pharma	BLA submission
LZM012		LIVZON	Phase III	2023-06-27
IL-36R	Imsidolimab	AnaptysBio	Phase III	2023-03-09
	TQH2929	Chiat'ai Tianqing	Phase I	2023-11-02
	HB0034	Huaota Biopharm; Huabo Bio	Phase I	2022-09-05

Source: NMPA, CDE, Frost & Sullivan Report

Note:

- (1) Reflects the median price for a drug’s minimum formulation unit as included in the NRDL.

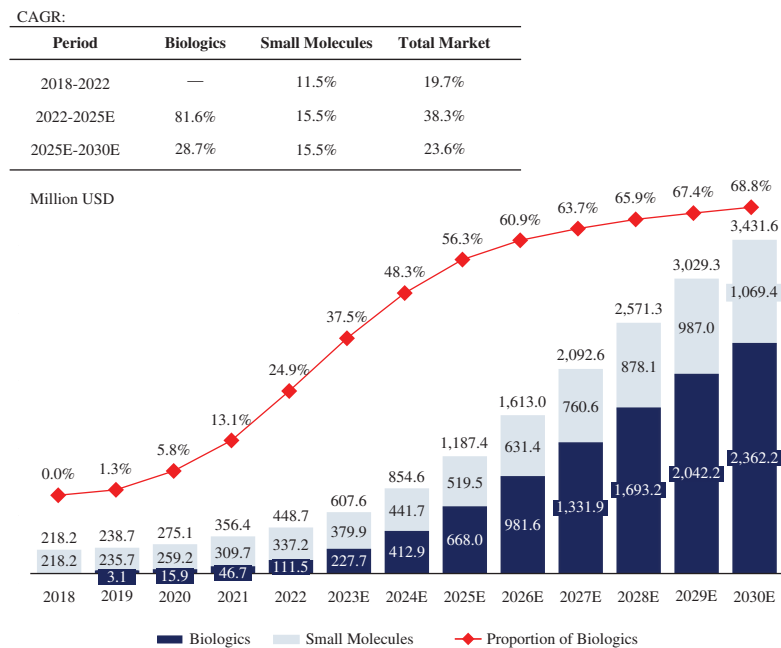
Systemic Lupus Erythematosus

Systemic lupus erythematosus (SLE) is an autoimmune disease associated with substantial morbidity and mortality. It is the most common type of lupus, causing widespread inflammation and tissue damage in the affected organs. The prevalence of SLE in China reached approximately 1 million in 2022 and is expected to remain relatively stable over the next decade.

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The SLE drug market in China increased from US\$218.2 million in 2018 to US\$448.7 million in 2022, at a CAGR of 19.7%. It is estimated to reach US\$1.2 billion in 2025, at a CAGR of 38.3% from 2022 to 2025, and US\$3.4 billion in 2030, representing a CAGR of 23.6% from 2025 to 2030. The market for biologic drugs indicated for SLE in China is estimated to increase from US\$111.5 million in 2022 to US\$2.4 billion in 2030, representing 24.9% and 68.8% of China’s SLE drug market in 2022 and 2030, respectively. The improving awareness and acceptance by the prevailing treatment guidelines and SLE patients for biologic therapies, as well as the reduced treatment costs of such therapies after their admission into the NRDL have led to a quickly increasing penetration rate of biologic drugs, which has been and is expected to continue to be the primary driver behind the growth of China’s SLE drug market despite a relatively stable patient population. The increasing penetration rate of China’s SLE biologic drugs is primarily attributable to the sales of biologics that have been successfully commercialized and admitted into the NRDL, *i.e.*, belimumab and telitacicept, and the number of biologic drugs expected to be approved in the future. The following chart sets forth the historical and estimated SLE drug market in China for the periods indicated.

SLE Drug Market in China, 2018-2030E



Source: Frost & Sullivan Report (based on annual reports of relevant companies, literature review and expert interviews)

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Treatment Paradigms for SLE in China

The types of drugs that have been used to treat SLE mainly include corticosteroids, traditional DMARDs (such as hydroxychloroquine), NSAIDs and biologic drugs. Corticosteroids are recommended as initial treatment for SLE patients. Low-dose corticosteroids, hydroxychloroquine or NSAIDs are recommended for patients with mild symptoms. For SLE patients with more severe conditions, combined therapies of corticosteroids, biologic drugs and traditional DMARDs are recommended. High doses of corticosteroids can be helpful in severe cases of SLE, but the patients face considerable risk of disease progression, relapse over time and serious side effects, including osteoporosis (weak bones), high blood pressure and diabetes. In addition, treatment with traditional DMARDs may result in an increased risk of serious infections and certain types of cancer. Hydroxychloroquine may offer relief for SLE-related symptoms, such as arthritis, fatigue and rashes, but is associated with increased risk of retinopathy. There remain significant unmet needs for new therapeutics for SLE that effectively control disease activity, have a favorable safety profile and improve the patients’ quality of life. Over the past decades, there has been growing interest in the development of biologic drugs indicated for SLE, including, most importantly, interferon (IFN) receptor inhibitors and B cell depletion therapies aiming to inhibit autoreactive B cell activation and autoantibody production.

As of the Latest Practicable Date, there were two approved B cell depletion therapies in China indicated for SLE, namely, belimumab and telitacept. Belimumab is a human monoclonal antibody that inhibits BlyS (or BAFF), a member of the TNF cytokine family produced by myeloid lineage cells, such as dendritic cells and macrophages, and a key factor in the differentiation and survival of B cells. Belimumab was also approved by the FDA in 2011, making it the first new drug approved for SLE treatment globally in more than 50 years. Telitacept targets two cell-signaling molecules critical for B cell development: BlyS and a proliferation inducing ligand (APRIL). As of the Latest Practicable Date, telitacept had not been approved outside of China. No biosimilar or generic of belimumab or telitacept had been approved for the treatment of SLE in China as of the Latest Practicable Date.

As of the Latest Practicable Date, there was only one IFN receptor inhibitor approved by the FDA for SLE treatment, namely, anifrolumab. It was approved by the FDA in 2021, making it the only new SLE treatment in more than 10 years. As of the same date, no drug of the same target was approved for SLE by the NMPA.

As of the same date, in addition to QX006N, there were 15 biologic drug candidates for SLE in the clinical stage in China, two of which were IFNAR1 inhibitors. Other targets under investigation include BAFF and various membrane/transmembrane proteins, such as CD38 and CD22. The following table sets forth details of QX006N and biologic drugs and drug candidates for SLE in the clinical stage in China as of the Latest Practicable Date.

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Marketed Targeted Biologics for SLE in China

Target	Brand Name	INN	Company	NMPA Approval Time	Median Price ⁽¹⁾	NRDL Inclusion
BAFF	Benlysta	Belimumab	GSK	2019	727.5	Yes
BAFF/APRIL	Tai'ai (泰愛)	Telitacicept	Remegen	2021	818.8	Yes

Clinical-Stage Biologic Drug Candidates for SLE in China

Target	Drug Code	Company	Status	First Posted Date
IFNAR1	Anifrolumab	AstraZeneca	Phase III	2021-08-09
	GR1603	Genrix Bio	Phase I/II	2021-12-03
	QX006N	the Company	Phase I	2021-11-23
BAFF	UBP1213sc	Junshi Bioscience	Phase I	2022-02-18
BAFFR	VAY736	Novartis	Phase III	2023-01-09
CLEC4C	BIIB059	Biogen; Vetter Pharma-Fertigung	Phase III	2022-06-07
CD20	Obinutuzumab	Roche	Phase III	2022-10-27
	MIL62	Mabworks	Phase II/III	2023-02-08
CD40L	Dapirolizumab Pegol	UCB Pharma	Phase III	2022-11-07
	IBI355	Innovent Bio	Phase I	2023-10-19
CD38	CM313	Keymed Bioscience	Phase I/II	2022-07-08
	SG301	Shangjian Biotech	Phase I	2023-11-06
CD22	SM03	Longrui	Phase I	2015-01-07
CD79B, FCGR2B	PRV-3279	Zhongmei Huadong	Phase II	2023-08-02
Undisclosed	SHR-2001	Hengrui	Phase I	2023-07-10
APRIL, BAFF	ALPN-303	Ajinomoto Bio-Pharma	Phase I	2023-12-22

Source: Frost & Sullivan Report (based on annual reports of relevant companies and information published by the NMPA)

Note:

(1) Reflects the NRDL median price for minimum formulation unit in 2022 in RMB.

Lupus Nephritis

Lupus Nephritis (LN) is the most common severe complication of SLE, involving inflammation of and possible organ damage to the kidneys. The prevalence of LN in China was approximately 567,700 in 2022, and is expected to remain relatively stable over the next decade.

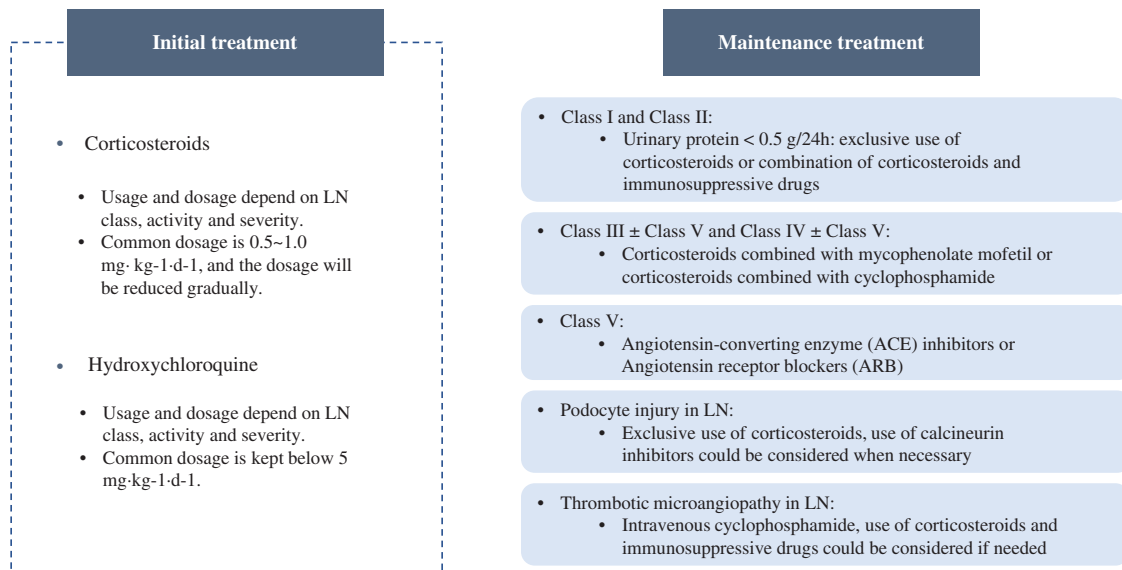
The LN drug market in China increased from US\$104.7 million in 2018 to US\$211.4 million in 2022. It is estimated to reach US\$550.3 million in 2025, at a CAGR of 37.6% from 2022 to 2025, and US\$1.6 billion in 2030, representing a CAGR of 24.5% from 2025 to 2030. The growth of China's LN drug market is mainly driven by the expected sales growth of recently approved biologic drug and the increase in the number of innovative drugs expected to be approved in the near future based on the progress of their clinical trials, especially biologic drugs that generally have higher prices than traditional treatment options.

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Additionally, the improving ability and propensity of the patients in China to pay for long-term advanced therapies also contribute to the expected expansion of the LN drug market. The market for biologic drugs indicated for LN in China is estimated to increase to US\$1.1 billion in 2030, representing 67.4% of China’s LN drug market in 2030.

Similar to treatment options for SLE, the types of drugs that have been used to treat LN mainly include corticosteroids, traditional DMARDs (such as hydroxychloroquine) and biologic drugs, with corticosteroids and hydroxychloroquine recommended as initial treatment options and standard of care. As the investigation of biologic drugs for the treatment of LN is still at an early stage, there is no clear designation of line of treatment for biologic drugs for this indication. Compared to SLE, biologic drugs and drug candidates indicated for LN are even more limited. The diagram below illustrates the recommended treatment paradigm for LN in China.

Treatment Diagram of LN in China



Source: *Standards for the Diagnosis and Treatment of Lupus Nephritis (2021)* and *Frost & Sullivan analysis*

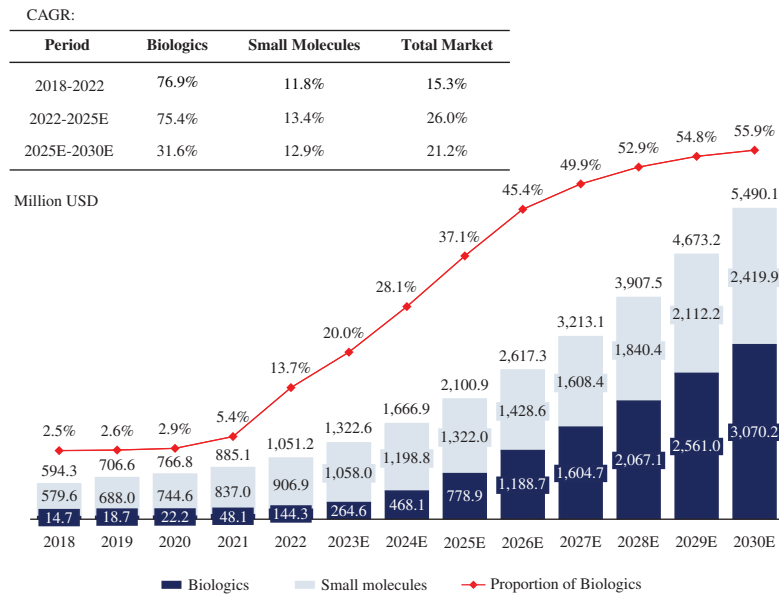
As of the Latest Practicable Date, belimumab was the only targeted biologic drug approved by the FDA or NMPA for the treatment of LN. See “—Systemic Lupus Erythematosus—Treatment Paradigms for SLE in China” for more details on belimumab. As of the same date, there were 11 biologic drug candidates for LN in the clinical stage in China, 3 of which were IL-17 inhibitors. Other targets under investigation include B cell membrane proteins, such as CD80/CD86 and CD20.

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Inflammatory Bowel Disease

Inflammatory bowel disease (IBD) is a broad term that describes conditions characterized by chronic inflammation of the gastrointestinal tract, including ulcerative colitis (UC) and Crohn’s disease (CD). The total prevalence of UC and CD in China increased from 490,500 in 2018 to 674,200 in 2022, at a CAGR of 8.3%, and is estimated to reach 1,154,200 in 2030, at a CAGR of 7.0% from 2022 to 2030. The UC/CD drug market in China grew rapidly in recent years, from US\$594.3 million in 2018 to US\$1,051.2 million in 2022, representing a CAGR of 15.3%. It is estimated to reach US\$2,100.9 million in 2025, representing a CAGR of 26.0% from 2022 to 2025, and is estimated to further increase to US\$5,490.1 million in 2030, representing a CAGR of 21.2% from 2025 to 2030. Biologic drugs accounted for 13.7% of the UC/CD drug market in China in 2022, which is estimated to increase to 55.9% in 2030. The following table sets forth the UC/CD drug market in China for the periods indicated.

UC/CD Drug Market in China, 2018-2030E



Source: Frost & Sullivan Report (based on annual reports of relevant companies, literature review and expert interviews)

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Treatment Paradigms for UC/CD in China

Treatment of UC/CD usually involves either drug therapy or surgery. Several types of medications may be used to treat UC/CD, including anti-inflammatory drugs, glucocorticoids, immunosuppressants and biologic drugs. Anti-inflammatory drugs mainly include aminosalicylic acids (5-ASA), which can reduce inflammation but studies have shown that they are not effective at inducing remission in active CD or preventing relapse in inactive CD. While patients can initially respond to glucocorticoid therapy, a large portion of them develop a dependency on glucocorticoids or have a relapse within one year. In addition, use of glucocorticoids is often limited by a relatively high risk of serious adverse effects including bone loss, metabolic complications, increased intraocular pressure and glaucoma and potentially lethal infections. Immunosuppressants may also trigger profound side effects such as short-term and long-term toxicities due to their non-specific, anti-proliferative or anti-metabolic features. In the past five years, the introduction of biologic drugs has heralded a new era of evolving biologically targeted treatments for UC/CD. As of the Latest Practicable Date, biologics have been recommended as a main treatment option for UC/CD by prevailing clinical guidelines.

There are three types of approved biologic drugs in China for the treatment of UC/CD, namely, TNF- α inhibitors, integrin α 4 (ITGA4)/integrin β 7 (ITGB7) inhibitors and IL-12/IL-23 inhibitors. TNF- α inhibitors block the binding of TNF to TNF receptors, thereby suppressing their biological effects. Integrin α 4/integrin β 7 inhibitors bind to the surface of white blood cells so they cannot pass through tissue layers and exacerbate inflammation. However, use of certain integrin α 4/integrin β 7 inhibitors carries an increased risk of progressive multifocal leukoencephalopathy, a severe brain condition. In contrast, IL-23 and IL-12 inhibitors, such as ustekinumab, have exhibited strong safety profile while maintaining satisfactory efficacy. However, all such classes of biologics are likely to result in drug resistance, forcing CD patients to switch between such classes of biologics to prolong treatment.

Competitive Landscape of Biologics for UC/CD Treatment in China

As of the Latest Practicable Date, there were 12 biologic drugs for UC/CD approved in China, including ten TNF- α inhibitors (including Remicade (infliximab), Humira (adalimumab), three infliximab biosimilars and five adalimumab biosimilars), one integrin α 4/integrin β 7 inhibitor, namely, vedolizumab, and one IL-12/IL-23 inhibitor, namely, ustekinumab. No biosimilar or generic of ustekinumab or vedolizumab had been approved for the treatment of UC/CD in China as of the Latest Practicable Date. The TNF- α inhibitors, integrin α 4/integrin β 7 inhibitors and IL-12/IL-23 inhibitors are expected to continue to be mainstream biologic treatments for UC/CD in the near future. As of the same date, there were 11 biologic drug candidates for UC/CD in clinical stage in China, seven of which were IL-12/IL-23 inhibitors or IL-23 inhibitors. The following tables set forth details of QX004N as well as approved biologic drugs and biologic drug candidates for UC/CD in the clinical stage in China as of the Latest Practicable Date.

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Marketed Targeted Biologics for UC/CD in China								
Target	Brand Name	INN	Company	Median Price ⁽¹⁾	Indications	NMPA Approval Time	NRDL Inclusion	
IL-12/IL-23	Stelara	Ustekinumab	Janssen (J&J)	4,318	CD	2020	Yes	
					UC	2006		
	Remicade	Infliximab	Janssen (J&J)	2,007	CD	2018	Yes	
					UC	2018		
	QLETLI (格樂立)	Adalimumab-BAT1406	Bio-Thera	1,080	CD	2019	Yes	
	Anjianing (安健寧)	Adalimumab-HS016	Hisun	1,148	CD	2019	Yes	
	Humira	Adalimumab	AbbVie	1,290	CD	2020	Yes	
	SULINNO (蘇立信)	Adalimumab-IBI303	Innovent	1,088	CD	2020	Yes	
	TNF-α	Leiting (類停)	Infliximab-CMAB008	MabPharm	1,268	CD	2021	Yes
						UC	2021	
Anbate (安佰特)		Infliximab-HS626	Hisun	1,268	CD	2021	Yes	
					UC	2021		
Jiayoujian (佳佑健)		Infliximab-GB242	Yuxi Genor Biotechnology	1,280	CD	2022	Yes	
Junmaikang (君邁康)		Adalimumab-UBP1211	Junshi Bioscience	998	CD	2022	Yes	
					UC	2022		
安佳潤®	Adalimumab-SCT630	SinoCelltech	N/A	CD	2023	No		
Integrin α4/ Integrin β7	Entyvio	Vedolizumab	Takeda	4,980	CD	2020	Yes	
					UC	2020		

Note:

- (1) Reflects the NRDL median price per minimum formulation unit in 2022 in RMB.

Clinical-Stage Biologic Drug Candidates for UC/CD Treatment in China						
Target	Drug Code	Company	Indications	Status	First Posted Date	
IL-12/IL-23	Ustekinumab-BAT2206	Bio-Thera	CD	Phase I	2020-05-06	
			UC	Phase I	2020-05-06	
	AK101	Akeso	UC	Phase I	2020-08-13	
	Risankizumab	AbbVie	UC/CD ⁽¹⁾	BLA submission	2023-07-06	
IL-23	LY3074828	Eli Lilly	CD	Phase III	2020-04-24	
			UC	Phase III	2020-01-15	
	Guselkumab	Janssen (J&J)	CD	Phase III	2020-06-08	
			UC	Phase II/III	2020-06-10	
	IBI112	Innovent	UC	Phase II	2022-04-28	
			QX004N	the Company	CD	Phase I
TNF-α	Adalimumab-TQZ2301	Chia Tai Tianqing	CD	Phase I	2018-11-13	
			UC	Phase I	2018-11-13	
TNFSF15	PF-06480605	Pfizer	UC	Phase II	2021-03-11	
			CD	Phase I	2021-11-17	
IL6ST	Olamkicept	IMAB	UC	Phase II	2018-08-03	
Undisclosed	HZBio2	Grand pharma	CD	Phase I	2022-05-16	
			UC	Phase I	2022-05-16	

Source: Frost & Sullivan Report (based on annual reports of relevant companies and information published by the NMPA)

Note:

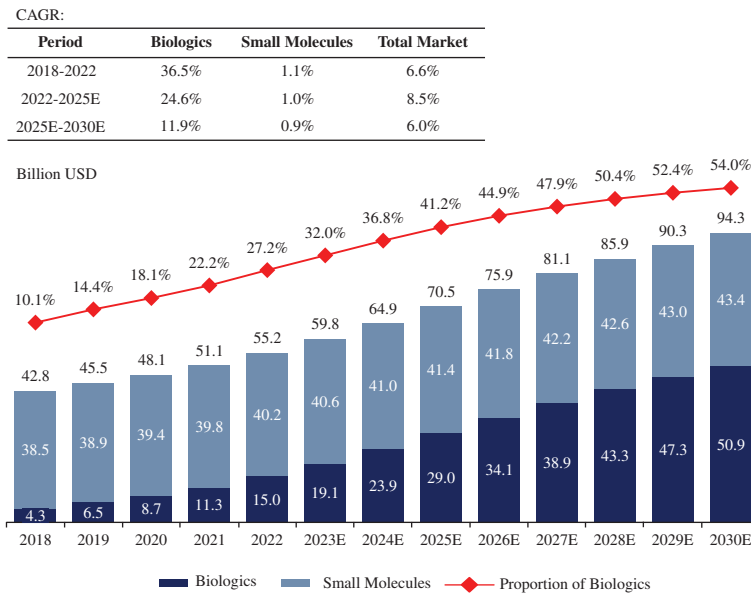
- (1) AbbVie has not announced the specific indication for BLA submission of Risankizumab for UC/CD.

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OVERVIEW OF THE ALLERGIC DISEASE DRUG MARKET

The global allergic disease drug market increased from US\$42.8 billion in 2018 to US\$55.2 billion in 2022, at a CAGR of 6.6%. It is estimated to reach US\$70.5 billion in 2025, at a CAGR of 8.5% from 2022 to 2025, and is estimated to further increase to US\$94.3 billion in 2030, at a CAGR of 6.0% from 2025 to 2030. Biologic drugs’ share of the global market is estimated to increase from 27.2% in 2022 to 54.0% in 2030. The following table sets forth the global allergic disease drug market for the periods indicated.

Global Allergic Disease Drug Market, 2018-2030E

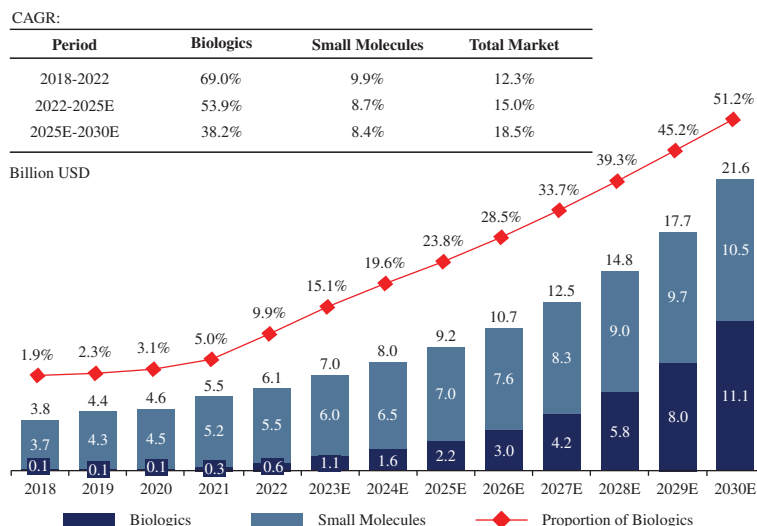


Source: Frost & Sullivan Report (based on annual reports of relevant companies, literature review and expert interviews)

The allergic disease drug market is further driven by a huge patient pool and increasing awareness of early diagnosis and treatment in China. The allergic disease drug market in China increased from US\$3.8 billion in 2018 to US\$6.1 billion in 2022, at a CAGR of 12.3%. It is estimated to reach US\$9.2 billion in 2025, at a CAGR of 15.0% from 2022 to 2025, and is estimated to further increase to US\$21.6 billion in 2030, at a CAGR of 18.5% from 2025 to 2030. Biologic drugs’ share of China’s allergic disease drug market is estimated to increase rapidly from 9.9% in 2022 to 51.2% in 2030. The following table sets forth the allergic disease drug market in China for the periods indicated.

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China Allergic Disease Drug Market, 2018-2030E



Source: Frost & Sullivan Report (based on annual reports of relevant companies, literature review and expert interviews)

Evolution of Allergic Disease Treatments

Allergy desensitization is a therapy that aims to weaken a patient’s allergic reactions by exposing them to gradually increasing doses of allergens. Allergy desensitization is widely used for treatment of allergies of pollen, mites, animal dander and certain medications, but it is barely effective for systemic allergic diseases without a specific allergen, such as AD, PN, CRSwNP, asthma and COPD. Antihistamines and glucocorticoids are then introduced into the treatment of allergic diseases to suppress or alleviate symptoms in various allergic diseases. However, such traditional treatment options are generally limited in efficacy and associated with severe adverse events, especially for long-term treatment.

Since the first biologic drug, an IgE inhibitor, was approved for the treatment of allergic diseases by the FDA in 2003, biologic drugs have been widely used globally for the treatment of allergic diseases. Several cytokines and pathways, such as IL-4, IL-5, IL-13, TSLP and JAK, were found to be involved in the activation of type 2 immune response. Among all type 2 inflammatory cytokines, IL-4 and its receptor are the most studied.

The market for anti-IL-4R α antibodies emerged when the first anti-IL-4R α antibody, dupilumab, was approved by the FDA in 2017. In China, dupilumab was approved by the NMPA in 2020 and included in the NRDL in 2021, and remains the only marketed anti-IL-4R α . Dupilumab is currently approved in U.S., Europe, Japan and other countries around the world for the treatment of moderate-to-severe AD as well as asthma or CRSwNP in different age populations. Dupilumab’s global sales increased from US\$0.3 billion in 2017 to US\$8.7 billion in 2022, at a CAGR of 102.3%. As of the Latest Practicable Date, there were 13 IL-4R α -targeting biologic drug candidates (excluding dupilumab) in the clinical stage in China, including QX005N.

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Due to the relative late start of development, biologic antibodies were first approved for the treatment of allergic diseases in China in 2017. To date, market penetration and treatment compliance with biological therapies for allergic diseases remain relatively low in China as a result of the high costs associated with current biologic therapies. For example, biologic drugs only accounted for 3.5% of the asthma drug market in China in 2022.

Small-molecule targeted therapies, such as JAK inhibitors, can also be used to treat allergic diseases. However, the FDA and the EMA has required warning for several JAK inhibitors with respect to their safety concerns. See “—Overview of the Autoimmune Disease Drug Market—Evolution of Autoimmune Disease Treatments.”

Major Allergic Diseases

Atopic Dermatitis

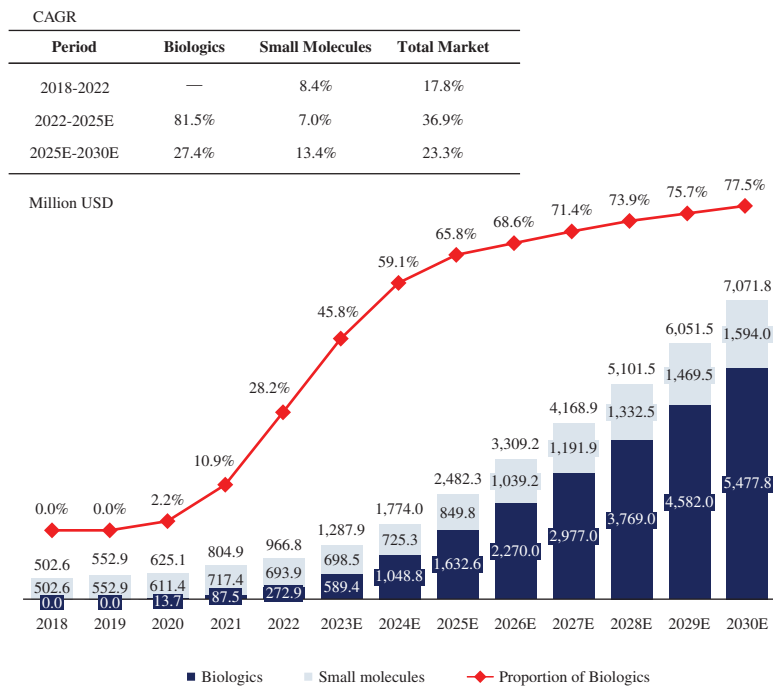
Atopic Dermatitis (AD) is one of the most common skin disorders globally and in China. The prevalence of AD in China increased from 64.0 million in 2018 to 70.3 million in 2022, at a CAGR of 2.4%, and is anticipated to reach 78.5 million in 2030, at a CAGR of 1.4% from 2022 to 2030. The number of adult patients with AD in China increased from 31.5 million in 2018 to 35.8 million in 2022 and is anticipated to further increase to 43.4 million in 2030. The number of children/adolescent patients with AD in China increased from 32.5 million in 2018 to 34.5 million in 2022 and is anticipated to further increase to 35.1 million in 2030. In addition, 30% of the patients have moderate-to-severe AD. The number of patients with moderate-to-severe AD increased from 17.7 million in 2018 to 19.5 million in 2022 and is anticipated to reach 21.9 million in 2030. The number of patients with mild AD increased from 46.3 million in 2018 to 50.8 million in 2022 and is anticipated to reach 56.5 million in 2030.

The AD drug market in China increased from US\$502.6 million in 2018 to US\$966.8 million in 2022, at a CAGR of 17.8% and is estimated to grow rapidly to reach US\$2,482.3 million in 2025, at a CAGR of 36.9% from 2022 to 2025, and further increase to US\$7,071.8 million in 2030, at a CAGR of 23.3% from 2025 to 2030. The expected rapid growth from 2022 to 2023 is primarily because (i) the sales of dupilumab (the only biologic drug approved in China for AD and included in the NRDL as of the Latest Practicable Date) in China since its approval for AD in 2020 experienced substantial growth from US\$13.7 million in 2020 to US\$248.1 million in 2022, at a CAGR of 325.0%, indicating a high demand for AD biologics in China and further growth of the China AD drug market; (ii) there has been increasing R&D of AD biologics by domestic companies and several domestically developed AD biologic drug candidates have entered the clinical trial stage, which, once approved for commercialization, are expected to further drive the growth of the China AD drug market; and (iii) the diagnosis and treatment rates of AD are expected to increase due to improving affordability and health awareness of Chinese AD patients, which is also expected to contribute to the rapid growth of the China AD drug market. In addition, the anticipated significant growth of AD drug market in China from 2021 to 2030 is also attributable to (i) the improved penetration rate of biologics with a high growth rate in China, which is expected to increase from 28.2% in 2022 to 77.5% in 2030 and mainly driven by the sales of dupilumab in China, and other potential IL-4R α

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inhibitors to be approved in China are also taken into consideration; (ii) dupilumab has been included in the NRDL and experienced a decrease in its prices, which is expected to further drive the significant growth of the AD drug market in China; and (iii) the increasing prevalence of moderate-to-severe AD in China and the number of patients with moderate-to-severe AD in China is anticipated to reach 21.9 million in 2030, which also contributes to the growth of the AD drug market in China. Biologic drugs accounted for 28.2% of the AD drug market in China in 2022, which is estimated to increase to 77.5% in 2030. The following table sets forth the size of the AD drug market in China for the periods indicated.

Atopic Dermatitis Drug Market in China, 2018-2030E

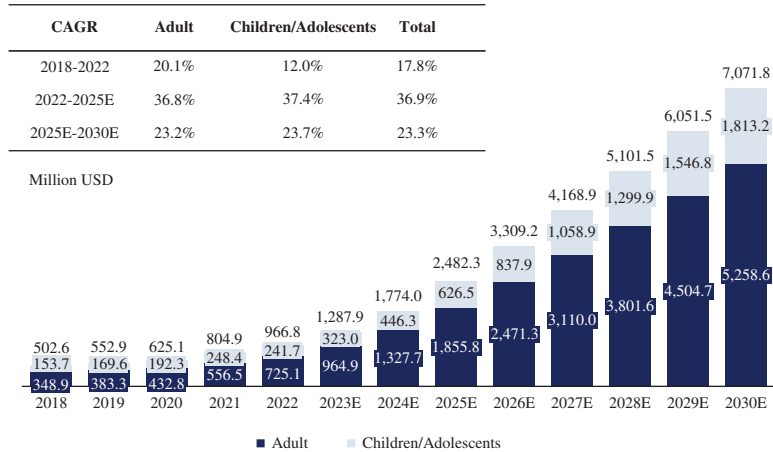


Source: Frost & Sullivan Report (based on annual reports of relevant companies, literature review and expert interviews)

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The following table sets forth the breakdown of the AD drug market in China by age for the periods indicated.

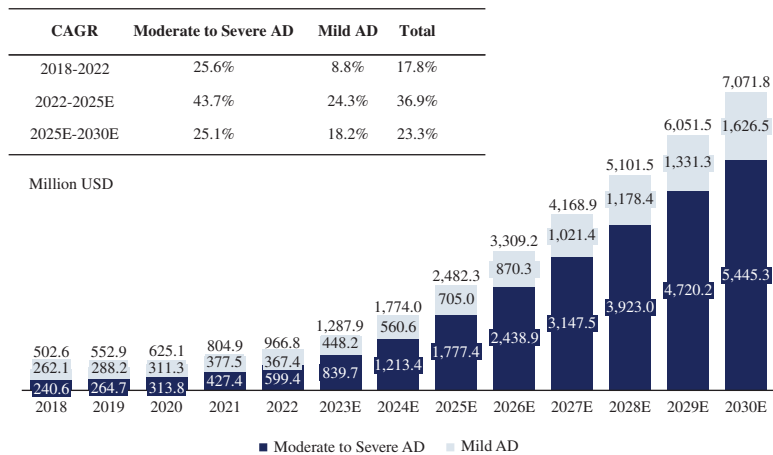
Atopic Dermatitis Drugs Market in China Breakdown by Age, 2018-2030E



Source: Literature review, Frost & Sullivan Report

The following table sets forth the breakdown of the AD drug market in China by severity for the periods indicated.

Atopic Dermatitis Drugs Market in China Breakdown by Severity, 2018-2030E



Source: Literature review, Frost & Sullivan Report

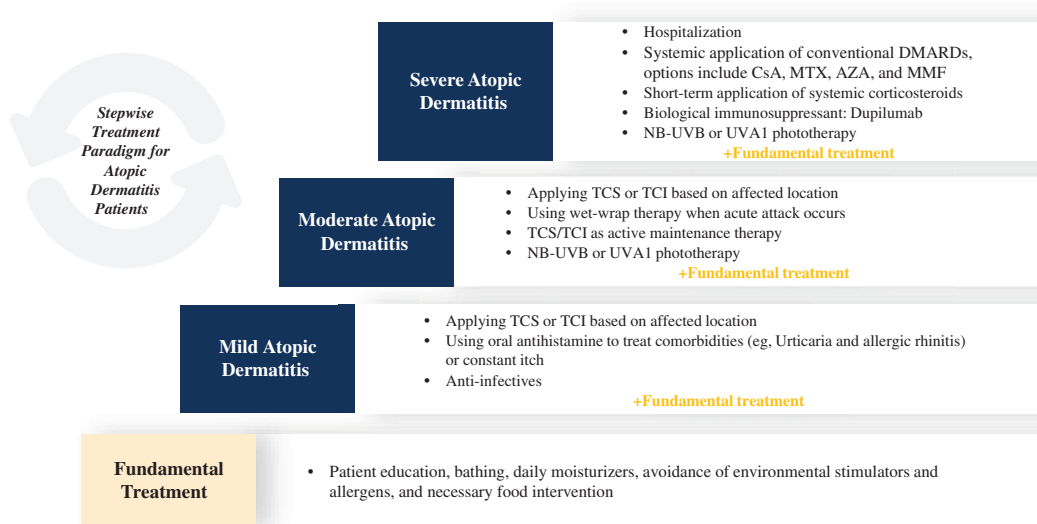
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Treatment Paradigms for AD in China

Treatment of AD usually involves a step-up approach, *i.e.*, depending on the severity and extent of a patient’s symptoms, different medication and treatment options may be recommended. The standard of care for AD in China mainly includes bathing, improvement of the living environment and food intervention. In addition, topical corticosteroids and calcineurin inhibitors are the first line of treatment and important drugs for AD. However, overuse of these drugs may cause side effects, including thinning skin or impaired immune system. In severe cases of AD, phototherapy and conventional DMARDs are recommended by the Guideline for Diagnosis and Treatment of AD in China (2020) (《中國特應性皮炎診療指南(2020版)》). In recent years, biologic drugs with better safety and efficacy profiles have become an emerging treatment for both moderate and severe AD. They could be used as a standalone treatment or in combination with other existing treatments such as phototherapy. Systematic application of biologics may be recommended if a patient has an inadequate response or intolerance to existing topical treatments or phototherapy. For example, dupilumab (an anti-IL-4R α antibody) is recommended for an initial injection of 600 mg for adults and subsequent injections of 300 mg at a frequency of Q2W, and it can be used for long-term maintenance therapy in combination with topical drugs and moisturizers. Furthermore, dupilumab was studied in over 2,800 patients across 6 pivotal trials that included monotherapy and concomitant TCS, and demonstrated clinically meaningful improvement in concomitant TCS trials (in adults, children and infants to preschoolers with AD) and improvement in monotherapy trials (in adults and adolescents with AD), as measured by improvements in the IGA (IGA 0 or 1) and EASI (EASI-75) scores at week 16. According to the Guideline for Diagnosis and Treatment of AD in China (2020), biologics, as a main treatment option for AD patients, are recommended to be combined with topical drugs and moisturizers for long-term use. In particular, as IL-4, IL-13, IL-5 and IL-10 are important cytokines involved in the pathogenesis of AD, they present potential targets suitable for biologics development. IL-4R α is the mainstream target under investigation for AD treatment due to its role in controlling the signaling of both IL-4 and IL-13, and research on other targets, such as IL-31, IL-33 and OX40, is also ongoing. However, these targets remain early-stage in their R&D progress and will continue to be subject to scientific uncertainty, while IL-4R α has already been validated and has also led to successful commercialization of biologics with this target. In addition, small-molecule treatments, including PDE-4 inhibitors and JAK inhibitors, have been explored as potential treatment options for AD patients. As of the Latest Practicable Date, two JAK inhibitors (sold under the brand names of RINVOQ and CIBINQO, respectively) and one PDE-4 inhibitor (sold under the brand name of Staquis) had been approved for AD in China, according to Frost & Sullivan. The JAK inhibitors had only recently been included in the latest Guideline for Diagnosis and Treatment of Moderate-to-severe AD (2023) in China with limited recommendation for certain patient populations, and the PDE-4 inhibitor is listed under other topical drugs in the Guideline for Basic Diagnosis and Treatment of AD in China (2022).

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The diagram below illustrates the treatment paradigm for AD in China:



*CsA: cyclosporine A; MTX: methotrexate; AZA: azathioprine; MMF: mycophenolate mofetil; TCS: topical corticosteroids; TCI: topical calcineurin inhibitors

Sources: Chinese Society of Dermatology, Frost & Sullivan

Notes:

- PDE-4 inhibitors are recommended in Guideline for Basic Diagnosis and Treatment of AD in China (2022) as other topical drugs, which provides that topical PDE-4 inhibitors (cliborol ointment) can be used to treat mild-to-moderate AD patients who are two years old and older.
- The Guideline for Diagnosis and Treatment of Moderate-to-severe AD (2023) recommends JAK inhibitors as systemic therapeutic agents. As of the Latest Practicable Date, two JAK inhibitors were approved in China for the treatment of AD, including abcxitinib and upatinib. A number of screenings are required prior to the use of JAK inhibitors, including screening of tuberculosis and hepatitis viral infection.

Competitive Landscape of Biologics for AD Treatment in China

As of the Latest Practicable Date, dupilumab (an anti-IL-4R α antibody) was the only biologic drug approved in China for AD, which had also been admitted to the NRD. Since its launch in 2017, the global sales of dupilumab (under the brand name Dupixent) increased sharply from US\$256.5 million in 2017 to US\$8,681.2 million in 2022, at a CAGR of 102.3%. Since its approval in China in 2020, the sales of dupilumab in China (as disclosed by Sanofi) also experienced a sharp increase from US\$13.7 million in 2020 to US\$248.1 million in 2022, at a CAGR of 325.0%. As of the same date, in addition to QX005N, there were 20 biologic drug candidates for AD in the clinical stage in China, among which 9 were IL-4R α inhibitors and other disclosed targets under investigation included IL-13, TSLP, IL-33, ST2, CD200R, OX40, IL-2R and IL-17RB. As IL-4R α remains the mainstream target under investigation for AD treatment, we believe QX005N will primarily compete with other IL-4R α inhibitors. The following table sets forth details of QX005N as well as approved biologic drugs and drug candidates for AD in the clinical stage in China that target IL-4R α as of the Latest Practicable Date.

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Marketed Anti-IL-4R α Biologics for AD in China

Target	Brand Name	INN	Company	NMPA Approval Time	Branded or Biosimilar	Availability of biosimilar	2022 NRDL covered	NRDL Median price in 2022 ⁽¹⁾ (RMB)
IL-4R α	Dupilixent	Dupilumab	Sanofi / Regeneron	2020	Branded	—	Yes	3,160.0

Clinical-Stage Anti-IL-4R α Biologic Drug Candidates for AD in China

Target	Drug Code	Company	Status	First posted Date
IL-4R α	CM310	Keymed Bioscience	BLA submission	2023-12-07
	CBP-201	Connect Biopharmaceuticals	Phase II	2020-11-20
	TQH2722	Chia Tai-tianqing	Phase II	2023-03-27
	QX005N	the Company	Phase II	2022-07-14
	MG-K10	Mabgeek	Phase III	2023-11-29
	SSGJ-611	Sunshine Guojian	Phase III	2023-12-18
	SHR-1819	Hengrui	Phase II	2022-09-27
	GR1802	Genrix Bio	Phase III	2023-12-14
	AK120	Akeso	Phase I / II	2021-08-20
	BA2101	Boan Bio	Phase I	2023-01-16

Source: NMPA, CDE, Frost & Sullivan Report

Note:

- (1) Reflects the median price for a drug’s minimum formulation unit as included in the NRDL.

Prurigo Nodularis

Prurigo Nodularis (PN) is a chronic skin disorder characterized by the presence of hard and extremely itchy bumps known as nodules, which tend to be found in easy-to-scratch areas, such as the arms, legs, the upper back and abdomen. The prevalence of PN in China increased slightly from 1.9 million in 2018 to 2.0 million in 2022, and is anticipated to reach approximately 2.1 million in 2030.

There has been a lack of effective treatments for PN and development of the PN drug market in China is still at an early stage with dupilumab being the only biologic drug approved in China as of the Latest Practicable Date.

Treatment Paradigms for PN in China

The standard of care for PN involves topical creams, such as topical antihistamine, steroids and anesthetics, and systemic drugs, such as antihistamine, steroids and opioid receptor agonists or antagonists. However, some PN treatments such as topical steroids and topical anesthetics are recommended to be used only for a limited duration due to their side effects. Because of the discovery of new therapeutic targets in recent years, there has been increasing research on biologic drugs for treating PN as a potentially promising treatment option. Biologics have become a guideline treatment option but as a relatively new class of drugs, they have not yet been recommended as a main treatment option for PN.

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The diagram below illustrates the treatment paradigm for PN in China:

Medical treatment options	
Topical treatment	Systemic treatment
<ul style="list-style-type: none"> Topical antihistamine: treat local or generalized pruritus. 	<ul style="list-style-type: none"> Antihistamine: effective control of histamine-based pruritus.
<ul style="list-style-type: none"> Topical steroids: critical treatment for inflammatory skin irritations, also used in non-inflammatory and systemic cases. 	<ul style="list-style-type: none"> Steroids: systemic steroids to rapidly and effectively control inflammatory skin disease condition.
<ul style="list-style-type: none"> Topical anaesthetics: used to effectively control local itchiness. 	<ul style="list-style-type: none"> Opioid receptor agonists or antagonist: effective treatment of pruritus subtypes.
<ul style="list-style-type: none"> Topical capsaicin: used externally to control local and limited itchiness. 	<ul style="list-style-type: none"> Antiepileptic drugs: effectively treat pruritus subtypes.
<ul style="list-style-type: none"> Topical calcineurin inhibitors: used to control itchiness caused by inflammatory skin diseases. 	<ul style="list-style-type: none"> Antidepressant: act on 5-hydroxytryptamine (serotonin) and histamine to control itchiness.
<ul style="list-style-type: none"> Others: include mint, zinc oxide, camphor to reduce itchiness. 	<ul style="list-style-type: none"> Serotonin receptor inhibitor: inhibit serotonin receptor to control itchiness.
	<ul style="list-style-type: none"> Thalidomide: commonly used to control prurigo nodularis and persistent pruritus that is not responsive to other treatments.
	<ul style="list-style-type: none"> Immunosuppressant: used to control inflammatory skin disease itchiness.
	<ul style="list-style-type: none"> Biologic targeted therapy: monoclonal antibody against interleukin-31 receptor that is associated with prurigo nodularis.

Sources: *Guidelines for Management of Chronic Pruritus (2018), Mayo Clinic, Frost & Sullivan*

Competitive Landscape of Biologics for PN Treatment in China

As of the Latest Practicable Date, dupilumab was the only biologic drug approved for PN by the FDA and by the NMPA in China. As of the same date, there were only two biologic drug candidates for PN in the clinical stage in China, including QX005N, as set out below.

Marketed Targeted Biologics for PN in China				
Brand Name	INN	Company	Target	NMPA Approval Time
Dupixent	Dupilumab	Sanofi	IL-4R α	2023

Clinical-Stage Biologic Drug Candidates for PN in China				
Target	Drug Code	Company	Status	First posted Date
IL-4R α	QX005N	the Company	Phase II	2022-12-16
	BA2101	Boan Biotech	Phase I	2023-01-16

Source: *NMPA, Frost & Sullivan Report*

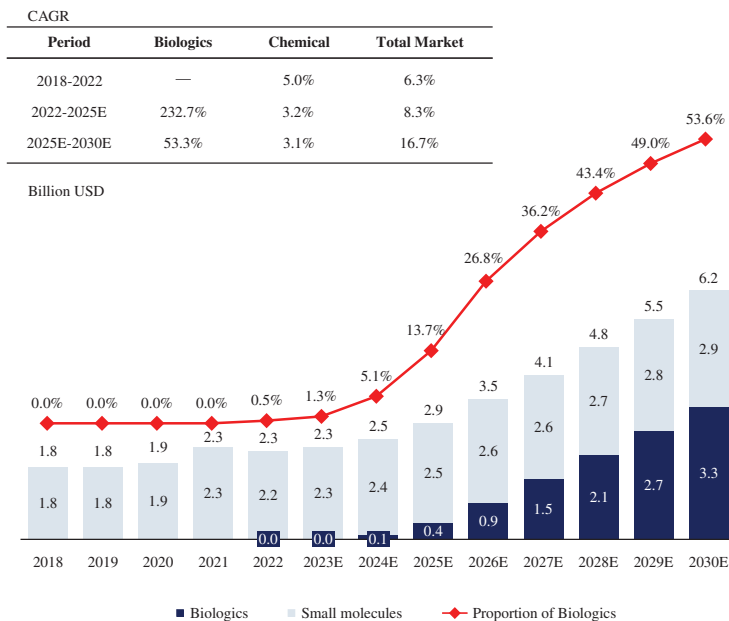
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Chronic Spontaneous Urticaria

Chronic spontaneous urticaria (CSU) is characterized by the occurrence of urticaria (a common and heterogeneous inflammatory skin disorder characterized by itchy swelling on the skin surface and can be accompanied by angioedema, which is swelling of the subcutaneous tissues under the skin) for six weeks or longer without identifiable specific triggers. The prevalence of CSU in China was approximately 25.0 million in 2022, and is anticipated to reach approximately 29.7 million in 2030.

There has been a lack of effective treatments for CSU and development of the CSU drug market in China is still at an early stage, with omalizumab (an IgE inhibitor and sold under the brand name Xolair) being the only biologic drug approved for CSU in China as of the Latest Practicable Date. The CSU drug market in China increased from approximately US\$1.8 billion in 2018 to approximately US\$2.3 billion in 2022, at a CAGR of 6.3%, and is estimated to increase to US\$2.9 billion in 2025, at a CAGR of 8.3% from 2022 to 2025, and further reach approximately US\$6.2 billion in 2030, at a CAGR of 16.7% from 2025 to 2030. Omalizumab, the first biologic drug approved in China, was approved in 2022, which accounted for approximately 0.5% of the CSU drug market in China in the same year. Biologic drugs are estimated to account for approximately 53.6% of the CSU drug market in China in 2030. The following table sets forth the size of the CSU drug market in China for the periods indicated.

CSU Drugs Market in China, 2018-2030E



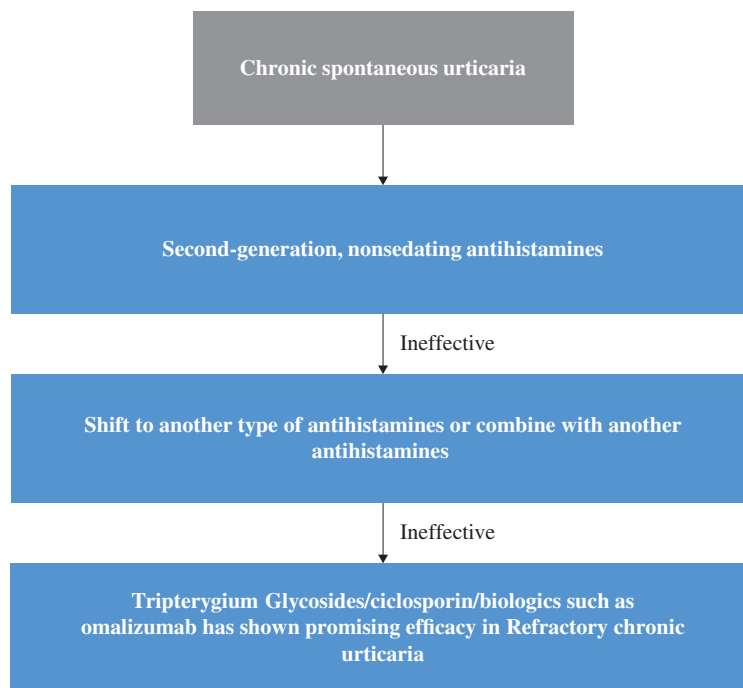
Source: Frost & Sullivan report (based on annual reports of relevant companies, literature review and expert interviews)

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Treatment Paradigms for CSU in China

The standard of care for CSU in China includes H₁ antihistamines, the most common first-line treatment of urticaria, which are shifted to tripterygium glycosides, ciclosporin or biologics (such as omalizumab) when antihistamine treatments become ineffective, particularly for patients with refractory chronic urticaria. Because of the discovery of new therapeutic targets in recent years, there has been increasing research on biologic drugs for treating CSU as a potentially promising treatment option, which (including IgE inhibitors) are recommended by prevailing clinical guidelines as third-line treatment for CSU patients.

The diagram below illustrates the treatment paradigm for CSU in China:



Sources: *Diagnosis and Treatment of Urticaria in China (2018 ver.)*, Frost & Sullivan

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Competitive Landscape of Biologics for CSU Treatment in China

As of the Latest Practicable Date, omalizumab was the only biologic drug approved for CSU in China. As of the same date, there were six biologic drug candidates for CSU in the clinical stage in China, including three IgE inhibitors and three IL-4R α inhibitors, as set out below.

Marketed Targeted Biologics for Chronic Spontaneous Urticaria in China								
Brand Name	INN	Company	Target	NMPA Approval Time	Branded or Biosimilar	Availability of biosimilar	2022 NRDL covered	NRDL Median price in 2022 ⁽²⁾ (RMB)
Xolair	Omalizumab	Novartis/ Genentech ⁽¹⁾	IgE	2022	Branded	–	Yes	1,406.0

Biologic Pipeline for Chronic Spontaneous Urticaria Treatment in China				
Target	Drug Code	Company	Status	First posted Date
IgE	Omalizumab-SYN008	CSPC Baike	BLA submission	2023-06-21
	UB-221	United Biopharma	Phase II	2023-11-14
	LP-003	LongBio Pharma	Phase II	2023-10-27
IL-4R α	Dupilumab	Sanofi	Phase III	2020-04-24
	GR1802	Genrixbio	Phase II	2023-03-03
	BA2101	Boan Biotech	Phase I	2023-01-16

Source: MNPA, Clinical Trials, Frost & Sullivan Report

Notes:

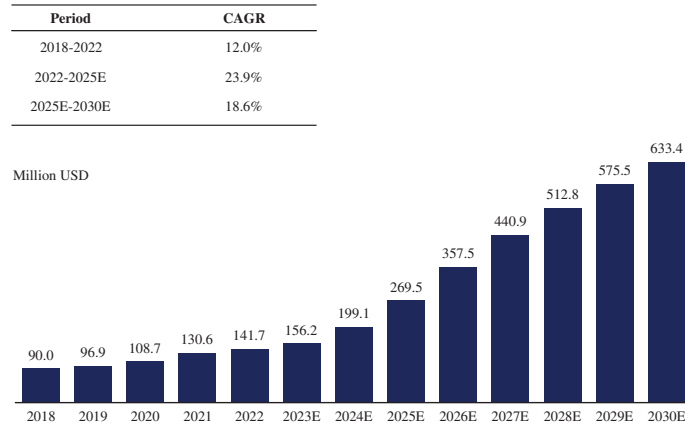
- (1) Novartis and Genentech co-develop and co-promote omalizumab. Novartis markets omalizumab outside the United States.
- (2) Reflects the median price for a drug’s minimum formulation unit as included in the NRDL.

Chronic Rhinosinusitis with Nasal Polyposis

Chronic rhinosinusitis with nasal polyps (CRSwNP) is a subgroup of chronic rhinosinusitis (CRS) characterized by the presence of fleshy swellings (nasal polyps) that develop in the lining of the nose and paranasal sinuses, which is believed to arise due to chronic inflammation. The prevalence of CRSwNP in China increased from 19.1 million in 2018 to 20.4 million in 2022, and is estimated to reach 22.3 million in 2030. The CRSwNP drug market in China increased from US\$90.0 million in 2018 to US\$141.7 million in 2022, representing a CAGR of 12.0%. It is estimated to reach US\$269.5 million in 2025, representing a CAGR of 23.9% from 2022 to 2025, and is estimated to further increase to US\$633.4 million in 2030, representing a CAGR of 18.6% from 2025 to 2030. The following table sets forth the CRSwNP drug market in China for the periods indicated.

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CRSwNP Drug Market in China, 2018-2030E

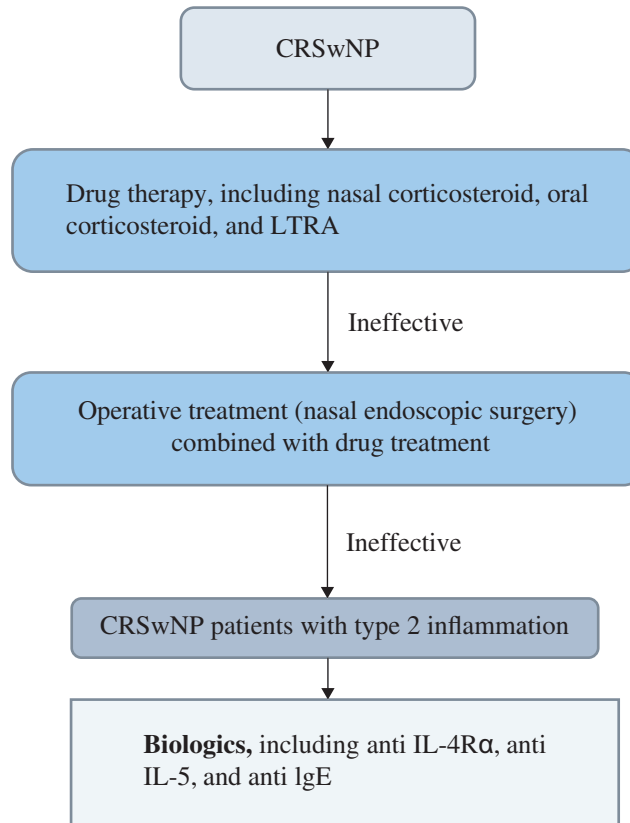


Source: Frost & Sullivan Report (based on annual reports of relevant companies, literature review and expert interviews)

Treatment Paradigms for CRSwNP in China

CRSwNP was traditionally treated with nasal saline irrigations and surgery. However, efficacy of nasal saline irrigation is limited, and there is a high nasal polyps recurrence rate of up to 60% post surgery. Corticosteroids, leukotriene receptor antagonist (LTRA), biologics and antibiotics have subsequently emerged as treatment options for CRSwNP patients. Antibiotics therapy after desensitization are primarily used for NSAID-exacerbated respiratory disease, a chronic eosinophilic, inflammatory disorder of the respiratory tract occurring in patients with asthma and/or CRSwNP. Corticosteroids for CRSwNP include intranasal corticosteroids, systemic corticosteroids and corticosteroid-eluting implants, which are primarily used following endoscopic sinus surgery. While intranasal and systemic corticosteroids are effective to some extent in the management of CRSwNP, their long-term benefits are limited. According to the Guidelines for the Diagnosis and Treatment of CRS in China (2018) (中國慢性鼻竇炎診斷和治療指南(2018)), it is difficult to maintain the clinical efficacy of systemic corticosteroids in the treatment of CRSwNP, which may lead to recurrence of nasal polyps. Moreover, systemic corticosteroids can only be administered cautiously given their association with serious systemic side effects. In contrast, biologics are proved to be more effective and safer in the treatment of CRSwNP in both clinical and animal studies. However, as a relatively new class of drugs, they have not yet been recommended as a main treatment option for CRSwNP in China by prevailing clinical guidelines. Currently, the standard of care for CRSwNP include corticosteroid, LTRA and surgery. The diagram below illustrates the recommended treatment pathway for CRSwNP in China.

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Source: *Chinese Guidelines for Diagnosis and Treatment of Chronic Rhinosinusitis (2018)*, *Chinese Expert Consensus on the Use of Biologics in Patients with Chronic Rhinosinusitis (2022)*, *Frost & Sullivan analysis*

Biologic drug candidates for CRSwNP in China primarily include IL-4R α inhibitors, IL-5 inhibitors and TSLP inhibitors. IL-4R α is a promising target for CRSwNP as IL-4R α controls the signaling of both IL-4 and IL-13, the key Th2 cytokines. As IL-5 is a key signaling factor for eosinophil activation by Th2 cells and is highly expressed in eosinophilic diseases, IL-5 inhibitors can be particularly effective for treatment of eosinophilic CRSwNP. However, the efficacy of IL-4R α inhibitors and IL-5 inhibitors has shown to be correlated to the levels of certain type 2 biomarkers, such as blood eosinophil counts and IgE. In contrast, as TSLP is an upstream regulator of type 2 inflammation, TSLP inhibitors can be a treatment for patients with low-level or no expression of type 2 biomarkers.

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Competitive Landscape of Biologics for CRSwNP Treatment in China

As of the Latest Practicable Date, only three biologics had been approved by the FDA for the treatment of CRSwNP, namely, dupilumab targeting IL-4R α , omalizumab targeting IgE and mepolizumab targeting IL-5, and none had been approved in China. As of the same date, there were 13 biologic drug candidates for CRSwNP in the clinical stage in China, including five IL-4R α inhibitors, three IL-5 inhibitors, four TSLP inhibitors and one IL-5R α inhibitor. The following table sets forth details of QX005N as well as the biologic drug candidates for CRSwNP in the clinical stage in China as of the Latest Practicable Date.

Clinical-Stage Biologic Drug Candidates for CRSwNP in China				
Target	Drug Code	Company	Status	First posted Date
IL-4R α	CM310	Keymed Bioscience	Phase III	2022-06-20
	Dupilumab	Sanofi	Phase III	2023-03-24
	GR1802	Genrix Bio	Phase II	2023-01-03
	QX005N	the Company	Phase II	2023-01-06
	SSGJ-611	Sunshine Guojian	Phase II	2023-04-27
IL-5	Mepolizumab	GSK	Phase III	2021-04-12
	Depemokimab	GSK	Phase III	2022-05-20
	Mepolizumab-BAT2606	Biothera	Phase I	2022-07-27
TSLP	Tezepelumab	Amgen/AstraZeneca	Phase III	2021-03-25
	SHR-1905	Hengrui	Phase II	2023-05-29
	TQC2731	Chia Tai Tianqing	Phase II	2023-08-01
	CM326	Keymed Bioscience	Phase I / II	2022-03-14
IL-5R α	Benralizumab	AstraZeneca	Phase III	2020-06-02

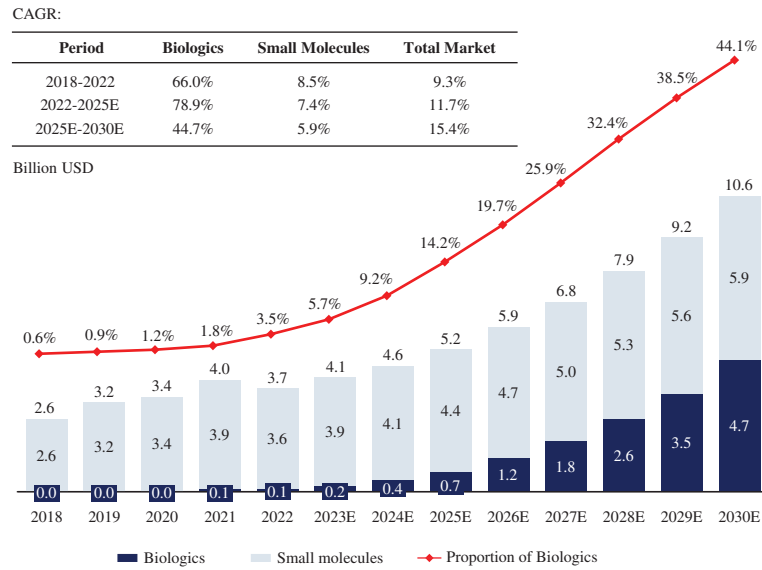
Source: Frost & Sullivan Report (based on annual reports of relevant companies and information published by the NMPA)

Asthma

Asthma, a condition that affects the lungs and respiratory functions, is one of the world’s most common diseases. The prevalence of asthma in China increased from 62.5 million in 2018 to 67.3 million in 2022, and is estimated to reach 78.1 million in 2030. The number of patients with moderate-to-severe asthma increased from 21.9 million in 2018 to 23.6 million in 2022 and is anticipated to reach 27.4 million in 2030. The number of patients with mild asthma increased from 40.7 million in 2018 to 43.7 million in 2022 and is anticipated to reach 50.8 million in 2030. The asthma drug market in China grew from US\$2.6 billion in 2018 to US\$3.7 billion in 2022, representing a CAGR of 9.3%. It is estimated to reach US\$5.2 billion in 2025, representing a CAGR of 11.7% from 2022 to 2025, and is estimated to further increase to US\$10.6 billion in 2030, representing a CAGR of 15.4% from 2025 to 2030. Biologic drugs accounted for 3.5% of the asthma drugs market in China in 2022, which is estimated to increase to 44.1% in 2030. The following table sets forth the asthma drug market in China for the periods indicated.

INDUSTRY OVERVIEW

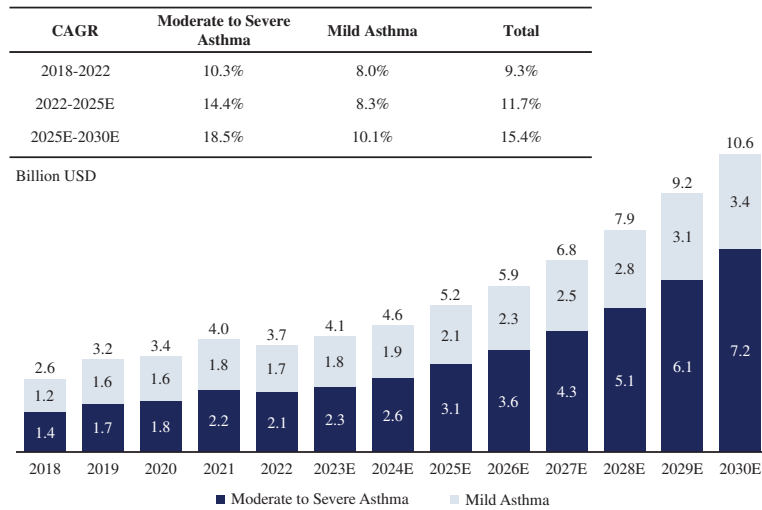
Asthma Drug Market in China, 2018-2030E



Source: Frost & Sullivan Report (based on annual reports of relevant companies, literature review and expert interviews)

The following table sets forth the breakdown of the asthma drug market in China by severity for the periods indicated.

Asthma Drugs Market in China Breakdown by Severity, 2018-2030E

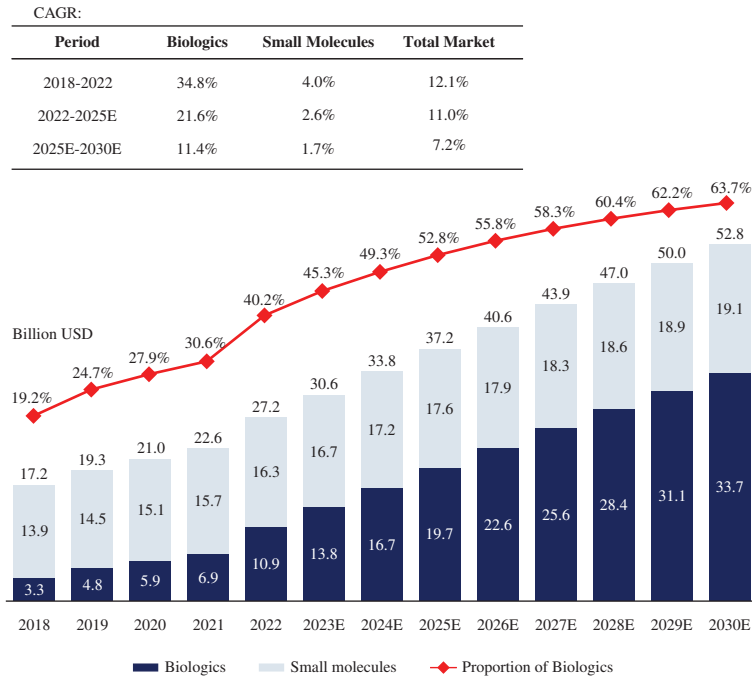


Source: Frost & Sullivan Report (based on literature review and Frost & Sullivan analysis)

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The global prevalence of asthma increased from 742.1 million in 2018 to 783.3 million in 2022, and is estimated to reach 860.1 million in 2030. The global asthma drug market grew from US\$17.2 billion in 2018 to US\$27.2 billion in 2022, representing a CAGR of 12.1%. Driven by the sales of biologic drugs, the market is estimated to reach US\$37.2 billion in 2025, representing a CAGR of 11.0% from 2022 to 2025, and is estimated to further increase to US\$52.8 billion in 2030, representing a CAGR of 7.2% from 2025 to 2030. The following table sets forth the global asthma drug market for the periods indicated.

Global Asthma Drug Market, 2018-2030E



Source: Frost & Sullivan Report (based on annual reports of relevant companies, literature review and expert interviews)

Treatment Paradigms for Asthma

The primary treatment for asthma is often long-term medications for the control and management of asthma symptoms because it is considered a chronic disease. Such long-term medications mainly include inhaled corticosteroids (ICSs) and bronchodilators, including long-acting β 2-agonist (LABA), long-acting muscarinic antagonist (LAMA), short-acting β 2-agonist (SABA), and short-acting muscarinic antagonist (SAMA). Conventional treatment options, such as corticosteroids, lack effectiveness in controlling moderate and severe asthma conditions. Moreover, the maintenance treatment of systemic corticosteroids can cause dose-dependent growth suppression and a series of severe adverse effects in children and adolescents, which leaves them with even more limited treatment options. In recent years, certain biologic drugs were introduced to treat asthma. However, as a relatively new class of drugs, they have not yet been recommended as a main treatment option for asthma by prevailing clinical guidelines. Currently, the standard of care for moderate-to-severe asthma includes ICS and LABA. The diagram below illustrates the recommended treatment pathway for adults and adolescents with moderate-to-severe asthma in China.

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		Moderate Asthma	Severe Asthma	
Preferred Controller		Low-dose ICS/LABA	Medium-dose and high-dose ICS/LABA	Add-on therapy, including tiotropium, oral corticosteroid, anti-IgE, anti-IL-4Rα and anti-IL-5 medications
Alternative Controller		Medium-dose and high-dose ICS; Low-dose ICS/LTRA (or theophylline)	Add-on tiotropium bromide; Medium-dose and high-dose ICS/LTRA (or theophylline)	—
		Anti-IL-4R α (dupilumab) and anti-IgE (omalizumab) are both approved for the treatment of moderate to severe asthma aged 12 years and older.		
Reliever Options		As-needed SABA or low-dose ICS-formoterol		

Source: Asthma Group of Chinese Thoracic Society, Literature Review, Frost & Sullivan analysis

Note:

- (1) The treatment options can be applied to adults, adolescents, and children \geq 6 years old; theophylline is not recommended for children \leq 12 years old.

Biologic drugs and candidates for asthma primarily include IgE inhibitors, IL-5 inhibitors, IL-4R α inhibitors and TSLP inhibitors. Omalizumab, an IgE inhibitor, was the first targeted biologic therapy developed and approved for severe asthma. IgE inhibitors can limit the degree of release of mediators of the allergic response by inhibiting the interaction between IgE and the IgE receptors. As IL-5 is a key signaling factor for eosinophil activation by Th2 cells and is highly expressed in eosinophilic diseases, IL-5 inhibitors have also been developed for treatment of asthma and are the most common type of biologics for treatment of asthma in the United States. An IL-4R α inhibitor, which blocks both the IL-4 and IL-13 signaling pathways, and an TSLP inhibitor, which can be effective for patients with low-level or no expression of type 2 biomarkers, subsequently obtained FDA approval for treatment of asthma.

Competitive Landscape of Biologics for Asthma Treatment in China

As of the Latest Practicable Date, there were three biologic drugs for asthma approved in China, including omalizumab, omalizumab alfa and dupilumab. As of the Latest Practicable Date, no generic or biosimilar of omalizumab, omalizumab alfa or dupilumab had been approved for the treatment of asthma in China. As of the same date, there were 31 biologic drug candidates for asthma in the clinical stage in China, including ten TSLP inhibitors, six IL-4R α inhibitors, four IL-5 inhibitors and four IgE inhibitors (including four omalizumab biosimilars), as well as drugs targeting IL-5R α , ST2 and IL-25. The following tables sets forth details of QX008N as well as the approved biologic drug and biologic drug candidates for asthma in clinical stage in China as of the Latest Practicable Date.

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Marketed Targeted Biologics for Asthma in China

Target	Brand Name	INN	Company	Median Price ⁽¹⁾	NMPA Approval Time	NRDL Inclusion
IgE	Xolair	Omalizumab	Novartis/Genentech ⁽²⁾	1,406	2017	Yes
	Aomaishu (奥邁舒)	Omalizumab alfa	Mabpharm	N/A	2023	No
IL-4Ra	Dupilixent	Dupilumab	Sanofi	3,160	2023	No ⁽³⁾

Notes:

- (1) Reflects the NRDL median price per minimum formulation unit in 2022 in RMB.
- (2) Novartis and Genentech co-develop and co-promote omalizumab. Novartis markets omalizumab outside the United States.
- (3) Dupilumab was included in 2022 NRDL for other indications.

Clinical-Stage Biologic Drug Candidates for Asthma in China

Target	Drug Code	Company	Status	First posted Date
TSLP	Tezepelumab	AstraZeneca	Phase III	2019-07-15
	TQC2731	Chia Tai Tianqing	Phase II	2022-06-21
	SHR-1905	Hengrui	Phase II	2022-09-29
	CM326	Keymed Bioscience	Phase II	2023-03-17
	QX008N	the Company	Phase I	2022-07-08
	HBM9378	Harbour Biomed; Kelun-Biotech	Phase I	2022-08-29
	LQ043	Novamab	Phase I	2023-01-13
	GR2002	Genrixbio	Phase I	2023-05-25
	STSA-1201	Staidson Biopharmaceuticals	Phase I	2023-08-01
IL-4Ra	MG-ZG122	Mabgeek	Phase I	2022-12-12
	CM310	Keymed Bioscience	Phase II/III	2023-03-08
	CBP-201	Connect Biopharmaceuticals	Phase II	2021-08-18
	GR1802	Genrix Bio	Phase II	2022-05-12
	MG-K10	Mabgeek	Phase I / II	2022-04-29
	SHR-1819	Hengrui	Phase I	2021-02-01
IL-5	LQ036	Novamab	Phase II	2024-02-04
	Mepolizumab	GSK	BLA submission	2023-03-14
	Depemokimab	GSK	Phase III	2021-09-18
	SSGJ-610	Sunshine Guojian	Phase II	2022-08-22
IL-4Ra, IL-5	SHR-1703	Hengrui	Phase II	2022-09-05
IL-4Ra, IL-5	RC1416	Regenecore	Phase I	2023-06-20
IL-5Ra	Benralizumab	AstraZeneca	Phase III	2017-07-26
IgE	Omalizumab-HS632	Hisun	Phase I	2020-04-29
	Omalizumab-SYN008	CSPC Baike	Phase I	2020-11-03
	Omalizumab-SYB507	Yuanda Shuyang	Phase I	2020-11-09
IL-25	JYB1904	Jiye Biotechnology	Phase I	2022-04-28
	XKH001	Kanova biopharma	Phase I	2022-03-07
ST2	9MW1911	Mabwell	Phase I	2021-10-13
	TQC2938	Chia Tai Tianqing	Phase I	2023-03-31
Undisclosed	Recombinant ε and γ Human Immunoglobulin Fc Fusion Protein	Kexin Biotech	Phase I	2018-11-16
	ZHB107-108	ZonHon Biopharma	Phase I	2023-11-17

Source: Frost & Sullivan Report (based on annual reports of relevant companies and information published by the NMPA)

INDUSTRY OVERVIEW

Competitive Landscape of Biologics for Asthma Treatment outside China

As of the Latest Practicable Date, there were six biologic drugs for the treatment of asthma approved by FDA, including only one TSLP-targeting biologic (tezepelumab by Amgen/AstraZeneca, approved in December 2021). As of the same date, there were 21 biologic drug candidates for asthma in clinical stage outside China, including only two TSLP inhibitors. The following tables sets forth details of the approved biologic drug and biologic drug candidates for asthma in clinical stage outside China as of the Latest Practicable Date.

FDA Approved Targeted Biologics for Asthma						
Target	Brand Name	INN	Company	Median Price ⁽¹⁾	FDA Approval Time	NRDL Inclusion
IgE	Xolair®	Omalizumab	Genentech/Novartis ⁽²⁾	1,406	2003	Yes
	Nucala®	Mepolizumab	GSK	N/A	2015	No
IL-5	Cinqair®	Reslizumab	Teva Pharmaceutical	N/A	2016	No
	Fasenra®	Benralizumab	AstraZeneca	N/A	2017	No
IL-4R α	Dupixent®	Dupilumab	Sanofi/Regeneron	3,160	2018	No ⁽³⁾
TSLP	Tezspire®	Tezepelumab	Amgen/AstraZeneca	N/A	2021	No

Notes:

- (1) Reflects the NRDL median price per minimum formulation unit for the drug’s included indication in 2022 in RMB.
- (2) Genentech and Novartis co-develop and co-promote omalizumab.
- (3) This drug has not been included in the NRDL for the treatment of asthma.

Global Clinical-Stage Biologic Drug Candidates in Asthma Treatment				
Target	Drug Code	Company	Status	First Posted Date
TSLP	SHR-1905	Atridia	Phase I	2021-03-16
	AZD8630	AstraZeneca	Phase I	2021-11-08
IL-4R α	CBP-201	Connect Biopharmaceuticals	Phase II	2021-02-26
IL-5	Depemokimab	GSK	Phase III	2021-01-22
IgE	FB825	Oneness Biotech	Phase II	2021-08-17
IL-33	Itepekimab	Sanofi/Regeneron	Phase II	2018-01-02
	Tozorakimab	AstraZeneca	Phase II	2020-09-30
IL-17A	CJM112	Novartis	Phase II	2017-10-03
Tryptase	MTPS9579A	Genentech	Phase II	2019-09-17
PSGL-1	SelK2	Tetherex Pharmaceuticals	Phase II	2020-09-07
CD4	Tregalizumab	T-Balance Therapeutics	Phase II	2020-12-17
IL-6	FB704A	Oneness Biotech	Phase II	2021-08-24
LIGHT	AVTX-002	Avalo Therapeutics	Phase II	2022-03-21
OX40L	Amlitelimab	Sanofi	Phase II	2022-06-16
CD6	Itozumab	Equillium	Phase I	2019-07-05
ST2	melrilimab	GSK	Phase I	2020-04-28
IL-17RB	SM17	SinoMab	Phase I	2022-04-18
IL-13	SAR443765	Sanofi	Phase II	2023-10-20
	Lebrikizumab	Roche	Phase III	2023-11-16
TLSPR	UPB-101	Upstream Bio	Phase I	2022-07-07
IFNG	ETH47	Ethisis	Phase I	2023-12-18

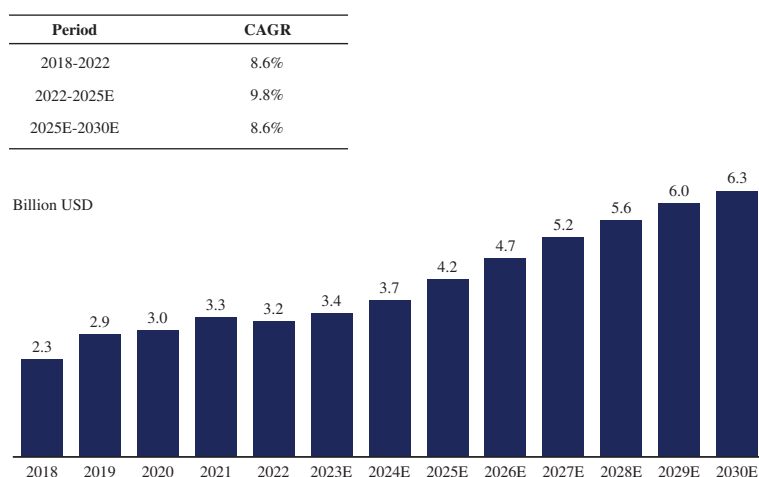
Source: Frost & Sullivan Report (based on annual reports of relevant companies and information published by the FDA)

INDUSTRY OVERVIEW

Chronic Obstructive Pulmonary Disease

Chronic obstructive pulmonary disease (COPD) is a chronic inflammatory lung disease which obstructs air flow from the lungs. The prevalence of COPD in China increased from 103.5 million in 2018 to 106.4 million in 2022, and is estimated to reach 110.7 million in 2030. The COPD drug market in China increased from US\$2.3 billion in 2018 to US\$3.2 billion in 2022, representing a CAGR of 8.6%. It is estimated to reach US\$4.2 billion in 2025, representing a CAGR of 9.8% from 2022 to 2025, and is estimated to further increase to US\$6.3 billion in 2030, representing a CAGR of 8.6% from 2025 to 2030. The following table sets forth the COPD drug market in China for the periods indicated.

COPD Drug Market in China, 2018-2030E



Source: Frost & Sullivan Report (based on annual reports of relevant companies, literature review and expert interviews)

Treatment Paradigms for COPD in China

COPD is mainly treated with drugs to prevent and control chronic inflammation and reduce clinical symptoms. Meanwhile, COPD patients can also be treated by rehabilitation, oxygen therapy and surgery. Control drugs for long-term treatment of COPD primarily include corticosteroids, including inhaled corticosteroids (ICSs) and systemic corticosteroids, long-acting bronchodilators (LABA and LAMA) and anti-inflammatory drugs, such as PDE4 inhibitors. Other drug treatments such as mucolytic, antioxidant drugs and immunomodulators can also be used to control inflammation. In the initial treatment of COPD, patients are recommended to use one type of bronchodilator. For patients with higher moderate exacerbations and more severe dyspnea, combination therapy of LABA and LAMA are recommended. For patients with higher eosinophil count, combined therapy of ICS with LABA and LAMA are recommended to improve lung function and reduce exacerbations. However, approximately 40% of moderate-to-severe COPD patients on the triple therapy of ICS with LABA and LAMA still remain uncontrolled and continue to experience exacerbations. Therefore, there are significant unmet clinical needs from COPD patients.

INDUSTRY OVERVIEW

Biologic drug candidates for COPD in China primarily include IL-4R α inhibitors, IL-5 inhibitors, ST2 inhibitors and IL-33 inhibitors. As asthma and COPD share common pathophysiological mechanisms, IL-4R α and IL-5, two of the most commonly developed targets for treatment of asthma, are also being developed as targets for treatment of COPD. Since IL-33 can induce Th2 cytokine production and promote the pathogenesis of COPD, IL-33 and its receptor, ST2, can be promising targets for the treatment of COPD as well. However, as a relatively new class of drugs, biologics have not yet been recommended as a main treatment option for COPD by prevailing clinical guidelines.

Competitive Landscape of Biologics for COPD Treatment in China

As of the Latest Practicable Date, no biologic had been approved for the treatment of COPD. As of the same date, there were seven biologic drug candidates for COPD in the clinical stage in China, including two IL-4R α inhibitors, one IL-5 inhibitor, two IL-33 inhibitors, one IL-5R α inhibitor and one ST2 inhibitor. The following table sets forth details of the biologic candidates for COPD in the clinical stage in China as of the Latest Practicable Date.

Clinical-Stage Biologic Drug Candidates for COPD in China				
Target	Drug Code	Company	Status	First Posted Date
IL-4R α	Dupilumab	Sanofi	BLA submission	2024-01-25
	SSGJ-611	Sansheng Guojian	Phase II	2023-10-12
IL-5	Mepolizumab	GSK	Phase III	2021-02-02
IL-33	Itepekimab	Sanofi	Phase III	2021-04-28
	MEDI3506	AstraZeneca	Phase III	2022-06-02
IL-5R α	Benralizumab	AstraZeneca	Phase III	2021-05-27
ST2	9MW1911	Mabwell Bioscience	Phase I/II	2023-02-14

Source: Frost & Sullivan Report (based on annual reports of relevant companies and information published by the NMPA)

Sanofi announced on March 23, 2023 that dupilumab reached the primary endpoint and all key secondary endpoints and demonstrated significant reduction in exacerbations of moderate-to-severe COPD in its Phase III clinical trial for COPD, and further announced on November 27, 2023 that dupilumab significantly reduced COPD exacerbations in its second positive Phase III clinical trial for COPD, demonstrating a potential that an IL-4R α inhibitor will become the first approved biologic drug for the effective treatment of COPD. Sanofi then completed the supplemental BLA of dupilumab in COPD in the U.S. in December 2023.

INDUSTRY OVERVIEW

SOURCE OF INFORMATION

In connection with the [REDACTED], we have commissioned Frost & Sullivan to conduct an analysis of and prepare an industry report on the global and Chinese drug market for autoimmune and allergic diseases. Frost & Sullivan is an independent global market research and consulting company which was founded in 1961 and is based in the United States. Services provided by Frost & Sullivan include market assessments, competitive benchmarking and strategic and market planning for a variety of industries. The sum of our contract with Frost & Sullivan for preparation of its report and conducting clinical audit is RMB860,000. The payment of such amount was not contingent upon our successful [REDACTED] or on the results of the report. Except for the report prepared by Frost & Sullivan, we did not commission any other industry report in connection with the [REDACTED]. Frost & Sullivan prepared its report based on its in-house database, independent third-party reports and publicly available data from reputable industry organizations. Where necessary, Frost & Sullivan contacts companies operating in the industry to gather and synthesize information in relation to the market, prices and other relevant information. Frost & Sullivan believes that the basic assumptions used in preparing its report, including those used to make future projections, are factual, correct and not misleading. Frost & Sullivan has independently analyzed the information, but the accuracy of the conclusions of its review largely relies on the accuracy of the information collected. Frost & Sullivan research may be affected by the accuracy of these assumptions and the choice of these primary and secondary sources.

REGULATORY OVERVIEW

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

PRINCIPAL REGULATORY AUTHORITIES

NMPA and Center for Drug Evaluation

National Medical Products Administration (國家藥品監督管理局) (formerly the China Food and Drug Administration (國家食品藥品監督管理總局) (the “CFDA”)) (the “NMPA”) is the department in charge of the pharmaceutical industry of China. It is responsible for drawing up the laws and regulations related to pharmaceuticals and medical devices, making policy planning, formulating departmental regulations, organizing the development and issuance of pharmaceutical and medical device standards, classification and management systems, such as national formulary, and supervising the implementation.

Center for Drug Evaluation (the “CDE”) is the technical evaluation unit for drug registration with NMPA. It is mainly responsible for conducting technical evaluation on the drugs applying for registration and verifying the relevant drug registrations.

NHC

The National Health Commission (國家衛生健康委員會) (formerly known as the National Health and Family Planning Commission (國家衛生和計劃生育委員會)) (the “NHC”), is primary national regulator for public health and family planning management. It is primarily responsible for drafting national health policies, supervising and regulating public health, healthcare services, and health emergency systems, coordinating the reform of medical and health system, organizing the formulation of national drug policies and national essential medicine system, launching an early warning mechanism for the monitoring of the use and clinical comprehensive evaluation of medicine as well as the drug shortage, giving suggestions on the pricing policy of national essential medicine, and regulating the operation of medical institutions and practicing of medical personnel.

NHSA

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

REGULATORY OVERVIEW

Ministry of Commerce

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

PRINCIPAL REGULATORY PROVISIONS

Laws and Regulations on New Drugs

Research and development of new drugs

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

Non-clinical research

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

REGULATORY OVERVIEW

Application for clinical trial

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

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

Conduct of clinical trial

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

Clinical trials must be conducted in accordance with the Good Clinical Practice for Drug Trials (《藥物臨床試驗質量管理規範》) promulgated by NMPA and NHC on April 23, 2020 and effective on July 1, 2020, which stipulates the requirements for the procedures of conducting clinical trials, including pre-clinical trial preparation, trial protocols, protection of testees’ rights and interests, duties of researchers, sponsors and monitors, as well as data management and statistical analysis.

REGULATORY OVERVIEW

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

New drug registration

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

Marketing Authorization Holder Mechanism

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

REGULATORY OVERVIEW

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

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

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

Gathering, Collection and Filing of Human Genetic Resources

In June 1998, the Ministry of Science and Technology and the Ministry of Health (which was canceled in the institutional reform of the State Council in 2013, its functions were first inherited by the National Health and Family Planning Commission and then by the NHC, which was established in 2018) promulgated the Interim Measures for the Management of Human Genetic Resources (《人類遺傳資源管理暫行辦法》) which sets out rules for the protection and use of human genetic resources in China. Pursuant to the Service Guide for Administrative Licensing of Gathering, Collection, Deal, Export and Exit Approval of Human Genetic Resources of Human genetic resources (《人類遺傳資源採集、收集、買賣、出口、出境審批行政許可事項服務指南》) promulgated by the Ministry of Science and Technology in July 2015 and the Notice on the Implementation of the Administrative License for the Gathering, Collection, Deal, Export and Exit of Human Genetic Resources (《關於實施人類遺傳資源採集、收集、買賣、出口、出境行政許可的通知》) promulgated by the Ministry of Science and Technology in August 2015, the gathering and collection of human genetic resources through clinical trials by a foreign-invested sponsor shall be filed for record with the China Human Genetic Resources Management Office through an online system. The Ministry of Science and Technology promulgated the Notice on Optimizing the Administrative Examination and Approval Process of Human Genetic Resources (《關於優化人類遺傳資源行政審批流程的通知》) in October 2017, which has simplified the approval process for the gathering and collection of human genetic resources for the marketing of drugs in China.

REGULATORY OVERVIEW

Pursuant to the Regulations on the Management of Human Genetic Resources of the People’s Republic of China (《中華人民共和國人類遺傳資源管理條例》) promulgated by the State Council in May 2019 and came into effect on July 1, 2019, the state supports the rational use of human genetic resources for scientific research, development of the biomedical industry, improvement of diagnosis and treatment technology, improvement of China’s ability to guarantee biosafety and improvement of the level of people’s health. Foreign organizations, individuals and institutions established or actually controlled by them shall not gather or preserve Chinese genetic resources in China, or provide Chinese genetic resources to foreign countries. In addition, the gathering, preservation, utilization and external provision of Chinese genetic resources shall conform to ethical principles and conduct ethical review in accordance with relevant regulations.

Regulations of Biosimilars

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

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

According to the Biosimilar Guidelines, biosimilars shall be filed under the application procedures for new drugs. Application materials for therapeutic biological products shall be submitted following specific requirements in the Biosimilar Guidelines. According to Guidelines on the Acceptance and Review for Registration of Therapeutic Biological Products (Trial) (《治療用生物製品註冊受理審查指南(試行)》), in general, therapeutic biological products under Categories 13 to 15 shall conduct Phase 3 clinical trial only and may submit plans for Phase 3 clinical trial and relevant clinical application materials.

REGULATORY OVERVIEW

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

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

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

REGULATORY OVERVIEW

The Technical Guidance for Clinical Pharmacology Studies of Biosimilars (《生物類似藥臨床藥理學研究技術指導原則》) issued by the CDE in February 2022 provides further guidance recommendations for clinical pharmacology studies of biosimilars in the framework of The Biosimilar Guidelines and the Technical Guidelines for Similarity Evaluation and Indication Extrapolation of Biosimilars, in which it is clear whether the candidate and reference drugs have similarity in clinical pharmacology needs to be evaluated based on statistical methods; currently, the average bioequivalence statistical approach is generally recommended for the comparison of PK and PD parameters.

Laws and Regulations on the Manufacturing of Drugs

Drug Manufacturing Certificate

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

Good Manufacturing Practice

Prior to December 1, 2019, pursuant to the Certification Measures for Good Manufacturing Practice for Drugs (《藥品生產質量管理規範認證管理辦法》) issued by the CFDA in August 2011, when establishing a pharmaceutical manufacturer or a new factory or expanding the production scope, the drug manufacturer is required to submit an application for a good manufacturing practice certification (the “GMP certification”) with the drug regulatory authority. If the Good Manufacturing Practices (the “GMP”) are satisfied, a GMP certificate will be issued. Pursuant to the Circular on the Relevant Issues Concerning the Implementation of the Drug Administration Law of the PRC (《關於貫徹實施<中華人民共和國藥品管理法>有關事項的公告》), promulgated by the NMPA on November 29, 2019, and the Drug Administration Law, since December 1, 2019, the GMP and Good Supply Practice (the “GSP”) certifications have been canceled, applications for GMP and GSP certifications are no longer accepted, and GMP and GSP certificates are no longer issued. The legal representative of and principal person in charge of a drug manufacturer are fully responsible for the drug manufacturing activities of the enterprise.

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

REGULATORY OVERVIEW

Contract manufacturing of drugs

Pursuant to the Administrative Regulations for the Contract Manufacturing of Drugs (《藥品委託生產監督管理規定》) (the “Contract Manufacturing Regulations”) issued by the CFDA in August 2014, only when a drug manufacturer temporarily lacks manufacturing conditions due to technology upgrade or is unable to ensure market supply due to insufficient manufacturing capabilities, can such drug manufacturer entrust the manufacturing of the drug to another domestic drug manufacturer. Such contract manufacturing arrangements shall be approved by the provincial branch of the NMPA.

The Administrative Measures on Supervision of Drug Manufacturing (《藥品生產監督管理辦法》) (the “Revised Administrative Measures of Drug Manufacturing”) promulgated by the State Administration for Market Regulation on January 22, 2020 and effective on July 1, 2020 further implements the drug marketing authorization holder system as stipulated in the Drug Administration Law. Drug marketing authorization holders entrusting others to manufacture drugs shall enter into outsourcing agreements and quality agreements with qualified drug manufacturing enterprises and submit the relevant agreements together with the actual manufacturing site application materials to the competent drug administrative authority in order to apply for the Drug Manufacturing Certificate.

Laws and Regulations on Intellectual Properties

Patent

Patents in the PRC are mainly protected by the Patent Law of the PRC (《中華人民共和國專利法》), which was promulgated by the SCNPC on March 12, 1984, last amended on October 17, 2020 and became effective on June 1, 2021, and the Implementation Rules of the Patent Law of the PRC (《中華人民共和國專利法實施細則》), which were promulgated by the State Council on June 15, 2001 and last amended on December 11, 2023 and will become effective on January 20, 2024. The Patent Law of the PRC and its Implementation Rules provide for three types of patents, “invention”, “utility model” and “design.” “Invention” refers to any new technical solution relating to a product, a process or improvement thereof; “utility model” refers to any new technical solution relating to the shape, structure, or their combination, of a product, which is suitable for practical use; and “design” refers to any new design of the shape, pattern, color or the combination of any two of them, of a product, which creates an aesthetic feeling and is suitable for industrial application. The duration of a patent right for “invention” is 20 years, the duration of a patent right for “utility model” is 10 years, and the duration of a patent right for “design” is 15 years, from the date of application. According to the Patent Law of the PRC, for the purpose of public health, the patent administrative department of the State Council may grant mandatory licensing to manufacture and export patented drugs to countries or regions in comply with provisions of the relevant international treaty participated by the PRC.

REGULATORY OVERVIEW

Trade Secret

According to the Anti-Unfair Competition Law of the PRC (《中華人民共和國反不正當競爭法》), promulgated by the SCNPC in September 1993 and last amended on April 23, 2019, the term “trade secrets” refers to technical and business information that is unknown to the public, has utility, may create business interests or profits for its legal owners or holders, and is maintained as a secret by its legal owners or holders. Under the Anti-Unfair Competition Law of the PRC, business persons are prohibited from infringing others’ trade secrets by: (1) acquiring a trade secret from the right holder by theft, bribery, fraud, coercion, electronic intrusion, or any other means; (2) disclosing, using, or allowing another person to use a trade secret acquired from the right holder by any means as specified in the item (1) above; (3) disclosing, using, or allowing another person use a trade secret in its possession, in violation of its confidentiality obligation or the requirements of the right holder for keeping the trade secret confidential; (4) abetting a person, or tempting another person into or in acquiring, disclosing, using, or allowing another person to use the trade secret of the right holder in violation of his or her non-disclosure obligation or the requirements of the right holder for keeping the trade secret confidential. If a third party knows or should have known of the above-mentioned illegal conduct but nevertheless obtains, uses or discloses trade secrets of others, the third party may be deemed to have committed a misappropriation of the others’ trade secrets. The parties whose trade secrets are being misappropriated may petition for administrative corrections, and regulatory authorities may stop any illegal activities and impose fine on the infringing parties.

Trademark

Pursuant to the Trademark Law of the PRC (《中華人民共和國商標法》) promulgated by the SCNPC on August 23, 1982, last amended on April 23, 2019 and became effective on November 1, 2019, the period of validity for a registered trademark is 10 years, commencing from the date of registration. Upon expiry of the period of validity, the registrant shall go through the formalities for renewal within twelve months prior to the date of expiry as required if the registrant needs to continue to use the trademark. Where the registrant fails to do so, a grace period of six months may be granted. The period of validity for each renewal of registration is 10 years, commencing from the day immediately after the expiry of the preceding period of validity for the trademark. In the absence of a renewal upon expiry, the registered trademark shall be canceled. Industrial and commercial administrative authorities have the authority to investigate any behavior in infringement of the exclusive right under a registered trademark in accordance with the law. In case of a suspected criminal offense, the case shall be timely referred to a judicial authority and decided in accordance with applicable laws.

REGULATORY OVERVIEW

Copyright

Copyright in the PRC is primarily protected by the Copyright Law of the PRC (《中華人民共和國著作權法》), which was promulgated by the SCNPC on September 7, 1990, last amended on November 11, 2020 and became effective on June 1, 2021, and Implementation Regulations of the Copyright Law of PRC (《中華人民共和國著作權法實施條例》), which was promulgated by the State Council on August 2, 2002 and last amended on January 30, 2013. These law and regulation provide provisions on the classification of works and the obtaining and protection of copyright.

Domain Names

In accordance with the Measures for the Administration of Internet Domain Names (《互聯網域名管理辦法》) which was issued by the Ministry of Information Industry on August 24, 2017 and came into effect on November 1, 2017, the Ministry of Industry and Information Technology is responsible for supervision and administration of domain name services in the PRC. Communications administrative bureaus at provincial levels shall conduct supervision and administration of the domain name services within their respective administrative jurisdictions. Domain name registration services shall, in principle, be subject to the principle of “first apply, first register.” A domain name registrar shall, in the process of providing domain name registration services, ask the applicant for which the registration is made to provide authentic, accurate and complete identity information on the holder of the domain name and other domain name registration related information.

Laws and Regulations on Labor and Employee Incentives

Labor, Social Insurance and Housing Provident Funds

According to the Labor Law of the PRC (《中華人民共和國勞動法》), which was promulgated by the SCNPC in July 1994 and last amended and came into effect in December 2018, the Labor Contract Law of the PRC (《中華人民共和國勞動合同法》), which was promulgated by the SCNPC in June 2007 and amended in December 2012 and came into effect in July 2013, and the Implementing Regulations of the Labor Contracts Law of the PRC (《中華人民共和國勞動合同法實施條例》), which was promulgated by the State Council and came into effect in September 2008, labor contracts in written form shall be executed to establish labor relationships between employers and employees. In addition, wages shall not be lower than local minimum wages. The employers must establish a system for labor safety and sanitation, strictly comply with national rules and standards, provide education regarding labor safety and sanitation to its employees, provide employees with labor safety and sanitation conditions and necessary protection materials in compliance with national rules, and carry out regular health examinations for employees engaged in work involving occupational hazards.

REGULATORY OVERVIEW

According to the Social Insurance Law of PRC (《中華人民共和國社會保險法》), which was promulgated by the SCNPC in October 2010 and last amended and came into effect in December 2018, and the Interim Regulations on the Collection and Payment of Social Security Funds (《社會保險費徵繳暫行條例》), which was promulgated by the State Council in January 1999 and last amended in March 2019, and the Regulations on the Administration of Housing Provident Funds (《住房公積金管理條例》), which was promulgated by the State Council in April 1999 and last amended in March 2019, employers are required to contribute, on behalf of their employees, to a number of social security funds, including funds for basic pension insurance, unemployment insurance, basic medical insurance, occupational injury insurance and maternity insurance and to housing provident funds. Any employer who fails to make the required contributions may be fined and ordered to compensate the deficit within a stipulated time limit.

The Prevention and Control of Occupational Diseases Law of the PRC (《中華人民共和國職業病防治法》), which was promulgated by the SCNPC on October 27, 2001 and latest amended on December 29, 2018 (the “Prevention and Control of Occupational Diseases Law”), is the basic law for the prevention and control of occupational diseases. According to the Prevention and Control of Occupational Diseases Law, budget for facilities for the prevention and control of occupational diseases of a construction project shall be included in the budget of the project and those facilities shall be designed, constructed and put into operation simultaneously with the main body of the project. The entity that takes charge of the project should carry out the assessment of the effectiveness of measures for the prevention and control of occupational diseases before the final acceptance of the construction project. In addition, employers shall take required administrative measures to prevent and control occupational diseases in work.

Employee Stock Incentive Plans

On February 15, 2012, SAFE issued the Circular on Issues concerning the Foreign Exchange Administration for Domestic Individuals Participating in Share Incentive Plans of Overseas Publicly Listed Companies (《關於境內個人參與境外上市公司股權激勵計劃外匯管理有關問題的通知》) (the “Share Incentive Rules”). Under the Share Incentive Rules and relevant rules and regulations, PRC citizens or non-PRC citizens residing in China for a continuous period of not less than one year, who participate in any stock incentive plan of an overseas publicly listed company, subject to a few exceptions, are required to register with SAFE through a domestic qualified agent, which could be a PRC domestic company participating in such stock incentive plan, and complete certain procedures. In addition, the STA has issued circulars concerning employee share options or restricted shares. Under these circulars, employees working in the PRC who exercise share options, or whose restricted shares vest, will be subject to PRC individual income tax. The domestic qualified agent have obligations to file documents related to employee share options or restricted shares with relevant tax authorities and to withhold individual income tax of those employees related to their share options or restricted shares. If the employees fail to pay, or the PRC domestic companies fail to withhold, their individual income tax according to relevant laws, rules and regulations, the PRC domestic companies may face sanctions imposed by the tax authorities or other relevant PRC government authorities.

REGULATORY OVERVIEW

Laws and Regulations on Environmental Protection

Environment Protection

The Environmental Protection Law of the PRC (《中華人民共和國環境保護法》) (“the Environmental Protection Law”), which was promulgated by the SCNPC on December 26, 1989, came into effect on the same day and last amended on April 24, 2014, outlines the authorities and duties of various environmental protection regulatory agencies. The Ministry of Ecology and Environment is authorized to issue national standards for environmental quality and emissions, and to monitor the environmental protection scheme of the PRC. Meanwhile, local environment protection authorities may formulate local standards which are more rigorous than the national standards, in which case, the concerned enterprises must comply with both the national standards and the local standards.

Environmental Impact Appraisal

According to the Administration Rules on Environmental Protection of Construction Projects (《建設項目環境保護管理條例》), which was promulgated by the State Council on November 29, 1998, amended on July 16, 2017 and became effective on October 1, 2017, depending on the impact of the construction project on the environment, a construction employer shall submit an environmental impact report or an environmental impact statement, or file a registration form. As to a construction project, for which an environmental impact report or the environmental impact statement is required, the construction employer shall, before the commencement of construction, submit the environmental impact report or the environmental impact statement to the relevant authority at the environmental protection administrative department for approval. If the environmental impact assessment documents of the construction project have not been examined or approved upon examination by the approval authority in accordance with the law, the construction employer shall not commence the construction. According to the Environmental Impact Appraisal Law of PRC (《中華人民共和國環境影響評價法》) (“the Environmental Impact Appraisal Law”), which was promulgated by the SCNPC on October 28, 2002, amended on July 2, 2016 and December 29, 2018, for any construction projects that have an impact on the environment, an entity is required to produce either a report, or a statement, or a registration form of such environmental impacts depending on the seriousness of effect that may be exerted on the environment.

Laws and Regulations on Foreign Investment

Since January 1, 2020, the Foreign Investment Law of the PRC (《中華人民共和國外商投資法》) (“the Foreign Investment Law”), promulgated by the NPC has come into effect. The Sino-Foreign Equity Joint Ventures Law of the PRC, the Wholly Foreign-Owned Enterprises Law of the PRC and the Sino-Foreign Cooperative Joint Ventures Law of the PRC abolished at the same time. Since then, the Foreign Investment Law has become the basic law regulating foreign-invested enterprises wholly or partially invested by foreign investors. While the organization form, institutional framework and standard of conduct of foreign-invested enterprises shall be subject to the provisions of the Company Law of the PRC and other laws.

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The PRC government will implement the management system of pre-entry national treatment and the Negative List for foreign investment abolished the original approval and filing administration system for the establishment and change of foreign-invested enterprises. Pre-entry national treatment refers to the treatment accorded to foreign investors and their investments at the stage of investment entry which is no less favorable than the treatment accorded to domestic investors and their investments. Negative List refers to a special administrative measure for the entry of foreign investment in specific sectors as imposed by the PRC. The PRC accords national treatment to foreign investment outside of the Negative List. The Negative List lists the special management measures for foreign investment access for industries regulated by the Negative List, such as equity requirements and senior management requirements.

While strengthening investment promotion and protection, the Foreign Investment Law further regulates foreign investment management and proposes the establishment of a foreign investment information reporting system that replaces the original foreign investment enterprise approval and filing system of the Ministry of Commerce. The foreign investment information reporting is subject to the Foreign Investment Information Reporting Method (《外商投資信息報告辦法》) jointly developed by the MOFCOM and the SAMR, which came into effect on January 1, 2020. According to the Foreign Investment Information Reporting Method, foreign investors who directly or indirectly carry out investment activities in China shall submit investment information to the competent commercial department through the enterprise registration system and the National Enterprise Credit Information Publicity System and the reporting methods include initial reports, change reports, cancelation reports, and annual reports.

Laws and Regulations on Foreign Exchange and Taxation

Foreign Exchange

On January 29, 1996, the State Council promulgated the Administrative Regulations on Foreign Exchange of the PRC (《中華人民共和國外匯管理條例》) which became effective on April 1, 1996 and was amended on January 14, 1997 and August 5, 2008. Foreign exchange payments under current account items shall, pursuant to the administrative provisions of the foreign exchange control department of the State Council on payments of foreign currencies and purchase of foreign currencies, be made using self-owned foreign currency or foreign currency purchased from financial institutions engaging in conversion and sale of foreign currencies by presenting the valid document. Domestic entities and domestic individuals making overseas direct investments or engaging in issuance and trading of overseas securities and derivatives shall process registration formalities pursuant to the provisions of the foreign exchange control department of the State Council.

REGULATORY OVERVIEW

On November 19, 2012, the SAFE issued the Circular of Further Improving and Adjusting Foreign Exchange Administration Policies on Foreign Direct Investment (《國家外匯管理局關於進一步改進和調整直接投資外匯管理政策的通知》) (“the SAFE Circular 59”), which came into effect on December 17, 2012 and was revised on May 4, 2015, October 10, 2018 and partially abolished on December 30, 2019. The SAFE Circular 59 aims to simplify the foreign exchange procedure and promote the facilitation of investment and trade. According to the SAFE Circular 59, the opening of various special purpose foreign exchange accounts, such as pre-establishment expenses accounts, foreign exchange capital accounts and guarantee accounts, the reinvestment of RMB proceeds derived by foreign investors in the PRC, and remittance of foreign exchange profits and dividends by a foreign-invested enterprise to its foreign shareholders no longer require the approval or verification of SAFE, as well multiple capital accounts for the same entity may be opened in different provinces. Later, the SAFE promulgated the Circular on Further Simplifying and Improving Foreign Exchange Administration Policies in Respect of Direct Investment (《關於進一步簡化和改進直接投資外匯管理政策的通知》) on February 13, 2015, which was partially abolished on December 30, 2019 and prescribed that the bank instead of SAFE can directly handle the foreign exchange registration and approval under foreign direct investment while SAFE and its branches indirectly supervise the foreign exchange registration and approval under foreign direct investment through the bank.

On May 11, 2013, the SAFE issued the Administrative Provisions on Foreign Exchange in Domestic Direct Investment by Foreign Investors (《外國投資者境內直接投資外匯管理規定》) (“the SAFE Circular 21”), which became effective on May 13, 2013, amended on October 10, 2018 and partially abolished on December 30, 2019. The SAFE Circular 21 specifies that the administration by SAFE or its local branches over direct investment by foreign investors in the PRC must be conducted by way of registration and banks must process foreign exchange business relating to the direct investment in the PRC based on the registration information provided by SAFE and its branches.

According to the Notice of the State Administration of Foreign Exchange on Issues Concerning the Foreign Exchange Administration of Overseas Listing (《國家外匯管理局關於境外上市外匯管理有關問題的通知》) issued by the SAFE on December 26, 2014, a domestic company shall, within 15 business days from the date of the end of its overseas listing issuance, register the overseas listing with the local branch office of state administration of foreign exchange at the place of its establishment; the proceeds from an overseas listing of a domestic company may be remitted to the domestic account or deposited in an overseas account, but the use of the proceeds shall be consistent with the content of the document and other disclosure documents.

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According to the Notice of the State Administration of Foreign Exchange on Reforming the Management Mode of Foreign Exchange Capital Settlement of Foreign Investment Enterprises (《國家外匯管理局關於改革外商投資企業外匯資本金結匯管理方式的通知》) (“the SAFE Circular 19”) promulgated on March 30, 2015, coming effective on June 1, 2015 and partially abolished on December 30, 2019, foreign-invested enterprises could settle their foreign exchange capital on a discretionary basis according to the actual needs of their business operations. Whilst, foreign-invested enterprises are prohibited to use the foreign exchange capital settled in RMB (a) for any expenditures beyond the business scope of the foreign-invested enterprises or forbidden by laws and regulations; (b) for direct or indirect securities investment; (c) to provide entrusted loans (unless permitted in the business scope), repay loans between enterprises (including advances by third parties) or repay RMB bank loans that have been on lent to a third party; and (d) to purchase real estate not for self-use purposes (save for real estate enterprises).

On June 9, 2016, SAFE issued the Notice of the State Administration of Foreign Exchange on Reforming and Standardizing the Foreign Exchange Settlement Management Policy of Capital Account (《國家外匯管理局關於改革和規範資本項目結匯管理政策的通知》) (“the SAFE Circular 16”), which came into effect on the same day and was partly amended according to Notice of the State Administration of Foreign Exchange on Further Deepening Reforming to Facilitate Cross-border Trade and Investment (《國家外匯管理局關於進一步深化改革促進跨境貿易投資便利化的通知》). The SAFE Circular 16 provides that discretionary foreign exchange settlement applies to foreign exchange capital, foreign debt offering proceeds and remitted foreign listing proceeds, and the corresponding RMB capital converted from foreign exchange may be used to extend loans to related parties or repay inter-company loans (including advances by third parties). However, there remain substantial uncertainties with respect to SAFE Circular 16’s interpretation and implementation in practice.

On October 23, 2019, SAFE promulgated the Notice on Further Facilitating Cross-Board Trade and Investment (《國家外匯管理局關於進一步促進跨境貿易投資便利化的通知》), which became effective on the same date (except for Article 8.2, which became effective on January 1, 2020) and was partly amended according to Notice of the State Administration of Foreign Exchange on Further Deepening Reforming to Facilitate Cross-border Trade and Investment (《國家外匯管理局關於進一步深化改革促進跨境貿易投資便利化的通知》). This notice canceled restrictions on domestic equity investments made with capital funds by non-investing foreign-funded enterprises. In addition, restrictions on the use of funds for foreign exchange settlement of domestic accounts for the realization of assets have been removed and restrictions on the use and foreign exchange settlement of foreign investors’ security deposits have been relaxed. Eligible enterprises in the pilot area are also allowed to use revenues under capital accounts, such as capital funds, foreign debts and overseas listing revenues for domestic payments without providing materials to the bank in advance for authenticity verification on an item by item basis, while the use of funds should be true, in compliance with applicable rules and conforming to the current capital revenue management regulations.

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Taxation

Enterprise Income Tax

The Enterprise Income Tax Law of the PRC (《中華人民共和國企業所得稅法》) (“the EIT Law”), promulgated by the NPC on March 16, 2007, came into effect on January 1, 2008 and amended on February 24, 2017 and December 29, 2018, as well as the Implementation Rules of the EIT Law (《中華人民共和國企業所得稅法實施條例》) (“the Implementation Rules”), promulgated by the State Council on December 6, 2007, came into force on January 1, 2008 and amended on April 23, 2019, are the principal law and regulation governing enterprise income tax in the PRC. According to the EIT Law and its Implementation Rules, enterprises are classified into resident enterprises and non-resident enterprises. Resident enterprises refer to enterprises that are legally established in the PRC, or are established under foreign laws but whose actual management bodies are located in the PRC. And non-resident enterprises refer to enterprises that are legally established under foreign laws and have set up institutions or sites in the PRC but with no actual management body in the PRC, or enterprises that have not set up institutions or sites in the PRC but have derived incomes from the PRC. A uniform income tax rate of 25% applies to all resident enterprises and non-resident enterprises that have set up institutions or sites in the PRC to the extent that such incomes are derived from their set-up institutions or sites in the PRC, or such income are obtained outside the PRC but have an actual connection with the set-up institutions or sites. And non-resident enterprises that have not set up institutions or sites in the PRC or have set up institutions or sites but the incomes obtained by the said enterprises have no actual connection with the set-up institutions or sites, shall pay enterprise income tax at the rate of 10% in relation to their income sources from the PRC.

Value-Added Tax (the “VAT”)

The major PRC law and regulation governing value-added tax are the Interim Regulations on Value-added Tax of the PRC (《中華人民共和國增值稅暫行條例》) issued on December 13, 1993 by the State Council, came into effect on January 1, 1994, and revised on November 10, 2008, February 6, 2016 and November 19, 2017, as well as the Implementation Rules for the Interim Regulations on Value-Added Tax of the PRC (《中華人民共和國增值稅暫行條例實施細則》) issued on December 25, 1993 by the Ministry of Finance (中華人民共和國財政部) (the “MOF”), came into effect on the same day and revised on December 15, 2008 and October 28, 2011, any entities and individuals engaged in the sale of goods, supply of processing, repair and replacement services, and import of goods within the territory of the PRC are taxpayers of VAT and shall pay the VAT in accordance with the law and regulation. The rate of VAT for sale of goods is 17% unless otherwise specified, such as the rate of VAT for sale of transportation is 11%. With the VAT reforms in the PRC, the rate of VAT has been changed several times. The MOF and the STA issued the Notice of on Adjusting VAT Rates (《財政部、國家稅務總局關於調整增值稅稅率的通知》) on April 4, 2018 to adjust the tax rates of 17% and 11% applicable to any taxpayer’s VAT taxable sale or import of goods to 16% and 10%, respectively, this adjustment became effect on May 1, 2018. Subsequently, the MOF, the STA and the General Administration of Customs jointly issued the Announcement on

REGULATORY OVERVIEW

Relevant Policies for Deepening the VAT Reform (《財政部、國家稅務總局關於深化增值稅改革有關政策的公告》) on March 20, 2019 to make a further adjustment, which came into effect on April 1, 2019. The tax rate of 16% applicable to the VAT taxable sale or import of goods shall be adjusted to 13%, and the tax rate of 10% applicable thereto shall be adjusted to 9%.

Laws and Regulations on Overseas Securities Offering and Listing by Domestic Companies

On February 17, 2023, the CSRC promulgated the 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”) and relevant supporting guidelines, which came into effect on March 31, 2023. The Overseas Listing Trial Measures comprehensively improves and reforms the existing regulatory regime for overseas offering and listing of PRC domestic companies’ securities and regulates both direct and indirect overseas offering and listing of PRC domestic companies’ securities. Any domestic company that is deemed to conduct overseas offering and listing activities shall file with the CSRC in accordance with the Overseas Listing Trial Measures.

The Overseas Listing Trial Measures provide that the overseas securities offering and listing will be considered a direct overseas offering by a PRC domestic company if the issuer is a company limited by shares registered and established in mainland China. In addition, the overseas securities offering and listing will be considered an indirect overseas offering by a PRC domestic company if the issuer meets both of the following criteria: (i) 50% or more of any of the issuer’s operating revenue, total profit, total assets or net assets as documented in its audited consolidated financial statements for the most recent fiscal year is accounted for by a domestic company; and (ii) the main parts of the issuer’s business activities are conducted in mainland China, or its main place(s) of business are located in mainland China, or the majority of senior management staff in charge of its business operations and management are PRC citizens or have their usual place(s) of residence located in mainland China.

Pursuant to the Overseas Listing Trial Measures, an issuer shall file with the CSRC within three business days after its application for initial public offering is submitted to competent overseas securities regulators.

H-share Full Circulation

“Full circulation” means listing and circulating on the stock exchange of the domestic unlisted shares of an H-share listed company, including unlisted domestic shares held by domestic shareholders prior to overseas listing, unlisted domestic shares additionally issued after overseas listing, and unlisted shares held by foreign shareholders. On November 14, 2019, the CSRC issued the Guidelines for the “Full Circulation” Program for Domestic Unlisted Shares of H-share Listed Companies (《H股公司境內未上市股份申請“全流通”業務指引》)

REGULATORY OVERVIEW

(the “Guidelines for the Full Circulation”), which was partly revised on August 10, 2023 according to the Decision on Revising and Abolishing Part of Securities and Futures Policy Documents by CSRC (《中國證券監督管理委員會關於修改、廢止部分證券期貨制度文件的決定》).

According to the Guidelines for the Full Circulation, shareholders of domestic unlisted shares may determine by themselves through consultation the amount and proportion of shares, for which an application will be filed for circulation, provided that the requirements laid down in the relevant laws and regulations and set out in the policies for state-owned asset administration, foreign investment and industry regulation are met, and the corresponding H-share listed company may be entrusted to file the said application for full circulation. To apply for full circulation, an H-share listed company shall file the application with the CSRC according to the administrative filing procedures necessary for the Overseas Listing Trial Measures. After the filing with the CSRC for full circulation has been completed, the H-share listed company shall submit a report on the relevant situation to the CSRC within 15 days after the registration with CSDCC of the shares related to the application has been completed.

On December 31, 2019, CSDCC and the Shenzhen Stock Exchange (“SZSE”) jointly announced the Measures for Implementation of H-share Full Circulation Business (《H股“全流通”業務實施細則》) (the “Measures for Implementation”). The businesses in relation to the H-share full circulation business, such as cross-border transfer registration, maintenance of deposit and holding details, transaction entrustment and instruction transmission, settlement, management of settlement participants, services of nominal holders, etc. are subject to the Measures for Implementation.

In order to fully promote the reform of H-share full circulation and clarify the business arrangement and procedures for the relevant shares’ registration, custody, settlement and delivery, CSDCC promulgated the Guide to the Program for Full Circulation of H-shares (《H股“全流通”業務指南》) on February 7, 2020, which specifies the business preparation, account arrangement, cross-border share transfer registration and overseas centralized custody, and other relevant matters. In February 2020, China Securities Depository and Clearing (Hong Kong) Limited (“CSDC (Hong Kong)”) also promulgated the Guide of China Securities Depository and Clearing (Hong Kong) Limited to the Program for Full Circulation of H-shares to specify the relevant escrow, custody, agent service, arrangement for settlement and delivery, risk management measures and other relevant matters.

According to the Measures for Implementation and the Guide to the Program for Full Circulation of H-shares, shareholders who apply for H Share Full Circulation (“Participating Shareholders”) shall complete the cross-border transfer registration for conversion of relevant domestic unlisted shares into H Shares before dealing in the shares, i.e., CSDCC as the nominal shareholder, deposits the relevant securities held by Participating Shareholders at CSDC (Hong Kong), and CSDC (Hong Kong) will then deposit the securities at HKSCC in its own name, and exercise the rights to the securities issuer through HKSCC, while HKSCC Nominees as the ultimate nominal shareholder is listed on the register of shareholders of H-share listed companies.

REGULATORY OVERVIEW

According to the Guide to the Program for Full Circulation of H-shares, H-share listed companies shall be authorized by Participating Shareholders to designate the only domestic securities company (“Domestic Securities Company”) to participate in the transaction of converted H shares. The specific procedure is as follows:

Participating Shareholders submit trading orders of the converted H Shares through the Domestic Securities Company, which transmits the orders to the Hong Kong Securities Company designated by the Domestic Securities Company through Shenzhen Securities Communications Co., Ltd.; and Hong Kong Securities Company conducts corresponding securities transactions in the Hong Kong market in accordance with the aforementioned trading orders and the rules of the Stock Exchange.

According to the Guide to the Program for Full Circulation of H-shares, upon the completion of the transaction, settlements between each of the Hong Kong Securities Company and CSDC (Hong Kong), CSDC (Hong Kong) and CSDCC, CSDCC and the Domestic Securities Company, and the Domestic Securities Company and the Participating Shareholders, will all be conducted separately.

HISTORY AND CORPORATE STRUCTURE

OVERVIEW

We are a clinical-stage biotech company exclusively focused on biologic therapies for autoimmune and allergic diseases. Leveraging our integrated R&D and manufacturing platform, we have built a broad pipeline that covers the four major disease areas in the field, including skin, rheumatic, respiratory and digestive diseases.

Our history can be traced back to June 2015, when our Company was established by Mr. Qiu, our founder, and Mr. Yu Guo’an, our founding investor, in Taizhou as a limited liability company under the PRC Company Law, through entities controlled and/or owned by them. For further details of Mr. Qiu, see “Directors, Supervisors and Senior Management” in this document. For further details of Mr. Yu Guo’an, see “Relationship with our Controlling Shareholders” in this document.

KEY MILESTONES

The following table sets forth the key milestones of our corporate and business development.

<u>Year</u>	<u>Milestone events</u>
2015	Our Company was established in Taizhou, the PRC in June 2015. We completed the Pre-Series A Financing and raised RMB14 million in November 2015.
2016	We completed the Series A Financing and raised RMB120 million in March 2016.
2018	We received IND approval of QX001S from the NMPA for the treatment of moderate-to-severe plaque Ps in China in January 2018. Cellularforce, our CMC-focused subsidiary, was established in Taizhou, the PRC in August 2018.
2019	We received IND approval of QX002N* from the NMPA for the treatment of active AS in adults in China in April 2019.
2020	We completed the Phase I clinical trial of QX001S for the treatment of Ps in China in May 2020. We completed the Series B Financing and raised RMB230 million in May 2020.

HISTORY AND CORPORATE STRUCTURE

<u>Year</u>	<u>Milestone events</u>
	<p>We received IND approval of QX005N* from the NMPA for the treatment of moderate-to-severe AD in adults in China in June 2020.</p> <p>We entered into a collaboration agreement in August 2020 with Zhongmei Huadong, a subsidiary of Huadong Medicine, with respect to the joint development and commercialization of QX001S in the PRC.</p> <p>We completed the Series B+ Financing and raised RMB370 million in October 2020.</p>
2021	<p>We completed the Series B++ Financing and raised RMB300 million in April 2021.</p> <p>We received IND approvals from the NMPA for: (i) QX004N for the treatment of Ps in August 2021; (ii) QX006N for the treatment of SLE in September 2021; and (iii) QX005N* for the treatment of CRSwNP in November 2021.</p> <p>Our Company was converted from a limited liability company into a joint stock company with limited liability in September 2021.</p> <p>We completed the Phase Ia clinical trial of QX002N* for the treatment of AS in China in September 2021.</p>
2022	<p>We received IND approvals from the NMPA for: (i) QX005N* for the treatment of CSU in January 2022; (ii) QX005N* for the treatment of PN in March 2022; (iii) QX008N for the treatment of asthma in May 2022; (iv) QX008N for the treatment of moderate-to-severe COPD in May 2022; (v) QX005N* for the treatment of moderate-to-severe asthma in February 2022; and (vi) QX004N for the treatment of Crohn’s disease in November 2022. We also received an IND approval from the FDA for QX008N for the treatment of severe asthma in September 2022.</p> <p>We initiated the Phase II clinical trial of QX002N* for the treatment of AS in China in January 2022.</p> <p>We completed the Series C Financing and raised RMB227.5 million in March 2022.</p> <p>We initiated the Phase II clinical trial of QX005N* for the treatment of AD in China in September 2022.</p>

HISTORY AND CORPORATE STRUCTURE

<u>Year</u>	<u>Milestone events</u>
	<p>We completed the Phase Ib clinical trial of QX002N* for the treatment of AS in China in September 2022.</p>
	<p>We completed patient enrollment for the Phase II clinical trial of QX002N* for the treatment of AS in China in September 2022.</p>
2023	<p>We completed the Phase Ia clinical trial of QX005N* in healthy subjects in China in January 2023.</p> <p>We commenced a Phase II clinical trial in adult patients with PN in China for QX005N* for the treatment of PN in February 2023.</p> <p>We completed subject enrollment for our Phase II clinical trial of QX005N* for the treatment of AD in China in February 2023.</p> <p>We completed the Phase Ib clinical trial of QX005N* for the treatment of AD in China in February 2023.</p> <p>We commenced a Phase II clinical trial in adult patients with CRSwNP in China for QX005N* for the treatment of CRSwNP in April 2023.</p> <p>We completed subject enrollment for our Phase II clinical trial of QX005N* for the treatment of PN in China in May 2023.</p> <p>Zhongmei Huadong and we completed the Phase III clinical trial of QX001S in patients with moderate-to-severe plaque Ps in China for the treatment of moderate-to-severe plaque Ps in June 2023.</p> <p>Zhongmei Huadong, our commercialization partner for QX001S, submitted a BLA in China in July 2023, which was accepted by the NMPA in August 2023.</p> <p>We completed the Phase II clinical trial of QX002N* for the treatment of AS in China in August 2023.</p> <p>We initiated the Phase III clinical trial of QX002N* for the treatment of AS in China in September 2023.</p> <p>We received IND approvals from the NMPA for QX005N*: (i) for the treatment of COPD in September 2023; and (ii) for the treatment of AD in adolescents aged between 12 and 17 years in October 2023.</p>

HISTORY AND CORPORATE STRUCTURE

<u>Year</u>	<u>Milestone events</u>
2024	<p>We entered into a technology transfer agreement in January 2024 with Joincare Pharmaceutical Group Industry Co., Ltd. (“Joincare”), to grant Joincare an exclusive license to develop, manufacture and commercialize QX008N in mainland China, Hong Kong and Macau.</p> <p>Our QX005N* received the breakthrough therapy designation for the treatment of PN from the CDE in January 2024.</p>

* Core Product

OUR CORPORATE DEVELOPMENTS

Establishment and major shareholding changes of our Company

Our Company was established in Taizhou, the PRC as a limited liability company on June 16, 2015 with an initial registered capital of RMB50,000,000, of which RMB40,000,000 was paid up by Hangzhou Quanyi on July 14, 2015 with the remaining balance to be paid up by Hangzhou Quanli pursuant to the articles of association of our Company. As of the date of its establishment, our Company was owned as to 80% by Hangzhou Quanyi, a general partnership owned as to 50% by Mr. Qiu and 50% by Mr. Yu Guo’an, both being its general partners acting in concert, and 20% by Hangzhou Quanli, one of our original employee incentive platforms owned as to 1% by Mr. Qiu as its general partner and 99% by Mr. Yu Guo’an as its limited partner. Our Company is principally engaged in discovery of antibody drugs, antibody screening, preclinical and clinical development, registration and other regulatory affairs of our drug candidates, and is also responsible for the future sales and marketing activities of our Group. Our Company has not recorded any revenue for the two years ended December 31, 2022 and the nine months ended September 30, 2023 and the loss for the corresponding periods was approximately RMB379.93 million, RMB266.80 million and RMB353.51 million, respectively.

Since its establishment, our Company has undertaken a series of capital increases to raise funds for the development of its business and to bring in new shareholders to our Company. The major shareholding changes of our Company are set out below.

1. Pre-Series A Financing

Pursuant to (i) the capital increase agreement dated October 14, 2015 entered into among our Company, Hangzhou Quanyi, Hangzhou Quanli and Shenzhen Qianhai Efung Taihe Equity Investment Fund Enterprise (Limited Partnership) (深圳市前海倚鋒太和股權投資基金企業(有限合夥)) (“Qianhai Efung”); (ii) the capital increase agreement dated October 15, 2015 entered into among our Company, Hangzhou Quanyi, Hangzhou Quanli and Nanjing Yuzhuhua Pharmaceutical Technology Partnership (Limited Partnership) (南京裕之華醫藥科技合夥企業(有限合夥)) (“Nanjing Yuzhuhua”); and (iii) the capital increase agreement dated November 5, 2015 entered into among our Company, Hangzhou Quanyi, Hangzhou Quanli and Shanghai Quanyou (Qianhai Efung, Nanjing Yuzhuhua and Shanghai Quanyou are collectively referred to as the “Pre-Series A Investors”), the Pre-Series A Investors agreed to make a total capital

HISTORY AND CORPORATE STRUCTURE

contribution of RMB14,000,000 to our Company (the “Pre-Series A Financing”), among which RMB10,000,000 was contributed to the registered capital of our Company and RMB4,000,000 was contributed to the capital reserve of our Company, details of which are set out below:

<u>Name of [REDACTED] Investors</u>	<u>Registered capital subscribed for</u>	<u>Consideration</u>	<u>Date of full settlement of consideration in cash</u>
	(RMB)	(RMB)	
Qianhai Efung	3,000,000	4,200,000	October 30, 2015
Nanjing Yuzhuhua ⁽¹⁾	2,000,000	2,800,000	October 30, 2015
Shanghai Quanyou	5,000,000	7,000,000	November 30, 2015
Total	10,000,000	14,000,000	

Note:

- (1) Formerly known as Nanjing Huayuxiang Asset Management Center (General Partnership) (南京華裕祥資產管理中心(普通合夥)).

The consideration of the Pre-Series A Financing was determined based on arm’s length negotiations between our Company and the Pre-Series A Investors with reference to, among others, the substantial investment made by our founder, the value of our management team with extensive industry experience and our long-term development strategies and potential. For further details of the Pre-Series A Financing and the background information of the Pre-Series A Investors, see “[REDACTED] Investments” below.

Upon completion of the Pre-Series A Financing, the registered capital of our Company was increased from RMB50,000,000 to RMB60,000,000 and the shareholding structure of our Company was as follows:

<u>Name of Shareholders</u>	<u>Registered capital</u>	<u>Approximate equity interest percentage held</u>
	(RMB)	
Hangzhou Quanyi	40,000,000	66.67%
Hangzhou Quanli	10,000,000	16.67%
Shanghai Quanyou	5,000,000	8.33%
Qianhai Efung	3,000,000	5.00%
Nanjing Yuzhuhua	2,000,000	3.33%
Total	60,000,000	100.00%

HISTORY AND CORPORATE STRUCTURE

2. Series A Financing

Pursuant to the capital increase agreement dated January 18, 2016 entered into among our Company, Taizhou China Medical City Rongjianda Venture Capital Co., Ltd. (泰州中國醫藥城融健達創業投資有限公司) (“Rongjianda”), Taizhou Jianxin Venture Capital Co., Ltd. (泰州健鑫創業投資有限公司) (“Taizhou Jianxin”), Qianhai Efung, Nanjing Tongren Boda Equity Investment Center (Limited Partnership) (南京同人博達股權投資中心(有限合夥)) (“Tongren Boda”) and Shanghai Shuochen Investment Management Co., Ltd. (上海碩臣投資管理有限公司) (“Shanghai Shuochen”, together with Rongjianda, Taizhou Jianxin, Qianhai Efung and Tongren Boda are collectively referred to as the “Series A Investors”), the Series A Investors agreed to make a total capital contribution of RMB120,000,000 to our Company (the “Series A Financing”), among which RMB30,000,000 was contributed to the registered capital of our Company and RMB90,000,000 was contributed to the capital reserve of our Company, details of which are set out below:

Name of [REDACTED] Investors	Registered capital subscribed for	Consideration	Date of full settlement of consideration in cash
	<i>(RMB)</i>	<i>(RMB)</i>	
Rongjianda	7,500,000	30,000,000	January 28, 2016
Taizhou Jianxin	7,500,000	30,000,000	January 28, 2016
Qianhai Efung	5,000,000	20,000,000	March 29, 2016
Tongren Boda	5,000,000	20,000,000	March 22, 2016
Shanghai Shuochen	5,000,000	20,000,000	March 29, 2016
Total	30,000,000	120,000,000	

The consideration of the Series A Financing was determined based on the valuation of the equity interests of our Company as of December 31, 2015 according to a valuation report dated January 10, 2016 issued by an independent valuer. For further details of the Series A Financing and the background information of the Series A Investors, see “[REDACTED] Investments” below.

HISTORY AND CORPORATE STRUCTURE

Upon completion of the Series A Financing, the shareholding structure of our Company was as follows:

Name of Shareholders	Registered capital (RMB)	Approximate equity interest percentage held
Hangzhou Quanyi	40,000,000	44.44%
Hangzhou Quanli	10,000,000	11.11%
Qianhai Efung	8,000,000	8.89%
Rongjianda	7,500,000	8.33%
Taizhou Jianxin	7,500,000	8.33%
Shanghai Quanyou	5,000,000	5.56%
Tongren Boda	5,000,000	5.56%
Shanghai Shuo Chen	5,000,000	5.56%
Nanjing Yuzhifeng	2,000,000	2.22%
Total	90,000,000	100.00%

3. *Capital increase and subscription by Taizhou Quanli*

Pursuant to a written resolution of our then Shareholders passed on August 22, 2018, the registered capital of our Company was increased from RMB90,000,000 to RMB110,000,000. The increased registered capital of RMB20,000,000 was subscribed by Taizhou Quanli at a consideration of RMB80,000,000, among which RMB20,000,000 was contributed to the registered capital of our Company and RMB60,000,000 was contributed to the capital reserve of our Company. Taizhou Quanli was established on August 17, 2018 as one of our original employee incentive platforms, which was owned as to 1% by Mr. Qiu as its general partner and 99% by Mr. Wu Yiliang (吳亦亮), our executive Director and executive deputy general manager of Cellularforce, as its limited partner. Due to the re-establishment of our Employee Share Incentive Scheme and the shareholding platform thereunder, Taizhou Quanli had not actually paid up such consideration and it ceased to be a shareholder of our Company on June 11, 2021. Taizhou Quanli was subsequently deregistered on February 18, 2022. For further details of the cessation of Taizhou Quanli as our Shareholder and the re-establishment of our Employee Share Incentive Scheme, see “—9. Capital decrease” and “—Employee Share Incentive Scheme” below.

HISTORY AND CORPORATE STRUCTURE

4. Series B Financing

Pursuant to (i) the capital increase agreements dated April 10, 2019 entered into among our Company, Mr. Qiu, Mr. Yu Guo’an, our then Shareholders, Taizhou Hongtai Health Investment Management Center (Limited Partnership) (泰州洪泰健康投資管理中心(有限合夥)) (“Hongtai Health”), Suzhou Hefu Ruitai Equity Investment Center (Limited Partnership) (蘇州合富瑞泰股權投資中心(有限合夥)) (“Hefu Ruitai”) and Shenzhen Triwise Rozman Phase II Investment Partnership (Limited Partnership) (深圳勤智羅茲曼二期投資合夥企業(有限合夥)) (“Triwise Rozman”); and (ii) the written confirmation dated November 8, 2019 signed by Shenzhen Triwise Kangxin Venture Capital Partnership (Limited Partnership) (深圳勤智康信創業投資合夥企業(有限合夥)) (“Shenzhen Triwise Kangxin”), a limited partnership under the common control with Triwise Rozman, for its subscription of the registered capital of RMB1,250,000 of our Company, Hongtai Health, Hefu Ruitai, Triwise Rozman and Shenzhen Triwise Kangxin agreed to make a total capital contribution of RMB200,000,000 to our Company, among which RMB25,000,000 was contributed to the registered capital of our Company and RMB175,000,000 was contributed to the capital reserve of our Company, details of which are set out below:

Name of [REDACTED] Investors	Registered capital subscribed for	Consideration	Date of full settlement of consideration in cash
	(RMB)	(RMB)	
Hongtai Health	18,750,000	150,000,000	June 11, 2019
Hefu Ruitai	3,750,000	30,000,000	March 28, 2019
Triwise Rozman	1,250,000	10,000,000	May 29, 2019
Shenzhen Triwise Kangxin	1,250,000	10,000,000	November 18, 2019
Total	25,000,000	200,000,000	

Such consideration was determined based on the valuation of the equity interests of our Company as of February 28, 2019 according to a valuation report dated March 16, 2019 issued by an independent valuer.

Pursuant to the capital increase agreement dated April 15, 2020 entered into among our Company, Mr. Qiu, Mr. Yu Guo’an, our then Shareholders, Shenzhen Lucky-source III Venture Capital Center (Limited Partnership) (深圳瑞享源三號創業投資中心(有限合夥)) (“Lucky-source III”) and Gongqingcheng Jiayin Ruixin Investment Management Partnership (Limited Partnership) (共青城佳銀瑞鑫投資管理合夥企業(有限合夥)) (“Jiayin Ruixin”, together with Hongtai Health, Hefu Ruitai, Triwise Rozman, Shenzhen Triwise Kangxin and Lucky-source III are collectively referred to as the “Series B Investors”), each of Lucky-source III and Jiayin Ruixin agreed to make a capital contribution of RMB20,000,000 and RMB10,000,000 to our Company, among which RMB2,500,000 and RMB1,250,000 were contributed to the registered capital of our Company and RMB17,500,000 and RMB8,750,000 were contributed to the capital reserve of our Company, respectively. The consideration was determined based on the

HISTORY AND CORPORATE STRUCTURE

valuation of the equity interests of our Company as of March 31, 2020 according to a valuation report dated April 5, 2020 issued by an independent valuer and our future prospect, and was fully settled on May 22, 2020. For further details of the Series B Financing and the background information of the Series B Investors, see “[REDACTED] Investments” below.

Upon completion of the Series B Financing, the shareholding structure of our Company was as follows:

Name of Shareholders	Registered capital (RMB)	Approximate equity interest percentage held
Hangzhou Quanyi	40,000,000	28.83%
Taizhou Quanli	20,000,000	14.41%
Hongtai Health	18,750,000	13.51%
Hangzhou Quanli	10,000,000	7.21%
Qianhai Efung	8,000,000	5.77%
Rongjianda	7,500,000	5.41%
Taizhou Jianxin	7,500,000	5.41%
Shanghai Quanyou	5,000,000	3.60%
Tongren Boda	5,000,000	3.60%
Shanghai Shuochen	5,000,000	3.60%
Hefu Ruitai	3,750,000	2.70%
Lucky-source III	2,500,000	1.80%
Nanjing Yuzhijia	2,000,000	1.44%
Triwise Rozman	1,250,000	0.90%
Shenzhen Triwise Kangxin	1,250,000	0.90%
Jiayin Ruixin	1,250,000	0.90%
Total	<u>138,750,000</u>	<u>100.00%</u>

Note: Equity interest percentages may not add up to 100% due to rounding.

5. Equity transfer by Qianhai Efung

Pursuant to the equity transfer agreement dated May 14, 2020 entered into among Qianhai Efung, Shenzhen Lucky-source IV Venture Capital Center (Limited Partnership) (深圳瑞享源肆號創業投資中心(有限合夥)) (“Lucky-source IV”) and our Company, Qianhai Efung agreed to transfer approximately 3.24% of the then equity interest in our Company held by it to Lucky-source IV at a consideration of RMB30,000,000, which was determined based on arm’s length negotiations between Qianhai Efung and Lucky-source IV with reference to, among others, the post-money valuation of our Company upon completion of the Series B Financing, and was fully settled on June 10, 2020. For further details of such equity interest transfer and the background information of Lucky-source IV, see “[REDACTED] Investments” below.

HISTORY AND CORPORATE STRUCTURE

6. Series B+ Financing

Pursuant to the capital increase agreement dated August 14, 2020 entered into among our Company, Mr. Qiu, Mr. Yu Guo’an, our then Shareholders and Zhongmei Huadong (the “Series B+ Investor”), Zhongmei Huadong agreed to make a capital contribution of RMB370,000,000 to our Company, among which RMB35,900,000 was contributed to the registered capital of our Company and RMB334,100,000 was contributed to the capital reserve of our Company (the “Series B+ Financing”). Such consideration was determined based on the valuation of the equity interests of our Company as of June 30, 2020 according to a valuation report dated August 1, 2020 issued by an independent valuer and our future prospect, and was fully settled on October 9, 2020. For further details of the Series B+ Financing and the background information of Zhongmei Huadong, see “[REDACTED] Investments” below.

Upon completion of the Series B+ Financing, the shareholding structure of our Company was as follows:

Name of Shareholders	Registered capital (RMB)	Approximate equity interest percentage held
Hangzhou Quanyi	40,000,000	22.90%
Zhongmei Huadong	35,900,000	20.56%
Taizhou Quanli	20,000,000	11.45%
Hongtai Health	18,750,000	10.74%
Hangzhou Quanli	10,000,000	5.73%
Rongjianda	7,500,000	4.29%
Taizhou Jianxin	7,500,000	4.29%
Shanghai Quanyou	5,000,000	2.86%
Tongren Boda	5,000,000	2.86%
Shanghai Shuochen	5,000,000	2.86%
Lucky-source IV	4,500,000	2.58%
Hefu Ruitai	3,750,000	2.15%
Qianhai Efung	3,500,000	2.00%
Lucky-source III	2,500,000	1.43%
Nanjing Yuzhuhua	2,000,000	1.15%
Triwise Rozman	1,250,000	0.72%
Shenzhen Triwise Kangxin	1,250,000	0.72%
Jiayin Ruixin	1,250,000	0.72%
Total	174,650,000	100.00%

Note: Equity interest percentages may not add up to 100% due to rounding.

HISTORY AND CORPORATE STRUCTURE

7. Series B++ Financing

Pursuant to the capital increase agreement dated April 2, 2021 entered into among our Company, Saifu Juli, Mr. Qiu, Mr. Yu Guo’an, our then Shareholders, Matrix Partners China VI Hong Kong Limited (“Matrix Partners VI”), Suzhou Guanhong Venture Capital Center (Limited Partnership) (蘇州冠鴻創業投資中心(有限合夥)) (“Suzhou Guanhong”), Xinyu Tongchuang Guosheng Science and Innovation Industry Investment Partnership (Limited Partnership) (新余市同創國盛科創產業投資合夥企業(有限合夥)) (“Cowin Guosheng”), Everest No. 37 (Shenzhen) Venture Capital Center (Limited Partnership) (朗瑪三十七號(深圳)創業投資中心(有限合夥)) (“Everest No. 37”), Shenzhen Triwise Detai New Technology Venture Capital Enterprise (Limited Partnership) (深圳勤智德泰新科技創業投資企業(有限合夥)) (“Triwise Detai”), Shenzhen Yuanzhi Fuhai New Industry II Investment Enterprise (Limited Partnership) (深圳遠致富海新興產業二期投資企業(有限合夥)) (“Yuanzhi Fuhai”) and Lucky-source III (Matrix Partners VI, Suzhou Guanhong, Cowin Guosheng, Everest No. 37, Triwise Detai, Yuanzhi Fuhai and Lucky-source III are collectively referred to as the “Series B++ Investors”), the Series B++ Investors agreed to make a total capital contribution of RMB300,000,000 to our Company (the “Series B++ Financing”), among which RMB21,830,000 was contributed to the registered capital of our Company and RMB278,170,000 was contributed to the capital reserve of our Company, details of which are set out below:

Name of [REDACTED] Investors	Registered capital subscribed for	Consideration	Date of full settlement of consideration in cash
	(RMB)	(RMB)	
Matrix Partners VI	10,920,000	150,000,000	April 26, 2021
Suzhou Guanhong	6,540,000	90,000,000	April 15, 2021
Cowin Guosheng	1,450,000	20,000,000	April 26, 2021
Everest No. 37	730,000	10,000,000	April 20, 2021
Triwise Detai	730,000	10,000,000	April 23, 2021
Yuanzhi Fuhai	730,000	10,000,000	April 22, 2021
Lucky-source III	730,000	10,000,000	April 23, 2021
Total	21,830,000	300,000,000	

The consideration of the Series B++ Financing was determined based on our products under development, our research and development capabilities, the milestones our Company has achieved or expects to achieve and the market condition at the material time. For further details of the Series B++ Financing and the background information of the Series B++ Investors, see “[REDACTED] Investments” below.

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Upon completion of the Series B++ Financing, the shareholding structure of our Company was as follows:

<u>Name of Shareholders</u>	<u>Registered capital</u> <i>(RMB)</i>	<u>Approximate equity interest percentage held</u>
Hangzhou Quanyi	40,000,000	20.36%
Zhongmei Huadong	35,900,000	18.27%
Taizhou Quanli	20,000,000	10.18%
Hongtai Health	18,750,000	9.54%
Matrix Partners VI	10,920,000	5.56%
Hangzhou Quanli	10,000,000	5.09%
Rongjianda	7,500,000	3.82%
Taizhou Jianxin	7,500,000	3.82%
Suzhou Guanhong	6,540,000	3.33%
Shanghai Quanyou	5,000,000	2.54%
Tongren Boda	5,000,000	2.54%
Shanghai Shuo Chen	5,000,000	2.54%
Lucky-source IV	4,500,000	2.29%
Hefu Ruitai	3,750,000	1.91%
Qianhai Efung	3,500,000	1.78%
Lucky-source III	3,230,000	1.64%
Nanjing Yuzhijia	2,000,000	1.02%
Cowin Guosheng	1,450,000	0.74%
Triwise Rozman	1,250,000	0.64%
Shenzhen Triwise Kangxin	1,250,000	0.64%
Jiayin Lucky-source	1,250,000	0.64%
Everest No. 37	730,000	0.37%
Triwise Detai	730,000	0.37%
Yuanzhi Fuhai	730,000	0.37%
Total	196,480,000	100.00%

8. *Capital decrease*

Pursuant to a written resolution of our then Shareholders passed on June 11, 2021, our registered capital was decreased from RMB196,480,000 to RMB166,480,000 due to the cessation of Hangzhou Quanli and Taizhou Quanli, both being our original employee incentive platforms, as our Shareholders, for the re-establishment of our Employee Share Incentive Scheme and the shareholding platform thereunder. For details of the re-establishment of our Employee Share Incentive Scheme, see “—Employee Share Incentive Scheme” below. Hangzhou Quanli and Taizhou Quanli were deregistered on March 21, 2022 and February 18, 2022, respectively.

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Upon completion of the capital decrease, the shareholding structure of our Company was as follows:

Name of Shareholders	Registered capital <i>(RMB)</i>	Approximate equity interest percentage held
Hangzhou Quanyi	40,000,000	24.03%
Zhongmei Huadong	35,900,000	21.56%
Hongtai Health	18,750,000	11.26%
Matrix Partners VI	10,920,000	6.56%
Rongjianda	7,500,000	4.51%
Taizhou Jianxin	7,500,000	4.51%
Suzhou Guanhong	6,540,000	3.93%
Shanghai Quanyou	5,000,000	3.00%
Tongren Boda	5,000,000	3.00%
Shanghai Shuo Chen	5,000,000	3.00%
Lucky-source IV	4,500,000	2.70%
Hefu Ruitai	3,750,000	2.25%
Qianhai Efung	3,500,000	2.10%
Lucky-source III	3,230,000	1.94%
Nanjing Yuzhijia	2,000,000	1.20%
Cowin Guosheng	1,450,000	0.87%
Triwise Rozman	1,250,000	0.75%
Shenzhen Triwise Kangxin	1,250,000	0.75%
Jiayin Lucky-source	1,250,000	0.75%
Everest No. 37	730,000	0.44%
Triwise Detai	730,000	0.44%
Yuanzhi Fuhai	730,000	0.44%
Total	166,480,000	100.00%

Note: Equity interest percentages may not add up to 100% due to rounding.

9. Conversion into a joint stock limited liability company

On September 2, 2021, our then Shareholders passed resolutions approving, among other matters, the conversion of our Company from a limited liability company into a joint stock limited liability company and the change of name of our Company from Qyuns Therapeutics Co., Ltd. (江蘇荃信生物醫藥有限公司) to Qyuns Therapeutics Co., Ltd. (江蘇荃信生物醫藥股份有限公司). Pursuant to the promoters’ agreement dated September 2, 2021 entered into by all of our then Shareholders, all promoters approved the conversion of the net assets value of

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our Company as of July 31, 2021 into 166,480,000 Shares at a ratio of 4.7015:1. On September 17, 2021, our Company convened our inaugural meeting and our first general meeting, and passed the relevant resolutions approving the conversion of our Company into a joint stock limited liability company, the adoption of the articles of association of our Company and the conduct of the relevant procedures. Upon the completion of the conversion, the registered capital of our Company became RMB166,480,000 divided into 166,480,000 Shares with a nominal value of RMB1.00 each, which were subscribed by all our then Shareholders in proportion to their respective equity interests in our Company before the conversion. The conversion was completed on September 30, 2021 when our Company obtained a new business license.

10. Series C Financing

Pursuant to the capital increase agreement dated January 31, 2022 entered into among our Company, Saifu Juli, Mr. Qiu, Mr. Yu Guo’an, our then Shareholders, Gongqingcheng Triwise Kangxin Venture Capital Partnership (Limited Partnership) (共青城勤智康鑫創業投資合夥企業(有限合夥)) (“Gongqingcheng Triwise Kangxin”), Jiaxing Jiquan Equity Investment Partnership (Limited Partnership) (嘉興集荃股權投資合夥企業(有限合夥)) (“Jiaxing Jiquan”), Shenzhen Kaitian Yunqi Venture Capital Center (Limited Partnership) (深圳開天雲起創業投資中心(有限合夥)) (“Shenzhen Kaitian”), TWVC Panglin Qyuns Investment Limited (“TWVC Panglin”) and Gongqingcheng Triwise Huisheng Venture Capital Partnership (Limited Partnership) (共青城勤智慧升創業投資合夥企業(有限合夥)) (“Triwise Huisheng”, together with Gongqingcheng Triwise Kangxin, Jiaxing Jiquan, Shenzhen Kaitian and TWVC Panglin are collectively referred to as the “Series C Investors”), the Series C Investors agreed to invest in our Company by subscribing an aggregate of 13,545,200 Shares at a total consideration of RMB227,500,000 (the “Series C Financing”), among which RMB13,545,200 was contributed to the registered capital of our Company and RMB213,954,800 was contributed to the capital reserve of our Company, details of which are set out below:

Name of [REDACTED] Investors	Number of Shares subscribed for	Consideration	Date of full settlement of consideration in cash
		(RMB)	
Gongqingcheng Triwise Kangxin	3,899,800	65,500,000	February 22, 2022
Jiaxing Jiquan	3,572,400	60,000,000	February 24, 2022
Shenzhen Kaitian	2,977,000	50,000,000	February 24, 2022
TWVC Panglin	2,500,600	42,000,000	March 1, 2022
Triwise Huisheng	595,400	10,000,000	February 22, 2022
Total	13,545,200	227,500,000	

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The consideration of the Series C Financing was determined based on arm’s length negotiations between our Company and the Series C Investors with reference to, among others, our products under development, our research and development capabilities and the milestones our Company has achieved or expects to achieve. For further details of the Series C Financing and the background information of the Series C Investors, see “[REDACTED] Investments” below.

Upon completion of the Series C Financing, the shareholding structure of our Company was as follows:

Name of Shareholders	Number of Shares	Approximate shareholding percentage held
Hangzhou Quanyi	40,000,000	22.22%
Zhongmei Huadong	35,900,000	19.94%
Hongtai Health	18,750,000	10.42%
Matrix Partners VI	10,920,000	6.07%
Rongjianda	7,500,000	4.17%
Taizhou Jianxin	7,500,000	4.17%
Suzhou Guan hong	6,540,000	3.63%
Shanghai Quanyou	5,000,000	2.78%
Tongren Boda	5,000,000	2.78%
Shanghai Shuochen	5,000,000	2.78%
Lucky-source IV	4,500,000	2.50%
Gongqingcheng Triwise Kangxin	3,899,800	2.17%
Hefu Ruitai	3,750,000	2.08%
Jiaxing Jiquan	3,572,400	1.98%
Qianhai Efung	3,500,000	1.94%
Lucky-source III	3,230,000	1.79%
Shenzhen Kaitian	2,977,000	1.65%
TWVC Panglin	2,500,600	1.39%
Nanjing Yuzhijia	2,000,000	1.11%
Cowin Guosheng	1,450,000	0.81%
Triwise Rozman	1,250,000	0.69%
Shenzhen Triwise Kangxin	1,250,000	0.69%
Jiayin Lucky-source	1,250,000	0.69%
Everest No. 37	730,000	0.41%
Triwise Detai	730,000	0.41%
Yuanzhi Fuhai	730,000	0.41%
Triwise Huisheng	595,400	0.33%
Total	180,025,200	100.00%

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11. Capital increase and subscription

Pursuant to a written resolution of our then Shareholders passed on September 15, 2022, our registered capital was increased from RMB180,025,200 to RMB210,025,200. The additional registered capital of RMB30,000,000 was subscribed by (i) Dr. Yu Guoliang (余國良), a consultant of our Company and brother of Mr. Yu Guo’an, Dr. Qiu Zhihua (裘之華), vice president of our Company at the time of grant of options, and Mr. Guo Xinjun (郭新軍), a consultant of our Company at the time of grant of options, pursuant to the original share option scheme (the “Original Share Option Scheme”) adopted by our Company on November 14, 2018; and (ii) Mr. Qiu, Dr. Li Jianwei (李建偉), our chief operating officer and deputy general manager and the general manager of Cellularforce, Dr. Yu Guoliang and Xinfu Tongxin, our employee share incentive platform, pursuant to the Employee Share Incentive Scheme, at a total consideration of RMB30,000,000, details of which are set out below:

<u>Name of Shareholders</u>	<u>Number of Shares subscribed for</u> (RMB)	<u>Consideration</u> (RMB)	<u>Date of full settlement of consideration in cash</u>
Xinfu Tongxin	15,550,000	15,550,000	March 10, 2023
Mr. Qiu	10,000,000	10,000,000	March 2, 2023
Dr. Yu Guoliang	1,500,000	1,500,000	January 6, 2023
Dr. Li Jianwei	1,450,000	1,450,000	January 6, 2023
Dr. Qiu Zhihua	1,000,000	1,000,000	January 6, 2023
Mr. Guo Xinjun	500,000	500,000	December 27, 2022
Total	30,000,000	30,000,000	

12. Share transfer by Tongren Boda

Pursuant to the share transfer agreement dated November 29, 2022 entered into between Nanjing Talent Innovation Venture Capital Fund Partnership (Limited Partnership) (南京市人才創新創業投資基金合夥企業(有限合夥)) (“Nanjing Talent”) and Tongren Boda, Tongren Boda agreed to transfer 625,000 Shares held by it to Nanjing Talent at a consideration of RMB10 million, which was determined based on arm’s length negotiations between Tongren Boda and Nanjing Talent with reference to, among others, the post-money valuation of our Company upon completion of the Series C Financing, and was fully settled on December 14, 2022. For further details of such share transfer and the background information of Nanjing Talent, see “[REDACTED] Investments” below.

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Upon completion of the share transfer, the shareholding structure of our Company was as follows:

Name of Shareholders	Number of Shares	Approximate shareholding percentage held
Hangzhou Quanyi	40,000,000	19.05%
Zhongmei Huadong	35,900,000	17.09%
Hongtai Health	18,750,000	8.93%
Xinfu Tongxin	15,550,000	7.40%
Mr. Qiu	10,000,000	4.76%
Matrix Partners China VI, L.P.	9,853,116	4.69%
Rongjianda	7,500,000	3.57%
Taizhou Jianxin	7,500,000	3.57%
Suzhou Guanhong	6,540,000	3.11%
Shanghai Quanyou	5,000,000	2.38%
Shanghai Shuochen	5,000,000	2.38%
Lucky-source IV	4,500,000	2.14%
Tongren Boda	4,375,000	2.08%
Gongqingcheng Triwise Kangxin	3,899,800	1.86%
Hefu Ruitai	3,750,000	1.79%
Jiaxing Jiquan	3,572,400	1.70%
Qianhai Efung	3,500,000	1.67%
Lucky-source III	3,230,000	1.54%
Shenzhen Kaitian	2,977,000	1.42%
TWVC Panglin	2,500,600	1.19%
Nanjing Yuzhijia	2,000,000	0.95%
Dr. Yu Guoliang	1,500,000	0.71%
Cowin Guosheng	1,450,000	0.69%
Dr. Li Jianwei	1,450,000	0.69%
Triwise Rozman	1,250,000	0.60%
Shenzhen Triwise Kangxin	1,250,000	0.60%
Jiayin Lucky-source	1,250,000	0.60%
Matrix Partners China VI-A, L.P.	1,066,884	0.51%
Dr. Qiu Zhihua	1,000,000	0.48%
Everest No. 37	730,000	0.35%
Triwise Detai	730,000	0.35%
Yuanzhi Fuhai	730,000	0.35%
Nanjing Talent	625,000	0.30%
Triwise Huisheng	595,400	0.28%
Mr. Guo Xinjun	500,000	0.24%
Total	210,025,200	100.00%

Note: Shareholding percentages may not add up to 100% due to rounding.

HISTORY AND CORPORATE STRUCTURE

Our subsidiaries

Saifu Juli

Saifu Juli was established in the PRC as a limited liability company on July 6, 2018 with an initial registered capital of RMB51,000,000. As of the date of its establishment, Saifu Juli was owned as to approximately 70.59% by our Company and 29.41% by Suzhou Aibituo Biotechnology Co., Ltd. (蘇州艾比拓生物技術有限公司) (“Suzhou Aibituo”), an Independent Third Party.

On July 20, 2019, the registered capital of Saifu Juli was increased from RMB51,000,000 to RMB90,000,000. The additional registered capital of RMB39,000,000 was subscribed by our Company at a consideration of RMB39,000,000 and was fully settled on July 2, 2019. Upon completion of such capital increase, Saifu Juli became owned as to approximately 83.33% by our Company and 16.67% by Suzhou Aibituo. On September 29, 2020, Suzhou Aibituo transferred its 16.67% equity interest in Saifu Juli to our Company at nil consideration which was determined after taking into account that Suzhou Aibituo had not actually paid up the registered capital of RMB15,000,000 subscribed by it. Upon completion of such equity transfer, Saifu Juli became wholly owned by our Company. On October 27, 2022, the registered capital of Saifu Juli was further increased to RMB116,470,000, which was fully paid up in cash. As of the Latest Practicable Date, Saifu Juli was an investment holding company wholly owned by our Company and had not commenced any business.

Cellularforce

Cellularforce was established in the PRC as a limited liability company on August 2, 2018 with an initial registered capital of RMB100,000,000. As of the date of its establishment, Cellularforce was owned as to 51% by Saifu Juli, 34% by Taizhou Huacheng Medical Investment Group Co., Ltd. (泰州華誠醫學投資集團有限公司) (“Taizhou Huacheng”) and 15% by Taizhou Saifu Meibo Enterprise Management Partnership (Limited Partnership) (泰州市賽孚美博企業管理合夥企業(有限合夥)) (“Saifu Meibo”), a limited partnership whose general partner is Mr. Qiu. Taizhou Huacheng is controlled by Taizhou Medicine City Holding Group Co., Ltd. (泰州醫藥城控股集團有限公司) (“Taizhou Medicine”), a company wholly owned by the Management Committee of Taizhou Medical New and High-tech Industrial Development Zone (泰州醫藥高新技術產業開發區管理委員會) (“Taizhou High-tech Committee”), which is an administrative agency of Jiangsu Provincial Committee of the Communist Party of China (中國共產黨江蘇省委員會) and Jiangsu Provincial People’s Government (江蘇省人民政府) for the management of Taizhou Medical New and High-tech Industrial Development Zone and is therefore a PRC governmental body. Mr. Qiu first became acquainted with Taizhou High-tech Committee in 2007 when he attended the investment promotion activities organized by Taizhou High-tech Committee in Taizhou and became acquainted with Taizhou Huacheng through the introduction by Taizhou High-tech Committee, whose objective was to invest in a CDMO service platform managed by a professional operation team in order to promote the development of Taizhou-China Medical City (中國醫藥城) (also known as Taizhou Medical High-tech Industrial Park (泰州醫藥高新技術產業園區) or Taizhou Medical New and High-tech Industrial Development Zone (Taizhou Gaogang District) Medical Industrial Park (泰州醫

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藥高新技術產業開發區(泰州市高港區)醫藥產業園)) (“**China Medical City**”). China Medical City is a national comprehensive bio-medical industrial park in Taizhou Medical New and High-tech Industrial Development Zone, with a total planned area of 30 square kilometers and constructed area exceeding 22 square kilometers, according to the information published on the website of the Taizhou High-tech Committee. The management committee of China Medical City (now known as the Management Office of Taizhou Medical New and High-tech Industrial Development Zone (Taizhou Gaogang District) Medical Industrial Park (泰州醫藥高新技術產業開發區 (泰州市高港區) 醫藥產業園管理辦公室)) is an administrative management institution jointly set up by the CPC Working Committee of Taizhou Medical New and High-tech Industrial Development Zone (中共泰州醫藥高新技術產業開發區工作委員會), Taizhou High-tech Committee, the CPC Committee of Taizhou Gaogang District (中共泰州市高港區委員會) and Taizhou Gaogang District People’s Government (泰州市高港區人民政府) for the management of China Medical City and is a local PRC governmental body. Having taken into account (i) the demand for CDMO services from R&D-driven biotech companies; (ii) our demand for the development of in-house manufacturing capability of antibody drugs; and (iii) the strategic benefits that could be brought by Taizhou Huacheng and Taizhou High-tech Committee including the initial capital provided by Taizhou Huacheng and the synergy generated by combining the resources of Taizhou Huacheng and Taizhou High-tech Committee in financing capabilities and business development, we jointly established Cellularforce with Taizhou Huacheng in 2018.

To facilitate Cellularforce to settle by constructing its headquarters and manufacturing facilities in China Medical City, Cellularforce entered into an entry agreement with the management committee of China Medical City in March 2019, pursuant to which Cellularforce is entitled to enjoy certain benefits and support from the management committee of China Medical City, including: (i) reimbursement of certain capital expenditure incurred for the manufacturing facilities; (ii) subsidies to Cellularforce in respect of corporate income tax and value-added tax paid by Cellularforce and subsidies to Cellularforce in respect of personal income tax paid by the senior management of Cellularforce; (iii) assistance from the management committee of China Medical City in talent recruitment activities; (iv) free office leasing for a term of two years from May 2019 to April 2021; (v) staff dormitories leasing of no more than five years on favorable price to eligible talents; and (vi) assistance from the management committee of China Medical City in obtaining a bank loan of RMB300 million and subsidizing certain interest expenses incurred for such bank loan. Please see “Financial Information—Indebtedness—Interest-bearing Borrowings” for the details of such bank loan.

On June 26, 2019, the registered capital of Cellularforce was increased from RMB100,000,000 to RMB176,470,000. The additional registered capital of RMB76,470,000 was subscribed by Saifu Juli, Taizhou Huacheng and Saifu Meibo in proportion to their respective equity interest. On September 19, 2022, Saifu Meibo transferred its approximately 15% equity interest in Cellularforce to Saifu Juli at nil consideration which was determined after taking into account that Saifu Meibo had not actually paid up the registered capital of RMB26,470,000 subscribed by it. Upon completion of such equity transfer and as of the Latest Practicable Date, Cellularforce was owned as to 66% by Saifu Juli and 34% by Taizhou Huacheng.

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Saifu Juli and Taizhou Huacheng are entitled to exercise the voting rights and receive dividends and other economic distributions in proportion to their shareholdings. According to the articles of association of Cellularforce, the following matters require unanimous consent by all shareholders of Cellularforce: (i) amendment of the articles of association; (ii) increase or decrease in registered capital; (iii) establishment of new subsidiaries; (iv) merger, division, dissolution or change in the corporate form of Cellularforce; (v) obtaining loans or issue of bonds; (vi) provision of guarantees or loans to external parties; (vii) making of external equity investments; (viii) substantial changes in its main business; and (ix) conducting any equity transfer, equity pledge, mortgage or other disposal of major assets that may directly or indirectly result in a change in the actual controller of Cellularforce. Save for the above, all other matters shall be decided by an ordinary resolution where a simple majority of the votes held by the shareholders of Cellularforce is required. There are no special rights granted to Taizhou Huacheng in respect of its shareholding in Cellularforce. The board of the directors of Cellularforce consists of three directors, two of whom were nominated by us and one of whom was nominated by Taizhou Huacheng. Accordingly, our Company has sufficient control and influence over the board of directors and the management of Cellularforce by nominating a majority of its directors and all of its supervisor and key management. Based on the above, our Directors are of the view that Taizhou Huacheng does not have material control and is not able to exert substantial influence over Cellularforce.

Cellularforce is our CMC-focused subsidiary and is primarily responsible for cell line development, process development, formulation development, analytical method development, quality control, quality assurance, pilot and commercial scale manufacturing of our Group. For each of the two years ended December 31, 2022 and the nine months ended September 30, 2023, Cellularforce recorded a revenue of approximately RMB54.48 million, RMB84.96 million and RMB58.42 million, respectively, which was generated from leasing, provision of CDMO and testing services to our Company, and the loss for the corresponding periods was approximately RMB45.39 million, RMB41.52 million and RMB33.95 million, respectively. In respect of the leasing, CDMO and testing services provided by Cellularforce to our Company during the Track Record Period, (i) the rent and property management service fees for the leased premises were determined with reference to the prevailing rent and property management service fees charged for comparable properties in China Medical City where the premises leased from Cellularforce are located; (ii) the fees charged under the CDMO related transactions were determined on a cost-plus basis, with the cost-plus margin ranging from approximately 5% to 30% of the cost depending on the nature, scope and complexity of services to be provided, the expected cost and expenses for provision of the required services and the prevailing market price for similar services; and (iii) the fees charged under the testing services were determined on a cost-plus basis, with the cost-plus margin ranging from approximately 5% to 30% of the cost depending on the scope and complexity of testing services to be provided, the expected cost and expenses for provision of the required testing services and the prevailing market price for similar testing services.

HISTORY AND CORPORATE STRUCTURE

PRC Legal Advisors’ Confirmation

Our PRC Legal Advisors have confirmed that the above mentioned equity transfers and changes in the registered capitals of our Group have been properly and legally completed and our Group has obtained all necessary approvals and made all necessary filings, and has complied with applicable PRC laws and regulations in relation to the changes in shareholdings as set out above.

Employee Share Incentive Scheme

For the purpose of awarding our employees and consultants for their contributions to our Group and to incentivize them to further promote our development, Hangzhou Quanli and Taizhou Quanli were established on May 15, 2015 and August 17, 2018, respectively, as our original employee incentive platforms to hold equity interests in our Company. The general partner of Hangzhou Quanli and Taizhou Quanli is Mr. Qiu, who managed the daily affairs and exercise the voting rights of Hangzhou Quanli and Taizhou Quanli as shareholders of our Company pursuant to their partnership agreements. Pursuant to the Original Share Option Scheme adopted by our Company on November 14, 2018, an aggregate of 10,000,000 options to subscribe for an equivalent amount of RMB10,000,000 in the registered capital of our Company through Hangzhou Quanli were granted to the following employees or consultants of our Group on May 31, 2019.

<u>Grantees</u>	<u>Position(s) in our Group</u>	<u>Vesting period⁽¹⁾</u>	<u>Equivalent amount in the registered capital of our Company in respect of the options granted</u>	<u>Exercise price</u>
			<i>(RMB)</i>	<i>(RMB)</i>
Directors				
Mr. Qiu	Executive Director, chairman of our Board, chief executive officer and general manager of our Company	From January 1, 2019 to December 31, 2021	3,000,000	3,000,000
Mr. Wu Yiliang	Executive Director and executive deputy general manager of Cellularforce	From January 1, 2019 to December 31, 2021	1,000,000	1,000,000

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Grantees	Position(s) in our Group	Vesting period ⁽¹⁾	Equivalent amount in the registered capital of our Company in respect of the options granted (RMB)	Exercise price (RMB)
Supervisor				
Ms. Wang Yujiao	Employee representative Supervisor and assistant to general manager of our Company	From January 1, 2019 to December 31, 2021	300,000	300,000
Other employees or consultants of our Group				
Dr. Yu Guoliang ⁽²⁾	Consultant of our Company	From January 1, 2019 to December 31, 2021	1,000,000	1,000,000
Dr. Qiu Zhihua	Vice president of our Company at the time of grant	From January 1, 2019 to December 31, 2021	1,000,000	1,000,000
Mr. Guo Xinjun ⁽³⁾	Consultant of our Company at the time of grant	From January 1, 2019 to December 31, 2021	500,000	500,000
12 other grantees ⁽⁴⁾		From January 1, 2019 to December 31, 2021	3,200,000	3,200,000
Total			10,000,000	10,000,000

Notes:

- Save for (i) Mr. Ke Yaohuang, our former consultant, who chose not to exercise the 1,000,000 options granted to him due to his personal financial arrangement and such options were lapsed and canceled in September 2020 accordingly; (ii) Ms. Wu Meijuan, our former director (總監), who sold her 100,000 vested options to Xinfu Tongxin pursuant to the Original Share Option Scheme after her departure from our Group in March 2022; and (iii) Dr. Yu Guoliang, Dr. Qiu Zhihua and Mr. Guo Xinjun who had exercised all of the options granted to them under the Original Share Option Scheme in October, 2022, each of the other grantees agreed to reflect their interests under the Original Share Option Scheme in the Employee Share Incentive Scheme and the options granted to them were deemed canceled.

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2. *Upon the establishment of our Company, with a view to leveraging Dr. Yu’s reputation and influence in biotech and pharmaceutical industry, Dr. Yu Guoliang was nominated as our non-executive Director and the chairman of our Board. During his tenure as our non-executive Director from June 2015 to February 2022, he participated in discussions at our Board meetings on Board matters, provided market insights and strategic advice on the overall development of the Group and introduced a variety of resources including investors, technical cooperation partners, business development partners and talents resources to our Group. In February 2022, due to his plan to focus on his other businesses, Dr. Yu Guoliang resigned as our non-executive Director and the chairman of our Board. Having taken into account the strategic benefits that could be brought by Dr. Yu Guoliang in our future commercialization and international expansion opportunities, Dr. Yu Guoliang was appointed as our consultant in October 2022 and is primarily responsible for providing strategic advice and guidance on our development strategy and pipeline development.*

Save for the 1,500,000 Shares granted to Dr. Yu Guoliang pursuant to the Original Share Option Scheme and the Employee Share Incentive Scheme, representing approximately 0.71% of the share capital of our Company, Dr. Yu Guoliang has never been interested in any other Shares since our establishment.

3. *During his tenure as our consultant from July 2015 to December 2021, Mr. Guo Xinjun assisted in the strategic planning of domestic and foreign drug registration for our pipeline candidates and introduced high-quality CRO institutions and supplier resources to our Group. For example, Mr. Guo (i) assisted in formulating the overall development strategy of pharmaceutical and non-clinical research of QX001S throughout its IND stage and provided advice to file IND application under the pathway for biosimilars on the basis of adequate similarity comparison studies with its originator drug, which helped our Company successfully obtain IND approval of QX001S; (ii) provided advice to choose ankylosing spondylitis (AS) as the first indication of QX002N having considered the overall R&D and competing environment of antibody drugs in China during the relevant time, which helped our Company differentiate QX002N from other domestic drugs with same target but different indications to form a competitive advantage; (iii) introduced experts in the fields of pharmacy, pharmacology, toxicology, etc. to our colleagues who are responsible for drug regulatory affairs; (iv) introduced high-quality CRO institutions such as Bona Xiya (Hefei) Pharmaceutical Technology Co., Ltd. (博納西亞(合肥)醫藥科技有限公司) and Junke Zhengyuan (Beijing) Pharmaceutical Research Co., Ltd. (軍科正源(北京)藥物研究有限責任公司) to our Group; and (v) regularly visited our Company and provided guidance on the organizational structure, pharmacy affairs, personnel composition and manufacturing processes, etc. of our Company.*
4. *The 12 other grantees include (i) Ms. Fang Min, a deputy general manager of our Company; (ii) four existing directors (總監) of our Company, namely Mr. Chen Tao, Mr. Kong Yong, Mr. Chen Wei and Mr. Wang Yi; (iii) Ms. Wu Meijuan, a former director (總監) of our Company; (iv) Mr. Ke Yaohuang, a former consultant of our Company; (v) Mr. Xu Zuixiao, a deputy general manager of Cellularforce; (vi) Mr. Qiao Huaiyao, a senior director (高級總監) of Cellularforce; (vii) Mr. Xu Zhengxue, a director (總監) of Cellularforce; and (viii) two managers of Cellularforce, namely Mr. Li Tao and Mr. Huang Wenjun.*

Having taken into account (i) the conversion plan of our Company from a limited liability company into a joint stock company with limited liability at the material time which required all registered capital of our Company to be fully paid up before the conversion; (ii) Hangzhou Quanli and Taizhou Quanli had not actually paid up the registered capital of our Company subscribed by them where such contribution shall indeed be funded by the exercise price payable by the relevant grantees upon the full exercise of (a) all options granted above; and (b) the options in respect of an equivalent amount of RMB20,000,000 in the registered capital of our Company held by Taizhou Quanli which had yet to be granted at the material time; (iii) the list of grantees of options to be granted with the right to subscribe for an equivalent amount in the registered capital of our Company held by Taizhou Quanli had not yet been determined at the material time; (iv) the intention of our Group to adopt a new share incentive scheme which involves the grant of restricted shares instead of share options of our Company; (v) the administrative procedure to amend the existing scheme documents to reflect the above intended

HISTORY AND CORPORATE STRUCTURE

changes; (vi) each of Dr. Yu Guoliang, Dr. Qiu Zhihua and Mr. Guo Xinjun intended to become our direct Shareholders upon the exercise of the options granted under the Original Share Option Scheme; and (vii) each of the other grantees intended to have their interests under the Original Share Option Scheme reflected in the new employee share incentive scheme of our Company after the conversion, we established our Employee Share Incentive Scheme and the employee incentive platforms thereunder by decreasing the registered capital of our Company through the cessation of Hangzhou Quanli and Taizhou Quanli as our Shareholders, establishing our new employee incentive platforms for administrative convenience and increasing the registered capital of our Company through the subscription as disclosed in “—Establishment and major shareholding changes of our Company—11. Capital increase and subscription” above. For details of the Employee Share Incentive Scheme, see “Appendix VIII—Statutory and General Information—D. Employee Share Incentive Scheme” to this document.

Xinfu Tongxin was established in the PRC as one of our new employee share incentive platforms on August 19, 2021. As of the Latest Practicable Date, Mr. Qiu was the general partner of Xinfu Tongxin and held approximately 7.20% of the interest in Xinfu Tongxin. The remaining 40 limited partners of Xinfu Tongxin which held approximately 92.80% interest in Xinfu Tongxin comprised (i) Mr. Wu Yiliang, our executive Director and executive deputy general manager of Cellularforce, holding approximately 10.68% interest in Xinfu Tongxin; (ii) Mr. Lin Weidong, our executive Director and deputy general manager, holding approximately 6.43% interest in Xinfu Tongxin; (iii) Ms. Wang Yujiao, our Supervisor and assistant to general manager, holding approximately 5.72% interest in Xinfu Tongxin; (iv) Xinfu Quanxin, one of our new employee share incentive platforms, holding approximately 11.38% interest in Xinfu Tongxin; and (v) 36 other employees of our Group in aggregate holding approximately 58.59% interest in Xinfu Tongxin, and none of them held 30% or more of the interest in Xinfu Tongxin. The voting rights of the Shares held by Xinfu Tongxin are controlled and exercisable by Mr. Qiu as its general partner.

Given that (i) the maximum number of partners in a limited partnership shall be 50 according to the Partnership Enterprise Law of the People’s Republic of China (中華人民共和國合夥企業法); and (ii) the number of eligible participants who would be granted the underlying incentive Shares and would invest in our Company by way of becoming limited partners of our employee share incentive platform exceeded 50, our Company decided to establish another employee share incentive platform which would be one of the limited partners of Xinfu Tongxin where part of the participants of the Employee Share Incentive Scheme could invest in our Company by way of becoming limited partners of the new employee share incentive platform. Under such circumstance, Xinfu Quanxin was established in the PRC as one of our new employee share incentive platforms on February 27, 2023. As of the Latest Practicable Date, Mr. Wu Yiliang was the general partner of Xinfu Quanxin and held approximately 0.56% interest in Xinfu Quanxin. The remaining 28 limited partners of Xinfu Quanxin were employees of our Group in aggregate holding approximately 99.44% interest in Xinfu Quanxin and none of them held 30% or more interest in Xinfu Quanxin. Save as disclosed above, there is no difference between the nature of Xinfu Tongxin and Xinfu Quanxin as employee share incentive platforms of our Company.

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[REDACTED] INVESTMENTS

Principal Terms of the [REDACTED] Investments

Name of [REDACTED] Investor(s)	Pre-Series A Investors	Series A Investors	Series B Investors ^{(1) (2)}	Lucky-source IV ⁽¹⁾	Series B+ Investor	Series B++ Investors ⁽³⁾	Series C Investors	Nanjing Talent ⁽⁴⁾
Date of agreement	October 14, 2015 October 15, 2015 November 5, 2015	January 18, 2016	April 10, 2019 April 15, 2020	May 14, 2020	August 14, 2020	April 2, 2021	January 31, 2022	November 29, 2022
Date of full settlement of all consideration	November 30, 2015	March 29, 2016	May 22, 2020	June 10, 2020	October 9, 2020	April 26, 2021	March 1, 2022	December 14, 2022
Approximate cost per RMB1.00 of registered capital/Share paid under the [REDACTED] Investments	RMB1.40	RMB4.00	RMB8.00	RMB6.67	RMB10.31	RMB13.74	RMB16.80	RMB16.00
Amount of registered capital/number of Shares held	RMB10,000,000	RMB30,000,000	RMB28,750,000	RMB4,500,000	RMB35,900,000	RMB21,830,000	13,543,200 Shares	625,000 Shares
Amount of consideration paid	RMB14.00 million	RMB120.00 million	RMB230.00 million	RMB30.00 million	RMB370.00 million	RMB300.00 million	RMB227.50 million	RMB10.00 million
Approximate post-money valuation of our Company	RMB84.00 million	RMB360.00 million ⁽⁵⁾	RMB1,110.00 million ⁽⁶⁾	N/A	RMB1,800.00 million ⁽⁷⁾	RMB2,700.00 million ⁽⁸⁾	RMB3,527.50 million ⁽⁹⁾	N/A
Discount to the mid-point of the indicative [REDACTED] range ⁽¹⁰⁾ (approximate %)	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

HISTORY AND CORPORATE STRUCTURE

Name of [REDACTED] Investor(s)	Pre-Series A Investors	Series B Investors ^{(1) (2)}	Lucky-source IV ⁽¹⁾	Series B+ Investor	Series B++ Investors ⁽³⁾	Series C Investors	Nanjing Talent ⁽⁴⁾
Shareholding in our Company immediately upon completion of the [REDACTED]	For the shareholding in our Company held by the [REDACTED] Investors immediately after completion of the [REDACTED], see “—Shareholding and Corporate Structure Immediately After the Completion of the [REDACTED]” in this section.						
[REDACTED]	We used or will use the [REDACTED] to finance our research and development activities and fund our daily operations.						
[REDACTED]	As of the Latest Practicable Date, approximately [REDACTED]% of the [REDACTED] from the [REDACTED] Investments had been utilized for the aforementioned purposes. We expect to use the remaining [REDACTED] from the [REDACTED] Investments for the same purposes.						
Lock-up period	All current Shareholders (including the [REDACTED] Investors) are subject to a lock-up period of 12 months following the [REDACTED] according to the PRC Company Law.						
Strategic benefits	Our Directors were of the view that (i) our Group would benefit from the additional capital provided by the [REDACTED] Investors for our research and development and daily operations; (ii) the [REDACTED] Investments have broadened our shareholder base and demonstrated the [REDACTED] Investors’ confidence in the operation and development of our Group; (iii) the [REDACTED] Investors include experienced investors in the area of biotech and healthcare industry, who can share their insight on business strategies and provide professional advice on our Group’s corporate governance, financial reporting, internal control and future development; and (iv) our Group could be benefited from the synergy generated by combining the resources and expertise of the [REDACTED] Investors such as introduction of medical or research resources, qualified suppliers, talents and other investors to our Group to facilitate our clinical trials, commercialization and equity financing activities. In addition, we entered into a collaboration agreement with Zhongmei Huadong with respect to the joint development and exclusive commercialization of QX001S in China. On the other hand, the [REDACTED] Investors could participate in the investment of our Company with a view to be benefited from increase in the value of their respective equity interest in our Company with the development of our business.						

HISTORY AND CORPORATE STRUCTURE

Notes:

- (1) Pursuant to the equity transfer agreement dated May 14, 2020 entered into among Qianhai Efung, Lucky-source IV and our Company, Qianhai Efung agreed to transfer approximately 3.24% of the then equity interest in our Company held by it to Lucky-source IV at a consideration of RMB30,000,000, which was determined based on arm’s length negotiations between Qianhai Efung and Lucky-source IV with reference to, among others, the post-money valuation of our Company upon completion of the Series B Financing.
- (2) Pursuant to the equity transfer agreement dated March 29, 2021 entered into between Jiayin Ruixin and Jiayin Lucky-source, Jiayin Ruixin agreed to transfer approximately 0.72% of the then equity interest in our Company held by it to Jiayin Lucky-source at a consideration of RMB10,000,000, which was determined with reference to the total investment made by Jiayin Ruixin in our Company and was fully settled on February 20, 2021. Such equity transfer was conducted between entities under common control for the purpose of their internal restructuring and Jiayin Ruixin was no longer a Shareholder upon completion of such equity transfer.
- (3) Pursuant to the share transfer agreement dated October 14, 2022 entered into among Matrix Partners VI, Matrix Partners China VI, L.P. and Matrix Partners China VI-A, L.P., Matrix Partners VI agreed to transfer 9,853,116 Shares and 1,066,884 Shares, representing approximately 5.47% and 0.59% of the then share capital of our Company to Matrix Partners China VI, L.P. and Matrix Partners China VI-A, L.P., respectively. Such equity transfers were conducted among entities under common control for the purpose of their internal management and Matrix Partners VI was no longer a Shareholder upon completion of such equity transfers.
- (4) Pursuant to the share transfer agreement dated November 29, 2022 entered into between Nanjing Talent and Tongren Boda, Tongren Boda agreed to transfer 625,000 Shares held by it to Nanjing Talent at a consideration of RMB10 million, which was determined based on arm’s length negotiations between Tongren Boda and Nanjing Talent with reference to, among others, the post-money valuation of our Company upon completion of the Series C Financing.
- (5) The increase from our post-money valuation upon completion of the Pre-Series A Financing to our post-money valuation upon completion of the Series A Financing was primarily because the consideration of the Pre-Series A Financing was not negotiated and determined in October 2015 and November 2015 when the formal capital increase agreements were entered into among our Company and the respective Pre-Series A Investors. Instead, such consideration was negotiated and determined at the early stage of our business preparation in May 2015 with reference to the expected substantial investment made by our founder, the value of our management team with extensive industry experience and our long-term development strategies and potential. Given the capital injection by Mr. Qiu and Mr. Yu Guo’an into our Company had not been completed until July 2015, the formal capital increase agreements and capital injection by the Pre-Series A Investors were completed after the capital injection by Mr. Qiu and Mr. Yu Guo’an. On the other hand, the consideration of the Series A Financing was negotiated and determined in January 2016 based on the valuation of the equity interests of our Company as of December 31, 2015 according to a valuation report dated January 10, 2016 issued by an independent valuer (the “Valuation Report”). From May 2015 to December 2015, (i) our Company was established in Taizhou and Mr. Qiu and Mr. Yu Guo’an made their capital injection into our Company through Hangzhou Quanyi; and (ii) certain experienced management and R&D personnel including Dr. Qiu Zhihua, Mr. Qiao Huaiyao and Dr. Kong Yong joined our Group to strengthen our R&D capabilities; and (iii) we completed the cell line screening and process development of QX001S. Accordingly, the valuation of the equity interest of our Company based on the Valuation Report was significantly higher than that of the valuation of the equity interest of our Company at the early stage of our business preparation in May 2015.
- (6) The increase from our post-money valuation upon completion of the Series A Financing to our post-money valuation upon completion of the Series B Financing was primarily due to the progress of research and development of our products, the milestone we achieved and our business prospects. For instance, (i) we received IND approval of QX001S from the NMPA for the treatment of moderate-to-severe plaque Ps in China in January 2018 and IND approval of QX002N from the NMPA for the treatment of AS in China in April 2019; and (ii) we, through our CMC-focused subsidiary, Cellularforce, have established an in-house manufacturing capability to support our R&D activities.

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- (7) The increase from our post-money valuation upon completion of the Series B Financing to our post-money valuation upon completion of the Series B+ Financing was primarily due to the progress of research and development of our products, the milestones we achieved and our business prospects. For instance, we completed the Phase I clinical trial of QX001S for the treatment of Ps in China in May 2020 and received IND approval of QX005N from the NMPA for the treatment of moderate-to-severe AD in adults in China in June 2020.
- (8) The increase from our post-money valuation upon completion of the Series B+ Financing to our post-money valuation upon completion of the Series B++ Financing was primarily due to (i) the strategic benefits that have been brought by Zhongmei Huadong to our Group since the Series B+ Financing such as our strategic collaboration with Zhongmei Huadong in respect of the joint development and exclusive commercialization of QX001S in China which will help ensure the effective and efficient commercialization of QX001S, our first expected commercial drug; and (ii) the progress of research and development of our products, the milestones we achieved and our business prospects. For instance, we initiated the Phase Ib clinical trial of QX002N in September 2020 for treating AS and the Phase Ia clinical trial of QX005N in December 2020 in healthy subjects.
- (9) The increase from our post-money valuation upon completion of the Series B++ Financing to our post-money valuation upon completion of the Series C Financing was primarily due to the progress of research and development of our products, the milestone we achieved and our business prospects. For instance, (i) we received IND approvals from the NMPA for: (a) QX004N for the treatment of Ps in August 2021; (b) QX006N for the treatment of SLE in September 2021; (c) QX005N for the treatment of CRSwNP in November 2021; and (d) QX005N for the treatment of CSU in January 2022; and (ii) we completed the Phase Ia clinical trial and initiated the Phase II clinical trial of QX002N for the treatment of AS in China in September 2021 and January 2022, respectively.
- (10) The discount to the [REDACTED] is calculated based on the foreign exchange rate as of the Latest Practicable Date and the assumption that the [REDACTED] is HK\$[REDACTED] per H Share (being the mid-point of the indicative [REDACTED] range).

Following the completion of the Series C Financing, our Company expects that the market capitalization of our Company upon [REDACTED] would be increased having taken into account: (i) the expected capital raising during the [REDACTED]; (ii) our business development since completion of the Series C Financing; (iii) the risks undertaken by the Series C Investors investing in an unlisted company which justifies a discount in valuation vis-à-vis investors investing in a public company; and (iv) the premium attached to the H Shares issued under the [REDACTED] as they become freely tradeable upon [REDACTED]. Subsequent to the completion of the Series C Financing, we have continued to advance in the R&D of our pipeline products. In particular, (i) we initiated the Phase II clinical trial of QX005N for the treatment of AD in China in September 2022; (ii) we completed the Phase Ib clinical trial and patient enrollment for the Phase II clinical trial of QX002N for the treatment of AS in China in September 2022; (iii) we completed the Phase Ib clinical trial of QX005N and completed subject enrollment for the Phase II clinical trial of QX005N for the treatment of AD in China in February 2023; (iv) we commenced a Phase II clinical trial in adult patients with PN in China for QX005N for the treatment of PN in February 2023; (v) we commenced a Phase II clinical trial in adult patients with CRSwNP in China for QX005N for the treatment of CRSwNP in April 2023; (vi) we completed subject enrollment for Phase II clinical trial of QX005N for the treatment of PN in China in May 2023; (vii) Zhongmei Huadong and we completed the Phase III clinical trial of QX001S in patients with moderate-to-severe plaque Ps in China for the treatment of moderate-to-severe plaque Ps in June 2023, (viii) Zhongmei Huadong, our commercialization partner for QX001S, submitted a BLA in China in July 2023, which was accepted by the NMPA in August 2023; (ix) we completed the Phase II clinical trial of QX002N for the treatment of AS in China in August 2023 and initiated the Phase III clinical trial in September 2023; and (x) we received IND approvals from the NMPA for QX005N for the treatment of COPD in September 2023 and for the treatment of AD in adolescents aged between 12 and 17 years in October 2023. For details of the aforesaid advancements in our business and pipeline products, see “Business” in this document.

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Information Relating to Our [REDACTED] Investors

Among our [REDACTED] Investors, each of Zhongmei Huadong, Hongtai Aplus (as defined below), Taizhou Huayin (as defined below), Matrix Partners China, Triwise Capital (as defined below) and Shenzhen Lucky-source (as defined below) is a [REDACTED] who has made meaningful investment in our Company in accordance with Chapter 2.3 of the Guide. We became acquainted with each of the [REDACTED] Investors through introduction by Mr. Qiu or Dr. Yu Guoliang or through introduction by the other [REDACTED] Investors or in our networking activities in the biotech industry. The background information of our [REDACTED] Investors who remained as our Shareholders as of the Latest Practicable Date is set out below.

<u>[REDACTED] Investors</u>	<u>Background</u>
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Zhongmei Huadong	Zhongmei Huadong is a pharmaceutical company established in the PRC with limited liability, which is a comprehensive pharmaceutical enterprise deeply engaged in medication for specialized departments, chronic diseases and special drugs, and has built solid market foundation in fields such as chronic kidney diseases, transplantation immunity, internal secretion and digestive system. Zhongmei Huadong is a wholly-owned subsidiary of Huadong Medicine, a pharmaceutical company whose shares are listed on the Shenzhen Stock Exchange (stock code: 000963). As a major pharmaceutical company, Zhongmei Huadong is a [REDACTED].
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HISTORY AND CORPORATE STRUCTURE

[REDACTED] Investors Background

Hongtai Health

Hongtai Health is a limited partnership established in the PRC, which is owned as to approximately 0.88% by Beijing Hongtai Tongchuang Investment Management Co., Ltd. (北京洪泰同創投資管理有限公司) (“Hongtai Aplus”) as its general partner, 55.07% by Taizhou Huacheng and 44.05% by Zijin Trust Co., Ltd. (紫金信託有限責任公司) (“Zijin Trust”) as its limited partners. Hongtai Aplus was co-founded by Mr. Yu Minhong (俞敏洪) and Mr. Sheng Xitai (盛希泰) and is wholly owned by Qingdao Xincheng Technology Innovation Industrial Co., Ltd. (青島鑫宸科創實業有限公司) (a company owned as to 60% by Mr. Sheng Xitai and 10% by Mr. Yu Minhong). Hongtai Aplus is an investment company focusing on equity investments, including investing in information technology, advanced manufacturing, healthcare and medicine, new consumption, new energy and new materials, with approximately RMB30 billion of assets under its management as of the Latest Practicable Date. Therefore, Hongtai Aplus is a [REDACTED]. Taizhou Huacheng is a substantial shareholder of Cellularforce and is controlled by Taizhou Medicine, a company wholly owned by Taizhou High-tech Committee, a governmental body. Zijin Trust is ultimately controlled by Nanjing People’s Municipal Government State-owned Assets Supervision and Administration Commission (南京市人民政府國有資產監督管理委員會). To the best of our Directors’ knowledge, information and belief having made all reasonable enquiries, each of Hongtai Health, Hongtai Aplus, Mr. Sheng Xitai, Mr. Yu Minhong and Zijin Trust is an Independent Third Party.

The decision of Hongtai Health in exercising its voting rights in our Company is determined by Hongtai Aplus. As one of the limited partners of Hongtai Health, Taizhou Huacheng is entitled to receive its portion of economic interest but is not involved in the management of Hongtai Health or exercising the voting rights of Hongtai Health in our Company.

Save for Dr. Ding Chao (丁超) who was nominated by Hongtai Health as its representative in the Supervisory Committee of our Company, Hongtai Health has no other representative in the board of directors, supervisory committees or senior management of our Company and/or Cellularforce.

HISTORY AND CORPORATE STRUCTURE

[REDACTED] Investors

Background

Taizhou Jianxin and
Rongjianda

Taizhou Jianxin is an investment fund established in the PRC with limited liability focusing on private equity investment in great health industry. It is managed by Taizhou Huaxin Venture Capital Management Co., Ltd. (泰州華鑫創業投資管理有限公司) (“Taizhou Huaxin”), a company controlled by Taizhou Medical New and High-tech Industrial Development Zone Huayin Finance Investment Co., Ltd. (泰州醫藥高新區華銀金融投資有限公司) (“Taizhou Huayin”). Rongjianda is an investment fund established in the PRC with limited liability focusing on private equity investment in great health industry. It is managed by Taizhou China Medical City Rongjianda Venture Capital Management Co., Ltd. (泰州中國醫藥城融健達創業投資管理有限公司) (“Rongjianda VC”), which is owned as to 81% by Taizhou Huayin, 7.5% by Ms. Dong Qiuming (董秋明), an Independent Third Party, 5% by Mr. Ye Xiang (葉翔), our Supervisor, 3% by Mr. You Ronghui (遊榮輝), an Independent Third Party, 1.5% by Mr. Song Ronghua (宋榮華), an Independent Third Party, 1.5% by Mr. Hu Yanbao, our Board secretary and joint company secretary, and 0.5% by Mr. Gu Minghu (顧明虎), an Independent Third Party. Taizhou Huayin is owned as to approximately 41.76% by Taizhou Medical High-tech Industry Investment Development Co., Ltd. (泰州醫藥高新技術產業投資發展有限公司) (“Taizhou Medical High-tech”) (a company wholly owned by the Finance Bureau of Taizhou Medical New and High-tech Industrial Development Zone (泰州醫藥高新技術產業開發區財政局), a bureau under Taizhou High-tech Committee), 31.50% by Taizhou Oriental China Medical City Holding Group Co., Ltd. (泰州東方中國醫藥城控股集團有限公司) (“Taizhou Oriental”) (a company owned as to 90% by Taizhou Medicine) and 10.50% by Taizhou Huacheng (a company owned as to approximately 93.23% by Taizhou Medicine). Taizhou Huayin had approximately RMB1.48 billion of assets under management as of the Latest Practicable Date and is therefore a [REDACTED].

HISTORY AND CORPORATE STRUCTURE

[REDACTED] Investors Background

Taizhou Jianxin and Rongjianda have the same management team and decision making committee. The decisions of Taizhou Jianxin and Rongjianda in exercising their voting rights in our Company are ultimately determined by Taizhou High-tech Committee. Taizhou Huacheng is not involved in such decision making process of Taizhou Jianxin and Rongjianda.

Save for Mr. Wu Zhiqiang (吳志強) who was nominated by Taizhou Jianxin and Rongjianda as their representative in our Board, Taizhou Jianxin and Rongjianda have no other representative in the board of directors, supervisory committees or senior management of our Company and/or Cellularforce.

There is no special agreement or arrangement among Hongtai Health, Taizhou Jianxin and Rongjianda in respect of their shareholding in our Company.

Matrix Partners China VI, L.P. and Matrix Partners China VI-A, L.P.

Each of Matrix Partners China VI, L.P. and Matrix Partners China VI-A, L.P. is a venture capital fund incorporated under the laws of the Cayman Islands with a primary purpose of making investments in the PRC, mainly focusing on companies in the advanced technology, mobile Internet, healthcare, consumer sectors, etc.. The general partner of Matrix Partners China VI, L.P. and Matrix Partners China VI-A, L.P. is Matrix China Management VI, L.P.. The general partner of Matrix China Management VI, L.P. is Matrix China VI GP GP, Ltd.. David Su, Ho Kee Harry Man and Xiaoning Liu are directors of Matrix China VI GP GP, Ltd. and are deemed to have shared investment voting power over the shares held by Matrix Partners China VI, L.P. and Matrix Partners China VI-A, L.P.. Matrix Partners China VI, L.P. and Matrix Partners China VI-A, L.P. has 55 and 75 limited partners, respectively, and none of such limited partners holds 30.00% or more interest in Matrix Partners China VI, L.P. and Matrix Partners China VI-A, L.P.. Matrix Partners China is a [REDACTED]. To the best of our Directors' knowledge, information and belief having made all reasonable enquiries, each of Matrix Partners China VI, L.P., Matrix Partners China VI-A, L.P., Matrix China Management VI, L.P., Matrix China VI GP GP, Ltd., David Su, Ho Kee Harry Man, Xiaoning Liu, the limited partners of Matrix Partners China VI, L.P. and Matrix Partners China VI-A, L.P. is an Independent Third Party.

HISTORY AND CORPORATE STRUCTURE

[REDACTED] Investors

Background

Tongren Boda and
Hefu Ruitai

Each of Tongren Boda and Hefu Ruitai is a limited partnership established in the PRC. The general partner of Tongren Boda and Hefu Ruitai is Nanjing Tongren Boda Investment Management Co., Ltd. (南京同人博達投資管理有限公司) (“Nanjing Tongren”), an investment company focusing on private equity investment in medical health industry with approximately RMB566 million assets under its management as of the Latest Practicable Date and ultimately controlled by Mr. Sun Jianjun (孫建軍). Save for Zhejiang Hengjingtang Information Consulting Service Co., Ltd (浙江恒景堂信息諮詢服務有限公司) (formerly known as Jiangsu Hengjingtang Consulting Service Co., Ltd. (江蘇恒景堂諮詢服務有限公司)) (“Zhejiang Hengjingtang”), a company wholly owned by Ms. Cao Dongling (曹冬玲) and Zhejiang Ningtai Enterprise Management Co., Ltd (浙江寧泰企業管理有限公司) (formerly known as Jiangsu Lvkejian Enterprise Management Co., Ltd (江蘇綠科建企業管理有限公司)) (“Zhejiang Ningtai”), a company controlled by Mr. Han Qihong (韓秋宏) holding 40.00% and 30.00% interest in Tongren Boda, respectively, none of the other limited partners of Tongren Boda holds 30% or more interest in the partnership. Save for Mr. Chen Zhenqun (陳振群) holding approximately 33.33% interest in Hefu Ruitai, none of the other limited partners of Hefu Ruitai holds 30.00% or more interest in the partnership. To the best of our Directors’ knowledge, information and belief having made all reasonable enquiries, each of Tengren Boda, Hefu Ruitai, Nanjing Tongren, Mr. Sun Jianjun, Zhejiang Hengjingtang, Ms. Cao Dongling, Zhejiang Ningtai, Mr. Han Qihong, Mr. Chen Zhenqun, the other limited partners of Tongren Boda and Hefu Ruitai is an Independent Third Party.

HISTORY AND CORPORATE STRUCTURE

[REDACTED] Investors

Background

Triwise Rozman,
Shenzhen Triwise
Kangxin, Triwise
Detai, Gongqingcheng
Triwise Kangxin and
Triwise Huisheng

Each of Triwise Rozman, Shenzhen Triwise Kangxin, Triwise Detai and Gongqingcheng Triwise Kangxin is a limited partnership established in the PRC. Shenzhen Qianhai Triwise International Capital Management Co., Ltd. (深圳前海勤智國際資本管理有限公司) (“Triwise Capital”) is the general partner of each of them. Triwise Huisheng is a limited partnership established in the PRC, the general partner of which is Gongqingcheng Triwise Investment Co., Ltd. (共青城勤智投資有限公司) (“Triwise Investment”), a subsidiary of Triwise Capital. Triwise Capital is ultimately controlled by Mr. Tang Dajie (湯大傑). As an investment company focusing on investment in healthcare industry which had established an advanced investment portfolio with more than RMB3 billion of assets currently under its management as of the Latest Practicable Date, Triwise Capital is a [REDACTED]. Save for (i) Ms. Peng Longmei (彭龍妹) holding approximately 72.07% interest in Shenzhen Triwise Kangxin; (ii) Shengtak New Material Co., Ltd. (盛德鑫泰新材料股份有限公司) (“Shengtak”), a company whose shares are listed on Shenzhen Stock Exchange (stock code: 300881), holding 95.00% interest in Triwise Detai; and (iii) Mr. Xu Shensheng (徐申升) holding 88% interest in Triwise Huisheng, none of the other limited partners holds 30.00% or more interest in Triwise Rozman, Shenzhen Triwise Kangxin, Triwise Detai, Gongqingcheng Triwise Kangxin and Triwise Huisheng. To the best of our Directors’ knowledge, information and belief having made all reasonable enquiries, each of Triwise Rozman, Shenzhen Triwise Kangxin, Triwise Detai, Gongqingcheng Triwise Kangxin, Triwise Huisheng, Triwise Investment, Triwise Capital, Mr. Tang Dajie, Ms. Peng Longmei, Shengtak, Mr. Xu Shensheng and the other limited partners of Triwise Rozman, Shenzhen Triwise Kangxin, Triwise Detai and Gongqingcheng Triwise Kangxin is an Independent Third Party.

HISTORY AND CORPORATE STRUCTURE

[REDACTED] Investors

Background

Lucky-source III and Lucky-source IV

Each of Lucky-source III and Lucky-source IV is a limited partnership established in the PRC focusing on equity investment in biomedical industry. The general partner of Lucky-source III and Lucky-source IV is Shenzhen Lucky-source Fund Management Co., Ltd. (深圳瑞享源基金管理有限公司) (“Shenzhen Lucky-source”), an investment company ultimately controlled by Mr. Hu Guo’an (胡國安). Shenzhen Lucky-source had approximately RMB2 billion of assets under its management as of the Latest Practicable Date and is therefore a [REDACTED]. Save for Mr. Li Siyuan (李思遠) holding approximately 31.24% of the partnership interest in Lucky-source IV, none of the other limited partners of Lucky-source III and Lucky-source IV holds 30.00% or more interest in Lucky-source III or Lucky-source IV. To the best of our Directors’ knowledge, information and belief having made all reasonable enquiries, each of Lucky-source III, Lucky-source IV, Shenzhen Lucky-source, Mr. Hu Guo’an, Mr. Li Siyuan and the other limited partners of Lucky-source III and Lucky-source IV is an Independent Third Party.

Suzhou Guanhong

Suzhou Guanhong is a limited partnership established in the PRC focusing on investment in biopharmaceutical industry. It is managed by its general partner, Suzhou Rongshi Private Equity Management Co., Ltd. (蘇州融實私募基金管理有限公司) (formerly known as Suzhou Guanya Investment Management Co., Ltd (蘇州冠亞投資管理有限公司)) (“Suzhou Rongshi”), which is ultimately controlled by Mr. Huang Yimin (黃益民). Suzhou Rongshi had over RMB2 billion of assets under its management as of the Latest Practicable Date. Save for Mr. Zhang Jianjun (張建軍) holding approximately 44.05% interest in Suzhou Guanhong, none of the other limited partners holds 30.00% or more interest in the partnership. To the best of our Directors’ knowledge, information and belief having made all reasonable enquiries, each of Suzhou Guanhong, Suzhou Rongshi, Mr. Huang Yimin, Mr. Zhang Jianjun and the other limited partners of Suzhou Guanhong is an Independent Third Party.

HISTORY AND CORPORATE STRUCTURE

[REDACTED] Investors

Background

Shanghai Quanyou

Shanghai Quanyou is a limited partnership established in the PRC focusing on equity investment. It is owned as to approximately 45.71% by Mr. Qiu as its general partner, 8.57% by Ms. Xu Qiu (許秋), the spouse of Mr. Qiu, as one of its limited partners, and 45.72% by three other limited partners. All the three other limited partners of Shanghai Quanyou are Independent Third Parties and none of them holds 30.00% or more interest in Shanghai Quanyou.

Shanghai Shuochen

Shanghai Shuochen is a company established in the PRC with limited liability focusing on equity investment in pharmaceutical industry. It is owned as to 80.00% by Mr. Huang Huibin (黃慧斌) and 20.00% by Mr. Huang Guoming (黃國明). To the best of our Directors’ knowledge, information and belief having made all reasonable enquiries, each of Shanghai Shuochen, Mr. Huang Huibin and Mr. Huang Guoming is an Independent Third Party.

Jiaying Jiquan

Jiaying Jiquan is a limited partnership established in the PRC focusing on equity investment in biomedical industry. The general partner of Jiaying Jiquan is Shanghai Jincheng Equity Investment Fund Management Co., Ltd. (上海晉成股權投資基金管理有限公司) (“Shanghai Jincheng”), which is ultimately controlled by Mr. Gu Dongchen (顧棟臣) and Mr. Gu Zhiqiang (顧志強). Shanghai Jincheng had approximately RMB7.89 billion of assets under its management as of the Latest Practicable Date. Save for Mr. Xiong Yongxiang (熊永祥) and Ms. Zheng Qing’ai (鄭青愛) holding 45% and approximately 33.33% interest in Jiaying Jiquan, respectively, none of the other limited partners of Jiaying Jiquan holds 30% or more interest in the partnership. To the best of our Directors’ knowledge, information and belief having made all reasonable enquiries, each of Jiaying Jiquan, Shanghai Jincheng, Mr. Gu Dongchen, Mr. Gu Zhiqiang, Mr. Xiong Yongxiang, Ms. Zheng Qing’ai and the other limited partners of Jiaying Jiquan is an Independent Third Party.

HISTORY AND CORPORATE STRUCTURE

[REDACTED] Investors

Background

Qianhai Efung

Qianhai Efung is a limited partnership established in the PRC. The general partner of Qianhai Efung is Shenzhen Efung Investment Management Enterprise (Limited Partnership) (深圳市倚鋒投資管理企業(有限合夥)) (“Efung Capital”), an investment enterprise ultimately controlled by Mr. Zhu Jinqiao (朱晉橋). Efung Capital is one of the earliest biomedical investment institutions in the PRC with approximately more than RMB4 billion of assets under its management. Save for Ms. Shen Xueyu (沈雪雨) holding approximately 33.83% interest in Qianhai Efung, none of the other limited partners of Qianhai Efung holds 30.00% or more interest in the partnership. To the best of our Directors’ knowledge, information and belief having made all reasonable enquiries, each of Qianhai Efung, Efung Capital, Mr. Zhu Jinqiao and Ms. Shen Xueyu and the other limited partners of Qianhai Efung is an Independent Third Party.

Shenzhen Kaitian

Shenzhen Kaitian is a limited partnership established in the PRC. The general partner of Shenzhen Kaitian is Shenzhen Yunqi Private Equity Investment Fund Management Co., Ltd. (深圳雲起私募股權投資基金管理有限公司) (“Shenzhen Yunqi”), which was ultimately controlled by Mr. Tong Shanbing (童善炳). Shenzhen Yunqi is a private equity fund management company focusing on equity investment in medical and biotech industries with approximately RMB100 million of assets under its management as of the Latest Practicable Date. None of the limited partners of Shenzhen Kaitian holds 30% or more interest in the partnership. To the best of our Directors’ knowledge, information and belief having made all reasonable enquiries, each of Shenzhen Kaitian, Shenzhen Yunqi, Mr. Tong Shanbing and the limited partners of Shenzhen Kaitian is an Independent Third Party.

HISTORY AND CORPORATE STRUCTURE

[REDACTED] Investors

Background

TWVC Panglin

TWVC Panglin is a company incorporated in Hong Kong with limited liability which is wholly owned by TWVC Panglin Fund SPC (“TWVC SPC”). TWVC SPC is a segregated portfolio company registered under the laws of the Cayman Islands whose investment manager is TW Venture Capital Limited (“TW VC”). TW VC is an approved investment manager in the British Virgin Islands and is wholly owned by Tong Group Holdings Limited (“Tong Group”), which is in turn wholly owned by Ms. Cai Li Na (蔡麗娜). TW VC had approximately US\$60 million of assets under its management as of the Latest Practicable Date. To the best of our Directors’ knowledge, information and belief having made all reasonable enquiries, each of TWVC Panglin, TWVC SPC, TW VC, Tong Group and Ms. Cai Li Na is an Independent Third Party.

Nanjing Yuzhijia

Nanjing Yuzhijia is a limited partnership established in the PRC focusing on equity investment in biomedical industry. It was owned as to 99.90% by Ms. Shen Xiaoqin (沈小芹) as its limited partner and 0.10% by Mr. Shen Hui (沈輝) as its general partner. To the best of our Directors’ knowledge, information and belief having made all reasonable enquiries, each of Nanjing Yuzhijia, Ms. Shen Xiaoqin and Mr. Shen Hui is an Independent Third Party.

Cowin Guosheng

Cowin Guosheng is a limited partnership established in the PRC. The general partner of Cowin Guosheng is Cowin Jinxiu Capital Firm (深圳同創錦繡資產管理有限公司) (“Cowin Jinxiu”), a wholly-owned subsidiary of Shenzhen Cowin Asset Management Co., Ltd. (深圳同創偉業資產管理股份有限公司) (“Cowin Weiye”) whose shares are listed on the National Equities Exchange and Quotations in the PRC (stock code: 832793). Cowin Weiye is an investment company focusing on investing in a pioneering enterprise on a long-term basis which has 23 years of experience of capital management with more than RMB30 billion of assets under its management as of the Latest Practicable Date. None of the limited partners of Cowin Guosheng holds 30% or more interest in the partnership. To the best of our Directors’ knowledge, information and belief having made all reasonable enquiries, each of Cowin Guosheng, Cowin Jinxiu, Cowin Weiye and the limited partners of Cowin Guosheng is an Independent Third Party.

HISTORY AND CORPORATE STRUCTURE

[REDACTED] Investors

Background

Jiayin Lucky-source

Jiayin Lucky-source is a limited partnership established in the PRC. The general partner of Jiayin Lucky-source is Shenzhen Jiayin Private Equity Fund Management Co., Ltd. (深圳市佳銀私募股權基金管理有限公司) (“Shenzhen Jiayin”), an investment company focusing on investment in innovative enterprises in new energy, new materials, biomedicine, high-end manufacturing, semiconductors and other fields with high technology, high value-added and high growth and ultimately controlled by Mr. Wang Siqi (汪斯奇). Shenzhen Jiayin had approximately RMB250 million of assets under its management as of the Latest Practicable Date. Jiayin Lucky-source has two limited partners, namely Gongqingcheng Jiarui Investment Co., Ltd. (共青城佳睿投資有限公司) (“Gongqingcheng Jiarui”), an investment company ultimately controlled by Mr. Wang Siqi, holding 79.95% interest in Jiayin Lucky-source, and Lucky-source III, one of our [REDACTED] Investors, holding 20.00% interest in Jiayin Lucky-source, respectively. To the best of our Directors’ knowledge, information and belief having made all reasonable enquiries, each of Jiayin Lucky-source, Shenzhen Jiayin, Mr. Wang Siqi, Gongqingcheng Jiarui and Lucky-source III is an Independent Third Party.

HISTORY AND CORPORATE STRUCTURE

[REDACTED] Investors Background

Yuanzhi Fuhai

Yuanzhi Fuhai is a limited partnership established in the PRC. The general partner of Yuanzhi Fuhai is Shenzhen Yuanzhi Fuhai Investment Management Co., Ltd. (深圳市遠致富海投資管理有限公司) (“Shenzhen Yuanzhi”), an investment company focusing on investment in health, internet application, artificial intelligence, new energy car, energy saving, and new-advanced manufacturing fields which is controlled by Shenzhen Capital Operation Group Co., Ltd (深圳市資本運營集團有限公司) (“Shenzhen Capital”), a company wholly owned by Shenzhen People’s Municipal Government State-owned Assets Supervision and Administration Commission (深圳市人民政府國有資產監督管理委員會). Shenzhen Yuanzhi had approximately RMB13.7 billion of assets under its management as of the Latest Practicable Date. Save for Harbin City Investment Holding Co., Ltd. (哈爾濱市城投投資控股有限公司) (“Harbin Investment”), an investment company ultimately controlled by Harbin People’s Municipal Government State-owned Assets Supervision and Administration Commission (哈爾濱市人民政府國有資產監督管理委員會) holding approximately 57.73% interest in Yuanzhi Fuhai, none of the other limited partners of Yuanzhi Fuhai holds 30.00% or more interest in the partnership. To the best of our Directors’ knowledge, information and belief having made all reasonable enquiries, each of Yuanzhi Fuhai, Shenzhen Yuanzhi, Shenzhen Capital, Harbin Investment and the other limited partners of Yuanzhi Fuhai is an Independent Third Party.

Everest No. 37

Everest No. 37 is a limited partnership established in the PRC. The general partner of Everest No. 37 is Everest Venture Capital Co., Ltd. (朗瑪峰創業投資有限公司) (“Everest VC”), which is controlled by Mr. Xiao Jiancong (肖建聰). Everest VC is an investment company focusing on investment in high-tech companies. Everest VC had approximately RMB10 billion of assets under its management as of the Latest Practicable Date. None of the limited partners of Everest No. 37 holds 30% or more interests in the partnership. To the best of our Directors’ knowledge, information and belief having made all reasonable enquiries, each of Everest No. 37, Everest VC, Mr. Xiao Jiancong and the limited partners of Everest No. 37 is an Independent Third Party.

HISTORY AND CORPORATE STRUCTURE

[REDACTED] Investors Background

Nanjing Talent

Nanjing Talent is a limited partnership established in the PRC, which is owned as to 0.04% by Nanjing Talent is Nanjing Zijin Venture Capital Fund Management Co., Ltd. (南京紫金創投基金管理有限責任公司) (“Nanjing Zijin”) as its general partner and 99.96% by Nanjing Zijin Emerging Industry Venture Capital Fund Co., Ltd. (南京紫金新興產業創業投資基金有限公司) (“Nanjing Emerging”) as its limited partner. Nanjing Zijin is an investment company focusing on investment in China’s strategic emerging industries and is ultimately controlled by Nanjing People’s Municipal Government State-owned Assets Supervision and Administration Commission. Nanjing Zijin had over RMB20 billion of assets under its management as of the Latest Practicable Date. Nanjing Emerging is a state-owned company and none of its shareholders holds 30% or more interests in Nanjing Emerging. To the best of our Directors’ knowledge, information and belief having made all reasonable enquiries, each of Nanjing Talent, Nanjing Zijin, Nanjing Emerging is an Independent Third Party.

Special Rights of the [REDACTED] Investors

Pursuant to the shareholders agreement (the “Shareholders Agreement”) dated November 30, 2022 entered into among our Company, Mr. Qiu, Mr. Yu Guo’an and our then Shareholders, the [REDACTED] Investors were granted certain special rights, including, amongst others, (i) the right to elect Directors and Supervisors; (ii) the right to receive financial statements and other information about our Company and inspect assets, records and books of the members of our Group; (iii) pre-emptive right; (iv) right of first refusal in certain circumstances; (v) tag-along right; (vi) right to prior consent to certain corporate actions; (vii) redemption rights to request Mr. Qiu, Mr. Yu Guo’an and Hangzhou Quanyi to repurchase the Shares upon occurrence of specified redemption events; (viii) anti-dilution right; and/or (ix) right of entitlement of same favorable terms offered to other investors. Pursuant to the supplemental agreement to the Shareholders Agreement dated March 10, 2023, the redemption rights were terminated at the time of the first submission of the [REDACTED] application but can be reinstated if the [REDACTED] application has been withdrawn or the [REDACTED] is not completed within 18 months from the date of the [REDACTED] application, and all the other special rights under the Shareholders Agreement shall be automatically terminated upon the [REDACTED] in accordance with the guidance on [REDACTED] investments (Chapter 4.2 of the Guide).

HISTORY AND CORPORATE STRUCTURE

Shareholding of our [REDACTED] Investors in our Company upon the [REDACTED]

Immediately after the completion of the [REDACTED] and conversion of [REDACTED] Shares into H Shares, the shareholding of our [REDACTED] Investors in our Company will be as follows:

Name of [REDACTED] Investors	Description of Shares	Number of Shares	Approximate shareholding percentage in our total issued share capital
Zhongmei Huadong	H Shares to be converted from [REDACTED] Shares	35,900,000	[REDACTED]%
Hongtai Health	H Shares to be converted from [REDACTED] Shares	18,750,000	[REDACTED]%
Matrix Partners China VI, L.P.	H Shares to be converted from [REDACTED] Shares	9,853,116	[REDACTED]%
Rongjianda	H Shares to be converted from [REDACTED] Shares	7,500,000	[REDACTED]%
Taizhou Jianxin	[REDACTED] Shares	3,750,000	[REDACTED]%
	H Shares to be converted from [REDACTED] Shares	3,750,000	
Suzhou Guanhong	H Shares to be converted from [REDACTED] Shares	6,540,000	[REDACTED]%
Shanghai Quanyou	H Shares to be converted from [REDACTED] Shares	5,000,000	[REDACTED]%
Shanghai Shuochen	H Shares to be converted from [REDACTED] Shares	5,000,000	[REDACTED]%
Lucky-source IV	H Shares to be converted from [REDACTED] Shares	4,500,000	[REDACTED]%
Tongren Boda	H Shares to be converted from [REDACTED] Shares	4,375,000	[REDACTED]%
Gongqingcheng Triwise Kangxin	H Shares to be converted from [REDACTED] Shares	3,899,800	[REDACTED]%
Hefu Ruitai	H Shares to be converted from [REDACTED] Shares	3,750,000	[REDACTED]%
Jiaxing Jiquan	[REDACTED] Shares	3,572,400	[REDACTED]%
Qianhai Efung	H Shares to be converted from [REDACTED] Shares	3,500,000	[REDACTED]%
Lucky-source III	H Shares to be converted from [REDACTED] Shares	3,230,000	[REDACTED]%
Shenzhen Kaitian	H Shares to be converted from [REDACTED] Shares	2,977,000	[REDACTED]%
TWVC Panglin	H Shares to be converted from [REDACTED] Shares	2,500,600	[REDACTED]%
Nanjing Yuzhijia	H Shares to be converted from [REDACTED] Shares	2,000,000	[REDACTED]%
Cowin Guosheng	H Shares to be converted from [REDACTED] Shares	1,450,000	[REDACTED]%
Triwise Rozman	H Shares to be converted from [REDACTED] Shares	1,250,000	[REDACTED]%
Shenzhen Triwise Kangxin	H Shares to be converted from [REDACTED] Shares	1,250,000	[REDACTED]%
Jiayin Lucky-source	H Shares to be converted from [REDACTED] Shares	1,250,000	[REDACTED]%
Matrix Partners China VI-A, L.P.	H Shares to be converted from [REDACTED] Shares	1,066,884	[REDACTED]%
Everest No. 37	H Shares to be converted from [REDACTED] Shares	730,000	[REDACTED]%

HISTORY AND CORPORATE STRUCTURE

Name of [REDACTED] Investors	Description of Shares	Number of Shares	Approximate shareholding percentage in our total issued share capital
Triwise Detai	H Shares to be converted from [REDACTED] Shares	730,000	[REDACTED]%
Yuanzhi Fuhai	H Shares to be converted from [REDACTED] Shares	730,000	[REDACTED]%
Nanjing Talent	H Shares to be converted from [REDACTED] Shares	625,000	[REDACTED]%
Triwise Huisheng	H Shares to be converted from [REDACTED] Shares	595,400	[REDACTED]%
Subtotal	[REDACTED] Shares	7,322,400	[REDACTED]%
	H Shares	132,702,800	[REDACTED]%
Total		140,025,200	[REDACTED]%

[REDACTED]

Mr. Qiu is our executive Director and Controlling Shareholder and therefore a core connected person of our Company. Hangzhou Quanyi, Shanghai Quanyou and Xinfu Tongxin are our Controlling Shareholders and therefore core connected persons of our Company. Zhongmei Huazhong is our substantial shareholder and therefore a core connected person of our Company. Taizhou Jianxin, Rongjianda and Taizhou Huacheng (a substantial shareholder of Cellularforce) are entities under common control, and Taizhou Jianxin and Rongjianda are therefore regarded as core connected persons of our Company. The subscription of Shares by Hongtai Health was partly financed by Taizhou Huacheng as one of the limited partners of Hongtai Health holding approximately 55.07% interest in Hongtai Health. Accordingly, an aggregate of [REDACTED] Shares held by Mr. Qiu, Hangzhou Quanyi, Shanghai Quanyou, Xinfu Tongxin, Zhongmei Huadong, Taizhou Jianxin, Rongjianda and Hongtai Health, representing approximately [REDACTED]% of our Shares in issue immediately following the completion of the [REDACTED] will not be counted as part of the [REDACTED] after the [REDACTED].

An aggregate of [REDACTED] Shares, representing approximately [REDACTED]% of our Shares in issue immediately following the completion of the [REDACTED] held by Jiaxing Jiquan will not be counted as part of the [REDACTED] after the [REDACTED] as the Shares held by Jiaxing Jiquan are [REDACTED] Shares which will not be converted into H Shares and [REDACTED] on the Stock Exchange following the completion of the [REDACTED].

An aggregate of 66,252,800 Shares, representing approximately [REDACTED]% of our Shares in issue immediately following the completion of the [REDACTED] held by Dr. Yu Guoliang, Dr. Li Jianwei, Dr. Qiu Zhihua, Mr. Guo Xinjun and the [REDACTED] investors including Matrix Partners China VI, L.P., Suzhou Guan hong, Tongren Boda, Shanghai Shuochen, Lucky-source IV, Gongqingcheng Triwise Kangxin, Hefu Ruitai, Qianhai Efung,

HISTORY AND CORPORATE STRUCTURE

Lucky-source III, Shenzhen Kaitian, TWVC Panglin, Nanjing Yuzhijia, Cowin Guosheng, Triwise Rozman, Shenzhen Triwise Kangxin, Jiayin Lucky-source, Matrix Partners China VI-A, L.P., Everest No. 37, Triwise Detai, Yuanzhi Fuhai, Nanjing Talent and Triwise Huisheng will be converted into H Shares and [REDACTED] on the Stock Exchange immediately following the completion of the [REDACTED]. As Dr. Yu Guoliang, Dr. Li Jianwei, Dr. Qiu Zhihua, Mr. Guo Xinjun and the above [REDACTED] Investors are not core connected persons of our Company and their investments are not financed directly or indirectly by any core connected persons of our Company, Shares held by them will be counted towards the [REDACTED] for the purpose of Rule 8.08 of the Listing Rules after the [REDACTED]. Over [REDACTED]% of the total issued share capital of our Company with a market capitalization of substantially over HK\$[REDACTED] will be held by the public upon completion of the [REDACTED] in accordance with Rule 8.08(1)(a) and Rule 18A.07, respectively, of the Listing Rules.

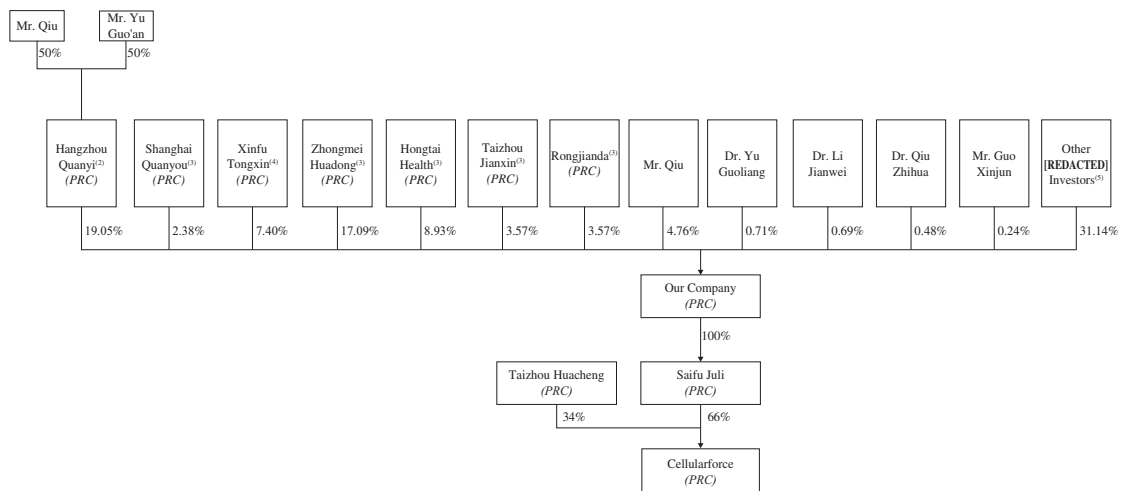
Compliance with the Guide

The Sole Sponsor is of the view that the [REDACTED] Investments are in compliance with the guidance on [REDACTED] investments (Chapter 4.2 of the Guide).

SHAREHOLDING AND CORPORATE STRUCTURE

Corporate Structure Immediately After the Completion of the [REDACTED] Investments But Before the [REDACTED]

The following chart sets forth our corporate and shareholding structure immediately after the completion of the [REDACTED] Investments, but before the completion of the [REDACTED]:



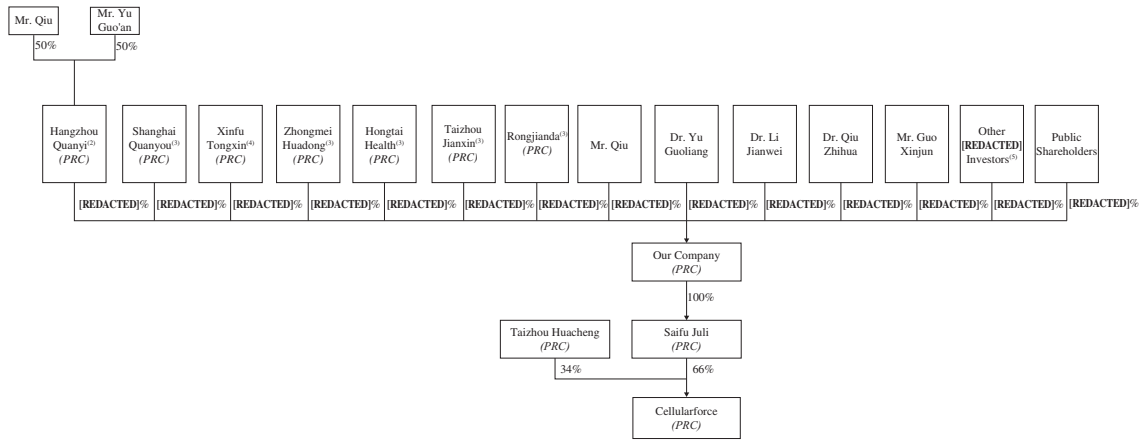
HISTORY AND CORPORATE STRUCTURE

Notes:

1. Shareholding percentages may not add up to 100% due to rounding.
2. Pursuant to the supplemental partnership agreement of Hangzhou Quanyi entered into between Mr. Qiu and Mr. Yu Guo’an on February 5, 2022, Mr. Qiu and Mr. Yu Guo’an agreed and confirmed, among others, that since the date of establishment of our Company, they have been and would continue to be parties acting in concert and they have agreed to consult with each other and reach a unanimous consensus between themselves before making the decisions and exercising their voting rights through Hangzhou Quanyi at the Board and Shareholders’ meetings and in the event that they are unable to reach consensus on any matter presented, the decisions of Mr. Qiu shall prevail.
3. For the details of the background information of Shanghai Quanyou, Zhongmei Huadong, Hongtai Health, Taizhou Jianxin and Rongjianda, see “[REDACTED] Investments” above.
4. Xinfu Tongxin was established in the PRC as one of our employee share incentive platforms on August 19, 2021, the general partner of which is Mr. Qiu. For further details, see “—Employee Share Incentive Scheme” above.
5. For the details of the background information of the Other [REDACTED] Investors, see “[REDACTED] Investments” above.

Corporate Structure Immediately After the Completion of the [REDACTED]

The following chart sets forth our corporate and shareholding structure immediately after the completion of the [REDACTED]:



Note: Please refer to the notes in “—Shareholding and Corporate Structure—Corporate Structure Immediately After the Completion of the [REDACTED] Investments But Before the [REDACTED]” above.

BUSINESS

OVERVIEW

Founded in the PRC in 2015, we are a clinical-stage biotech company exclusively focused on biologic therapies for autoimmune and allergic diseases, with a self-developed drug pipeline and an established commercial-scale in-house manufacturing capability. To address significant unmet medical needs in the autoimmune and allergic disease drug market in China, which is forecast by Frost & Sullivan to surpass one hundred billion yuan by 2025, we have built a broad pipeline that covers the four major disease areas in the field, including skin, rheumatic, respiratory and digestive diseases. According to Frost & Sullivan, among Chinese domestic companies, we had one of the most numbers of IND-approved drug candidates in autoimmune and allergic diseases as of the Latest Practicable Date. As of such date, our pipeline encompassed two Core Products, QX002N and QX005N, and seven other drug candidates. In particular, our pipeline featured QX001S, an IL-12/IL-23p40 inhibitor for psoriasis (Ps), the first domestically developed ustekinumab biosimilar with BLA submitted in China and potentially one of the first ustekinumab biosimilars to be approved in China; QX002N, an IL-17A inhibitor in Phase III clinical trial for ankylosing spondylitis (AS) with promising efficacy; and QX005N, a monoclonal antibody (mAb) blocking IL-4R α , a well-validated, broad-acting target for a wide range of indications. QX005N is one of the most advanced biologic drug candidates for atopic dermatitis (AD), and the first biologic drug candidate developed by a Chinese domestic company in clinical trial for prurigo nodularis (PN), in China. Our mission is to pursue scientific innovation and deliver affordable and quality therapeutics.

Autoimmune and allergic diseases represent the second-largest therapeutic area globally, only after oncology, and have witnessed a succession of blockbuster drugs. According to Frost & Sullivan, the market size of autoimmune and allergic disease drugs amounted to US\$187.5 billion in 2022, which was 12.5% for all drugs combined. Among the 100 top-selling drugs in 2022, around one fifth were autoimmune or allergic drugs, including two—Humira (adalimumab) (No. 2; US\$21.2 billion) and Stelara (ustekinumab) (No. 9; US\$9.7 billion)—in the top 10. Humira, in particular, was the world’s best-selling drug for eight years in the last ten (2013-2022). In contrast, market development in China has lagged significantly behind. According to Frost & Sullivan, the total patient population of autoimmune and allergic diseases in China exceeded 420 million as compared to 100 million in the United States in 2020. However, China’s autoimmune and allergic drug market was only US\$7.2 billion in 2020, approximately 7.5% of the U.S. market of US\$95.6 billion. Specifically, biologic drugs dominate developed markets, but their penetration in China remains low. In 2020, biologic drugs made up over 60% of the autoimmune and allergic disease drug market in the United States, but only about 10% of the China market.

The underdevelopment of the China market has historical reasons. Due to an innovation gap, most of the innovative biologic drugs available in China have been expensive blockbuster drugs developed by multinational corporations, or MNCs, typically not covered by public medical insurance. This has had two effects. On the one hand, because autoimmune and allergic diseases are often not fatal, Chinese patients, when they have limited ability to pay and are price-sensitive, are less inclined to address them with significant economic resources as committedly as they might with fatal diseases such as cancer, leading to discontinued treatment, ineffective traditional treatment or no treatment at all. On the other hand, due to limited returns, the MNCs have not invested extensively in physician and patient education in China, which has perpetuated poor awareness. As a result, diagnosis and treatment rates for

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many diseases in this field have been low. The *status quo* indicates a deep structural misalignment with the unmet medical need. Autoimmune and allergic diseases are serious diseases. They can severely affect patients’ quality of life in various manifestations, including great pain, persistent itchiness, disfigurement, disability, severe psychological pressure and social exclusion. They impose profound disease burden on patients and society and require safe and effective treatment.

Despite the historical underdevelopment, China’s autoimmune and allergic disease drug market has been changing in recent years, especially since 2021. Several important factors have driven the industry toward more alignment with global trends and more certainty in market prospect:

- *Approvals, NRDL admissions and accelerated sales ramp-up of blockbuster drugs.* A number of blockbuster drugs developed by MNCs were approved in China and admitted to the NRDL. While unit prices dropped, sales soared. For example, Cosentyx (secukinumab, an IL-17A inhibitor) was approved in China for moderate-to-severe plaque Ps in March 2019 and admitted to the NRDL in March 2021. While its unit price (150 mg) decreased from RMB2,998 in 2020 to RMB1,188 in 2022, its China sales increased from US\$72.5 million in 2020 to US\$279.0 million in 2021 and US\$601.4 million in 2022. Dupixent (dupilumab, an IL-4R α inhibitor) was approved for moderate-to-severe AD in June 2020 and admitted to the NRDL in January 2021. While its unit price (300 mg) decreased from RMB6,666 in 2020 to RMB3,160 in 2022, its China sales increased from US\$13.7 million in 2020 to US\$87.4 million in 2021 and US\$248.1 million in 2022. Apart from the expansion in sales volume, there has also been an evident acceleration in such expansion. According to Frost & Sullivan, it took seven years for Humira (adalimumab) to achieve annual sales of US\$100.0 million in China since its approval in the country in 2010, whereas it took Cosentyx only two years to reach the same milestone.
- *Evolution of treatment paradigm from traditional anti-inflammatory agents to biologics.* Traditional anti-inflammatory agents are commonly used treatment options for autoimmune diseases, particularly during the initial stages of the diseases. However, traditional anti-inflammatory agents are also noted with limited efficacy in patients with more severe symptoms and there remain concerns over the potential side effects from long-term use of some of these agents. Therefore, over the past decades, biologic drugs with superior efficacy and safety have been increasingly accepted by physicians and patients globally. The evolution of treatment paradigm from traditional anti-inflammatory agents to biologics is also accompanied by continuous upgrades in classes of biologic drugs. For example, compared to first-generation inhibitors targeting tumor necrosis factor alpha (TNF- α), which have relatively high risk of serious infections, certain biologics targeting interleukins (*e.g.*, IL-17 and IL-23) have demonstrated better efficacy and/or safety for certain indications and are under extensive investigation with more drugs potentially to be approved. The same trend is also found and followed in China, and drives an increasing demand for novel biologic drugs.

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- *Rise of domestic developers.* Recognizing the great potential of the therapeutic area, a growing number of Chinese pharmaceutical companies have begun to conduct R&D on autoimmune and allergic disease drugs. Drugs developed by Chinese domestic companies are expected to have a price advantage. Domestic companies may also leverage their in-depth understanding and extensive coverage of local patients and hospitals to, together with MNCs, improve awareness of autoimmune and allergic diseases and biologic therapies through more precise and effective marketing activities and patient education.

Due to these favorable changes, the autoimmune and allergic disease drug market in China expanded from US\$7.2 billion in 2020 to US\$9.0 billion in 2022, representing a CAGR of 11.8%, with the proportion of biologic drugs increased to 20.4% in 2022. The market is expected to continue to develop. According to Frost & Sullivan, it is estimated to grow to US\$41.5 billion in 2030, at a CAGR of 21.1% from 2022, and with the proportion of biologic drugs increased to about 60%. The market has significant further, long-term growth potential. On the demand side, although usually not fatal, autoimmune and allergic diseases are also usually incurable, and are classic chronic diseases that require long-term or even life-long care. Accordingly, patients have stable need for medication over long periods of time, resulting in high lifetime value (LTV). In addition, long-term medication causes drug resistance and adherence issues, creating a need for alternative therapies. Furthermore, the pathogenic mechanisms of many autoimmune and allergic diseases are not fully understood. One drug is often used for multiple indications, with varying response rates, indicating that the development of precision medicine and individualized treatment is still at a very early stage. On the supply side, compared with oncology, which is crowded with many international and domestic pharmaceutical companies, competition in the autoimmune and allergic drug market is relatively less intense. As indicated in the 2022 Drug Evaluation Report released by the NMPA, among 769 IND approvals granted in 2022, fewer than 140 were in the autoimmune and allergic field, compared with more than 430 in oncology.

We are well positioned to take advantage of this market opportunity. Since our establishment in 2015, we have exclusively focused on the autoimmune and allergic field and built a broad pipeline covering the four major disease areas in the field, namely, skin, rheumatic, respiratory and digestive diseases.

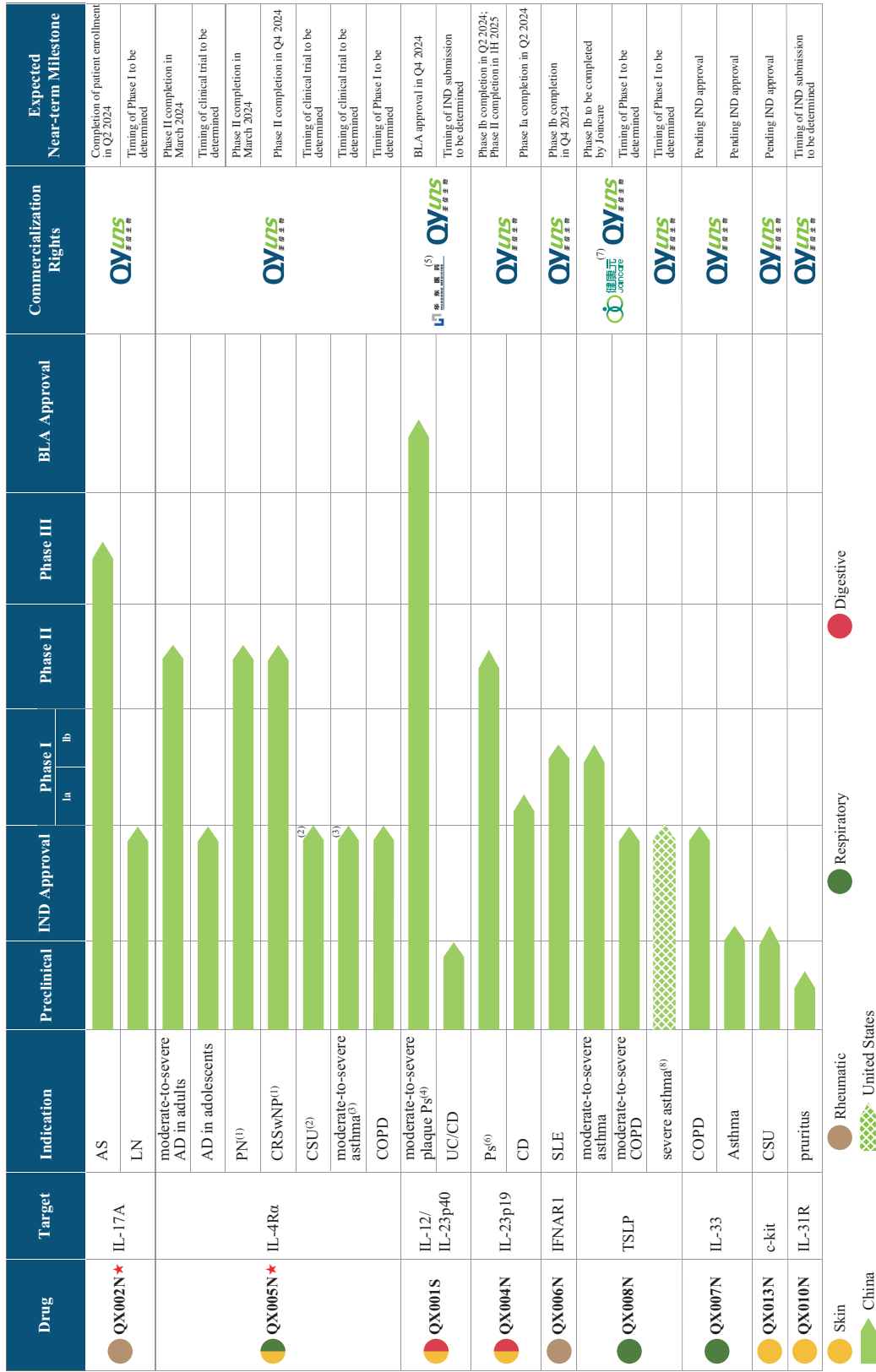
- *Skin diseases.* Inflammatory skin diseases have large patient populations in China. According to Frost & Sullivan, there are estimated to be 6.8 million Ps patients in China by 2030, 20% to 30% of whom having moderate-to-severe disease, indicating an estimated drug market of US\$9.9 billion. In the same year, there are estimated to be 78.5 million AD patients, 30% of whom having moderate-to-severe disease, indicating an estimated drug market of US\$7.1 billion, and 2.1 million PN patients, with no approved biologic therapies, indicating a market with substantial unmet medical needs. Our pipeline consists of five drug candidates for skin diseases, namely, QX001S, an IL-12/IL-23p40 inhibitor, for Ps; QX004N, an IL-23p19 inhibitor, for the same indication; QX005N, an IL-4R α inhibitor, for AD, PN and chronic spontaneous urticaria (CSU); QX013N, a humanized IgG1 mAb targeting c-kit, for CSU; and QX010N, an IL-31R inhibitor, for pruritus.

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- *Rheumatic diseases.* Inflammatory rheumatic diseases are multiple immune diseases, such as ankylosing spondylitis (AS), systemic lupus erythematosus (SLE) and lupus nephritis (LN). In addition to persistent and mysterious pain, rheumatic conditions can cause patients to develop deformities so severe that daily tasks like walking or getting dressed feel impossible. In 2030, there are estimated to be 4.0 million AS patients in China, with an estimated drug market of US\$6.5 billion, and 1.1 million SLE patients, with an estimated drug market of US\$3.4 billion. Our pipeline consists of two drug candidates for rheumatic diseases, namely, QX002N, targeting IL-17A, for AS and LN; and QX006N, targeting IFNAR1, for SLE.
- *Respiratory diseases.* Inflammatory respiratory diseases, such as asthma, chronic rhinosinusitis with nasal polyps (CRSwNP) and chronic obstructive pulmonary disease (COPD), have large patient populations in China. In 2030, there are estimated to be 78.1 million asthma patients in China, about 10% of whom having severe disease, indicating an estimated drug market of US\$10.6 billion. In the same year, there are estimated to be 22.3 million CRSwNP patients, with an estimated drug market of US\$0.6 billion, and 110.7 million COPD patients, with an estimated drug market of US\$6.3 billion. Our pipeline consists of three drug candidates for respiratory diseases, namely, QX005N, targeting IL-4R α , for CRSwNP, moderate-to-severe asthma and COPD; QX008N, targeting TSLP, for moderate-to-severe asthma and moderate-to-severe COPD; and QX007N, targeting IL-33, for COPD and asthma.
- *Digestive diseases.* Inflammatory digestive diseases, such as ulcerative colitis (UC) and Crohn’s disease (CD), are conditions characterized by chronic inflammation of the gastrointestinal tract, which can be aggressive and significantly impact the patient’s quality of life. In 2030, there are estimated to be 1.2 million UC and CD patients in China, with an estimated drug market of US\$5.5 billion. Our pipeline consists of two drug candidates for digestive diseases, namely, QX001S for UC/CD and QX004N for CD.

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The chart below sets forth key information about our pipeline as of February 20, 2024.



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★ Core Product

AD: atopic dermatitis	CRSwNP: chronic rhinosinusitis with nasal polyps	Ps: psoriasis
AS: ankylosing spondylitis	CSU: chronic spontaneous urticaria	SLE: systemic lupus erythematosus
CD: Crohn’s disease	LN: lupus nephritis	UC: ulcerative colitis
COPD: chronic obstructive pulmonary disease	PN: prurigo nodularis	
IFNAR1: interferon-alpha/beta receptor subunit 1	IL-17A: interleukin-17A	IL-33: interleukin-33
IL-4Rα: interleukin-4 receptor subunit α	IL-23p19: interleukin-23 subunit p19	TSLP: thymic stromal lymphopoietin
IL-12/IL-23p40: interleukin-12/interleukin-23 subunit p40	IL-31R: interleukin-31 receptor	

Notes:

- (1) We directly commenced a Phase II clinical trial of QX005N for PN and a Phase II clinical trial of QX005N for CRSwNP by leveraging the Phase Ia clinical trial results of QX005N in healthy subjects and the Phase Ib clinical trial results of QX005N for moderate-to-severe AD in adults.
- (2) We plan to consult with the NMPA about directly initiating a Phase III clinical trial of QX005N for CSU by leveraging the Phase I clinical trial results of QX005N for moderate-to-severe AD in adults as well as the Phase II clinical trial results of QX005N for moderate-to-severe AD in adults and/or PN.
- (3) We plan to consult with the NMPA about directly initiating a Phase III clinical trial of QX005N for asthma by leveraging the Phase I clinical trial results of QX005N for moderate-to-severe AD in adults as well as the Phase II clinical trial results of QX005N for CRSwNP.
- (4) Zhongmei Huadong and we directly commenced the Phase III clinical trial of QX001S for Ps after completion of the Phase I clinical trial as Phase II clinical trials are not required for biosimilars.
- (5) In August 2020, we entered into a collaboration agreement with Zhongmei Huadong, a subsidiary of Huadong Medicine, with respect to the joint development and exclusive commercialization of QX001S in China. We retain the exclusive development and commercialization rights of QX001S outside China. For further details, please refer to “—Collaboration with Zhongmei Huadong.”
- (6) As of February 20, 2024, we had completed subject enrollment for both the Phase Ib clinical trial and the Phase II clinical trial of QX004N for Ps. We expect to complete the Phase Ib clinical trial in the second quarter of 2024.
- (7) In January 2024, we entered into a technology transfer agreement with Joincare Pharmaceutical Group Industry Co., Ltd. (“Joincare”), to grant Joincare an exclusive license to develop, manufacture and commercialize QX008N in mainland China, Hong Kong and Macau. Joincare will be responsible for the BLA application and will be the MAH of QX008N in the licensed territory, once approved. We retain the exclusive rights to develop, manufacture and commercialize QX008N outside the licensed territory. See “Business—Our Other Key Product Candidates—QX008N—Licenses, Rights and Obligations” for details.
- (8) We obtained an IND approval of QX008N for the treatment of severe asthma from the FDA in September 2022 and intend to formulate a clinical development plan for QX008N in the United States depending on the data from our Phase Ia and Phase Ib clinical trials in China.

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Our Core Products

QX002N

One of our Core Products, QX002N, is a high-affinity mAb targeting IL-17A, a key player in the pathological mechanism of various autoimmune diseases. IL-17A inhibitors are recommended by prevailing clinical guidelines as second-line standalone treatment (the same designation as TNF inhibitors) for AS patients with high disease activity after receiving first-line traditional treatments. Between the two classes of biologics, IL-17A inhibitors have shown clear clinical benefit in patients who are intolerant to or fail to achieve adequate disease control with TNF- α inhibitors. We have obtained IND approval for QX002N for both AS and LN and plan to prioritize the development of the former indication. QX002N demonstrated promising efficacy in our Phase Ib and Phase II clinical trials for AS. In our Phase Ib clinical trial, 62.5% and 37.5% of subjects receiving QX002N (160 mg) once every 2 weeks achieved ASAS20 and ASAS40 responses at week 16, respectively. In our Phase II clinical trial, the ASAS20 and ASAS40 response rates of subjects receiving QX002N (160 mg) once every 4 weeks reached 60.0% and 40.0% at week 16, respectively. We conducted a pre-Phase III consultation with the NMPA, which raised no material questions and confirmed that it had no objections to the commencement of such trial in its official response in July 2023. We commenced the Phase III clinical trial in September 2023 and expect to complete it in the second half of 2025.

QX005N

Our other Core Product, QX005N, is designed to inhibit IL-4R α , a well-validated, broad-acting target for a wide range of indications. Because IL-4R α controls the signaling of both IL-4 and IL-13, which is critical in the initiation of type 2 inflammation, it has emerged as a key target for new drug development in related indications. According to Frost & Sullivan, IL-4R α inhibitors had been approved or were under development for 20 indications globally as of the Latest Practicable Date. Dupilumab, the first FDA-approved IL-4R α inhibitor, is one of the best-selling biologic drugs globally for allergic diseases, with annual sales of US\$8.7 billion in 2022. As of the Latest Practicable Date, we had obtained seven IND approvals for QX005N (namely, AD in adults, AD in adolescents, PN, CRSwNP, CSU, asthma and COPD), the most among IL-4R α -targeting drug candidates in China. QX005N demonstrated favorable safety and efficacy results in our Phase Ia and Phase Ib clinical trials for AD. In the Phase Ib clinical trial in patients with moderate-to-severe AD, in each of the 300 mg and 600 mg groups, 75.0% of subjects achieved Eczema Area and Severity Index-75 (EASI-75) responses (defined as $\geq 75\%$ improvement from baseline in the EASI score) and 50.0% of subjects reached Investigator’s Global Assessment (IGA) scores (0 or 1) at week 12 without significantly increased safety risks. We have started a Phase II clinical trial for AD and completed patient enrollment in February 2023. In addition, we commenced a Phase II clinical trial for PN in February 2023. According to Frost & Sullivan, QX005N was the first biologic drug candidate developed by a Chinese domestic company to start a clinical trial for PN in China. In January 2024, the CDE granted QX005N the breakthrough therapy designation for the treatment of PN, signifying its superior clinical benefits compared to current treatment methods. The designation is designed to expedite the development and regulatory review of innovative drugs demonstrating substantial potential in addressing serious conditions. We also commenced a Phase II clinical trial of QX005N for CRSwNP in April 2023.

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Our other key drug candidates

- QX001S: QX001S is our first expected commercial drug, the first domestically developed ustekinumab biosimilar with BLA submitted in China and potentially one of the first ustekinumab biosimilars to be approved in China. Initially approved by the FDA in 2009, ustekinumab was the first biologic treatment to selectively inhibit the IL-23 and IL-12 pathways and has been widely regarded as one of the major treatments for Ps worldwide. In 2022, it recorded sales of US\$9.7 billion globally and ranked the ninth best-selling drug worldwide in the same year, according to Frost & Sullivan. In our Phase I clinical trial for Ps, QX001S demonstrated a safety and PK profile comparable to that of ustekinumab. In our Phase III clinical trial for Ps, QX001S demonstrated clinical equivalence to ustekinumab in terms of efficacy, safety, immunogenicity and PK profile. Zhongmei Huadong, a subsidiary of Huadong Medicine and our commercialization partner for QX001S, submitted a BLA in China in July 2023, which was accepted by the NMPA in August 2023 and under review as of the Latest Practicable Date. We and Zhongmei Huadong plan to begin commercializing QX001S upon expected BLA approval in the fourth quarter of 2024. We expect QX001S to be an affordable drug for a broad section of Ps patients. We also plan to develop QX001S for the treatment of UC and CD.
- QX004N: We are developing QX004N, an IL-23p19 inhibitor, for Ps and CD. IL-23p19 has emerged as a key target associated with superior efficacy for Ps patients with more severe symptoms or inadequate response to existing treatments. We completed a Phase Ia clinical trial of QX004N in healthy subjects for the Ps indication in China in September 2023 and QX004N showed a good safety profile. As of September 30, 2023, we had also commenced a Phase Ib clinical trial and a Phase II clinical trial in China to evaluate QX004N for this indication and expect to complete them in the second quarter of 2024 and the first half of 2025, respectively. We also commenced a Phase Ia clinical trial of QX004N for CD in China in February 2023.
- QX006N: We are developing QX006N, an IFNAR1-targeting mAb, for the treatment of SLE. SLE has been a difficult indication for new drug development. SAPHNELO (anifrolumab), a first-in-class IFNAR1 inhibitor, was approved by the FDA in 2021, making it the only new SLE treatment in more than 10 years. (The previous approved SLE drug, belimumab, was, at its time, the first approved SLE drug in 50 years.) Anifrolumab demonstrated clear clinical benefit in patients with moderate-to-severe SLE in a Phase III study (TULIP-2) and a Phase IIb study (MUSE). As of the Latest Practicable Date, there were no approved IFNAR1 inhibitors in China for the treatment of SLE, indicating a huge underserved market. As of the same date, our QX006N was one of the only two IFNAR1 inhibitors developed by Chinese domestic companies that had entered the clinical stage for SLE in China. We completed our Phase Ia clinical trial in healthy subjects (individuals in good general health and not having any mental or physical disorder requiring regular or frequent medication) in July 2023, where QX006N showed a good safety profile. We also initiated a Phase Ib clinical trial in SLE patients in March 2023.

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- QX008N: QX008N is a humanized IgG1 mAb targeting TSLP, designed for the treatment of moderate-to-severe asthma and moderate-to-severe COPD. TSLP-targeting therapy is the only class of biologic drugs globally approved for asthma that can slow disease progression for asthma patients with low-level or no expression of type 2 biomarkers. QX008N demonstrated a potency superior to an internally prepared tezepelumab analog and exhibited a good safety profile in our Phase Ia clinical trial. We commenced a Phase Ib clinical trial in adult patients with moderate-to-severe asthma in August 2023, the remainder of which will be completed by Joincare Pharmaceutical Group Industry Co., Ltd. (“Joincare”), our licensing partner.

We are one of only a few Chinese biotech companies that are focused on autoimmune and allergic diseases and have an established commercial-scale in-house manufacturing capability, according to Frost & Sullivan. Our manufacturing facility, located at Taizhou, Jiangsu, was established according to the cGMP standards of China, the United States and the EU. Our drug substance manufacturing site has four 2,000L single-use bioreactors and one downstream purification/production line with an annual manufacturing capacity of approximately 300 kg therapeutic antibodies. Our drug product manufacturing site has one vial fill-finish and packaging production line and one prefilled syringe production line. We have successfully manufactured multiple batches of drug substance and drug products for various clinical trials, scale-up research and BLA-required process validation. We believe that our self-owned cGMP-standard manufacturing capability, coupled with our strong R&D capability, will allow us to achieve reliable cost control and ensure stable clinical and commercial drug supply to weather any supply chain disruptions.

In order to ensure the successful launch of our first expected commercial drug, QX001S, we formed a strategic collaboration with an established pharmaceutical company, Huadong Medicine, which is experienced in chronic disease management and has strong sales networks for autoimmune and allergic drugs. Huadong Medicine has established and comprehensive commercialization capabilities, with a sales team of more than 7,000 members experienced in the management of chronic diseases, such as diabetes and autoimmune diseases, an area it has focused on for over 30 years. According to Frost & Sullivan, Huadong Medicine has top-tier commercialization capabilities for autoimmune drugs in China, covering over 3,000, or more than 90% of all, Grade IIIA hospitals in China and over 15,500 hospitals of Grade II and below. A significant proportion of autoimmune and allergic disease patients (*e.g.*, Ps patients) in China initially receive treatment in local hospitals in vast, geographically dispersed areas, according to Frost & Sullivan. Therefore, an extensive sales network providing robust coverage of these areas is essential. We believe that the strategic cooperation with Huadong Medicine will help ensure effective and efficient commercialization of QX001S. Going forward, we also plan to leverage the strong physician resources and networks of established pharmaceutical companies to build connections with participants in the drug sales and distribution chain, to prepare us for future commercial launches of our other drug candidates. In the future, we plan to build a relatively small, indication-specialized in-house commercialization team, beginning with indications with relatively limited patient populations treated in a small number of key hospitals, leveraging our deep understanding of these indications and physician resources.

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We are led by a seasoned management team with successful track records. Mr. Qiu Jiwan, our founder and CEO, has nearly 30 years of experience in the biotech industry, where he started as a research scientist, and extended his expertise to the management and operation of biopharmaceutical companies. As an early participant in China’s nascent innovative biopharmaceutical industry, Mr. Qiu had founded Jiangsu T-mab BioPharma Co., Ltd., or Jiangsu T-mab, a venture before our Company which specialized in the R&D of genetically engineered therapeutic antibodies. During his tenure at Jiangsu T-mab, Mr. Qiu and his team developed four therapeutic biologic drugs, among which two had obtained IND approvals and two had submitted IND applications. Different from those scientist-founders who may have recently joined the industry with limited business experience, Mr. Qiu is a successful serial entrepreneur and industry veteran who has already launched and operated antibody-focused biotech companies. With in-depth insights into the market and strong resource integration capabilities, Mr. Qiu has since 2015 proactively focused on autoimmune and allergic diseases, and successfully driven the advancement of our six drug candidates to clinical stage within seven years. The rest of our management team members also have extensive and complementary experience in R&D, clinical operation, CMC and business development. Ms. Fang Min, our deputy general manager, previously worked in MNCs such as GSK plc, and has extensive experience in clinical management. Dr. Li Jianwei, the chief operating officer and deputy general manager of our Company and the general manager of Cellularforce, has over 14 years of experience in the R&D and manufacturing of recombinant protein drugs, and previously worked in a number of global biopharmaceutical companies such as Sorrento Therapeutics Inc., AbbVie Inc. and Syagen Technology Inc. Mr. Wu Shenglong, our chief business officer and deputy general manager, has extensive experience in business development, investment and financing, M&A and consultation in the pharmaceutical industry. Mr. Wu Yiliang, the executive deputy general manager of Cellularforce, has over 15 years of experience in the biotech industry, specialized in process development, quality control and commercial manufacturing of recombinant protein drugs.

We are proud to have a diverse pool of Shareholders. They include some of China’s top investment funds with significant experience in the biotech sector, including Hongtai Aplus, Matrix Partners China, Triwise Capital and Efung Capital, which could provide us with complementary capabilities, strategic insights and development opportunities. Our Shareholders also include strategic investors, such as Huadong Medicine, which create strategic synergy with us in terms of drug development and commercialization.

OUR STRENGTHS

Exclusive focus on autoimmune and allergic diseases, covering four major disease areas and key therapeutic pathways

Different from our peers, we have been exclusively focused on autoimmune and allergic diseases since our inception. With an “all in” mindset, we aim to take advantage of the massive market opportunity in China through specialization and domain expertise.

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There are significant unmet medical needs in autoimmune and allergic diseases in China. While autoimmune and allergic diseases represent the second-largest therapeutic area globally, only after oncology, market development in China has lagged significantly behind. According to Frost & Sullivan, China’s autoimmune and allergic drug market was approximately 7.5% of that of the United States in 2020 and with biologic drugs accounting for just about 10% of the market as compared to more than 60% for the U.S. market. Despite the historical underdevelopment, the China autoimmune and allergic disease drug market has been changing in recent years. Several important factors, including approvals, NRDL admissions and accelerated sales ramp-up of blockbuster drugs, evolution of treatment paradigm from chemical drugs to biologics as well as the rise of domestic developers, have driven the industry toward more alignment with global trends and more certainty. As a result of these favorable factors, the autoimmune and allergic disease drug market in China expanded from US\$7.2 billion in 2020 to US\$9.0 billion in 2022, representing a CAGR of 11.8%, with the proportion of biologic drugs increased to about 20% in 2022. The market is expected to continue to unlock. According to Frost & Sullivan, it is estimated to grow to US\$41.5 billion in 2030, at a CAGR of 21.1% from 2022, and with the proportion of biologic drugs increased to about 60%.

We have built a comprehensive drug pipeline that covers the four major disease areas in the field.

- *Skin diseases.* We believe that skin diseases represent one of the most desirable segments of the autoimmune and allergic disease drug market and our strategically designed skin disease drug pipeline presents a significant competitive advantage. Our pipeline comprises five drug candidates with great potential synergy, covering three indications in the area that we consider the most valuable: Ps, AD and PN. For Ps, we are developing QX001S, which is the first domestically developed biosimilar to ustekinumab, a global blockbuster biologic drug, with BLA submitted in China and potentially one of China’s first approved ustekinumab biosimilars, for a broad section of Ps patients. At the same time, to achieve better coverage of Ps patients in China, we are also developing QX004N, an mAb targeting IL-23p19, which has emerged as a key target associated with superior efficacy for Ps patients with more severe symptoms or inadequate response to existing treatments. For AD, PN and CSU, we are developing QX005N, one of our Core Products, an mAb blocking IL-4R α , a well-validated, broad-acting target for a wide range of indications. We are also developing QX013N for CSU and QX010N for pruritus. According to Frost & Sullivan, we ranked first in China in terms of the number of IND-approved biologic drug candidates and indications for skin diseases as of the Latest Practicable Date. We plan to rapidly commercialize QX001S by cooperating with Huadong Medicine. We anticipate that QX001S will benefit a large number of patients and prepare us for the future commercial launch of our other skin disease drug candidates.

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- *Rheumatic diseases.* Our rheumatic disease pipeline consists of two drug candidates. We are developing QX002N, our other Core Product, for AS, a rheumatic disease with a large patient population in China. QX002N is a high-affinity recombinant humanized IgG1 mAb designed to bind specifically to IL-17A, a key player in the pathogenesis of various autoimmune diseases, including Ps and AS. We strategically chose AS as the indication for QX002N considering that we have already built a tiered and competitive Ps drug pipeline with QX001S and QX004N, and IL-17A inhibitors have demonstrated clear clinical benefit in AS patients who are intolerant to or fail to achieve effective disease control with traditional therapies. We have also obtained an IND approval for QX002N for LN. In addition, we are developing QX006N for SLE, an indication with substantial unmet medical needs in China.
- *Respiratory diseases.* Our respiratory disease pipeline consists of three drug candidates. We are developing QX005N for CRSwNP, moderate-to-severe asthma and COPD. We are also developing an innovative drug candidate QX008N for moderate-to-severe asthma and moderate-to-severe COPD. We entered into a technology transfer agreement in January 2024 to grant Joincare an exclusive license to develop, manufacture and commercialize QX008N in mainland China, Hong Kong and Macau. See “—Our Other Key Product Candidates—QX008N—Licenses, Rights and Obligations” for details. QX008N, as a TSLP inhibitor, has the potential to become an effective treatment for asthma and COPD patients with low-level or no expression of type 2 biomarkers. We are also developing QX007N, an anti-IL-33 antibody for COPD and asthma.
- *Digestive diseases.* Our digestive disease pipeline consists of two drug candidates. We are developing QX004N for CD. We also plan to develop QX001S for the treatment of UC and CD.

Our broad pipeline can create strong synergies in various of aspects, from early-stage R&D to clinical resource sharing, patient education and commercialization. In early-stage R&D, especially drug discovery and target selection, leveraging our knowledge and technical expertise in the field, we are well-versed in global scientific advancement and are able to optimize our pipeline with technological upgrade or expanded indication coverage. This way we can build a product franchise for each disease, serving the needs of patients of varying levels of conditions and paying abilities, and hence improving patient retention. With regard to clinical resources, we build and leverage our solid cooperative relationships with hospitals (as trial sites) and principal investigators (PIs, usually physicians at the hospitals responsible for the conduct of our clinical trials) and provide them with in-depth understanding of our products and pipeline, enabling us to repeatedly use these resources during our clinical trials and sales and marketing and in so doing accelerate the clinical development and commercialization of our drug candidates. For patient education and commercialization, we expect the synergies created by our pipeline to materialize as our drug candidates enter the commercial stage, especially between drug candidates with the same indication. For example, as we rapidly push forward the development and commercialization of QX001S in collaboration with Huadong Medicine, we believe QX004N could also benefit from the commercialization network and market acceptance that we expect to establish for QX001S, as both are indicated for Ps.

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We are confident that our steadfast focus on the autoimmune and allergic field and our pipeline covering the four major disease areas will not only benefit patients with life-long protection and improved quality of life, but also enable us to establish ourselves as a leading Chinese innovative drug developer among physicians and patients and help us realize long-term growth.

Broad pipeline of biologics in autoimmune and allergic diseases, with Core Products in late-stage clinical development for the most advanced indications

We had built a pipeline of nine drug candidates as of the Latest Practicable Date, with six in the clinical stage. According to Frost & Sullivan, among Chinese domestic companies, we had one of the most numbers of IND-approved drug candidates in autoimmune and allergic diseases as of the Latest Practicable Date. Several of our key clinical trials have progressed or are progressing to the advanced stage according to our development plan.

- **QX002N:** One of our Core Products, QX002N, a high-affinity mAb targeting IL-17A, a key player in the pathological mechanism of various autoimmune diseases. IL-17A inhibitors are recommended by prevailing clinical guidelines as second-line standalone treatment (the same designation as TNF inhibitors) for AS patients with high disease activity after receiving first-line traditional treatments. Between the two classes of biologics, IL-17A inhibitors have shown clear clinical benefit in patients who are intolerant to or fail to achieve adequate disease control with TNF- α inhibitors. We have obtained IND approval for QX002N for both AS and LN and plan to prioritize the development of the former indication. QX002N has demonstrated promising efficacy in our Phase Ib and Phase II clinical trials for AS. In our Phase Ib clinical trial, 62.5% and 37.5% of subjects receiving QX002N (160 mg) once every 2 weeks achieved ASAS20 and ASAS40 responses at week 16, respectively. In our Phase II clinical trial, the ASAS20 and ASAS40 response rates of subjects receiving QX002N (160 mg) once every 4 weeks reached 60.0% and 40.0% at week 16, respectively. We conducted a pre-Phase III consultation with the NMPA, which raised no material questions and confirmed that it had no objections to the commencement of such trial in its official response in July 2023. We commenced the Phase III clinical trial in September 2023.
- **QX005N:** Our other Core Product, QX005N, is designed to inhibit IL-4R α , a well-validated, broad-acting target for a wide range of indications. Because IL-4R α controls the signaling of both IL-4 and IL-13, which is critical in the initiation of type 2 inflammation, it has emerged as a key target for new drug development in related indications. According to Frost & Sullivan, IL-4R α inhibitors had been approved or were under development for 20 indications globally as of the Latest Practicable Date. Dupilumab, the first FDA-approved IL-4R α inhibitor, is one of the best-selling biologic drugs globally for allergic diseases, with annual sales of US\$8.7 billion in 2022. As of the Latest Practicable Date, we had obtained seven IND approvals for QX005N (namely, AD in adults, AD in adolescents, PN, CRSwNP, CSU, asthma and COPD), the most among IL-4R α -targeting drug candidates in China. QX005N demonstrated favorable safety and efficacy results in

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our Phase Ia and Phase Ib clinical trials for AD. In the Phase Ib clinical trial in patients with moderate-to-severe AD, in each of the 300 mg and 600 mg groups, 75.0% of subjects achieved EASI-75 responses and 50.0% of subjects reached IGA scores (0 or 1) at week 12 without significantly increased safety risks. We have started a Phase II clinical trial for AD and completed patient enrollment in February 2023. In addition, we commenced a Phase II clinical trial for PN in February 2023. According to Frost & Sullivan, QX005N was the first biologic drug candidate developed by a Chinese domestic company to start a clinical trial for PN in China. In January 2024, the CDE granted QX005N the breakthrough therapy designation for the treatment of PN, signifying its superior clinical benefits compared to current treatment methods. The designation is designed to expedite the development and regulatory review of innovative drugs demonstrating substantial potential in addressing serious conditions.

- QX001S: QX001S is our first expected commercial drug, the first domestically developed ustekinumab biosimilar with BLA submitted in China and potentially one of the first ustekinumab biosimilars to be approved in China. Initially approved by the FDA in 2009, ustekinumab was the first biologic treatment to selectively inhibit the IL-23 and IL-12 pathways and has been widely regarded as one of the major treatments for Ps worldwide. In 2022, it recorded sales of US\$9.7 billion globally and ranked the ninth best-selling drug worldwide in the same year, according to Frost & Sullivan. In our Phase I clinical trial for Ps, our QX001S demonstrated a safety and PK profile comparable to that of ustekinumab. In our Phase III clinical trial for Ps, QX001S demonstrated clinical equivalence to ustekinumab in terms of efficacy, safety, immunogenicity and PK profile. We expect QX001S to be an affordable drug for a broad section of Ps patients. We also plan to develop QX001S for the treatment of UC and CD.
- QX004N: We are developing QX004N, an IL-23p19 inhibitor, for Ps and CD. IL-23p19 has emerged as a key target associated with superior efficacy for Ps patients with more severe symptoms or inadequate response to existing treatments. We completed a Phase Ia clinical trial of QX004N in healthy subjects for the Ps indication in China in September 2023 and QX004N showed a good safety profile. As of the Latest Practicable Date, we also commenced a Phase Ib and a Phase II clinical trial of QX004N for Ps in China. We also commenced a Phase Ia clinical trial of QX004N for CD in China in February 2023.
- QX006N: We are developing QX006N, an IFNAR1-targeting mAb, for the treatment of SLE. SLE has been a difficult indication for new drug development. SAPHNELO (anifrolumab), a first-in-class IFNAR1 inhibitor, was approved by the FDA in 2021, making it the only new SLE treatment in more than 10 years. (The previous approved SLE drug, belimumab, was, at its time, the first approved SLE drug in 50 years.) Anifrolumab demonstrated clear clinical benefit in patients with moderate-to-severe SLE in a Phase III study (TULIP-2) and a Phase IIb study (MUSE). As of the Latest Practicable Date, there were no approved IFNAR1 inhibitors in China for the treatment of SLE, indicating a huge underserved market. As of the same date, our

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QX006N was one of the only two IFNAR1 inhibitors developed by Chinese domestic companies that had entered the clinical stage for SLE in China. We completed our Phase Ia clinical trial in healthy subjects (individuals in good general health and not having any mental or physical disorder requiring regular or frequent medication) in July 2023, where QX006N showed a good safety profile. We also initiated a Phase Ib clinical trial in SLE patients in March 2023.

- **QX008N:** QX008N is a humanized IgG1 mAb targeting TSLP, designed for the treatment of moderate-to-severe asthma and moderate-to-severe COPD. TSLP is a key upstream cytokine mediating multiple inflammatory pathways. TSLP-targeting therapy is the only class of biologic drugs globally approved for asthma that can slow disease progression for asthma patients with low-level or no expression of type 2 biomarkers. QX008N demonstrated a potency superior to an internally prepared tezepelumab analog and exhibited a good safety profile in our Phase Ia clinical trial. We commenced a Phase Ib clinical in adult patients with moderate-to-severe asthma in China in August 2023, the remainder of which will be completed by Joincare, our licensing partner.

Our pipeline also consists of QX007N for COPD and asthma, QX013N for CSU and QX010N for pruritus.

Commercial-scale in-house manufacturing capacity ensuring stable and cost-controllable supply of our products

We are one of only a few Chinese biotech companies that are focused on autoimmune and allergic diseases and have an established commercial-scale in-house manufacturing capability, according to Frost & Sullivan. Our manufacturing facility, located at Taizhou, Jiangsu, was established according to the cGMP standards of China, the United States and the EU, and has an annual manufacturing capacity of approximately 300 kg therapeutic antibodies. We believe that our self-owned cGMP-standard manufacturing capability, coupled with our strong R&D capability, will allow us to achieve reliable cost control and ensure stable clinical and commercial drug supply to weather any supply chain disruptions.

- *Manufacturing facility.* We have a CMC team of more than 150 members at our Taizhou manufacturing facility, covering the full-cycle development of monoclonal antibodies. Our drug substance manufacturing site has four 2,000L single-use bioreactors and one downstream purification/production line with an annual manufacturing capacity of approximately 300 kg therapeutic antibodies. Our drug product manufacturing site has one vial fill-finish and packaging production line, with a manufacturing capability of 18,000 vials/hour, and one prefilled syringe production line, with a manufacturing capability of 9,000 syringes/hour. We have manufactured more than 30 batches of drug substance of both 200L and 2,000L scales, more than 30 batches of drug products in vials (with 2,000 to 5,000 vials per batch) and more than 10 batches of drug products in prefilled syringes (with 3,000 to 30,000 syringes per batch), for various clinical trials, scale-up research and BLA-required process validation.

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- *Cost control measures and supply chain security.* To achieve cost-controllable manufacturing and reduce risks associated with an international supply chain, we have begun to strategically seek domestic supply of cell culture media and downstream purification chromatography media since 2021, which we expect to reduce related one-off costs by, on average, approximately 40% and 30%-50%, respectively. Additionally, we have successfully developed a new drug substance upstream process, which starts a production run with high cell-density and large volume of working cell bank, and therefore could significantly shorten the production time required for each batch, improve capacity utilization and lower unit manufacturing costs. We believe our continuous cost control and efficiency improvement measures will enhance the accessibility of our drugs for both patients currently undergoing expensive biologic therapies and those who previously could not afford them. In the meantime, the strategic cooperation with domestic suppliers could also help us improve control and oversight of our supply chain to ensure stable supply of our products.

Practical commercialization model leveraging strategic partnership to secure early product launch

In order to ensure the successful launch of our first expected commercial drug, QX001S, we have formed a strategic collaboration with an established pharmaceutical company, Huadong Medicine, which is experienced with chronic disease management and has strong sales networks for autoimmune and allergic drugs. In August 2020, we entered into a strategic collaboration agreement with Zhongmei Huadong, a subsidiary of Huadong Medicine, with respect to the joint development and exclusive commercialization of QX001S in China. Huadong Medicine has established and comprehensive commercialization capabilities, with a sales team of more than 7,000 members experienced in the management of chronic diseases such as diabetes and autoimmune diseases, an area it has focused on for over 30 years. According to Frost & Sullivan, Huadong Medicine has top-tier commercialization capabilities for autoimmune drugs in China, covering over 3,000, or more than 90% of all, Grade IIIA hospitals in China and over 15,500 hospitals of Grade II and below. A significant proportion of autoimmune and allergic disease patients (*e.g.*, Ps patients) in China initially receive treatment in local hospitals in vast, geographically dispersed areas, according to Frost & Sullivan. Therefore, an extensive sales network providing robust coverage of these areas is essential. However, as we are at an early stage of preparation for future commercialization of our drug candidates, building a large commercialization team would be time-consuming and expensive, which would increase our commercial risk and distract us from our R&D efforts. To address this conundrum, we strategically choose to cooperate with established pharmaceutical companies to quickly and cost-effectively commercialize selected products. We believe that the strategic cooperation with Huadong Medicine will help ensure effective and efficient commercialization of QX001S. Going forward, we also plan to leverage the strong physician resources and networks of established pharmaceutical companies to build connections with participants in the drug sales and distribution chain, to prepare us for future commercial launches of our other drug candidates. In the future, we plan to build a relatively small, indication-specialized in-house commercialization team for some of our future drugs, beginning with indications with relatively limited patient populations treated in a small number of key hospitals, leveraging our deep understanding of these indications and physician resources.

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Seasoned management team with extensive industry experience and successful entrepreneurial track records

Mr. Qiu Jiwan, our founder and CEO, has nearly 30 years of experience in the biotech industry, where he started as a research scientist, and extended his expertise to the management and operation of biopharmaceutical companies. As an early participant in China's nascent innovative biopharmaceutical industry, Mr. Qiu had founded Jiangsu T-mab, a venture before our Company which specialized in the R&D of genetically engineered therapeutic antibodies. During his tenure at Jiangsu T-mab, Mr. Qiu and his team developed four therapeutic biologic drugs, among which two had obtained IND approvals and two had submitted IND applications before the disposal of such company by Mr. Qiu. During his tenure in Hangzhou Jiuyuan Gene Engineering Co., Ltd., Mr. Qiu was primarily responsible for the R&D of innovative drug candidates and awarded for his work on the research of recombinant human interleukins (ILs). Mr. Qiu was primarily responsible for the establishment of the R&D and manufacturing platform during his time as a deputy general manager of Epitomics (Hangzhou) Biotechnology Co., Ltd., a biotech company focused on the R&D and manufacturing of antibodies. Different from those scientist-founders who may have recently joined the industry with limited business experience, Mr. Qiu is a successful serial entrepreneur and industry veteran who has already launched and operated antibody-focused biotech companies. With in-depth insights into the market and strong resource integration capabilities, Mr. Qiu has since 2015 proactively focused on autoimmune and allergic diseases, and successfully driven the advancement of our six drug candidates to clinical stage within seven years.

The rest of our management team members also have extensive and complementary experience in R&D, clinical operation, CMC and business development. Ms. Fang Min, our deputy general manager, has extensive experience in clinical management. Prior to joining us, Ms. Fang worked at various global pharmaceutical companies, including as a senior clinical research manager at GlaxoSmithKline (China) R&D Company Limited, a wholly owned subsidiary of GSK plc. Dr. Li Jianwei, the chief operating officer and deputy general manager of our Company and the general manager of Cellularforce, has over 14 years of experience in the R&D and manufacturing of recombinant protein drugs. Prior to joining us, Dr. Li worked in a number of global biopharmaceutical companies, including serving as a vice president at Sorrento Therapeutics Inc., where he was primarily responsible for process development and manufacturing of recombinant protein therapeutics, and the principal scientist at Allergan, Inc. (currently known as AbbVie Inc.), a global pharmaceutical company. Mr. Wu Shenglong, our chief business officer and deputy general manager, has extensive experience in business development, investment and financing, M&A and consultation in the pharmaceutical industry. Prior to joining us, Mr. Wu worked in a business development capacity at multiple pharmaceutical consultancy or investment companies, such as Pfizer Investment Co., Ltd. (輝瑞投資有限公司), a subsidiary of Pfizer Inc. Mr. Wu Yiliang, the executive deputy general manager of Cellularforce, has over 15 years of experience in the biotech industry, specialized in process development, quality control and commercial manufacturing of recombinant protein drugs. Prior to joining us, Mr. Wu successively served various positions at Jiangsu T-mab and was primarily responsible for process development and scale-up, among other things.

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OUR STRATEGIES

Build leadership in dermatology, advance other drug candidates and strategically expand our pipeline

We plan to focus on advancing our broad pipeline in the near term, with a current priority on skin diseases. We aim to execute our multiple-asset, multiple-indication pipeline strategy for dermatology and rapidly build our leadership in this disease area. In the meantime, we also plan to advance our drug candidates for rheumatic, respiratory and digestive diseases.

- Skin diseases:
 - o QX001S: We understand that Zhongmei Huadong, a subsidiary of Huadong Medicine and our commercialization partner for QX001S, plans to begin commercializing QX001S upon expected BLA approval in the fourth quarter of 2024.
 - o QX005N: Among the seven indications for which we have obtained IND approvals, we plan to prioritize AD and PN in skin diseases and expect to complete the respective Phase II clinical trials for these two indications in March 2024.
 - o QX004N: We also commenced a Phase Ib clinical trial and a Phase II clinical trial of QX004N for Ps in February 2023 and September 2023, respectively, and expect to complete these trials in the second quarter of 2024 and the first half of 2025, respectively.
- Rheumatic diseases:
 - o QX002N: We will prioritize the development of QX002N for AS. We commenced the Phase III clinical trial in September 2023 and expect to complete it in the second half of 2025. We plan to continue the development of QX002N for LN after it obtains BLA approval for the treatment of AS.
 - o QX006N: We completed our Phase Ia clinical trial in healthy subjects in July 2023. We initiated a Phase Ib clinical trial in SLE patients in March 2023 and expect to complete the trial in the fourth quarter of 2024.

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- Respiratory diseases:
 - o QX005N: We commenced a Phase II clinical trial for CRSwNP in April 2023 and plan to complete the trial in the fourth quarter of 2024.
 - o QX008N: We commenced a Phase Ib clinical trial for moderate-to-severe asthma in August 2023, the remainder of which will be completed by Joincare, our licensing partner.
- Digestive diseases:
 - o QX004N: We commenced a Phase Ia clinical trial for CD in February 2023 and expect to complete the trial in the second quarter of 2024.

In early-stage R&D, we will continue to focus on the four major disease areas in the autoimmune and allergic field. As we continue to accumulate more clinical data, we plan to conduct translational medical research to discover and validate novel biomarkers through targeted analysis of patients’ response to biomarkers, which we believe will guide our preclinical evaluations and clinical studies. As we selectively expand our pipeline, we will consider our existing pipeline layout and market competition to strategically select indications for promising targets. We will also explore combination therapies based on our existing clinical data, thereby creating synergies and maximizing the value of our pipeline.

For certain indications (such as Ps, asthma and COPD), we are developing multiple drug candidates. We believe risk of competition among the drug candidates with the same indication would not cause material obstacles or market cannibalization in their commercialization because we position such drug candidates strategically as a “franchise” to serve the needs of patients of varying clinical characteristics or levels of conditions, and thereby improve patient coverage. Moreover, the drug candidates (including those with overlapping indications) have their own specific targets and achieve their therapeutic effect through different mechanisms of action. The chronic nature of autoimmune and allergic diseases dictates patients’ need for long-term medication, which, in turn, leads to drug resistance and adherence issues and creates an ongoing need for therapies with alternative MOAs in the field. Having multiple candidates with diverse MOAs indicated for the same disease could help improve patient retention if they become resistant or non-responsive to a particular class of drugs.

Generally, we will continue to monitor the global scientific advances and medical needs for autoimmune and allergic diseases, and endeavor to ensure that our pipeline is in a leading position in China scientifically and we can continuously provide accessible medical solutions for patients.

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Continue to optimize CMC quality management system and improve production efficiency and enhance manufacturing capacity utilization

We plan to continuously optimize our CMC quality system and improve production efficiency. In order to ensure the stability of the supply chain and further improve production efficiency, we will continue to procure quality raw materials from Chinese suppliers and develop high-density cell technology. We aim to further reduce the costs of production of biologic drugs and improve their accessibility.

While prioritizing internal R&D and commercialization demand, we plan to further enhance the utilization of our production capacity by retaining the manufacturing rights of drug candidates for which we may have established strategic collaborations. We will also continue to develop external CDMO services to diversify our source of revenue, which in turn can also support our R&D activities.

Cooperate with established pharmaceutical companies in commercialization

With respect to the commercialization of certain drug candidates, in particular, drug candidates indicated for diseases with patients located in vast, geographically dispersed areas, we plan to continue to strategically cooperate with established pharmaceutical companies that have extensive experience in chronic disease management and broad sales networks covering such areas. We believe that such strategic cooperation can improve the availability of our drugs in the fastest and most cost-effective manner. We also plan to utilize the abundant expert resources and networks of these established pharmaceutical companies to connect with participants in the drug sales and distribution chain, to set the stage for the commercialization of our forthcoming drugs. We also plan to continue working with business partners to address the insufficient awareness of chronic disease management and autoimmune and allergic diseases in China. Leveraging our business partners’ academic and marketing channels, we and our business partners will jointly conduct marketing activities and academic education to physicians and patients, to improve their understanding of biologic drugs for autoimmune and allergic diseases and chronic disease management. Given the chronic nature of autoimmune and allergic diseases and the need for long-term or even life-long medication, we plan to, together with our business partners, provide continuous support to physicians and patients. We also aim to have our Core Products, QX001S and other pipeline products admitted into the NRDL after they are approved in China, thereby further increasing market access.

In terms of the status of our collaboration with Zhongmei Huadong for the commercialization of QX001S, we and Zhongmei Huadong further entered into a manufacturing agreement in September 2022, which provided that we will be solely responsible for the commercial production and quality control of QX001S. Zhongmei Huadong has completed the onsite assessment and verification of our manufacturing facility. In addition, we and Zhongmei Huadong will establish a joint commercialization committee, which is responsible for preparing the commercialization plan and manufacturing and marketing budget. Going forward, we do not expect to commit material financial resources to the collaboration with Huadong Medicine for QX001S as the cost of the Phase III clinical trial was borne by Zhongmei Huadong and the commercial production will be paid by Zhongmei Huadong at a unit supply price which will be determined by taking into account our actual costs expected to be incurred for manufacturing of QX001S and a cost-plus margin of 25% for such

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manufacturing. Various departments of our team work with Zhongmei Huadong to implement the QX001S Agreements. In particular, our R&D and manufacturing teams of Cellularforce are responsible for process scale-up, process optimization, process verification, analytical method verification, stability study of drug substance or product, bio-similarity study and production of drug product for the clinical trials. We allocate relevant personnel depending on the progress of each project under the QX001S Agreements, which we do not expect to have a material impact on our R&D and manufacturing teams after the Track Record Period. Our Directors are of the view that the collaboration with Zhongmei Huadong for QX001S will unlikely affect our R&D progress of and manufacturing capacities for the Core Products, primarily because we have sufficient manufacturing capacities and the commercial production arrangement pursuant to the QX001S Agreements will be a small portion of our R&D and manufacturing activities, and we have built an efficient project management system to prioritize our R&D and manufacturing projects and we review/prioritize our annual R&D and manufacturing plans monthly. We believe the collaboration with Zhongmei Huadong will enable us to leverage Huadong Medicine’s nationwide sales and marketing network to ensure successful commercialization of QX001S and such collaboration will provide valuable insights and experience for any future cooperation we might consider with respect to the development and/or commercialization of our other drug products. As of the Latest Practicable Date, we had not entered into any licensing arrangements for our drug candidates other than QX001S and QX008N (see “—Our Other Key Product Candidates—QX008N—Licenses, Rights and Obligations” for details with respect to our cooperation with Joicare).

With respect to our Core Products, QX002N and QX005N, which we anticipate will be approved and commence commercialization in China subsequent to QX001S, we aim to devise a commercialization strategy that focuses on competitive pricing and expeditious market entry, with a strategic emphasis on market cultivation. We believe that market cultivation is critical because our future competition with the incumbent MNCs and domestic biotech companies offering competing products will not be a zero-sum game. Given the low penetration rates of biologic drugs for autoimmune and allergic diseases in China, it will be of paramount importance, for us and our competitors alike, to make our best endeavors to grow the market, so that clinical and commercial value of the innovative biologic drugs could be maximized.

In terms of pricing, upon initial commercialization, we expect the estimated annual costs of QX002N and QX005N to be 20% to 30% lower than those of the same-target drugs developed by MNCs. We believe that such indicative pricing could be competitive, based on analysis of target patient population’s unmet medical needs and affordability, evaluation of clinical trial data and cost analysis against competing products and comparable countries and regions. For example, our analysis includes a comparison of the annual costs of domestically developed innovative drugs with those of same-target MNC products in oncology, such as zanubrutinib and ibrutinib (comparable domestically and MNC-developed Bruton’s tyrosine kinase (BTK) inhibitors indicated for various types of lymphoma), because oncology is a highly competitive landscape where there is greater availability of approved products and pricing information. We will continue to monitor the competitive landscape and strive to respond swiftly and strategically in terms of pricing to any changes that arise.

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We attribute our cost advantages in part to our established in-house manufacturing capacities. Compared with most Chinese biotech companies in the autoimmune and allergic disease field, which rely on external CDMOs for product supply, our in-house manufacturing facilities enable us to better control our manufacturing costs through (i) efficient utilization of resources by effectively aligning manufacturing cycles with market feedback, maximizing utilization our existing capacity while ensuring prudent capacity planning; (ii) technological innovations and process improvements, such as the high cell-density and large-volume working cell bank that can shorten the manufacturing cycle for 2,000L drug substance batches by approximately 8-10 days and reduce unit manufacturing costs; (iii) standardization of raw materials and consumables across different projects, which promotes economies of scale and enhances our bargaining power in price negotiation with suppliers; and (iv) supply chain management, such as strategically seeking domestic supply of cell culture media and downstream purification chromatography media, which we expect to reduce related one-off costs by, on average, approximately 40% and 30%-50%, respectively.

In terms of market entry, we will adopt a multi-pronged, differentiated approach to different target market segments. We will actively seek admission for our Core Products into the NRDL upon approval, thereby attaining coverage of public hospitals in major cities and regional centers. We also aim to penetrate lower-tier markets, such as public hospitals in rural areas, through collaboration with local partners or resources to deliver our products as well as medical education on autoimmune and allergic diseases. For example, we plan to cooperate with professional academic organizations, such as the Dermatology Branch of the Chinese Medical Association, through online educational platforms as well as on-site training centers in hospitals to provide training programs for medical practitioners and relevant healthcare professionals to enhance their understanding of autoimmune and allergic diseases and the evolving treatment paradigms. We have closely cooperated with relevant hospitals and PIs through various clinical trials, especially in the dermatology area. With respect to out-of-pocket markets, we plan to achieve coverage of private hospitals, private clinics and direct-to-patient retail channels through collaborations with commercial insurance companies.

Explore international expansion opportunities

To maximize the commercial potential of our assets, we plan to explore opportunities for overseas commercialization for drug candidates that could have competitive advantages in the global market. To do so, we expect to cooperate with MNCs or pharmaceutical companies with established local sales networks to expedite the overseas clinical development, approval and commercialization efforts.

We have formulated specific development plans, including target regions and collaboration strategies, for several drug candidates. For example, for QX001S, we plan to explore collaborative opportunities in Europe, the United States and Southeast Asia and conduct trials in accordance with the local requirements, leveraging our Phase III trial results from China where possible. We obtained IND approval from the FDA for our self-developed innovative mAb QX008N for severe asthma in September 2022 and plan to explore collaboration opportunities for QX008N in the United States. In addition, considering the vast global market as evidenced by strong sales of blockbuster drugs developed by MNCs, we will also explore overseas collaboration opportunities for our drug candidates with potential competitive advantages. We intend to continue to promote our drug candidates to potential business partners globally.

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Continue to recruit and develop talent

Talent is key to our development. We plan to continually recruit and develop talent.

- *R&D, clinical and registration teams.* With the advancement of our pipeline, especially with more candidates entering Phase III clinical trials, we plan to recruit more R&D, clinical and registration personnel, including professionals with working experience in MNCs or rich experience in clinical development in China or overseas. We expect these measures to enhance our R&D capabilities, advance the development, registration and globalization of our drug candidates, and enable us to identify more innovative therapeutic targets for autoimmune and allergic diseases with significant unmet medical needs, continue to expand the coverage and depth of our pipeline and enhance our market position.
- *Marketing and business development team.* While strategically cooperating with established pharmaceutical companies on the commercialization of our future drugs for diseases with patients located in vast, geographically dispersed areas, we also plan to establish a relatively small, indication-specialized in-house commercialization team, beginning with indications with relatively limited patient populations treated in a small number of key hospitals. We believe these measures will help us cover medical institutions and patient groups more precisely and comprehensively.
- *CMC and quality management team.* With a view to supporting our R&D activities and the upcoming commercialization of our drug candidates and building and maintaining a manufacturing and quality system in compliance of GMP standards, we plan to train more CMC and quality management personnel to enhance our CMC technology development capabilities and improve our quality control standards.

OUR DRUG CANDIDATES

Our Pipeline

Leveraging our integrated R&D and manufacturing platform, we had developed a pipeline of nine drug candidates as of the Latest Practicable Date, including eight innovative and one biosimilar monoclonal antibodies. The following chart summarizes our pipeline of drug candidates as of February 20, 2024.

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Drug	Target	Indication	Preclinical	IND Approval	Phase I		Phase II	Phase III	BLA Approval	Commercialization Rights	Expected Near-term Milestone
					Ia	Ib					
● QX002N ★	IL-17A	AS									Completion of patient enrollment in Q2 2024
		LN									
● QX005N ★	IL-4Rα	moderate-to-severe AD in adults									Phase II completion in March 2024
		AD in adolescents									Timing of clinical trial to be determined
		PN ⁽¹⁾									Phase II completion in March 2024
		CRSWNP ⁽¹⁾									Phase II completion in Q4 2024
		CSU ⁽²⁾									Timing of clinical trial to be determined
		moderate-to-severe asthma ⁽³⁾									Timing of clinical trial to be determined
● QX001S	IL-12/IL-23p40	COPD									Timing of Phase I to be determined
		moderate-to-severe plaque Ps ⁽⁴⁾									BLA approval in Q4 2024
		UC/CD									Timing of IND submission to be determined
● QX004N	IL-23p19	Ps ⁽⁶⁾									Phase Ib completion in Q2 2024; Phase II completion in 1H 2025
		CD									Phase Ia completion in Q2 2024
● QX006N	IFNAR1	SLE									Phase Ib completion in Q4 2024
		moderate-to-severe asthma									Phase Ib to be completed by Joincare
● QX008N	TSLP	moderate-to-severe COPD									Timing of Phase I to be determined
		severe asthma ⁽⁸⁾									Timing of Phase I to be determined
● QX007N	IL-33	COPD									Pending IND approval
		Asthma									Pending IND approval
● QX013N	c-kit	CSU									Pending IND approval
● QX010N	IL-31R	pruritus									Timing of IND submission to be determined



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★ Core Product

AD: atopic dermatitis

AS: ankylosing spondylitis

CD: Crohn’s disease

COPD: chronic obstructive pulmonary disease

CRSwNP: chronic rhinosinusitis with nasal polyps

CSU: chronic spontaneous urticaria

LN: lupus nephritis

PN: prurigo nodularis

Ps: psoriasis

SLE: systemic lupus erythematosus

UC: ulcerative colitis

IFNAR1: interferon-alpha/beta receptor subunit 1

IL-4R α : interleukin-4 receptor subunit α

IL-12/IL-23p40: interleukin-12/interleukin-23

subunit p40

IL-17A: interleukin-17A

IL-23p19: interleukin-23 subunit p19

IL-31R: interleukin-31 receptor

IL-33: interleukin-33

TSLP: thymic stromal lymphopoietin














Notes:




- (1) We directly commenced a Phase II clinical trial of QX005N for PN and a Phase II clinical trial of QX005N for CRSwNP by leveraging the Phase Ia clinical trial results of QX005N in healthy subjects and the Phase Ib clinical trial results of QX005N for moderate-to-severe AD in adults.
- (2) We plan to consult with the NMPA about directly initiating a Phase III clinical trial of QX005N for CSU by leveraging the Phase I clinical trial results of QX005N for moderate-to-severe AD in adults as well as the Phase II clinical trial results of QX005N for moderate-to-severe AD in adults and/or PN.
- (3) We plan to consult with the NMPA about directly initiating a Phase III clinical trial of QX005N for asthma by leveraging the Phase I clinical trial results of QX005N for moderate-to-severe AD in adults as well as the Phase II clinical trial results of QX005N for CRSwNP.
- (4) Zhongmei Huadong and we directly commenced the Phase III clinical trial of QX001S for Ps after completion of the Phase I clinical trial as Phase II clinical trials are not required for biosimilars.
- (5) In August 2020, we entered into a collaboration agreement with Zhongmei Huadong, a subsidiary of Huadong Medicine, with respect to the joint development and exclusive commercialization of QX001S in China. We retain the exclusive development and commercialization rights of QX001S outside China. For further details, please refer to “—Collaboration with Zhongmei Huadong.”
- (6) As of February 20, 2024, we had completed subject enrollment for both the Phase Ib clinical trial and the Phase II clinical trial of QX004N for Ps. We expect to complete the Phase Ib clinical trial in the second quarter of 2024.
- (7) In January 2024, we entered into a technology transfer agreement with Joincare Pharmaceutical Group Industry Co., Ltd. (“Joincare”), to grant Joincare an exclusive license to develop, manufacture and commercialize QX008N in mainland China, Hong Kong and Macau. Joincare will be responsible for the BLA application and will be the MAH of QX008N in the licensed territory, once approved. We retain the exclusive rights to develop, manufacture and commercialize QX008N outside the licensed territory. See “Business—Our Other Key Product Candidates—QX008N—Licenses, Rights and Obligations” for details.
- (8) We obtained an IND approval of QX008N for the treatment of severe asthma from the FDA in September 2022 and intend to formulate a clinical development plan for QX008N in the United States depending on the data from our Phase Ia and Phase Ib clinical trials in China.

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Our Disease Area Coverage and Product Matrix

Our broad pipeline covers the four major disease areas in the autoimmune and allergic disease field, namely, skin, rheumatic, respiratory and digestive diseases. In this field, there are often complex relationships between and among various targets and indications across disease areas. For a drug developer, product positioning is key to the potential clinical and commercial value of its pipeline. We illustrate in the chart below the positioning of our product matrix in context, and further set out our pipeline design for each of the major disease areas.

	Skin					Rheumatic			Respiratory			Digestive	
													
	Ps	AD	PN	CSU	Pruritus	AS	SLE	LN	CRSwNP	Asthma	COPD	CD	UC
QX002N★ IL-17A						●		●					
QX005N★ IL-4Rα		●	●	●					●	●	●		
QX001S IL-12/IL-23p40	●											○	○
QX004N IL-23p19	●											●	
QX006N IFNAR1							●						
QX008N TSLP										●	●		
QX007N IL-33										○	●		
QX013N c-kit				○									
QX010N IL-31R					○								

 IND approved  Preclinical
 Core Product

Our Skin Disease Drug Pipeline

Inflammatory skin diseases, such as psoriasis, atopic dermatitis and chronic urticaria, are characterized by the activation of immune responses via production of pro-inflammatory cytokines. Patients with these conditions often experience symptoms such as itch, dry skin, changes in skin appearance (including redness and flaky skin) and sometimes pain, to varying degrees of severity and bodily involvement. In addition, chronic inflammatory skin diseases significantly affect patients’ quality of life, including their physical well-being, psychological health, social development and family relationships.

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The pathogenesis of skin diseases is complex and many aspects are not fully understood. Recent research and investigation have increasingly focused on the delineation of the precise roles particular pro-inflammatory cytokines play in causing skin inflammation and the development of cytokine-directed therapeutics, including strategies targeting cytokine signaling pathways. We believe that skin diseases represent one of the most desirable segments of the autoimmune and allergic disease drug market and our strategically designed skin disease drug pipeline presents a significant competitive advantage.

Our skin disease pipeline comprises five drug candidates with great potential synergy, covering three indications in the area that we consider the most valuable: Ps, AD and PN. Specifically, we are developing (i) QX005N, one of our Core Products, for treating AD, PN and CSU; (ii) QX001S, an affordable ustekinumab biosimilar, to reach a broad section of Ps patients; (iii) QX004N, a promising alternative treatment choice for Ps, which, together with QX001S, is expected to achieve better coverage of Ps patients in China; (iv) QX013N, a promising biologic drug candidate for treating CSU; and (v) QX010N, an early-stage biologic drug candidate for treating pruritus. The following chart summarizes our inflammatory skin disease drug candidates as of February 20, 2024.

Skin disease drug candidates	QX005N				QX001S	QX004N	QX013N	QX010N
Target	IL-4R α				IL-12/IL-23p40	IL-23p19	c-kit	IL-31R
Development stage	Phase II	Phase II	IND Approval	IND Approval	BLA Submission	Phase II	IND Submission	Preclinical
Indications	AD in adults	PN	CSU	AD in adolescents	Ps	Ps	CSU	Pruritus

Our Rheumatic Disease Drug Pipeline

Inflammatory rheumatic diseases encompass a wide variety of illnesses in which innate and adaptive immune responses lead to autoimmune-mediated inflammation and damage in the joints and connective tissues. The most common rheumatic diseases include rheumatoid arthritis (RA), spondyloarthropathies, such as ankylosing spondylitis (AS), psoriatic arthritis and reactive arthritis, and systemic lupus erythematosus (SLE). Patients with these conditions often experience symptoms such as swelling, stiffness and pain in the joints or affected area, fatigue and fever to varying degrees of severity and bodily involvement. Inflammatory rheumatic diseases could result in substantial morbidity, increased mortality and considerable financial burden for the patients in the long term.

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The pathogenesis of these diseases is usually multifaceted and not fully understood. In recent decades, based on the growing knowledge of the regulatory roles certain pro-inflammatory cytokines play in the immune system, research and investigation have increasingly focused on the development of cytokine-targeting biologic therapeutics. As of the Latest Practicable Date, we had two drug candidates indicated for rheumatic diseases, namely, QX002N, one of our Core Products, and QX006N. Specifically, we are developing (i) QX002N as a promising AS and lupus nephritis (LN) drug candidate with potentially improved efficacy and safety profile for patients with inadequate response or intolerant to existing treatments, and (ii) QX006N, a humanized mAb targeting the receptor for type I interferons (IFNs), for the treatment of SLE, an indication with substantial unmet medical needs in China.

The following table summarizes our inflammatory rheumatic disease drug candidates as of February 20, 2024.

Rheumatic disease drug candidates	QX002N		QX006N
Target	IL-17A		IFNAR1
Development stage	Phase III	IND Approval	Phase I
Indications	AS	LN	SLE

Our Respiratory Disease Drug Pipeline

Inflammatory respiratory diseases are conditions characterized by chronic inflammation of the respiratory system, such as asthma, chronic obstructive pulmonary disease (COPD) and chronic rhinosinusitis. People with these conditions often experience breathing problems and other symptoms such as coughing, wheezing, chest pressure and fatigue to varying degrees of severity. These conditions are not only frustrating to live with. They can also be life-threatening, particularly asthma and COPD. While current treatment of such inflammatory respiratory diseases are dominated by inhaled corticosteroids, target-specific biologics are an emerging treatment option. In addition, based on the particular pathology of each subtype of inflammatory respiratory diseases, especially asthma and COPD, some targets have been discovered to be specifically suitable for certain subtypes of such diseases. As of the Latest Practicable Date, we had three drug candidates indicated for chronic rhinosinusitis with nasal polyps (CRSwNP), asthma and COPD. By developing drug candidates for various subtypes of such inflammatory respiratory diseases, we believe we have a strong and comprehensive product pipeline to cover this field. Specifically, our respiratory disease pipeline consists of (i) QX005N as a drug candidate to reach a large number of CRSwNP and asthma patients and for patients with eosinophilic COPD, (ii) QX008N as a drug candidate for asthma and COPD patients, including those with low-level or no expression of type 2 inflammation biomarkers, and (iii) QX007N as a drug candidate with particular promising efficacy for COPD patients with prior smoking history and an alternative drug candidate for asthma patients. The following chart summarizes our inflammatory respiratory disease drug candidates as of February 20, 2024.

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Respiratory disease drug candidates	QX005N			QX008N		QX007N	
Target	IL-4R α			TSLP		IL-33	
Development stage	Phase II	IND	IND	Phase Ib	IND	IND	IND
		Approval	Approval		Approval	Approval	submission
Indications	CRSwNP	Asthma	COPD	Asthma	COPD	COPD	Asthma

Our Digestive Disease Drug Pipeline

Inflammatory digestive diseases, particularly inflammatory bowel disease (IBD), are conditions characterized by chronic inflammation of the digestive system. The two most common types of IBD are ulcerative colitis (UC) and Crohn’s disease (CD). Both conditions involve an abnormal response of the body’s immune system and have a significant impact on the patient’s quality of life. In many cases, both conditions can be aggressive and disabling. As of the Latest Practicable Date, we had two drug candidates indicated for inflammatory digestive diseases, including QX004N for CD and QX001S for UC/CD. Specifically, we are developing QX004N as a promising alternative drug candidate for CD with potentially improved efficacy for patients with more severe symptoms or inadequate response to existing treatments and plan to develop QX001S as an affordable drug to reach a large number of UC and CD patients. The following chart summarizes our digestive disease drug candidates as of February 20, 2024.

Digestive disease Drug candidates	QX004N	QX001S
Target	IL-23p19	IL-12/IL-23p40
Development stage	Phase Ia	Preclinical
Indications	CD	UC/CD

Our Core Products

QX002N

QX002N, discovered and developed by our Company, is one of the first domestically developed IL-17A antibodies to obtain an IND approval from the NMPA for the treatment of AS. IL-17A is a key pro-inflammatory cytokine involved in the regulation of inflammatory responses and bone metabolism. Research has shown that IL-17A plays an important role in the pathogenesis of AS and is also involved in autoantibody production and organ damage in SLE patients, which could lead to LN development. We believe that QX002N, as an anti-IL-17A therapy, can offer a much-needed effective treatment option with a different mechanism of action for AS and LN patients experiencing inadequate response, intolerance or unacceptable safety concerns with the currently available treatments.

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As of the Latest Practicable Date, we were developing QX002N for two indications, AS and LN.

- AS: We obtained an IND approval for QX002N for the treatment of active AS in adults in April 2019. QX002N showed favorable safety and immunogenicity properties in our Phase Ia study in healthy subjects and promising efficacy in our Phase Ib and Phase II clinical trials in AS patients in China. We conducted a pre-Phase III consultation with the NMPA, which raised no material questions and confirmed that it had no objections to the commencement of such trial in its official response in July 2023. We commenced the Phase III clinical trial in September 2023.
- LN: We received IND approval of QX002N for LN in October 2021 and expect to continue the development of QX002N for the treatment of LN after it obtains the BLA approval for the treatment of AS. As of the Latest Practicable Date, we had not initiated any clinical trial of QX002N for LN.

We hold the rights for the development and commercialization of QX002N globally and do not have any current plan to out-license QX002N in domestic or overseas markets.

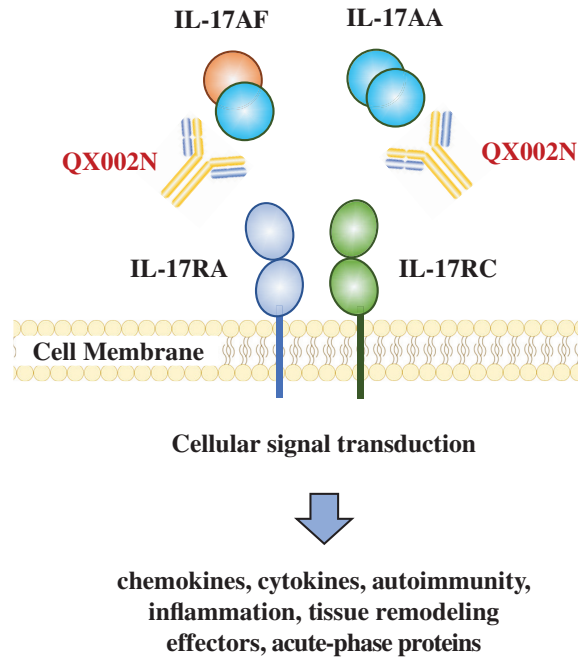
Mechanism of Action

IL-17A is a member of the IL-17 superfamily of cytokines, which perform regulatory functions in the host immune system by inducing and working in synergy with various other pro-inflammatory cytokines, enhancing chronic inflammation. In addition, IL-17A is also involved in the regulatory mechanism of bone remodeling, by inducing the expression of receptor activator of nuclear factor- κ B ligand (RANKL), which activates osteoclast, a type of bone cells responsible for bone erosion and remodeling. Elevated levels of IL-17A have been detected in the serum and synovial joint fluid of AS patients and identified as a major factor in AS pathogenesis and IL-17A inhibition has been shown to have significant clinical efficacy in treating AS. In addition, studies have shown that elevated expression of Th17-related cytokines (such as IL-17) in the urinary system is also associated with enhanced recruitment of immune cells to the kidney and thereby leading to LN development in SLE patients.

QX002N is a humanized IgG1 mAb that is designed to specifically bind to IL-17A, including IL-17AA and IL-17AF, thereby blocking their binding to the intended receptor complex, comprised of interleukin 17 receptor A (IL-17RA) and interleukin 17 receptor C (IL-17RC), and preventing the subsequent activation of several pro-inflammatory signaling pathways.

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The following diagram illustrates the mechanism of action of QX002N.



Source: the Company

Ankylosing Spondylitis

Ankylosing spondylitis (AS) is a chronic progressive inflammatory disease that is primarily characterized by inflammation of the spinal joints, leading to reduced flexibility of the joints and stiffness in the spine over time. The pathology mainly affects the entheses, where ligaments, tendons and capsules attach to the bone. In severe cases of AS, the entheses are affected by inflammation, as well as bone erosion and formation of syndesmophytes, aberrant bony growths as a result of the calcification of or hardening inside ligaments, which could cause the adjacent bones in the spine to fuse (grow together) and form one cohesive unit. Those parts of the spine become stiff and inflexible. Fusion can also stiffen the rib cage, restricting lung capacity and function. AS may also cause inflammation in other parts of the body, including the eyes, shoulders and knees, as well as the aorta, the main artery of the body.

There is currently no cure for AS and available treatments aim to control inflammation, prevent joint damage and provide symptom relief. In recent decades, the pivotal role of cytokines (small signal proteins that regulate the growth and activity of other immune system cells) in the development of AS has been closely studied and biologics targeting pro-inflammatory cytokines, in particular, tumor necrosis factors (TNFs) and interleukins (ILs), have been recommended as second-line treatment for AS patients with high disease activity after receiving first-line traditional treatments. We are developing our Core Product, QX002N, a monoclonal antibody (mAb) targeting IL-17A, as a treatment option with a potentially favorable efficacy and safety profile for AS patients.

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Market Opportunity and Competition

According to Frost & Sullivan, the AS patient population in China reached 3.9 million in 2022, and is expected to remain relatively stable over the next decade. A considerable proportion of AS patients first develop symptoms in their early adulthood or adolescence, and require long-term treatment to control disease progression.

Medications indicated for AS mainly include NSAIDs, which are widely accepted as the first-line medication for treating AS, traditional immunosuppressive disease-modifying anti-rheumatic drugs (DMARDs) and corticosteroids. However, NSAIDs are noted with limited efficacy in patients with more severe cases of AS and their effectiveness in suppressing bone erosion and remodeling associated with AS remains unclear. In addition, there are safety risks associated with long-term systemic use of such therapies, especially corticosteroids. Maintenance treatment with systemic use of corticosteroids can cause a series of severe adverse effects, such as osteoporosis, adrenal suppression and hyperglycemia (high blood sugar), and dose-dependent growth suppression in children and adolescents.

In the past decades, biologic drugs have emerged as effective innovative therapies for AS. According to Frost & Sullivan, the market for biologic drugs indicated for AS in China is estimated to increase from US\$0.3 billion in 2022 to US\$3.9 billion in 2030, at a CAGR of 37.8%. There are two classes of approved biologic drugs in China for the treatment of AS, namely, TNF inhibitors and IL-17 inhibitors. TNF, most prominently TNF- α , is a type of pro-inflammatory cytokine produced by certain types of white blood cells during acute inflammation and plays a role in the regulation of the immune system. Dysregulation of TNF may lead to excessive inflammation, which in turn may cause various autoimmune and immune-mediated disorders. TNF inhibitors block the binding of TNF to TNF receptors, thereby suppressing their biological effects. TNF inhibitors are currently one of the most commonly used biologic drugs for AS in China. However, studies have shown that up to 40% of patients with AS become intolerant to or fail to achieve adequate disease control with anti-TNF therapies, indicating significant heterogeneity in treatment response. Thus, there remains an unmet medical need for novel treatments with a different mechanism of action.

With recent scientific advancements demonstrating the role of IL-17A in AS pathogenesis, IL-17A antibodies have emerged as a new class of biologic drugs for AS and have been recommended by prevailing clinical guidelines as second-line standalone treatment (the same designation as TNF inhibitors) for AS patients with high disease activity after receiving first-line traditional treatments. We believe our QX002N will primarily compete with anti-IL-17 drugs and other biologic drugs, primarily TNF inhibitors, in China.

As of the Latest Practicable Date, there were 20 biologic drugs approved for AS treatment in China, comprising 18 TNF inhibitors (including adalimumab and 7 adalimumab biosimilars) and 2 IL-17A antibody drugs, namely, secukinumab and ixekizumab, both of which had also been approved by the FDA for the treatment of adults with AS. As of the same date, in addition to our QX002N, there were 21 biologic drug candidates indicated for AS in the clinical stage in China, comprising 11 TNF inhibitors (including 8 proposed adalimumab biosimilars) and 10 IL-17 inhibitors.

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The following table sets forth details of QX002N and IL-17 antibody drugs or drug candidates in the clinical stage for AS in China as of the Latest Practicable Date.

Marketed IL-17A Inhibitors for AS in China							
Target	Brand Name	INN	Company	NMPA Approval Time	Median Price ⁽¹⁾	NRDL Inclusion	Expected Patent Expiration ⁽²⁾
IL-17A	Cosentyx	Secukinumab	Novartis	2020	1,188.0	Yes	2025
	Taltz	Ixekizumab	Eli Lilly	2022	1,218.0	Yes	2026

Clinical-Stage IL-17A Inhibitor Candidates for AS in China				
Target	Drug Code	Company	Status	First Posted Date
IL-17A	GR1501	GenrixBio	BLA submission	2024-01-04
	SHR-1314	Hengrui	BLA submission	2024-02-08
	Netakimab	Biocad	Phase III	2022-09-30
	QX002N	the Company	Phase III	2023-08-31
	AK111	Akeso	Phase III	2023-10-08
	JS005	Junshi Bioscience	Phase II	2021-09-30
	HB0017	Huabo	Phase II	2023-04-12
	SSGJ-608	SunShine Guojian	Phase II	2024-01-29
	Secukinumab-CMAB015	MabPharm	Phase I	2023-01-18
	IL-17A, IL-17F	Bimekizumab	UCB Pharma	BLA submission
LZM012		Livzon	Phase III	2023-07-28

Source: Frost & Sullivan Report (based on annual reports of relevant companies and information published by the NMPA)

Notes:

- (1) Reflects the NRDL median price for minimum formulation unit in 2022 in RMB.
- (2) Reflects the present anticipated expiration time of the relevant amino acid sequence patent in the PRC.

In addition to the traditional and biologic therapies, tofacitinib by Pfizer, a small molecule Janus kinase (JAK) inhibitor, has also been approved for AS treatment by the FDA and the NMPA. JAK is a family of signaling molecules involved in the intracellular transduction of immune signaling of various cytokine receptor cells. JAK inhibitors have shown clear clinical benefit in AS patients in terms of symptom relief and reduction of inflammation. However, tofacitinib is recommended by the FDA only for AS patients who are intolerant or non-responsive to one or more TNF inhibitors as there remain concerns over the safety profile of JAK inhibitors.

Our Advantages

Compared with other biologic drugs and drug candidates indicated for AS, QX002N has the following potential advantages:

- Effective biologic drug for AS with a different mechanism of action. In the updated guidelines published by ASAS and European Alliance of Associations for Rheumatology (EULAR) for the management of AS, IL-17A inhibitors are recommended as second-line standalone treatment (the same designation as TNF inhibitors) for AS patients with persistently high disease activity after receiving

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first-line traditional treatments. Additionally, studies have shown that many patients with inflammatory rheumatic disease, particularly AS and psoriatic arthritis (PsA), who were intolerant or non-responsive to TNF inhibition therapies showed disease improvement when treated with anti-IL-17A drugs. A Phase III clinical study of ixekizumab (an IL-17A inhibitor) in AS patients showed that, at week 16, 69% and 52% of patients who had received 80 mg ixekizumab once every two weeks (Q2W) achieved ASAS20 and ASAS40 responses, respectively, as compared to 59% and 36% for patients who had received 40 mg adalimumab (one of the best-selling TNF inhibitors) Q2W, indicating a better trend of efficacy by ixekizumab. ASAS20 and ASAS40 are industry benchmarks for AS disease improvement, representing a 20% and 40% improvement, respectively, in key aspects of AS symptoms according to measurements selected by ASAS. Moreover, compared with TNF inhibitors, IL-17A inhibitors are more targeted and with generally fewer warnings and precautions. In particular, studies suggest that IL-17A inhibitors could be safer for patients with high risk for severe and opportunistic infections such as tuberculosis, which were the primary side effects of TNF inhibitors. As an IL-17A antibody drug candidate, QX002N has the potential to provide AS patients with an effective and well-tolerated biologic therapy.

- Promising efficacy. QX002N showed promising efficacy in AS patients in our Phase Ib and Phase II clinical trials. In our Phase Ib trial, 62.5% and 37.5% of subjects in the treatment group receiving QX002N (160 mg) Q2W achieved ASAS20 and ASAS40 responses, respectively, at week 16. In our Phase II clinical trial, the ASAS20 and ASAS40 response rates of subjects receiving QX002N (160 mg) once every four weeks (Q4W) reached 60.0% and 40.0% at week 16, respectively. For details, see “—Summary of Clinical Trials” below.
- Good safety profile. In comparison with approved and other clinical stage IL-17A inhibitors with reported clinical data, QX002N demonstrated a good safety profile in its clinical trials. No SAEs were reported in the Phase Ia and Phase Ib trials. In its Phase II clinical trial in 120 AS patients, only one SAE (unrelated to the drug) was reported, lower than those reported by secukinumab and ixekizumab in their respective registrational trials (5 SAEs among 249 patients in Measure 1 and 8 SAEs among 249 patients in Measure 2 for secukinumab, and 17 SAEs among 327 patients on Q4W regimen and 19 SAEs among 314 patients on Q2W regimen in Coast-V and Coast-W for ixekizumab). Additionally, in comparison with TNF inhibitors, QX002N, as an IL-17 inhibitor, could provide a more suitable treatment option for patients with high risk for tuberculosis infections, which were the primary side effects of TNF inhibitors.

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- Promising accessibility. Historically, treatment regimens of anti-IL therapies for AS have been relatively costly, which in turn limited patients’ access. For example, according to Frost & Sullivan, in 2022, the annual cost of ixekizumab for the treatment of AS in China was estimated to be approximately RMB15,000 to RMB17,000, with a treatment regimen of two doses of 80 mg for the first week and 80 mg Q4W thereafter. According to Frost & Sullivan, in 2022, the annual cost of secukinumab in China was estimated to be approximately RMB19,000 (with a loading dose regimen of 150 mg for five consecutive weeks and then Q4W thereafter) or RMB15,000 (with a dosing regimen of 150 mg Q4W without loading doses). Leveraging our integrated R&D and in-house manufacturing capabilities and cost control measures, we aim to make QX002N more accessible to AS patients in China. QX002N is designed to be administered with a dosing regimen of 160 mg Q4W. Its estimated annual cost would be lower than secukinumab and ixekizumab by approximately 20% to 30% upon commercialization, making it a more affordable option.

Summary of Clinical Trials

We commenced a Phase III clinical trial of QX002N for the treatment of AS in September 2023, which is expected to be completed in the second half of 2025.

Ongoing Phase III Clinical Trial

Trial design: Our phase III clinical trial in China is a multi-center, randomized, double-blind and placebo-controlled trial in adult patients with active AS. The primary endpoint is the efficacy and safety features of QX002N at week 16 in comparison to placebo. The secondary endpoints include QX002N’s long-term efficacy and safety features at week 52, PK and PD characteristics and immunogenicity. The full treatment period is expected to be 52 weeks, consisting of a 16-week placebo-controlled treatment period and a 36-week extended treatment period. A total of 640 patients with active AS are expected to be enrolled and randomly assigned at the ratio of 1:1 to a QX002N group, which would receive 160 mg QX002N Q4W through out the placebo-controlled treatment period and the extended treatment period, and a control group, which would receive placebo Q4W for the placebo-controlled treatment period and then 160 mg QX002N Q4W after the evaluation of all relevant parameters at week 16 and throughout the extended treatment period.

Trial status: The Phase III clinical trial was initiated in September 2023. We had enrolled 337 patients as of the Latest Practicable Date and expect to complete patient enrollment in the second quarter of 2024.

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Phase II Clinical Trial

Trial design: Our phase II clinical trial in China was a multi-center, randomized, double-blind and placebo-controlled trial in patients with AS. The primary endpoint was the percentage of patients achieving ASAS20 response at week 16 and safety parameters. The secondary endpoints included, among others, efficacy parameters, such as ASAS20/ASAS40 at weeks 2, 4, 8, 12, 20 and 24 and improvements in quality of life, PK parameters and immunogenicity. A total of 120 patients with AS would be enrolled and randomly assigned to four groups at the ratio of 1:1:1:1 to receive 80 mg QX002N, 160 mg QX002N, 240 mg QX002N or placebo Q4W, respectively. The treatment period would be 16 weeks, followed by eight weeks of follow-up visits.

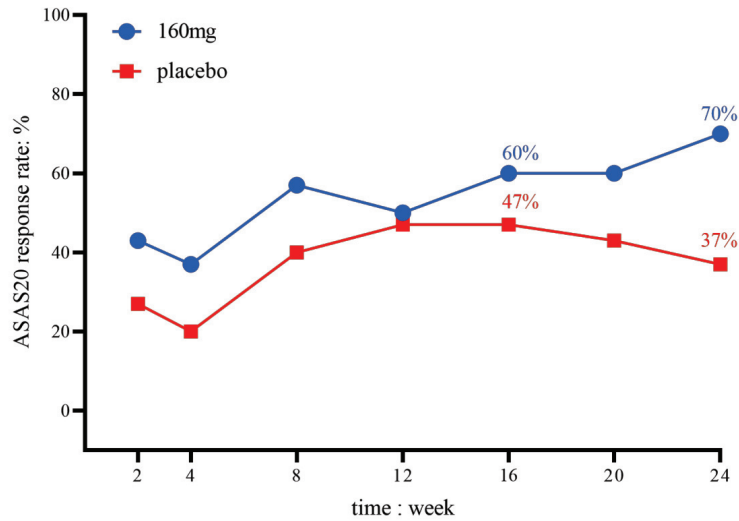
Trial status: The Phase II clinical trial was initiated in January 2022. We completed patient enrollment in September 2022, with a total of 120 patients enrolled. During the trial, we experienced delay in the completion of patient enrollment for approximately two months (from the expected completion in July 2022 to September 2022) and interruption in follow-up visits of some patients due to COVID-19-related lockdown measures in cities where our clinical trial sites/patients were located. We completed the trial in August 2023.

Safety results: QX002N showed a good safety profile among AS patients in all dose groups. The overall TEAE incidence rates of QX002N groups were slightly higher than that of the placebo group, but no significant difference was observed. Among the 119 patients who received at least one drug administration and were included in the safety analysis, 107 (89.9%) patients (28 in the 80 mg group, 28 in the 160 mg group, 26 in the 240 mg group and 25 in the placebo group) reported TEAEs, among which 61 (51.3%) patients (16 in the 80 mg group, 16 in the 160 mg group, 16 in the 240 mg group and 13 in the placebo group) reported TEAEs that were considered to be drug-related. Five patients (four in the 80 mg group and one in the 160 mg group) reported six TEAEs of grade 3 or above as defined in the CTCAE 5.0, consisting of one grade 4 AE of hypertriglyceridemia (HTG, indicating an excessive amount of fats in the blood, possibly resulting from the changes in fat metabolism induced by inflammatory responses of the immune system), one grade 3 AE of HTG, two grade 3 AEs of elevated blood triglycerides, one grade 3 AE of hematochezia (blood in the stool) and one grade 3 AE of AS. None of the grade 3 or grade 4 AEs were considered to be drug-related. In particular, one patient in the 160 mg group reported one grade 3 AE of AS worsening from day 135 to day 141 of the trial (after the treatment period) and was hospitalized for six days. This AE was determined to be unrelated to the drug and recorded as SAE due to hospitalization. The patient recovered after medical treatment before the end of trial. Two patients experienced TEAEs that resulted in the termination of the trial. In particular, one patient in the 160 mg QX002N group experienced a grade 2 TEAE of urticaria from day 14 to day 99 of the trial, which was considered to be possibly drug-related and resulted in the termination of the patient's participation in the trial and permanent discontinuation of the drug. The patient recovered from the TEAE after medical treatment. One patient in the 240 mg QX002N group experienced a grade 1 TEAE of rash at injection site from day 2 to day 16 of the trial, which was considered to be possibly drug-related and resulted in the termination of the patient's participation in the trial and permanent discontinuation of the drug. The patient recovered from the TEAE without medical treatment.

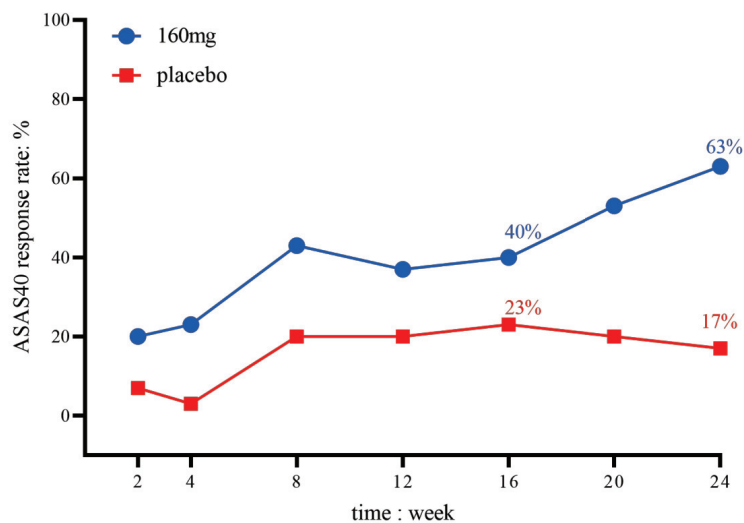
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Efficacy results: The ASAS20 response rates of the 80 mg, 160 mg and 240 mg QX002N groups reached 70.0%, 60.0% and 55.2%, respectively, at week 16, compared to 46.7% of the placebo group at the same week. The ASAS20 response rates of all QX002N groups demonstrated clear clinically significant (albeit not statistically significant) difference compared to that of the placebo group at week 16. At week 20, the ASAS40 response rates of all QX002N groups showed statistically significant advantage compared to that of the placebo group at the same week. At week 24, the ASAS20 response rates and ASAS40 response rates of all QX002N groups showed statistically significant advantage compared to those of the placebo group at the same week. The charts below illustrate the percentages of patients achieving ASAS20 and ASAS40 responses in the 160 mg QX002N group in comparison with the placebo group from week 2 to week 24.

ASAS20 response rates



ASAS40 response rates



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PK: During the treatment period, at the same follow-up visit point, the geometric means of drug plasma trough concentrations (C_{trough} , indicating the concentration reached by a drug immediately before the next dose) increased with dose escalation for patients receiving QX002N. Temporary steady-state was not achieved at week 8 after multiple administrations of QX002N, indicating a certain degree of accumulation with Q4W dosing. The geometric means of C_{trough} of QX002N groups prior to week 16 administration were similar to the simulation predictions based on the analysis of PK data from the Phase Ib trial of QX002N, indicating that QX002N reached the expected target concentration levels in this trial.

PD: The PD parameter measured the total concentration of IL-17A in serum, which consisted of the amount of free IL-17A and IL-17A complexed with QX002N. At all follow-up visit points after QX002N administration, the average total serum IL-17A concentrations of all QX002N groups significantly increased compared to that of the placebo group, which was similar to the trend observed for secukinumab, an FDA- and NMPA-approved IL-17A inhibitor and consistent with the hypothesis that the clearance of IL-17A as complexed with QX002N was slower than that of free IL-17A.

Immunogenicity: One patient (in the 240 mg group) reported a positive ADA response before week 12 administration, two patients (one in the 80 mg group and one in the 240 mg group) reported positive ADA responses before week 16 administration and five patients (two in the 80 mg group, one in the 160 mg group and two in the 240 mg group) reported positive ADA responses before week 24 administration. One patient with positive ADA response reported an AE of rash at the injection site and other ADA positives reported no injection site reactions or severe allergies.

Conclusion: In this trial, QX002N demonstrated a good safety profile in AS patients after multiple administrations, with no significant safety risk identified compared to the placebo group. The ASAS20 response rates of all QX002N groups demonstrated clear clinically significant (albeit not statistically significant) difference compared to that of the placebo group at week 16. The ASAS20 response rates of all QX002N groups at week 20 and the ASAS20 and ASAS40 response rates of all QX002N groups at week 24 showed statistically significant differences compared to those of the placebo group at the same weeks. Therefore, a Phase III clinical trial was recommended, with a dose regimen of 160 mg QX002N administered Q4W.

Phase Ib Clinical Trial

Trial design: Our Phase Ib clinical trial was a single-center, randomized, double-blind and placebo-controlled multiple-dose escalation trial in AS patients. The primary endpoints were safety, tolerability and PK parameters. The secondary endpoints included (i) efficacy parameters, including the percentage of patients achieving ASAS20 and ASAS40 responses, (ii) immunogenicity and (iii) recommending dosing regimen for a Phase II clinical trial. We planned to enroll 30 AS patients in this trial and randomly assign them into three groups to receive 40 mg, 80 mg and 160 mg QX002N or placebo, respectively, once every 2 weeks (Q2W). Within each dose group, eight patients would receive QX002N and two patients would receive placebo. The patients would receive a total of six doses of QX002N (or placebo) from week 0 to week 10, followed by 14 weeks of follow-up visits.

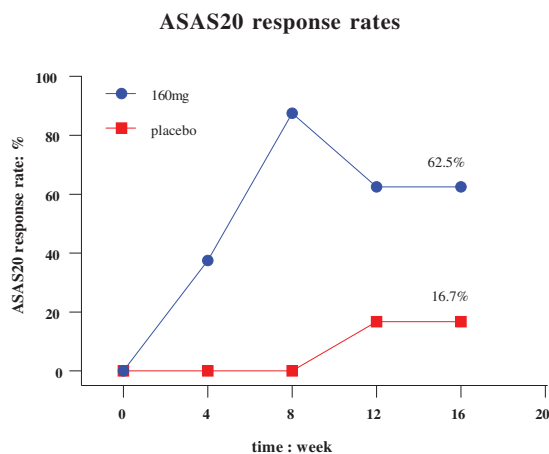
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Trial status: The phase Ib clinical trial was initiated in September 2020 and completed in September 2022. A total of 30 patients were enrolled, among which 28 completed the trial.

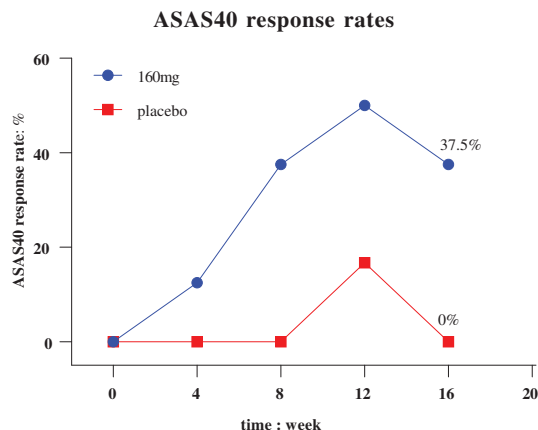
Safety results: QX002N was well-tolerated and showed a good safety profile in AS patients of all dose groups. No serious AEs (SAEs) were reported. No patients withdrew from the clinical trial due to AEs, and no patients were suspended or down-regulated due to AEs. 27 (90.0%) patients had 132 AEs, among which 85 AEs were considered to be drug-related. Four patients reported seven AEs of grade 3 or above (one of grade 4 and six of grade 3 as defined in the CTCAE 5.0), among which only one AE of grade 3 was considered to be drug-related. Specifically, one patient in the 40 mg group reported one grade 4 AE of HTG, which was determined to be possibly unrelated to the drug and the patient recovered from the AE without any medical treatment. One patient in the 40 mg group reported one grade 3 AE of high blood pressure that was possibly unrelated to the drug and recovered after medical treatment before the end of trial. One patient in the 80 mg group reported four grade 3 AEs of HTG, only one of which was determined to be possibly related to the drug and the patient received treatment for such AE and recovered before the end of the trial. One patient in 160 mg group reported one grade 3 AE of HTG that was possibly unrelated to the drug and recovered without any medical treatment.

PK: Over a dose range from 40 mg to 160 mg, systemic exposure of QX002N (C_{max} , AUC_{last} and AUC_{inf}) increased in a roughly proportional manner with increasing dose. The mean $T_{1/2}$ of QX002N ranged between 25.3 to 29.5 days in AS patients.

Efficacy results: The ASAS20 response rates in the 40 mg-160 mg dose groups reached 25.0%-62.5% at week 16, compared to 16.7% in the placebo group at the same week. The ASAS40 response rates in the 40 mg-160 mg dose groups reached 12.5%-37.5% at week 16, and no subject in the placebo group reached ASAS40 response at week 16. The charts below illustrate the percentages of patients achieving ASAS20 and ASAS40 responses in the 160 mg group in comparison with the placebo group from week 4 to week 16.



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Immunogenicity: In this trial, the immunogenicity risk of QX002N was low, with only one patient (in the 160 mg group) showing a positive ADA response on day 99 and returning to negative on day 127 of the trial.

Conclusion: The trial met its primary and secondary endpoints. In this trial, QX002N was well-tolerated in AS subjects, and demonstrated a good safety profile and dose-proportional PK after multiple administration. Over the dose range of 40 mg, 80 mg and 160 mg, the efficacy of QX002N enhanced as the dose level increased. In addition, the immunogenicity risk of QX002N was extremely low. Based on the trial results, the recommended starting dose for the Phase II clinical trial was 80 mg.

Phase Ia Clinical Trial

Trial design: The phase Ia clinical trial in China was a single-center, randomized, double-blind and placebo-controlled dose-escalation trial in healthy subjects. The primary objective of this trial was to evaluate the safety and tolerability of single escalating dose of QX002N in healthy subjects. The secondary objectives were to evaluate the PK and immunogenicity of QX002N, and to determine the recommended dose for a Phase Ib clinical trial. A total of 65 subjects would be assigned to seven groups to receive a single subcutaneous injection of 10 mg, 20 mg, 40 mg, 80 mg, 160 mg, 240 mg and 320 mg QX002N or placebo, respectively, with five subjects assigned to the 10 mg group and ten subjects assigned to each of the remaining six dose groups. Within each dose group, the ratio of subjects receiving QX002N to those receiving placebo would be 4:1.

Trial status: The phase Ia clinical trial was initiated in June 2019 and was completed in September 2021. A total of 65 subjects were enrolled and completed the trial.

Safety results: QX002N was well-tolerated in healthy subjects in the dose range from 10 mg to 320 mg. No SAEs were reported. 31 (59.6%) subjects in QX002N groups and 6 (46.2%) subjects in the placebo group reported 91 AEs, among which only one subject in 10 mg QX002N group experienced one grade 3 AE (as defined in the CTCAE 5.0) of HTG that was possibly related to the drug and recovered without any medical treatment. All subjects fully recovered from the AEs at the end of the study.

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PK: QX002N exhibited dose-proportional PK in healthy subjects over a dose range from 10 mg to 320 mg following single subcutaneous administration. The mean $T_{1/2}$ of QX002N ranged between 24.3 to 35.1 days, which is comparable to the previously published data of secukinumab (22 to 31 days in Ps patients) and better than the previously published data of ixekizumab (13 days in Ps patients).

Immunogenicity: In this trial, the immunogenicity risk of QX002N was low. One subject in the 20 mg group and one subject in the placebo group showed positive ADA responses.

Conclusion: The trial met its primary and secondary endpoints. In this trial, QX002N was well-tolerated in healthy subjects, and demonstrated a good safety profile and dose-proportional PK. In addition, the immunogenicity risk of QX002N was extremely low. Based on the trial results, the recommended starting dose for the Phase Ib clinical trial was 40 mg.

Summary of Preclinical Study Results

We conducted a series of preclinical studies in order to characterize the PD, PK and toxicology profile of QX002N. In our *in vitro* PD study, QX002N demonstrated high levels of affinity, and potency comparable to ixekizumab and better than secukinumab, both of which are FDA-approved IL-17A antibodies. In our preclinical PK study, QX002N exhibited dose-proportional PK in rhesus monkeys over a dose range from 1.5 mg/kg to 15 mg/kg following single subcutaneous or intravenous administration. In our preclinical toxicological studies, QX002N showed no obvious systemic toxicity.

Material Communications and Next Steps

We received IND approval of the Phase I, Phase II and Phase III clinical trials of QX002N for active AS in adults from the NMPA in April 2019. In compliance with the Administrative Measures for Drug Registration (《藥品註冊管理辦法》) issued by the NMPA, before the initiation of each of the Phase Ib and Phase II clinical trials, we had submitted requisite documents, including results from previous trial phase(s), to the NMPA and received no concerns or objections from the NMPA. Our PRC Legal Advisors are of the view that based on the results from the Phase Ia/Ib clinical trials, the NMPA had no objection to the commencement of each of the Phase Ib/II clinical trials of QX002N. We conducted a pre-Phase III consultation with the NMPA (as required by the IND approval of QX002N) and submitted, among others, key results from all prior trial phases and the Phase III trial design. We received the NMPA's official response in July 2023, which raised no material questions and confirmed that it had no objections to the commencement of the Phase III clinical trial. We commenced such trial in September 2023. As of the Latest Practicable Date, we had not received any relevant regulatory agency's concerns or objections to the commencement of any of our clinical trials or our clinical development plans. No material adverse changes had occurred since we obtained the IND approval and up to the Latest Practicable Date.

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Lupus Nephritis

Lupus nephritis (LN) is the most common severe complication of SLE, involving inflammation of and possible organ damage to the kidneys, which can harm the overall function of the renal system. LN affects 30% to 60% of adults and up to 70% of children with SLE, leading to increased risks of hospitalization, end-stage renal disease and death. There is no cure for LN and currently available treatments merely aim to provide symptom relief. As of the Latest Practicable Date, belimumab was the only targeted biologic drug approved by the FDA or NMPA for the treatment of LN. We are exploring the therapeutic potential of our Core Product, QX002N, for the treatment of LN.

Leveraging the promising profile QX002N demonstrated in our preclinical studies and Phase Ia clinical trial in healthy subjects, we plan to further explore its potential as a novel therapy for the treatment of LN. We received IND approval of the Phase I, Phase II and Phase III clinical trials of QX002N for LN from the NMPA in October 2021, and expect to continue the development of QX002N for the treatment of LN after it obtains the BLA approval for the treatment of AS. As of the Latest Practicable Date, we had not initiated any clinical trial of QX002N for LN. Pursuant to the Administrative Measures for Drug Registration, LN will be considered an indication expansion of QX002N and treated as the same product in the subsequent regulatory registration process.

Market Opportunity and Competition

According to Frost & Sullivan, the LN patient population in China reached approximately 567,700 in 2022, and is expected to remain relatively stable over the next decade.

Similar to treatment options for SLE, the types of drugs that have been used to treat LN mainly include corticosteroids, traditional DMARDs (such as hydroxychloroquine) and biologic drugs, with corticosteroids and hydroxychloroquine recommended as initial treatment options and standard of care. As the investigation of biologic drugs for the treatment of LN is still at an early stage, there is no clear designation of line of treatment for biologic drugs for this indication. Compared to SLE, biologic drugs and drug candidates indicated for LN are even more limited.

As of the Latest Practicable Date, belimumab was the only targeted biologic drug approved by the FDA or NMPA for the treatment of LN. See “—Our Other Key Product Candidates—QX006N—Systemic Lupus Erythematosus—Market Opportunity and Competition” for more details on belimumab.

As of the same date, there were 11 biologic drug candidates for LN in the clinical stage in China, 3 of which were IL-17 inhibitors. Other targets under investigation include B cell membrane proteins, such as CD80/CD86 and CD20.

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Our Advantages

In the last decade, LN therapy has remained largely unchanged, with limited probability of achieving complete or partial remission. Multiple immunological pathways are involved in inducing tissue damage in SLE and LN, therefore developing effective single-target biologic drugs has been challenging. Studies have shown that IL-17, alone or together with BLYS, may stimulate B cell survival and differentiation, indicating the ability of IL-17 to contribute to several pathological pathways of LN, such as the induction of vascular inflammation, recruitment of leukocytes, activation of B cells and autoantibody production, contributing to the persistence of inflammation and renal damage. Therefore, IL-17A inhibitors have the potential to become a novel therapeutic option for LN patients.

Summary of Clinical Trials and Preclinical Studies

See “—Ankylosing Spondylitis—Summary of Clinical Trials—Phase Ia Clinical Trial” and “—Ankylosing Spondylitis—Summary of Preclinical Study Results” for more details on our Phase Ia clinical study in healthy subjects and preclinical studies.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET QX002N SUCCESSFULLY.

QX005N

QX005N, our other Core Product and discovered and developed by our Company, is a recombinant humanized IgG4 monoclonal antibody directed against the interleukin-4 receptor subunit α (IL-4R α). IL-4R α is a well-validated, broad-acting target and controls the signaling of both IL-4 and IL-13, which is critical in the initiation of type 2 inflammation (a pattern of immune response that underpins the pathophysiology of several chronic allergic diseases). According to Frost & Sullivan, IL-4R α inhibitors had been approved or were under development for 20 indications globally as of the Latest Practicable Date.

As of the Latest Practicable Date, we were developing QX005N for seven indications: moderate-to-severe AD in adults, AD in adolescents, PN, CRSwNP, CSU, moderate-to-severe asthma and COPD.

- AD: We received an IND approval for QX005N for moderate-to-severe AD in adults from the NMPA in June 2020. QX005N has demonstrated favorable safety and efficacy results in our Phase Ia (in healthy subjects) and Phase Ib (in patients with moderate-to-severe AD) clinical trials in China. In the Phase Ib clinical trial, similar response rates of QX005N were observed in the 300 mg and 600 mg groups, with 75.0% of subjects in each group reaching EASI-75 and 50.0% of subjects in each group reaching IGA score (0 or 1) at week 12 without significantly increased safety risks. It is currently being evaluated in a Phase II clinical trial in patients with moderate-to-severe AD in China. In addition, we obtained an IND approval of QX005N for the treatment of AD in adolescents aged between 12 and 17 years from the NMPA in October 2023.

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- PN: We received an IND approval for QX005N for PN from the NMPA in March 2022. It is currently being evaluated in a Phase II clinical trial in PN patients in China.
- CRSwNP: We received an IND approval for QX005N for CRSwNP from the NMPA in November 2021. It is currently being evaluated in a Phase II clinical trial in CRSwNP patients in China.
- CSU: We received an IND approval for QX005N for CSU from the NMPA in January 2022.
- Moderate-to-severe asthma: We received an IND approval for QX005N for moderate-to-severe asthma from the NMPA in February 2022.
- COPD: We received an IND approval for QX005N for COPD from the NMPA in September 2023.

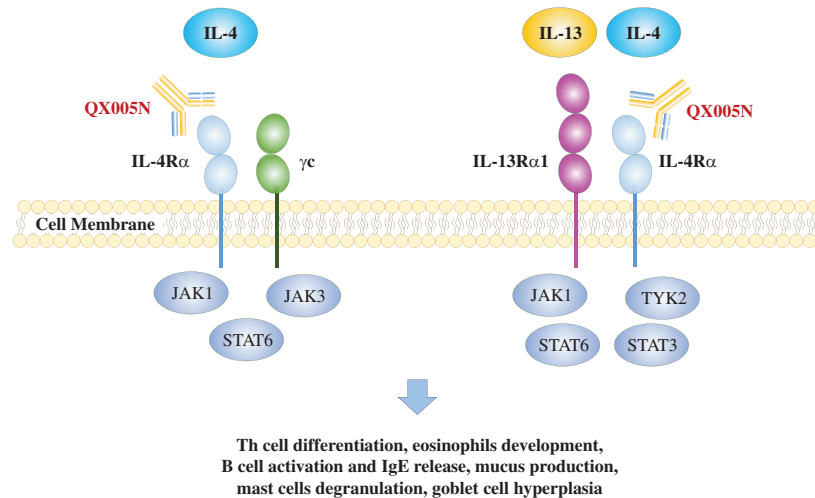
We do not have any current plan to out-license QX005N domestically or overseas.

Mechanism of Action

IL-4 and IL-13 are both key players in the inflammatory response triggered either by an invading parasite or allergen. IL-4 induces isotype switching to IgE in B cells (a type of white blood cells that produces antibodies) and causes an elevated IgE level. This leads to the degranulation of basophils and mast cells, which is a cellular process used by these cells involved in the immune system to release a mixture of compounds to destroy invading microorganisms, and release of pro-inflammatory mediators. IL-4 and IL-13 stimulate trafficking of eosinophils to the site of inflammation, leading to tissue eosinophilia. In addition, they are involved in causing other common pathophysiological effects, such as mucus overproduction, goblet cell hyperplasia (a feature of asthma and other respiratory diseases) and tissue remodeling. Furthermore, IL-4 drives CD4⁺ T cell differentiation toward the Th2 subtype, which produces IL-4, IL-13 and IL-5, thus creating a cyclical effect.

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IL-4 and IL-13 exert their signaling activities by interacting with specific receptors on the cell surface, *i.e.*, the type 1 IL-4R α /gamma common (γ c) and/or the type 2 IL-4R α /IL-13R α 1 receptor complexes. The type 1 receptor complexes can only be activated by IL-4 while the type 2 receptor complexes can be activated by both IL-4 and IL-13. By binding to IL-4R α , QX005N is designed to block the signaling pathways of both IL-4 and IL-13 that drive type 2 inflammatory response and presents a promising therapeutic solution to type 2-driven allergic diseases. The diagram below illustrates the mechanism of action of QX005N, which is designed to block the signaling pathways of both IL-4 and IL-13 by binding to IL-4R α .



Source: the Company

Atopic Dermatitis

Atopic dermatitis (AD) is one of the most common skin disorders globally and in China. It is a skin immune-mediated inflammatory disease that causes dry, itchy and inflamed skin, and is commonly developed in young children but can occur at any age. AD is chronic with acute exacerbations, or flares, as an integral part of its course, which are generally defined as worsening condition and require escalation or intensification of treatment. Such irritation can negatively impact patients' quality of life and potentially cause psychological damage. Additionally, AD patients are at risk of developing co-morbidities such as food allergies and asthma. According to Frost & Sullivan, there are few effective and safe treatment options for AD, with dupilumab being the only biologic drug approved by the NMPA for AD in China as of the Latest Practicable Date, indicating significant unmet clinical needs and huge market potential. As of the Latest Practicable Date, we were developing QX005N for the treatment of moderate-to-severe AD in adult patients, which is one of the most advanced biologic drug candidates for AD in China. In October 2023, we also received an IND approval for QX005N for AD in adolescents aged between 12 and 17 years from the NMPA.

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Market Opportunity and Competition

According to Frost & Sullivan, the prevalence of AD in China increased from 64.0 million in 2018 to 70.3 million in 2022 and is anticipated to reach 78.5 million in 2030. 20% of the patients have moderate-to-severe AD. The AD drug market in China increased from US\$502.6 million in 2018 to US\$966.8 million in 2022, at a CAGR of 17.8% and is estimated to grow rapidly to reach US\$7,071.8 million in 2030, at a CAGR of 28.2% from 2022 to 2030. Biologic drugs accounted for 28.2% of the AD drug market in China in 2022, which is estimated to increase to 77.5% in 2030.

Treatment of AD usually involves a step-up approach, *i.e.*, depending on the severity and extent of a patient’s symptoms, different medication and treatment options may be recommended. Mild cases of AD can be treated with moisturizing agents and topical treatments, such as corticosteroids and calcineurin inhibitors. However, overuse of these drugs may cause side effects, including thinning skin or impaired immune system. In moderate-to-severe cases, phototherapy and systemic conventional DMARDs, such as cyclosporine A (CsA), methotrexate and azathioprine, may be used. In recent years, biologic drugs with better safety and efficacy profiles have become an emerging treatment for moderate and severe AD. According to the Guideline for Diagnosis and Treatment of AD in China (2020), biologics, as a main treatment option for AD patients, are recommended to be combined with topical drugs and moisturizers for long-term use. In particular, as IL-4, IL-13, IL-5 and IL-10 are important cytokines involved in the pathogenesis of AD, they present potential targets suitable for biologics development. IL-4R α is the mainstream target under investigation for AD treatment due to its role in controlling the signaling of both IL-4 and IL-13, and research on other targets, such as IL-31, IL-33 and OX40, is also ongoing. In addition, small-molecule treatments, including PDE-4 inhibitors and JAK inhibitors, have been explored as potential treatment options for AD patients. As of the Latest Practicable Date, two JAK inhibitors (sold under the brand names of RINVOQ and CIBINQO, respectively) and one PDE-4 inhibitor (sold under the brand name of Staquis) had been approved for AD in China, according to Frost & Sullivan, the JAK inhibitors had only recently been included in the latest Guideline for Diagnosis and Treatment of Moderate-to-severe AD (2023) in China with limited recommendation for certain patient populations, and the PDE-4 inhibitor is listed under other topical drugs in the Guideline for Basic Diagnosis and Treatment of AD in China (2022).

As of the Latest Practicable Date, dupilumab (an anti-IL-4R α antibody) was the only biologic drug approved in China for AD, which had also been admitted to the NRDL. Since its launch in 2017, the global sales of dupilumab (under the brand name Dupixent) increased sharply from US\$256.5 million in 2017 to US\$8,681.2 million in 2022, at a CAGR of 102.3%. Since its approval in China in 2020, the sales of dupilumab in China (as disclosed by Sanofi) also experienced a sharp increase from US\$13.7 million in 2020 to US\$248.1 million in 2022, at a CAGR of 325.0%. As of the same date, in addition to QX005N, there were 20 biologic drug candidates for AD in the clinical stage in China, among which 9 were IL-4R α inhibitors and other disclosed targets under investigation included IL-13, TSLP, IL-33, ST2, CD200R, OX40, IL-2R and IL-17RB. As IL-4R α remains the mainstream target under investigation for AD treatment, we believe QX005N will primarily compete with other IL-4R α inhibitors. The following table sets forth details of QX005N as well as approved biologic drugs and drug candidates in the clinical stage in China that target IL-4R α as of the Latest Practicable Date.

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Marketed Anti-IL-4R α Biologics for AD in China

Target	Brand Name	INN	Company	NMPA Approval Time	Branded or Biosimilar	Availability of biosimilar	2022 NRDL covered	NRDL Median price in 2022 ⁽¹⁾ (RMB)
IL-4R α	Dupilixent	Dupilumab	Sanofi/Regeneron	2020	Branded	—	Yes	3,160.0

Clinical-Stage Anti-IL-4R α Biologic Drug Candidates AD in China

Target	Drug Code	Company	Status	First Posted Date
IL-4R α	CM310	Keymed Bioscience	BLA submission	2023-12-07
	CBP-201	Connect Biopharmaceuticals	Phase II	2020-11-20
	TQH2722	Chia Tai-tianqing	Phase II	2023-03-27
	QX005N	the Company	Phase II	2022-07-14
	MG-K10	Mabgeek	Phase III	2023-11-29
	SSGJ-611	Sunshine Guojian	Phase III	2023-12-18
	SHR-1819	Hengrui	Phase II	2022-09-27
	GR1802	Genrix Bio	Phase III	2023-12-14
	AK120	Akeso	Phase I / II	2021-08-20
	BA2101	Boan Bio	Phase I	2023-01-16

Source: NMPA, CDE, Frost & Sullivan Report

Note:

(1) Reflects the median price for a drug’s minimum formulation unit as included in the NRDL.

Our Advantages

We believe QX005N has the following potential advantages in comparison with the approved drugs and drug candidates targeting AD:

- Promising efficacy.** In our Phase Ib clinical trial of QX005N in adult patients with moderate-to-severe AD, similar response rates of QX005N were observed in the 300 mg and 600 mg groups, with 75.0% of subjects in each group reaching EASI-75 and 50.0% of subjects in each group reaching IGA score (0 or 1) at week 12 without significantly increased safety risks. Additionally, thymus and activation-regulated chemokine (TARC) and IgE are both PD biomarkers associated with type 2 immune responses. TARC is also a key PD biomarker in AD patients. In particular, TARC is expressed in AD patients and their TARC level in serum is significantly increased as compared to patients with other inflammatory skin diseases. Therefore, according to Frost & Sullivan, a reduction in TARC levels suggests that the AD symptom has been alleviated and indicates a favorable efficacy of the treatment. A reduction in IgE levels also suggests similar favorable outcomes, according to Frost & Sullivan, because the release of IgE from autoantigens and corresponding enhanced IgE levels are associated with repeated scratching, which is an important cause of aggravation and persistence of skin inflammation. In our Phase Ib clinical trial of QX005N for AD, the reduction of TARC and IgE levels from baseline in the active treatment groups were higher than those in the placebo group. We believe the reduction in TARC and IgE levels induced by QX005N may be indicative of its favorable efficacy profile.

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- Good safety profile. In comparison with other IL-4R α inhibitors under development and with reported clinical data, QX005N has demonstrated a good safety profile in its Phase Ia and Ib clinical trials. In our Phase Ib clinical trial of QX005N in adult patients with moderate-to-severe AD, no SAE was observed and none of the patients in the active treatment groups developed conjunctivitis, which is one of the most common AEs observed in patients using dupilumab, according to Frost & Sullivan. In our Phase Ia clinical trial, QX005N was also well-tolerated with a good safety profile in healthy subjects in the dose range from 75 mg to 800 mg. Additionally, in comparison with non-IL-4R α inhibitors (such as JAK inhibitors) and conventional AD therapies such as corticosteroids, we believe QX005N is potentially superior in terms of its long-term safety profile.
- Promising accessibility. The high annual costs of AD drugs, such as dupilumab, the only NMPA-approved anti-IL-4R α inhibitor for AD, may limit patient access. Dupilumab is designed to be administered with an initial injection of 600 mg (with two injections of 300 mg at different injection sites on the patient) and then with a treatment frequency of Q2W at 300 mg. According to Frost & Sullivan, since 2021, the annual cost for dupilumab as included in the NRDL has been RMB85,320 for 27 doses of 300 mg/2 mL in the first year and RMB82,160 for 26 doses of 300 mg/2 mL per year for subsequent treatment for AD patients. We aim to make QX005N more accessible to patients in China taking into account various factors such as our in-house manufacturing capacity and potential competitor pricing. QX005N is expected to be administered at the same dosage and frequency as dupilumab. Its estimated annual cost is expected to be lower than dupilumab by approximately 20% to 30% upon commercialization, making it a more affordable option in comparison to dupilumab.

Summary of Clinical Trial Results

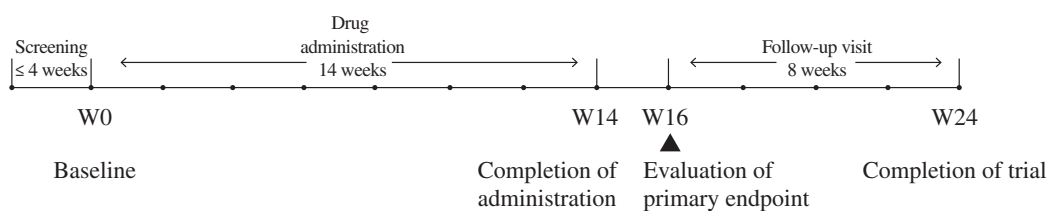
We completed a Phase Ia clinical trial of QX005N in healthy subjects in China in January 2023 and a Phase Ib clinical trial of QX005N in patients with moderate-to-severe AD in China in February 2023. We are currently evaluating the safety and efficacy of QX005N in a Phase II clinical trial in adult patients with moderate-to-severe AD in China, which we expect to complete in March 2024.

Ongoing Phase II Clinical Trial

The Phase II clinical trial in China is a multi-center, randomized, double-blind and placebo-controlled clinical study with multiple dosing to evaluate the efficacy, safety, PK and PD profile of QX005N in adult patients with moderate-to-severe AD.

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Trial design: The primary endpoint is the percentage of reduction from baseline in EASI scores at week 16. The secondary endpoints include efficacy parameters, such as percentage of subjects responding to the treatment as measured by reduction in the Investigator’s Global Assessment (IGA) score and EASI scores at week 16 as well as subjects’ IGA and EASI scores from baseline to week 24; safety and tolerability of QX005N in subjects from baseline to week 24; PK and PD parameters from baseline to week 24; and percentage of ADA-positive subjects from baseline to week 24. We plan to enroll a total of 120 subjects, who will be randomly assigned to three groups (each consisting of 40 subjects) with two active treatment groups receiving QX005N and one control group receiving placebo. Each of the two active treatment groups will receive a dose of QX005N of 300 mg (600 mg for the first dose) every two weeks (Q2W) and 600 mg (Q2W), respectively. The control group will receive the placebo (Q2W). The treatment period is expected to be 16 weeks, followed by eight weeks of follow-up visit. The chart below summarizes the design of this trial.



Trial status: Subject enrollment commenced in September 2022 and was completed in February 2023. A total of 120 subjects were enrolled, including 40 receiving QX005N in each of the 300 mg and 600 mg group and 40 receiving placebo in the control group. As of the Latest Practicable Date, we had completed data readout and this trial reached its primary endpoint as reviewed by the IDMC. We expect to complete this trial in March 2024.

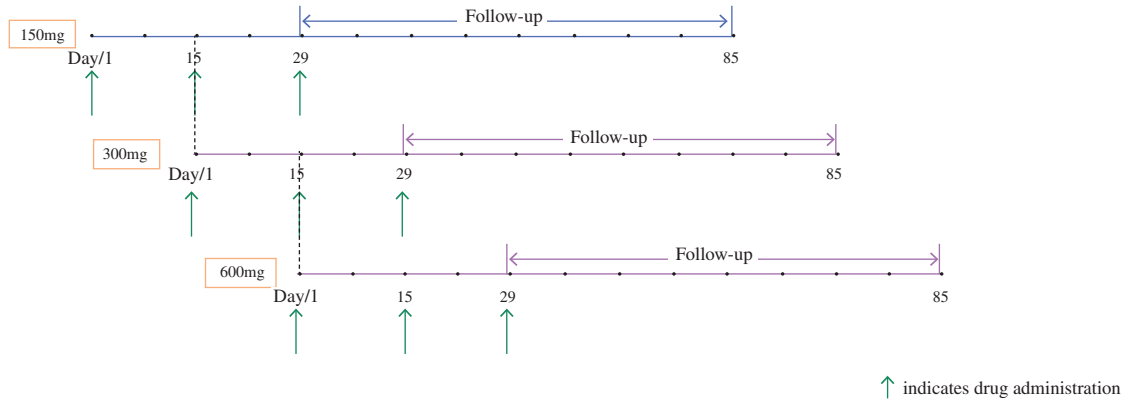
Phase Ib Clinical Trial

The Phase Ib clinical trial in China was a multi-center, randomized, double-blind, placebo-controlled and multiple-ascending-dose clinical study to evaluate the efficacy, safety, PK and PD profile of QX005N in adult patients with moderate-to-severe AD.

Trial design: The primary endpoints were safety and tolerability of QX005N in moderate-to-severe AD patients at week 12. The secondary endpoints included PK parameters; efficacy parameters at week 12, such as percentage of patients responding to the treatment as measured by reduction in the Investigator’s Global Assessment (IGA) score and the Eczema Area and Severity Index-50 (EASI-50) and EASI-75 response (defined as $\geq 50\%$ and $\geq 75\%$ improvement from baseline in the EASI score, respectively); and immunogenicity. The exploratory purpose was to evaluate the PD profile of QX005N in these patients. We planned to enroll a total of 30 patients, who would be assigned to three groups with ten patients in each group (eight receiving QX005N and two receiving placebo). Each group would receive three doses of either QX005N or placebo at their designated dose level (150 mg, 300 mg and 600 mg, respectively), to be administered on day 1, day 15 and day 29, followed by safety follow-up until day 85. The trial would proceed from one dose level to the next only if the evaluation of tolerability and safety on the previous dose level group on day 14 has been completed. In the

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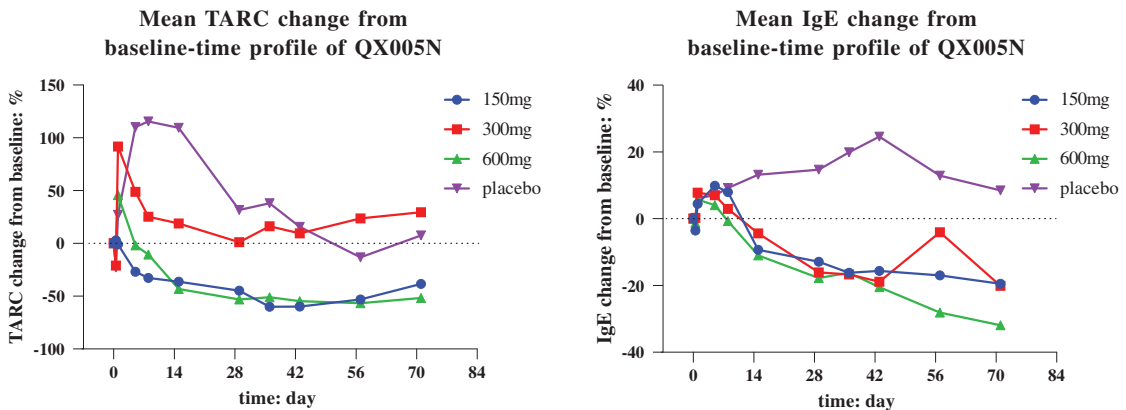
event where termination may be warranted, the sponsor and investigator would determine whether to terminate the trial or resume the trial with the median level of the previous and current dose levels. The maximum dose level is set at 600 mg, which may be adjusted based on the trial outcome at the dose level of 150 mg and 300 mg. The diagram below illustrates the design of this trial.



Trial status: This trial was initiated in November 2021 and completed in February 2023. A total of 30 subjects were enrolled with eight receiving QX005N and two receiving placebo in each of the 150 mg, 300 mg and 600 mg groups. Due to the COVID-19 pandemic, one subject in the 600 mg group was lost to follow-up, whose data were considered invalid.

PK: In this trial, there was no obvious difference in T_{max} (the time it takes for a drug to reach C_{max} after administration) among the active treatment groups. Systemic exposure of QX005N (C_{max} and AUC_{0-t}) showed an increasing trend as the dose level increased.

PD: TARC and IgE are both PD biomarkers associated with type 2 immune responses. TARC is also a key PD biomarker in AD patients. In this trial, the reduction of TARC and IgE levels from baseline in the active treatment groups were higher than those in the placebo group, as shown in the charts below. We believe the reduction in TARC and IgE levels induced by QX005N may be indicative of its favorable efficacy profile.



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Immunogenicity: Immunogenicity of monoclonal antibody drugs occurs when anti-drug antibodies (ADAs) are elicited from drug administration, which is common and may cause decreased drug exposure and/or formation of highly immunogenic complexes, which, in turn, could cause decreased efficacy and/ or increased safety risks. However, according to Frost & Sullivan, observation of immunogenicity in a clinical trial does not necessarily impact the PK, PD and/or safety of a drug candidate, which are key factors the NMPA considers when determining whether the drug candidate may be approved for marketing. Therefore, if the occurrence of immunogenicity shows no impact on these parameters, it will not affect a drug candidate's registration approval. In this trial, immunogenicity was observed in 13 subjects receiving QX005N and 1 subject in the control group but no impact on QX005N's efficacy or safety was observed.

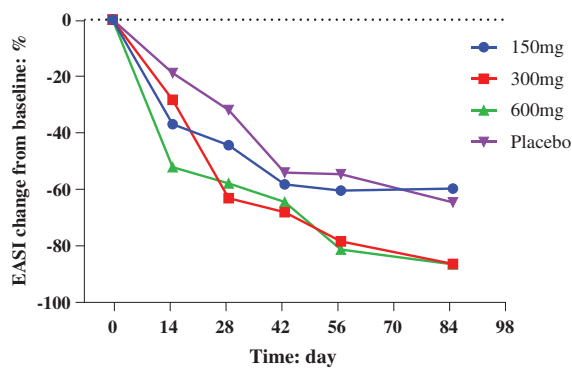
Safety results: In this trial, QX005N was well-tolerated and had a good safety profile in adult patients with moderate-to-severe AD. Among subjects receiving QX005N, 22 (91.7%) subjects reported a total of 95 TEAEs, with 2 AEs of Grade 3 (severe or medically significant but not immediately life-threatening) and above (1 of Grade 3 and 1 of Grade 4 (life-threatening consequences; urgent intervention indicated)) under the Common Terminology Criteria for Adverse Events (CTCAE version 5.0) observed in the 300 mg group. 6 (100%) subjects in the placebo group reported a total of 24 TEAEs, among which, 2 AEs of Grade 3 were reported. One subject with the AE of Grade 4 in the 300 mg group was found to have elevated creatine kinase (an enzyme that mainly exists in the heart and skeletal muscle) during the follow-up at day 29 before the third drug administration, which was determined to be Grade 4 and possibly related to the drug. One subject with the AE of Grade 3 in the 300 mg group was reported to have syncope (a loss of consciousness for a short period of time), and each of the two subjects with AEs of Grade 3 in the placebo group was reported to have elevated lipase (a family of enzymes that participates in fat digestion and metabolism) and elevated transaminases (a group of enzymes that is important in the synthesis of amino acids), respectively, which are not the same as the AEs of Grade 3 reported in the Phase Ia clinical trial of QX005N in healthy subjects. All subjects who experienced AEs of Grade 3 and above recovered in this trial. All other AEs observed in this trial were of Grade 1 (mild) or 2 (moderate) using CTCAE version 5.0. None of the patients in the trial developed conjunctivitis, which is one of the most common AEs observed in patients using dupilumab, according to Frost & Sullivan. No significant difference was observed in safety results between the QX005N active treatment groups and the placebo group. No SAE or death was observed and no patients discontinued treatment or withdrew from the study due to safety issues in this trial.

Efficacy results: The percentage of subjects in the 300 mg group responding to the treatment as measured by EASI-50, EASI-75 and IGA score (0 or 1) at week 12 was 100.0%, 75.0% and 50.0%, respectively. Such percentage in the 600 mg group was 87.5%, 75.0% and 50.0%, respectively. The mean EASI change from baseline exceeded 80% at week 12 in the 300 mg and 600 mg groups, which was better than that in the 150 mg group and placebo group, as shown in the chart below. According to Frost & Sullivan, the EASI and IGA scales are the most authoritative evaluation methods to determine the severity of an AD patient's symptoms. In this trial, the EASI-75 and IGA score (0 or 1) results of QX005N in the 300 mg and 600 mg groups

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at week 12 are similar to that of dupilumab at week 16 (53.1% and 29.7%) in a Phase IIb clinical trial in moderate-to-severe AD patients, where dupilumab of 300 mg was administered Q2W, suggesting a good preliminary clinical efficacy of QX005N, according to Frost & Sullivan.

Mean EASI change from baseline-time profile of QX005N



Conclusion: In this trial, similar response rates of QX005N were observed in the 300 mg and 600 mg groups, with 75.0% of subjects in each group reaching EASI-75 and 50.0% of subjects in each group reaching IGA score (0 or 1) at week 12 without significantly increased safety risks.

Phase Ia Clinical Trial

The Phase Ia clinical trial in China was a single-center, randomized, double-blind, single-ascending-dose and placebo-controlled clinical study to evaluate the PK profile, safety, tolerability and immunogenicity of QX005N in healthy subjects.

Trial design: The primary endpoints included safety and tolerability of QX005N in healthy subjects. The secondary endpoints included PK parameters and immunogenicity. The exploratory purpose is to evaluate the PD profile of QX005N in these subjects. We planned to enroll a total of 48 subjects, who would be assigned to six groups with eight subjects in each group (six receiving QX005N and two receiving placebo). The trial would start with the first group receiving a single subcutaneous injection of 75 mg and the subsequent five groups each receiving an increased single dose of 150 mg, 300 mg, 450 mg, 600 mg and 800 mg, respectively. Each subject would receive only one corresponding dose of QX005N (or placebo). The trial would proceed from one dose level to the next only if safety of the previous dose level is confirmed after a two-week evaluation period upon drug administration. In the event where termination may be warranted, the sponsor and investigator would determine whether to terminate the trial or resume the trial with the median level of the previous and current dose levels.

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Trial status: This trial was initiated in December 2020 and completed in January 2023. A total of 49 healthy volunteers were enrolled and 48 subjects completed dosing, including 36 receiving QX005N in the active treatment group and 12 receiving placebo in the control group.

PK: QX005N exhibited nonlinear PK in healthy subjects within the dose range from 75 mg to 800 mg following single subcutaneous administration. Systemic exposure of QX005N (C_{\max} , AUC_{last} and AUC_{inf}) increased in a greater-than-proportional manner with increasing dose. In addition, the $T_{1/2}$ of QX005N showed an increasing trend as the dose level increased from 75 mg to 450 mg and remained stable within the range of 600 mg and 800 mg.

Immunogenicity: In this trial, immunogenicity was observed in 31 subjects receiving QX005N but no impact on QX005N’s PK or safety was observed.

Safety results: In this trial, QX005N was well-tolerated and had a good safety profile in healthy subjects in the dose range from 75 mg to 800 mg. 34 (94.4%) subjects in the active treatment groups reported a total of 115 AEs and 11 (91.7%) subjects in the placebo group reported a total of 36 AEs, none of which led to a subject’s withdrawal from the trial. In the active treatment groups, two AEs of Grade 3 under CTCAE version 5.0 were reported, including one in each of the 300 mg group and 600 mg group. Each of the two subjects with AEs of Grade 3 in the 300 mg group and 600 mg group was reported to have elevated blood triglycerides (a type of fat that circulates in the blood) and right adrenal ganglioneuroma (a benign tumor of the sympathetic nervous system), respectively. Both subjects experiencing such AEs of Grade 3 recovered in this trial. All other AEs observed in this trial were of Grade 1 or 2 using CTCAE version 5.0. One subject receiving QX005N in the 600mg group experienced one SAE of Grade 3, which was considered to have no relationship with the drug, and the subject recovered after treatment. No death was observed in this trial. No significant difference was observed in the incidence of AEs between the QX005N groups and the control group and there was no significant correlation between the incidence of AEs and drug exposure.

Conclusion: In this trial, QX005N was safe and well-tolerated in healthy subjects in the dose range from 75 mg to 800 mg. Based on the trial results, we have initiated the Phase Ib and Phase II clinical trials to further evaluate QX005N for the treatment of moderate-to-severe AD in China.

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Material Communications and Next Steps

We received an IND approval of the Phase I, Phase II and Phase III clinical trials of QX005N for moderate-to-severe AD in adults from the NMPA in June 2020. In compliance with the Administrative Measures for Drug Registration (《藥品註冊管理辦法》) issued by the NMPA, before the initiation of the Phase Ib/Phase II clinical trial¹, we had submitted requisite documents, including results from the Phase Ia trial², to the NMPA and received no concerns or objections from the NMPA. In September 2023, we conducted a formal consultation with the CDE of the NMPA inquiring whether the NMPA had any objections to or additional requirements on our conduct of the Phase Ib/Phase II clinical trial, and the NMPA did not raise any objections or additional requirements. Our PRC Legal Advisors are of the view that based on the results from the Phase Ia clinical trial, the NMPA had no objection to the commencement of the Phase Ib/Phase II clinical trial of QX005N. We have completed the Phase Ia and Phase Ib clinical trials for this indication and are currently conducting the Phase II clinical trial, which we expect to complete in March 2024. We submitted an application to consult with the NMPA in December 2023 before initiating the Phase III clinical trial for this indication in accordance with the IND approval. As of the Latest Practicable Date, we had not received any relevant regulatory agency’s concerns or objections to the commencement of our Phase II clinical trial or our clinical development plans and no material adverse changes had occurred since we obtained the IND approval.

In October 2023, we also received an IND approval of QX005N for the treatment of AD in adolescents aged between 12 and 17 years from the NMPA. As of the Latest Practicable Date, we had not received any relevant regulatory agency’s concerns or objections to our clinical development plans and no material adverse changes had occurred since we obtained the IND approval and up to the Latest Practicable Date.

Notes:

1. The Phase Ib/Phase II trial was designed as a multiple-dose clinical study to evaluate the efficacy, safety, PK and PD profile of QX005N in adult patients with moderate-to-severe AD, consisting of two parts: a Phase Ib (30 subjects) and a Phase II (120 subjects). The trial design of Phase Ib and Phase II was submitted to the NMPA under the same title and with the same protocol number, with Phase Ib labeled as Part A of the trial and Phase II labeled as Part B of the trial.
2. For the avoidance of doubt, the emphasis on a Phase I trial is whether enough clinical safety data have been gathered and observed. While our Phase Ia trial was labeled as Ia, this trial was essentially a Phase I trial as it was conducted in healthy subjects and with safety and tolerability of the drug candidate as the primary endpoints, and equivalent to a conventional Phase I trial designed to evaluate similar drug candidates for similar indications, according to Frost & Sullivan. Additionally, the safety data generated from this trial allowed us to initiate the Phase Ib/II trial based on communication with the NMPA, which had the same effect as the completion of a Phase I trial.

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Prurigo Nodularis

Prurigo Nodularis (PN) is a chronic skin disorder characterized by the presence of hard and extremely itchy bumps known as nodules, which tend to be found in easy-to-scratch areas, such as the arms, legs, the upper back and abdomen. It is commonly associated with other skin diseases or underlying medical conditions that affect multiple body systems. Severe and chronic PN is painful and leaves visible nodules on the patients’ skin, which could significantly interfere with their quality of life, sleep and psychological well-being. However, the exact cause of PN is unknown, but symptoms of PN are believed to stem from dysregulation of the nerves and immune system in the skin, and its pathophysiology is increasingly attributed to nonhistaminergic mediators and type 2 inflammation. Compared to the healthy population, PN patients tend to have more immune cells in their skin producing inflammatory cytokines, including IL-4, IL-13 and IL-31. According to Frost & Sullivan, there has been significant unmet clinical needs from PN patients due to limited understanding of the pathogenesis of PN and a lack of effective PN treatments. As of the Latest Practicable Date, dupilumab was the only treatment approved for PN by the FDA and by the NMPA in China. As of the same date, we were developing QX005N for the treatment of PN, the first biologic drug candidate developed by a Chinese domestic company in clinical trial for PN in China. We believe QX005N has the potential to be an effective treatment of PN by targeting IL-4R α , a key target in mediating type 2 inflammation, and inhibiting the signaling pathways of both IL-4 and IL-13. In January 2024, the CDE granted QX005N the breakthrough therapy designation for the treatment of PN, signifying its superior clinical benefits compared to current treatment methods. The designation is designed to expedite the development and regulatory review of innovative drugs demonstrating substantial potential in addressing serious conditions.

Market Opportunity and Competition

According to Frost & Sullivan, the prevalence of PN in China increased slightly from 1.9 million in 2018 to 2.0 million in 2022 and is anticipated to reach approximately 2.1 million in 2030. There has been a lack of effective treatments for PN and development of the PN drug market in China is still at an early stage. The typical PN treatments for itch relief involve topical creams, such as topical antihistamine, steroids and anesthetics, and systemic drugs, such as antihistamine, steroids and opioid receptor agonists or antagonists. However, some PN treatments such as topical steroids and topical anesthetics are recommended to be used only for a limited duration due to their side effects. Because of the discovery of new therapeutic targets in recent years, there has been increasing research on biologic drugs for treating PN as a potentially promising treatment option. Biologics have become a guideline treatment option but as a relatively new class of drugs, they have not yet been recommended as a main treatment option for PN.

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As of the Latest Practicable Date, dupilumab was the only biologic drug approved for PN by the FDA and by the NMPA in China. As of the same date, there were only two biologic drug candidates for PN in the clinical stage in China, including QX005N, as set out below.

Marketed Targeted Biologics for PN in China				
Brand Name	INN	Company	Target	NMPA Approval Time
Dupixent	Dupilumab	Sanofi	IL-4R α	2023

Clinical-Stage Biologic Drug Candidates for PN in China				
Target	Drug Code	Company	Status	First posted Date
IL-4R α	QX005N	the Company	Phase II	2022-12-16
	BA2101	Boan Biotech	Phase I	2023-01-16

Source: NMPA, Frost & Sullivan Report

Our Advantages

PN is associated with many co-morbidities, resulting in a huge burden on patients, including impaired quality of life. High-potency topical steroids are commonly used but they are associated with safety risks if used long term. As of the Latest Practicable Date, dupilumab was the only treatment approved for PN by the FDA and by the NMPA in China. Our QX005N was the first biologic drug candidate for PN developed by a Chinese domestic company in the clinical stage in China as of the Latest Practicable Date, according to Frost & Sullivan.

Additionally, IL-4R α has been reported to be a promising target with good efficacy and safety profile in the treatment of diseases associated with type 2 inflammation by controlling the signaling of both IL-4 and IL-13 that drives type 2 inflammatory response. Dupilumab, an anti-IL-4R α antibody, has shown potentially significant improvements for patients with PN in its Phase III clinical trials. For details of other potential advantages of QX005N, see “—Atopic Dermatitis—Our Advantages” above.

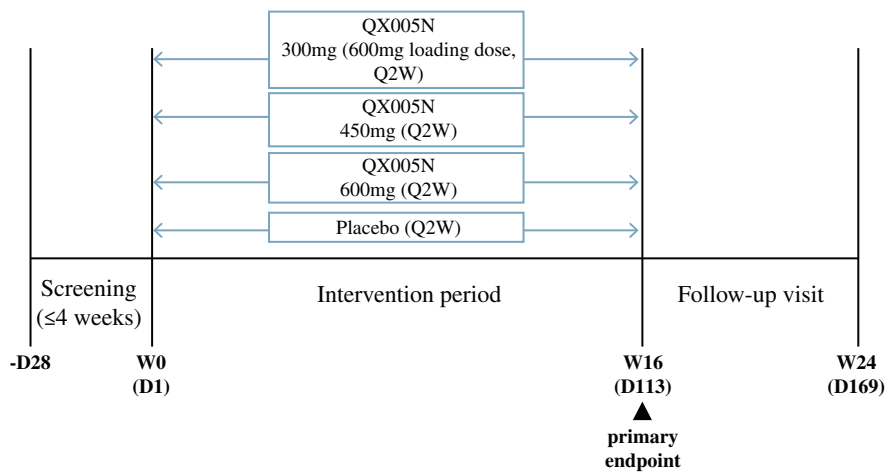
Summary of Ongoing Phase II Clinical Trial

We commenced a Phase II clinical trial of QX005N for the treatment of PN in February 2023, which was ongoing as of the Latest Practicable Date and is expected to be completed in March 2024. The Phase II clinical trial in China is a multi-center, randomized, double-blind and placebo-controlled clinical study to evaluate the efficacy, safety, PK and PD profile of QX005N in adult patients with PN.

Trial design: The primary endpoint is the percentage of subjects who experience a reduction from baseline in the weekly average of the Worst Itch Numeric Rating Scale (WI-NRS) score that is more than or equal to four points, from baseline to week 16. The secondary endpoints include safety and tolerability of QX005N in subjects from baseline to week 24; PK and PD parameters from baseline to week 24; percentage of ADA-positive subjects from baseline to week 24; and efficacy parameters from baseline to week 24, such as

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(i) the time when subjects first respond to the treatment between baseline and week 16, as measured by comparing the percentage of subjects experiencing a reduction from baseline in the weekly average of WI-NRS score that is more than or equal to four points in each group, (ii) changes from baseline in the weekly average of WI-NRS score at week 2, 4, 8, 12, 16, 20 and 24, (iii) the percentage of subjects experiencing a reduction from baseline in the weekly average of WI-NRS score that is more than or equal to four points at week 20 and 24, (iv) the percentage of subjects with an IGA of PN-Stage (PN-S) score (an instrument used to assess the overall number and thickness of PN lesions at a given time point) of 0 or 1 at week 4, 8, 12, 16, 20 and 24, (v) changes from baseline in the IGA PN-S score at week 4, 8, 12, 16, 20 and 24, (vi) the percentage of subjects with an IGA of PN-Activity (PN-A) score (an instrument used to assess the overall activity of PN lesions at a given time point) of 0 or 1 at week 4, 8, 12, 16, 20 and 24, and (vii) changes from baseline in DLQI score at week 4, 8, 12, 16, 20 and 24. We plan to enroll a total of 120 PN patients, who will be randomly assigned to four groups (each consisting of 30 patients) with three active treatment groups receiving QX005N and one control group receiving placebo. The three active treatment groups will each receive a dose of QX005N of 300 mg (600 mg for the loading dose, Q2W), 450 mg (Q2W) and 600 mg (Q2W), respectively. The control group will receive the placebo (Q2W). Both QX005N and placebo will be administered through subcutaneous injection. The treatment period is expected to be 16 weeks, with drug/placebo administration starting from week 0 and completing in week 14, and followed by eight weeks of follow-up visit. The chart below summarizes the design of this trial.



Trial status: Subject enrollment commenced in February 2023 and was completed in May 2023. A total of 120 subjects were enrolled, including 30 receiving QX005N in each of the 300 mg, 450 mg and 600 mg groups and 30 receiving placebo in the control group. As of the Latest Practicable Date, we had completed data readout and this trial reached its primary endpoint as reviewed by the IDMC. We expect to complete this trial in March 2024.

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Material Communications and Next Steps

We received an IND approval of the Phase I, Phase II and Phase III clinical trials of QX005N for PN from the NMPA in March 2022. In compliance with the Administrative Measures for Drug Registration (《藥品註冊管理辦法》) issued by the NMPA, before the initiation of the Phase II clinical trial, we had submitted requisite documents, including results from the Phase Ia clinical trial of QX005N in healthy subjects and the Phase Ib clinical trial of QX005N in AD patients, which we intended to leverage for this trial, to the NMPA and received no concerns or objections from the NMPA. Our PRC Legal Advisors are of the view that based on the results from such earlier trials, the NMPA had no objection to the commencement of the Phase II clinical trial of QX005N for PN. We commenced the Phase II clinical trial for this indication in February 2023, and expect to complete it in March 2024. We submitted an application to consult with the NMPA in December 2023 before initiating the Phase III clinical trial for this indication in accordance with the IND approval. In January 2024, the CDE granted QX005N the breakthrough therapy designation for the treatment of PN, signifying its superior clinical benefits compared to current treatment methods. The designation is designed to expedite the development and regulatory review of innovative drugs demonstrating substantial potential in addressing serious conditions. As of the Latest Practicable Date, we had not received any relevant regulatory agency’s concerns or objections to the commencement of our Phase II clinical trial or our clinical development plans and no material adverse changes had occurred since we obtained the IND approval. Pursuant to the Administrative Measures for Drug Registration, PN is considered an indication expansion of QX005N and will be treated as the same product in the subsequent regulatory registration process.

Chronic Rhinosinusitis with Nasal Polyps

Chronic rhinosinusitis with nasal polyps (CRSwNP) is a subgroup of chronic rhinosinusitis characterized by the presence of fleshy swellings (nasal polyps) that develop in the lining of the nose and paranasal sinuses, which is believed to arise due to chronic inflammation. Although the mechanisms underlying the pathogenesis of CRSwNP remain poorly understood, CRSwNP is a common comorbidity in type 2 inflammation-driven diseases, indicating that type 2 inflammation plays an important role in its disease pathogenesis. Studies show that patients diagnosed with CRSwNP had a significantly higher premorbid prevalence of acute rhinosinusitis, chronic rhinitis, asthma, gastroesophageal reflux disease and sleep apnea. CRSwNP is a challenging condition to cure, and patients usually need appropriate long-term treatment plans to manage symptoms. Efficacy of traditional treatments, such as surgery, is limited, with high nasal polyps recurrence rate, and biologics have shown better efficacy in both clinical and animal studies.

As IL-4R α is a promising therapeutic target for allergic diseases driven by the type 2 immune response we are developing QX005N, an anti-IL-4R α antibody, to address the unmet medical needs for treatment options of CRSwNP. We directly commenced a Phase II clinical trial for treatment of CRSwNP in April 2023, by leveraging the Phase I clinical trial results of QX005N for AD.

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Market Opportunity and Competition

According to Frost & Sullivan, the prevalence of CRSwNP in China increased from 19.1 million in 2018 to 20.4 million in 2022, and is estimated to reach 22.3 million in 2030. The CRSwNP drug market in China increased from US\$90.0 million in 2018 to US\$141.7 million in 2022, representing a CAGR of 12.0%, and is estimated to reach US\$633.4 million in 2030, representing a CAGR of 20.6% from 2022 to 2030.

CRSwNP was traditionally treated with nasal saline irrigations and surgery. However, efficacy of nasal saline irrigation is limited, and there is a high nasal polyps recurrence rate of up to 60% post surgery. Corticosteroids, biologics and antibiotics have subsequently emerged as treatment options for CRSwNP patients. Antibiotics therapy after desensitization are primarily used for NSAID-exacerbated respiratory disease, a chronic eosinophilic, inflammatory disorder of the respiratory tract occurring in patients with asthma and/or CRSwNP. Corticosteroids for CRSwNP include intranasal corticosteroids, systemic corticosteroids and corticosteroid-eluting implants, which are primarily used following endoscopic sinus surgery. While intranasal and systemic corticosteroids are effective to some extent in the management of CRSwNP, their long-term benefits are limited. According to the Guidelines for the Diagnosis and Treatment of CRS in China (2018) (中國慢性鼻竇炎診斷和治療指南(2018)), it is difficult to maintain the clinical efficacy of systemic corticosteroids in the treatment of CRSwNP, which may lead to recurrence of nasal polyps. Moreover, systemic corticosteroids can only be administered cautiously given their association with serious systemic side effects. In contrast, biologics are proved to be more effective and safer in the treatment of CRSwNP in both clinical and animal studies. However, as a relatively new class of drugs, they have not been recommended as a main treatment option for CRSwNP in China by prevailing clinical guidelines.

Currently, biologic drugs have a limited track record globally for CRSwNP treatment. Only three biologics had been approved by the FDA for the treatment of CRSwNP as of the Latest Practicable Date and none had been approved in China as of the same date, leaving a large unmet market opportunity in China. Biologic drug candidates for CRSwNP in China primarily include IL-4R α inhibitors, IL-5 inhibitors and TSLP inhibitors. IL-4R α is a promising target for CRSwNP as IL-4R α controls the signaling of both IL-4 and IL-13, the key Th2 cytokines. Since IL-5 is a key signaling factor for eosinophil activation by Th2 cells and is highly expressed in eosinophilic diseases, IL-5 inhibitors can be particularly effective for treatment of eosinophilic CRSwNP. However, the efficacy of IL-4R α inhibitors and IL-5 inhibitors has shown to be correlated to the levels of certain type 2 biomarkers, such as blood eosinophil counts and IgE. In contrast, as TSLP is an upstream regulator of type 2 inflammation, TSLP inhibitors can be a treatment for patients with low-level or no expression of type 2 biomarkers. As of the Latest Practicable Date, there were 13 biologic drug candidates for CRSwNP in the clinical stage in China, including five IL-4R α inhibitors, three IL-5 inhibitors, four TSLP inhibitors and one IL-5R α inhibitor. The following table sets forth details of QX005N as well as biologic drug candidates in the clinical stage in China as of the Latest Practicable Date.

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Clinical-Stage Biologic Drug Candidates for CRSwNP in China

Target	Drug Code	Company	Status	First posted Date
IL-4R α	CM310	Keymed Bioscience	Phase III	2022-06-20
	Dupilumab	Sanofi	Phase III	2023-03-24
	GR1802	Genrix Bio	Phase II	2023-01-03
	QX005N	the Company	Phase II	2023-01-06
	SSGJ-611	Sunshine Guojian	Phase II	2023-04-27
IL-5	Mepolizumab	GSK	Phase III	2021-04-12
	Depemokimab	GSK	Phase III	2022-05-20
	Mepolizumab-BAT2606	Biothera	Phase I	2022-07-27
TSLP	Tezepelumab	Amgen/AstraZeneca	Phase III	2021-03-25
	SHR-1905	Hengrui	Phase II	2023-05-29
	TQC2731	Chia Tai Tianqing	Phase II	2023-08-01
	CM326	Keymed Bioscience	Phase I / II	2022-03-14
	IL-5R α	Benralizumab	AstraZeneca	Phase III

Source: Frost & Sullivan Report (based on annual reports of relevant companies and information published by the NMPA)

Our Advantages

Treatments for patients with CRSwNP remain limited, which not only undermines quality of life but also causes a considerable socioeconomic burden. CRSwNP is considered difficult to treat, reflected by a high nasal polyps recurrence rate of up to 60% and frequent need of endoscopic sinus surgery. Biologic drugs are an emerging treatment option for patients with CRSwNP. As of the Latest Practicable Date, dupilumab was the only FDA-approved IL-4R α inhibitor for CRSwNP. While dupilumab can cost over RMB82,000 a year, based on its pricing in China for the treatment of AD in 2022, according to Frost & Sullivan, we aim to make QX005N more accessible to patients in China. See “—Atopic Dermatitis—Our Advantages” above for more details.

Summary of Clinical Trial

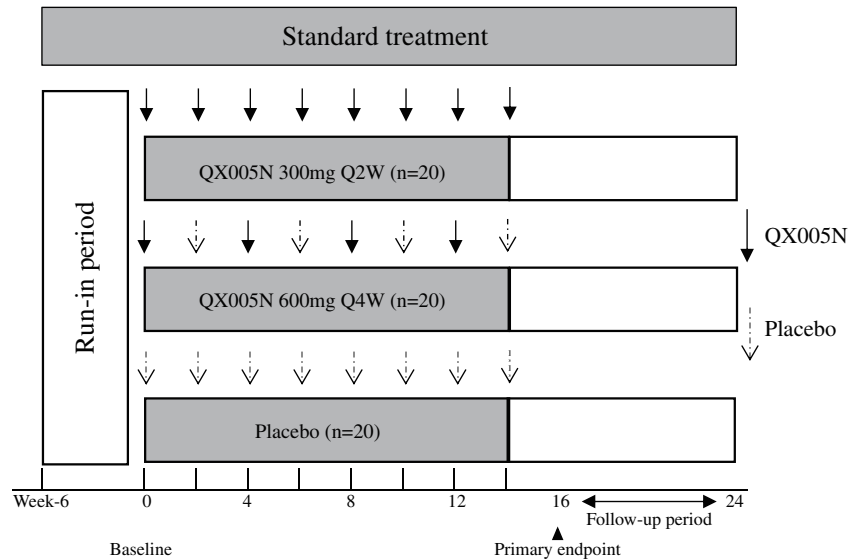
We commenced a Phase II clinical trial of QX005N in China for the treatment of CRSwNP in April 2023. We expect to complete such trial in the fourth quarter of 2024.

Ongoing Phase II Clinical Trial

Trial design: The Phase II clinical trial is a multi-center, randomized, double-blind, placebo-controlled clinical study evaluating the safety, efficacy, PK and PD of QX005N in adult patients with CRSwNP. The primary endpoint is the efficacy of repeated subcutaneous injection of QX005N in adult patients with CRSwNP, which is measured by the change in active treatment groups’ nasal polyp scores at week 16 from baseline as compared to the control group. The secondary endpoints include efficacy at week 16 and safety, tolerability, PK and immunogenicity parameters of repeated subcutaneous injection of QX005N. The exploratory endpoints include PD parameters of QX005N in these subjects. We plan to enroll a total of 60 patients, who will be randomly assigned to three groups (each consisting of 20 patients) with two active treatment groups receiving QX005N and one control group receiving

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placebo. The two active treatment groups will receive a dose of QX005N of 300 mg every two weeks (Q2W) and 600 mg every four weeks (Q4W), respectively. The control group will receive placebo (Q2W). The treatment period is expected to be 16 weeks, followed by eight weeks of follow-up. For subjects in the active treatment group of 600 mg of QX005N (Q4W), matching placebo will be administered at week 2, 6, 10 and 14 in order to ensure that all subjects will receive eight administrations during this trial. The chart below summarizes the design of this trial.



Trial status: As of the Latest Practicable Date, we had enrolled a total of 53 subjects. We expect to complete subject enrollment by the first quarter of 2024.

Phase Ia Clinical Trial

We completed a Phase Ia clinical trial of QX005N in healthy subjects in China in January 2023. In this trial, QX005N was safe and well-tolerated in healthy subjects in the dose range from 75 mg to 800 mg. See “—Atopic Dermatitis—Summary of Clinical Trial Results—Phase Ia Clinical Trial” for details.

Material Communications and Next Steps

We obtained an IND approval of the Phase I, Phase II and Phase III clinical trials of QX005N for treatment of CRSwNP from the NMPA in November 2021. In compliance with the Administrative Measures for Drug Registration (《藥品註冊管理辦法》) issued by the NMPA, before the initiation of the Phase II clinical trial, we had submitted requisite documents, including results from the Phase Ia clinical trial of QX005N in healthy subjects and the Phase Ib clinical trial of QX005N in AD patients, which we intended to leverage for this trial, to the NMPA and received no concerns or objections from the NMPA. Our PRC Legal Advisors are of the view that based on the results from such earlier trials, the NMPA had no objection to the commencement of the Phase II clinical trial of QX005N for CRSwNP. We commenced the

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Phase II clinical trial in China in April 2023 and plan to complete such trial in the fourth quarter of 2024. As of the Latest Practicable Date, we had not received any relevant regulatory agency’s concerns or objections to the commencement of our Phase II clinical trial or our clinical development plans. No material adverse changes had occurred since we obtained the IND approval and up to the Latest Practicable Date. Pursuant to the Administrative Measures for Drug Registration, CRSwNP is considered an indication expansion of QX005N and will be treated as the same product in the subsequent regulatory registration process.

Chronic Spontaneous Urticaria

Urticaria, or hives, is a common and heterogeneous inflammatory skin disorder characterized by itchy swelling on the skin surface and can be accompanied by angioedema, which is swelling of the subcutaneous tissues under the skin. Chronic spontaneous urticaria (CSU) is characterized by the occurrence of urticaria for six weeks or longer without identifiable specific triggers. CSU could cause significant impact on the patients’ quality of life, ability to perform daily tasks and their mental health. Urticaria is considered a disease driven mainly by mast cell degranulation, followed by the release of various mediators, including inflammatory cytokines such as IL-4. Establishing the cause of CSU and finding the appropriate cause-specific management can be difficult, leading to further frustration on the patients. According to Frost & Sullivan, typical treatments for CSU include second-generation non-sedating antihistamines, while for patients who are intolerant or have shown inadequate response to antihistamines, omalizumab, an anti-IgE mAb and the only biologic drug approved by the NMPA for urticaria in China as of the Latest Practicable Date, remains the mainstream treatment option. Biologics (including IgE inhibitors) are recommended by prevailing clinical guidelines as third-line treatment for CSU patients. As a result, the development of new therapies with improved efficacy and safety is underway.

As of the Latest Practicable Date, we were developing QX005N for the treatment of CSU, which we believe has the potential to be an effective treatment of CSU by targeting IL-4R α and inhibiting IL-4 signaling. We obtained an IND approval of the Phase I, Phase II and Phase III clinical trials of QX005N for CSU from the NMPA in January 2022. We plan to consult with the NMPA about directly initiating a Phase III clinical trial of QX005N for CSU by leveraging the Phase Ia clinical trial results of QX005N in healthy subjects, the Phase Ib clinical trial results of QX005N for AD as well as the Phase II clinical trial results of QX005N for AD and/or PN. As of the Latest Practicable Date, we had not initiated consultation with the NMPA about the proposed Phase III clinical trial. As of the same date, we had not received any relevant regulatory agency’s concerns or objections to our clinical development plans and no material adverse changes had occurred since we obtained the IND approval. Pursuant to the Administrative Measures for Drug Registration, CSU is considered an indication expansion of QX005N and will be treated as the same product in the subsequent regulatory registration process.

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Asthma

Asthma, a condition that affects the lungs and respiratory functions, is one of the world’s most common diseases. It is caused by inflammation of the breathing tubes that carry air in and out of the lungs. Asthma affects both children and adults, and is the most common chronic disease among children. For a significant number of patients, asthma may be a major problem that interferes with daily activities and may potentially lead to life-threatening attacks. Asthma cannot be cured and is often under-diagnosed and under-treated, particularly in low- and middle-income countries. Approximately 50% to 70% of asthma patients have predominant type 2 inflammation. As IL-4R α is a promising therapeutic target for type 2 inflammation-driven diseases, we are developing QX005N as a drug candidate aiming to reach such major portion of asthma patient population.

In addition to QX005N, to address the unmet medical needs for treatment options with efficacy over a broad range of asthma severities and subtypes, we have two other innovative drug candidates with different mechanism and clinical benefit from QX005N in our asthma pipeline, namely, (i) QX008N, an anti-TSLP antibody, as a drug candidate for asthma patients, including those with low-level or no expression of type 2 inflammation biomarkers and (ii) QX007N, an anti-IL-33 antibody, as an alternative drug candidate for asthma patients. See “—Our Other Key Product Candidates—QX008N—Asthma” and “—Our Other Product Candidates—QX007N—Asthma” for details.

Market Opportunity and Competition

The prevalence of asthma in China increased from 62.5 million in 2018 to 67.3 million in 2022, and is estimated to reach 78.1 million in 2030. The market for biologic drugs targeting asthma in China is estimated to increase from US\$0.1 billion in 2022 to US\$4.7 billion in 2030, at a CAGR of 61.8%. Biologic drugs accounted for 3.5% of the drug market for asthma in China in 2022, which is estimated to increase to 44.1% in 2030.

The long-term goals of asthma management are to control symptoms and reduce the risk of exacerbations, airway damage and side-effects of medication. Medications for asthma primarily include inhaled corticosteroids (ICSs) and bronchodilators. ICSs are widely used for long-term treatment of asthma in people of all ages who require daily management. Bronchodilators for the treatment of asthma include long-acting β 2 receptor agonist (LABA), long-acting muscarinic antagonist (LAMA), short-acting β 2 receptor agonist (SABA), and short-acting muscarinic antagonist (SAMA). However, for patients with moderate-to-severe asthma, treatment with ICS and bronchodilators alone may not be effective enough to control the disease due to a variety of factors including intolerance after long-term administrations and side effects. In addition, research has shown that SABA overuse and subsequent ICS underuse are responsible for safety concerns and poor outcomes, including hospitalization and possibly death. Therefore, the Global Initiative for Asthma (“GINA”), a medical organization that works with public health officials and healthcare professionals globally and publishes guidelines for the treatment of asthma, made a fundamental change to its recommendations for the pharmacological treatment of asthma in 2019, which no longer recommended regular use of SABAs for asthma patients who should all be prescribed ICSs, either regularly or as needed for respiratory symptoms. Moreover, the maintenance treatment of systemic corticosteroids can cause dose-dependent growth suppression and a series of severe adverse effects in children and adolescents, which leaves them with even more limited treatment options. In contrast, biologics that specifically target cytokine signaling pathways have shown to be a well-tolerated and effective option for patients with moderate-to-severe asthma. Therefore, for patients with

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moderate-to-severe asthma, biologics have a more important role in disease management and can work as an add-on treatment with LABA, LAMA, SABA, SAMA and/or ICS. However, as a relatively new class of drugs, they have not yet been recommended as a main treatment option for asthma by prevailing clinical guidelines.

As of the Latest Practicable Date, three biologic drugs were approved for the treatment of asthma in China, including omalizumab, omalizumab alfa and dupilumab. As of the Latest Practicable Date, there were six IL-4R α inhibitor candidates in the clinical stage in China. The following tables sets forth details of the approved biologic drugs and biologic drug candidates in clinical stage in China as of the Latest Practicable Date.

Marketed Targeted Biologics for Asthma in China						
Target	Brand Name	INN	Company	Median Price ⁽¹⁾	NMPA Approval Time	NRDL Inclusion
IgE	Xolair	Omalizumab	Novartis/Genentech ⁽²⁾	1,406	2017	Yes
	Aomaishu (奥邁舒)	Omalizumab alfa	Mabpharm	N/A	2023	No
IL-4R α	Dupilxent	Dupilumab	Sanofi	3,160	2023	Yes

Notes:

- Reflects the NRDL median price per minimum formulation unit in 2022 in RMB.
- Novartis and Genentech co-develop and co-promote omalizumab. Novartis markets omalizumab outside the United States.

Clinical-Stage Biologic Drug Candidates for Asthma in China				
Target	Drug Code	Company	Status	First posted Date
TSLP	Tezepelumab	AstraZeneca	Phase III	2019-07-15
	TQC2731	Chia Tai Tianqing	Phase II	2022-06-21
	SHR-1905	Hengrui	Phase II	2022-09-29
	CM326	Keymed Bioscience	Phase II	2023-03-17
	QX008N	the Company	Phase I	2022-07-08
	HBM9378	Harbour Biomed; Kelun-Biotech	Phase I	2022-08-29
	LQ043	Novamab	Phase I	2023-01-13
	GR2002	Genrixbio	Phase I	2023-05-25
	STSA-1201	Staidson Biopharmaceuticals	Phase I	2023-08-01
	MG-ZG122	Mabgeek	Phase I	2022-12-12
IL-4R α	CM310	Keymed Bioscience	Phase II/III	2023-03-08
	CBP-201	Connect Biopharmaceuticals	Phase II	2021-08-18
	GR1802	Genrix Bio	Phase II	2022-05-12
	MG-K10	Mabgeek	Phase I / II	2022-04-29
	SHR-1819	Hengrui	Phase I	2021-02-01
IL-5	LQ036	Novamab	Phase II	2024-02-04
	Mepolizumab	GSK	BLA submission	2023-03-14
	Depemokimab	GSK	Phase III	2021-09-18
	SSGJ-610	Sunshine Guojian	Phase II	2022-08-22
IL-4R α , IL-5	SHR-1703	Hengrui	Phase II	2022-09-05
	RC1416	Regenecore	Phase I	2023-06-20
IL-5R α	Benralizumab	AstraZeneca	Phase III	2017-07-26
IgE	Omalizumab-HS632	Hisun	Phase I	2020-04-29
	Omalizumab-SYN008	CSPC Baike	Phase I	2020-11-03
	Omalizumab-SYB507	Yuanda Shuyang	Phase I	2020-11-09
IL-25	JYB1904	Jiye Biotechnology	Phase I	2022-04-28
	XKH001	Kanova biopharma	Phase I	2022-03-07
ST2	9MW1911	Mabwell	Phase I	2021-10-13
	TQC2938	Chia Tai Tianqing	Phase I	2023-03-31
Undisclosed	Recombinant ϵ and γ Human Immunoglobulin Fc Fusion Protein	Kexin Biotech	Phase I	2018-11-16
	ZHB107-108	ZonHon Biopharma	Phase I	2023-11-17

Source: Frost & Sullivan Report (based on annual reports of relevant companies and information published by the NMPA)

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Our Advantages

Asthma has a complex and heterogeneous nature which each patient needs targeted treatment. Therefore, the demand for targeted biologic treatment is increasing. As of the Latest Practicable Date, dupilumab was the only approved IL-4R α inhibitor for asthma in China. While dupilumab can cost over RMB82,000 a year based on its pricing in China for the treatment of AD in 2022, according to Frost & Sullivan, we aim to make QX005N more accessible to patients in China. See “—Atopic Dermatitis—Our Advantages” for more details.

Material Communications and Next Steps

We obtained the IND approval of the Phase I, Phase II and Phase III clinical trials of QX005N for treatment of moderate-to-severe asthma from the NMPA in February 2022. As of the Latest Practicable Date, we had not received any relevant regulatory agency’s concerns or objections to our clinical development plans. No material adverse changes had occurred since we obtained the IND approval and up to the Latest Practicable Date. Pursuant to the Administrative Measures for Drug Registration, asthma is considered an indication expansion of QX005N and will be treated as the same product in the subsequent regulatory registration process.

Chronic Obstructive Pulmonary Disease

Chronic obstructive pulmonary disease (COPD) is a chronic inflammatory lung disease which obstructs air flow from the lungs. It consists of three separate illnesses: emphysema (a lung condition that causes shortness of breath), chronic bronchitis (long-term inflammation of the breathing tubes), and chronic obstructive asthma. COPD causes the destruction of barriers between alveoli inside lungs, causing airways to be swollen and clogged with mucus. COPD can be caused by smoking, long-term exposure to irritating gases such as second-hand smoke, chemical fumes or toxic substances, genetic defect and untreated asthma. In most cases, COPD develops very slowly and people may not experience any symptom for years before being diagnosed. The major diagnosis method for COPD is the lung function test, and the diagnosis is confirmed when the FEV1/FVC ratio, a ratio commonly used for COPD diagnosis that represents the maximum amount of air that a person can forcibly expel during the first second following maximal inhalation (FEV1) to the full forced vital capacity (FVC), is less than 70% after using bronchodilator.

COPD is mainly treated with drugs to prevent and control chronic inflammation and reduce clinical symptoms. Meanwhile, COPD patients can also be treated by rehabilitation, oxygen therapy and surgery. Control drugs for long-term treatment of COPD primarily include corticosteroids, such as ICSs and systemic corticosteroids, long-acting bronchodilators (LABA and LAMA) and anti-inflammatory drugs such as PDE4 inhibitors. Other drug treatments such as mucolytic, antioxidant drugs and immunomodulator can also be used to control inflammation. In the initial treatment of COPD, patients are recommended to use one type of bronchodilator. For patients with higher moderate exacerbations and more severe dyspnea, combination therapy of LABA and LAMA are recommended. For patients with higher eosinophil count, combined therapy of ICS with LABA and LAMA are recommended to improve lung function and reduce exacerbations. However, approximately 40% of moderate-to-severe COPD patients on the triple therapy of ICS with LABA and LAMA still remain

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uncontrolled and continue to experience exacerbations. Therefore, there are significant unmet clinical needs from COPD patients. According to Frost & Sullivan, approximately 20% to 40% of COPD patients have eosinophilic COPD, which is characterized by predominant type 2 inflammation. As IL-4R α is a promising therapeutic target for type 2 inflammation-driven diseases, we are developing QX005N as a drug candidate for such patients with eosinophilic COPD.

In addition to QX005N, to address the unmet medical needs for treatment options with efficacy over a broad range of COPD severities and subtypes, we have two other innovative drug candidates with differentiated mechanisms and clinical benefits in our COPD pipeline, which we believe can potentially address a broad COPD patient population, namely: (i) QX008N, an anti-TSLP antibody, as a drug candidate for COPD patients, including those with low-level or no expression of type 2 inflammation biomarkers; and (ii) QX007N, an anti-IL-33 antibody, as a drug candidate with particular promising efficacy for patients with prior smoking history. See “—Our Other Key Product Candidates—QX008N—Chronic Obstructive Pulmonary Disease” and “—Our Other Product Candidates—QX007N—Chronic Obstructive Pulmonary Disease” for details.

Market Opportunity and Competition

According to Frost & Sullivan, the prevalence of COPD in China increased from 103.5 million in 2018 to 106.4 million in 2022, and is estimated to reach 110.7 million in 2030. While ICSs and long-acting bronchodilators are the primary drug treatments for COPD, no biologics had been approved for the treatment of COPD as of the Latest Practicable Date. According to Frost & Sullivan, the COPD drug market in China is estimated to increase from US\$3.2 billion in 2022 to US\$6.3 billion in 2030, at a CAGR of 8.8%. Biologic drug candidates for COPD in China primarily include IL-4R α inhibitors, IL-5 inhibitors, ST2 inhibitors and IL-33 inhibitors. As asthma and COPD share common pathophysiological mechanisms, IL-4R α and IL-5, two of the most commonly developed targets for treatment of asthma, are also being developed as targets for treatment of COPD. Since IL-33 can induce Th2 cytokine production and promote the pathogenesis of COPD, IL-33 and its receptor, ST2, can be promising targets for the treatment of COPD as well. However, as a relatively new class of drugs, biologics have not yet been recommended as a main treatment option for COPD by prevailing clinical guidelines. As of the Latest Practicable Date, there were seven biologic drug candidates for COPD in the clinical stage in China, including two candidates targeting IL-4R α , namely, dupilumab and SSGJ-611. See “Industry Overview—Overview of the Allergic Disease Drug Market—Major Allergic Diseases—Chronic Obstructive Pulmonary Disease” for details.

Our Advantages

Approximately 20% to 40% of COPD patients have a predominant type 2 inflammation. IL-4R α has been reported to be a promising target with good efficacy and safety profile in the treatment of diseases associated with type 2 inflammation by controlling the signaling of both IL-4 and IL-13 that drives type 2 inflammatory response. While dupilumab, one of the two anti-IL-4R α drug candidates for COPD in China as of the Latest Practicable Date, can cost over RMB82,000 a year based on its pricing in China for the treatment of AD in 2022, according to Frost & Sullivan, we aim to make QX005N more accessible to patients in China. See “—Atopic Dermatitis—Our Advantages” for more details.

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Material Communications and Next Steps

We obtained the IND approval of the Phase I, Phase II and Phase III clinical trials of QX005N for treatment of COPD from the NMPA in September 2023. As of the Latest Practicable Date, we had not received any relevant regulatory agency’s concerns or objections to our clinical development plans. No material adverse changes had occurred since we obtained the IND approval and up to the Latest Practicable Date. Pursuant to the Administrative Measures for Drug Registration, COPD is considered an indication expansion of QX005N and will be treated as the same product in the subsequent regulatory registration process.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET QX005N SUCCESSFULLY.

Our Other Key Product Candidates

QX001S

QX001S, our most advanced drug candidate, is the first domestically developed ustekinumab biosimilar with BLA submitted in China and potentially one of the first ustekinumab biosimilars to be approved in China. It is a humanized monoclonal antibody inhibiting the bioactivity of the cytokines IL-12 and IL-23 by targeting their common p40 subunit. IL-12 and IL-23 are involved in inflammatory and immune responses and have been implicated as important contributors to chronic inflammation, a hallmark of many autoimmune diseases such as Ps.

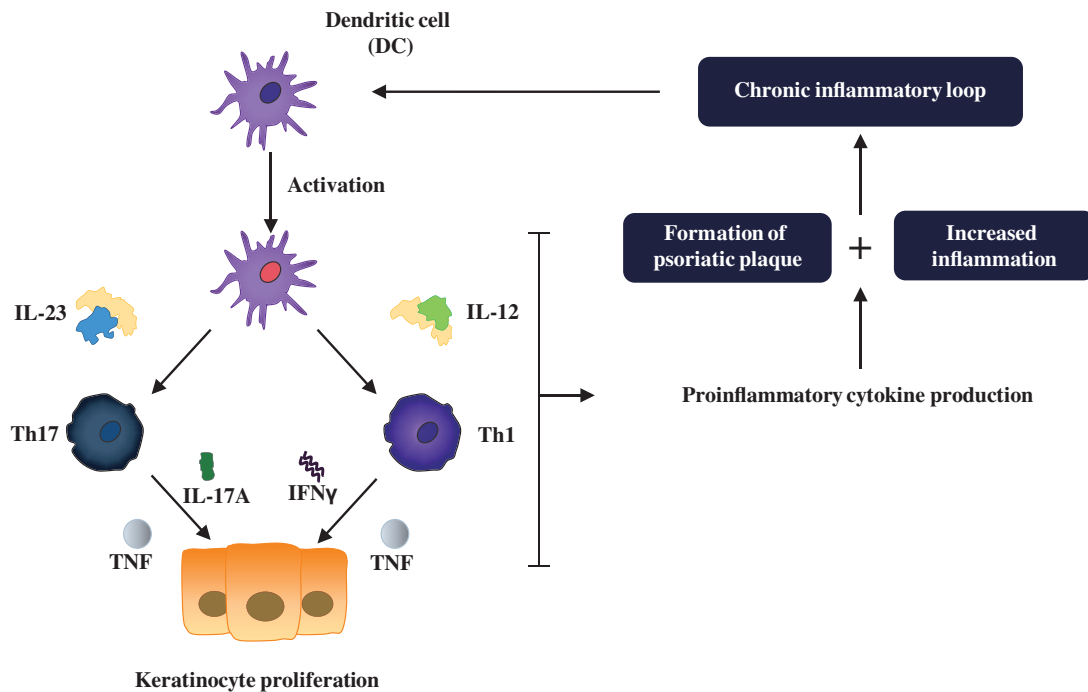
We received an IND approval of QX001S for the treatment of moderate-to-severe plaque Ps from the NMPA in January 2018. In our Phase I clinical trial, our QX001S demonstrated a safety and PK profile comparable to that of ustekinumab, indicating its potential to be an effective treatment for Ps suitable for long-term use. In our Phase III clinical trial for Ps, QX001S demonstrated clinical equivalence to ustekinumab in terms of efficacy, safety, immunogenicity and PK profile. In August 2020, we entered into a collaboration agreement with Zhongmei Huadong, a subsidiary of Huadong Medicine, with respect to the joint development and exclusive commercialization of QX001S in China. For details, see “—Collaboration with Zhongmei Huadong.” Zhongmei Huadong submitted a BLA in China in July 2023, which was accepted by the NMPA in August 2023 and under review as of the Latest Practicable Date. Additionally, we, together with our commercialization partner Zhongmei Huadong, plan to develop QX001S for the treatment of UC/CD.

Mechanism of Action

IL-12 and IL-23 are cytokines involved in inflammatory and immune responses. IL-12 and IL-23 are involved in the differentiation of T helper 1 (Th1) and Th17 cells (subsets of T helper cells), respectively, by binding to the receptor proteins expressed on the immune cell surface and activating the Janus kinase–signal transducer and activator of transcription (JAK-STAT) signaling pathway that allows signal transduction into the immune cells. Th1 cells and Th17 cells each release various cytokines, among which interferon-gamma (IFN- γ), tumor necrosis factor alpha (TNF- α) and IL-17 are considered key in the pathogenesis of chronic inflammatory diseases.

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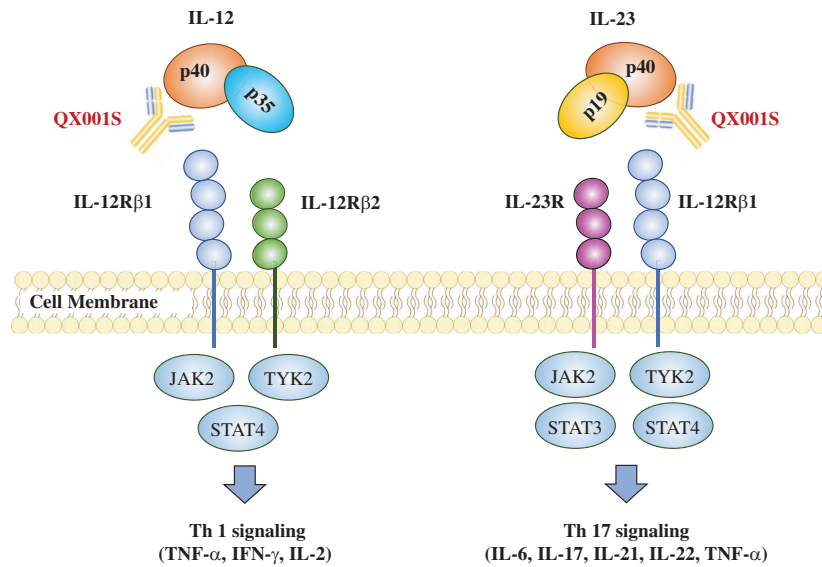
Structurally, IL-12 and IL-23 are both composed of two subunits. IL-12 comprises a p40 subunit linked to a p35 subunit, while IL-23 comprises the same p40 subunit linked to a unique p19 subunit. The common subunit, p40, is required for receptor binding of both IL-12 and IL-23, which is essential for their function. Similar to ustekinumab, QX001S is designed to bind to the p40 subunit of IL-12 and IL-23 and prevent it from binding to the cell surface IL-12R β 1 receptor, which in turn blocks signal transduction through the JAK-STAT pathway and inhibits the differentiation of Th1 and Th17 cells. This way, QX001S reduces the production of those pro-inflammatory cytokines and alleviates inflammatory response. The diagram below illustrates the involvement of IL-12 and IL-23 in causing inflammatory and immune responses that lead to plaque Ps.



Source: Frost & Sullivan Report

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The diagram below illustrates the mechanism of action of QX001S.



Source: the Company

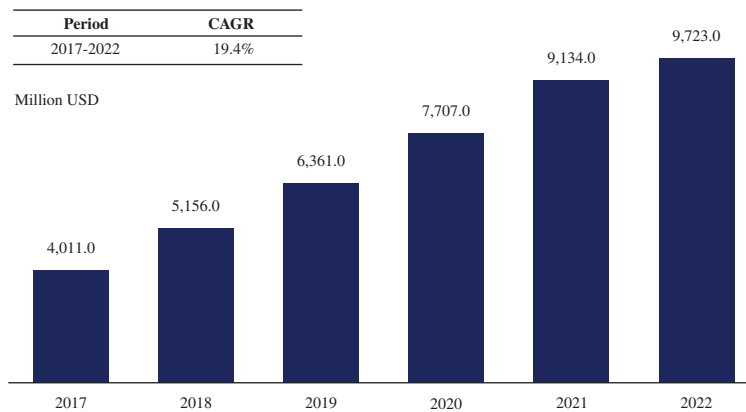
Background of Reference Drug

According to the Guidelines for the R&D and Evaluation Techniques of Biosimilar Drugs (Trial) (《生物類似藥研發與評價技術指導原則(試行)》), all biosimilars must demonstrate a similar nature to the originator drug in terms of their safety and efficacy (including PK and PD parameters). This also applies to QX001S and other proposed biosimilars to ustekinumab, including their administration methods.

Ustekinumab is a humanized IgG1k monoclonal antibody that binds to the common p40 subunit of IL-12 and IL-23 in order to inhibit their bioactivity. It is developed by Johnson & Johnson and sold under the brand name Stelara. Initially approved by the FDA in 2009, ustekinumab was the first biologic treatment to selectively inhibit the IL-12 and IL-23 pathways and has been widely regarded as one of the major treatments for Ps worldwide. In 2022, it recorded sales of US\$9.7 billion globally and ranked the ninth best-selling drug worldwide, according to Frost & Sullivan. The following chart sets forth the global sales of ustekinumab for the periods indicated.

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Global Sales of Ustekinumab (Stelara), 2017-2022



Source: Frost & Sullivan Report (based on the annual report of relevant company)

Ustekinumab was first approved for the treatment of moderate-to-severe Ps in China in 2017. The China patent on the amino acid sequence of ustekinumab expired in August 2021, and U.S. and European patents will expire in September 2023 and January 2024, respectively.

Licenses, Rights and Obligations

In August 2020, we entered into a collaboration agreement with Zhongmei Huadong with respect to the joint development and exclusive commercialization of QX001S in China. We retain the exclusive development and commercialization rights of QX001S outside China. For further details, please refer to “—Collaboration with Zhongmei Huadong.”

Psoriasis

Psoriasis (Ps) is a skin disease associated with dysregulation of the immune system that causes a rash with itchy and scaly patches, most commonly on the knees, elbows, trunk and scalp. It is a common chronic disease with no cure. It can sometime cause pain in patients and interfere with patients’ daily life. Plaque Ps is the most common type of Ps, causing dry, itchy and raised skin patches (plaques) covered with scales. The plaques may appear anywhere on the skin and their visibility could have a detrimental impact on the patients’ psychological health. Even worse, for many Ps patients, the skin may never be completely clear. As of the Latest Practicable Date, we were developing QX001S and QX004N indicated for Ps. We expect QX001S, which is the first domestically developed biosimilar to ustekinumab, a global blockbuster biologic drug, with BLA submitted in China and potentially one of China’s first approved ustekinumab biosimilars, to be an affordable therapy for a broad section of Ps patients. In addition, due to its chronic and relapsing nature, there is an unmet medical need for new Ps drugs with a superior efficacy and safety profile suitable for long-term disease management. We believe that QX004N, as an IL-23p19 inhibitor, will be a promising alternative for Ps patients with more severe symptoms or inadequate response to existing treatments. In doing so, we hope to improve accessibility of QX001S and QX004N and establish a comprehensive coverage of Ps patients who experience different levels of disease severity and have different abilities to pay.

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Market Opportunity and Competition

According to Frost & Sullivan, the prevalence of Ps in China has generally remained stable, which increased from 6.6 million in 2018 to 6.7 million in 2022, and is anticipated to reach 6.8 million in 2030. 20% to 30% of the patients have moderate-to-severe Ps. The Ps drug market in China grew rapidly from US\$604.2 million in 2018 to US\$1,435.8 million in 2022, at a CAGR of 24.2%, and is estimated to increase to US\$9,943.6 million in 2030, at a CAGR of 27.4% from 2022 to 2030. Biologic drugs accounted for 43.4% of the drug market for Ps in China in 2022, which is estimated to increase to 56.8% in 2030.

Topical drugs, NSAIDs and conventional DMARDs are commonly used to control Ps but with limited efficacy as compared to biologic drugs with specific targeting, which has become a main treatment option for moderate-to-severe plaque Ps in China. In addition, small-molecule targeted drugs are a relatively new class of medications as a potentially promising treatment option for Ps patients. For example, JAK inhibitors have shown promising clinical results but may lead to more severe side effects and higher toxicity, causing the FDA to advise that they should be used with caution for patients with certain risk factors. PDE-4 inhibitors, another family of small-molecule drugs, have shown a good safety profile but limited efficacy. As a result, their use as a recommended long-term treatment option for a broad section of Ps patients remains under evaluation. Recently, TYK2 inhibitors, a newer family of small-molecule targeted drugs, have demonstrated in clinical studies promising efficacy profiles for treating Ps and improvements on traditional limitations of JAK-related toxicities.

Since the first biologic drug for Ps treatment, namely, an anti-IL-8 humanized mAb, was approved in China in 2003, there have been over ten biologic drugs approved for Ps in China in recent years. They belong to two main types, namely, TNF inhibitors and IL inhibitors, which are considered first-generation and second-generation drugs, according to Frost & Sullivan. Adalimumab, a TNF- α inhibitor and sold under the brand name Humira, was the world's best-selling drug for eight years in the last ten (2013-2022). As TNF inhibitors have significant limitations, including multiple adverse effects and a high rate of non-responsiveness, IL inhibitors, such as those targeting IL-17A and IL-23, present promising treatments for Ps. Among IL inhibitors, IL-23 is expected to be one of the mainstream targets for Ps treatment given its key role in the alleviation of inflammation and its superior efficacy and safety profile in comparison with IL-17A inhibitors in clinical studies. The chart below sets forth the global sales of marketed biologics targeting IL-23 and IL-17A in 2022.

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Target	Drug	Global sales 2022 (million USD)	SUM – Global sales 2022 (million USD)
IL-23	Ustekinumab	9,723	17,556
	Guselkumab	2,668	
	Tildrakizumab-asmn	Undisclosed	
	Risankizumab-rzaa	5,165	
IL-17A	Secukinumab	4,788	7,270
	Ixekizumab	2,482	

Source: Frost & Sullivan Report (based on annual reports of relevant companies)

As of the Latest Practicable Date, there were 21 biologic drugs for Ps approved in China, including 13 TNF inhibitors (including adalimumab and 6 adalimumab biosimilars) and 8 IL inhibitors, among which ustekinumab was the only approved IL-12/IL-23 inhibitor while guselkumab and tildrakizumab were the only approved IL-23 inhibitors. As of the same date, besides QX001S and QX004N, there were 32 biologic drug candidates for Ps in the clinical stage in China, including 15 IL-17 inhibitors, 8 TNF- α inhibitors (including 7 proposed adalimumab biosimilars), 3 targeting IL-23, 3 targeting IL-12/IL-23 (including 2 proposed ustekinumab biosimilars) and 3 targeting IL-36R. Due to the aforementioned limitations of TNF inhibitors, we believe that QX001S and QX004N will primarily compete with other IL inhibitors. In particular, we expect QX001S to face intense competition upon its commercialization, see “Risk Factors—Our drug candidates will be subject to intense competition with biologics drugs and other drugs for autoimmune and allergic diseases after commercialization and may fail to compete effectively against competitors” for details. The following table sets forth details of QX001S and QX004N as well as approved biologic drugs and drug candidates in the clinical stage for Ps in China that are IL inhibitors as of the Latest Practicable Date.

Marketed IL Inhibitors for Psoriasis in China								
Target	Brand Name	International Nonproprietary Name (INN)	Company	NMPA Approval Time	Branded or Biosimilar	Availability of biosimilar	2022 NRDL covered	NRDL Median price in 2022 ⁽¹⁾ (RMB)
IL-23	Tremfya	Guselkumab	Janssen (J&J)	2019	Branded	—	No	—
	益路取	Tildrakizumab-asmn	Sun Pharma; Kangzhe Biotech	2023	Branded	—	No	—
IL-12, IL-23	Stelara	Ustekinumab	Janssen (J&J)	2017	Branded	—	Yes	4,318.0
IL-17A	Cosentyx	Secukinumab	Novartis	2019	Branded	—	Yes	1,188.0
	TALTZ	Ixekizumab	Eli Lilly	2019	Branded	—	Yes	1,218.0
IL-17RA	LUMICEF	Brodalumab	Kyowa Kirin	2020	Branded	—	No	—
IL-8	Enboke (恩博克)	—	ASIA SPACE	2003	Branded	—	Yes	270.0
IL-36R	Spevigo	Spesolimab	Boehringer Ingelheim	2022	Branded	—	No	—

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Clinical-Stage IL Inhibitor Candidates for Psoriasis in China

Target	Drug Code	Company	Status	First Posted Date
IL-23	IBI112	Innovent	Phase III	2022-12-26
	QX004N	the Company	Phase II	2023-01-06
	Risankizumab	Boehringer Ingelheim	Phase I	2019-07-18
IL-12, IL-23	NBL-012	NovaRock	Phase I	2021-06-03
	Ustekinumab-QX001S	the Company	BLA submission	2023-08-12
	Ustekinumab-BAT2206	Bio-Thera	Phase III	2021-06-25
	AK101	Akeso	BLA submission	2023-08-23
IL-17A	Ustekinumab-SYSA1902	CSPC	Phase III	2023-01-29
	GR1501	GenrixBio	BLA submission	2023-03-25
	SHR-1314	Henrui	BLA submission	2023-04-27
	JS005	Junshi Bioscience	Phase III	2023-07-12
	Secukinumab-BAT2306	Bio-Thera	Phase III	2022-07-25
	SSGJ-608	Sunshine Guojian	Phase III	2022-11-10
	AK111	Akeso	Phase III	2023-02-15
	HB0017	Huaota Biopharm; Huabo Bio	Phase II	2022-08-22
	SYS6012	CSPC	Phase I	2023-12-05
	BR201	BioRay	Phase I	2023-11-16
	Netakimab	BIOCAD	Phase I	2022-10-19
	Secukinumab-CMAB015	Mabpharm	Phase I	2023-01-18
	NVS451	National Vaccine & Serum Institute	Phase I	2023-05-08
IL-17A, IL-17F	FTC001/CNTO6785	Shandong Fontacea	Phase I	2023-06-26
	Bimekizumab	UCB Pharma	BLA submission	2023-07-20
	LZM012	LIVZON	Phase III	2023-06-27
IL-36R	Imsidolimab	AnaptysBio	Phase III	2023-03-09
	TQH2929	Chiatai Tianqing	Phase I	2023-11-02
	HB0034	Huaota Biopharm; Huabo Bio	Phase I	2022-09-05

Source: NMPA, CDE, Frost & Sullivan Report

Note:

- (1) Reflects the median price for a drug’s minimum formulation unit as included in the NRDL.

Our Advantages

We believe our QX001S has the following potential advantages in comparison with the approved drugs and drug candidates indicated for Ps:

- *Good efficacy and safety profile.* Ps is a chronic disease with no cure and typically requires long-term treatment plans to manage symptoms. However, a majority of patients discontinue treatment due to ineffectiveness. In comparison with other biologics currently approved for Ps in China, such as TNF- α and IL-17 inhibitors, ustekinumab, the reference drug of QX001S, has shown a promising safety and efficacy profile for long-term use. A head-to-head study in 903 patients with moderate-to-severe plaque Ps showed that at week 12, there was at least 75%

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improvement in the Psoriasis Area and Severity Index (PASI) score (PASI75) in 67.5% and 73.8% of patients who received 45 mg and 90 mg of ustekinumab, respectively, as compared with 56.8% of those who received etanercept, a TNF- α inhibitor, demonstrating better efficacy of ustekinumab. Additionally, several gastrointestinal symptoms have been reported after IL-17 inhibitor treatment despite their high levels of efficacy, which have not been observed in therapy with ustekinumab. Furthermore, ustekinumab is reported to have higher drug survival, which is a measure of the time period until treatment discontinuation that is used to evaluate the effectiveness of a Ps drug, than TNF- α and IL-17 inhibitors. A study in 1,606 patients with moderate-to-severe plaque Ps treated with biologics showed that ustekinumab also had higher drug survival and lower rates of discontinuation as compared to IL-17 inhibitors, such as secukinumab, which has been reported to have less long-term efficacy in clinical studies. These findings suggest that ustekinumab may be more suitable to be used in a long-term treatment plan for Ps patients. In our Phase I clinical trial, our QX001S demonstrated comparable safety and PK profile to ustekinumab, indicating its potential to be an effective treatment for Ps suitable for long-term use. In our Phase III clinical trial for Ps, QX001S also demonstrated clinical equivalence to ustekinumab in terms of efficacy, safety, immunogenicity and PK profile.

- Convenient treatment regimen. Benefiting from its strong efficacy and safety profile, ustekinumab can be administered with a lower dose frequency (typically one dose every three months after the loading doses) than IL-17 inhibitors (usually one dose every month after the loading doses). Similarly, QX001S is designed to be administered four times a year after the loading doses, which presents a convenient treatment regimen with lower administration frequency. It could potentially improve patient compliance and in turn further improve efficacy.
- Rapid commercialization strategy. To commercialize QX001S in China, we have entered into a collaboration agreement with a subsidiary of Huadong Medicine, a leading PRC pharmaceutical company. We believe that the collaboration with Huadong Medicine will enable us to leverage its market access, nationwide sales and marketing network targeting the autoimmune and allergic disease field as well as its extensive experience in chronic disease management, which will be crucial to help achieve rapid commercialization of QX001S in China.
- Promising accessibility. While ustekinumab has been included in the NRDL with a price cut, it is still an expensive treatment. Ustekinumab is designed to be administered with one initial injection of 45 mg at week 0 and week 4, respectively, and then with a treatment frequency of Q12W at 45 mg. Since 2022, the annual cost of ustekinumab has been approximately RMB21,590 for five doses in the first year and approximately RMB17,272 for four doses per year for subsequent treatment for Ps patients in China, according to Frost & Sullivan. Therefore, there is still room for this treatment to reach more patients, with further price deductions. In collaboration with Huadong Medicine, we aim to make QX001S more accessible to patients in

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China taking into account various factors such as our in-house manufacturing capacity, potential competitor pricing and regulatory requirements. QX001S is designed to be administered at the same dosage and frequency as ustekinumab. Its estimated annual cost is expected to be lower than ustekinumab by approximately 10% upon commercialization. By marketing QX001S as an affordable biosimilar to ustekinumab, we believe QX001S has the potential to benefit both patients currently undertaking ustekinumab therapy and those who previously could not afford it.

Summary of Clinical Trial Results

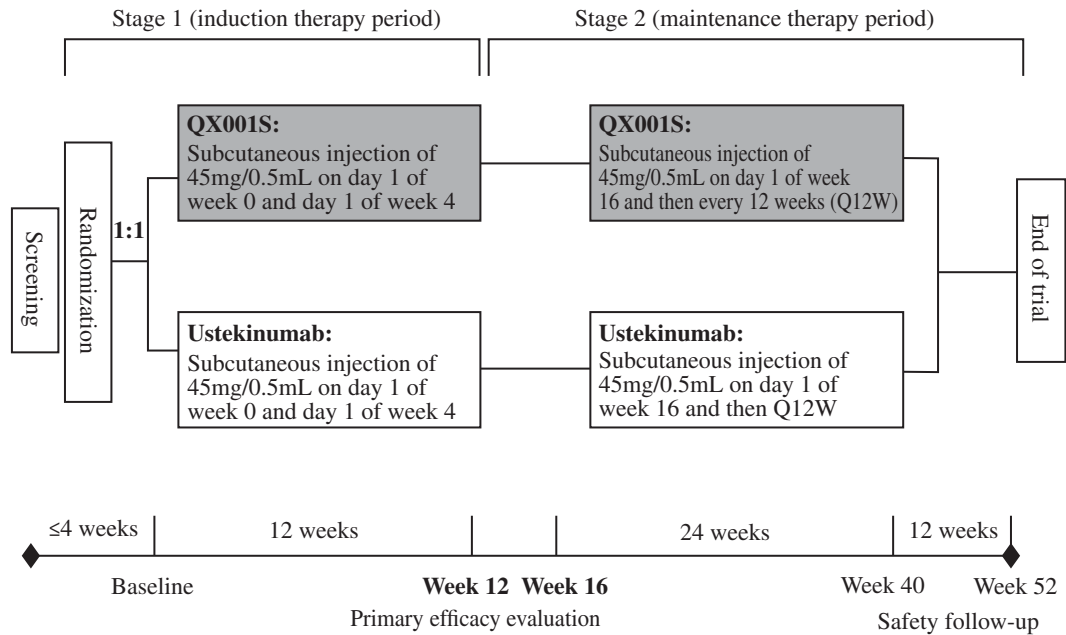
We completed a Phase I clinical trial of QX001S in healthy subjects (individuals in good general health and not having any mental or physical disorder requiring regular or frequent medication) in China in May 2020, and Zhongmei Huadong and we completed a Phase III clinical trial of QX001S in patients with moderate-to-severe plaque Ps in China in June 2023.

Phase III Clinical Trial

The Phase III clinical trial in China was a multi-center, randomized, double-blind and parallel-controlled head-to-head clinical study in patients with moderate-to-severe plaque Ps to evaluate the efficacy and safety of QX001S versus ustekinumab.

Trial design: The primary endpoint of this trial was the proportion of subjects who experience at least 75% improvement in the PASI score (“PASI-75”), the current benchmark of primary endpoints for most clinical trials for Ps treatments, at week 12. The secondary endpoints included safety parameters, PK, immunogenicity and efficacy parameters, such as (i) the percentage of improvement in PASI, (ii) the proportion of subjects who experience PASI-75 at weeks 4, 16, 20, 28, 40 and 52, (iii) the proportion of subjects who achieve clearance or near elimination of Ps symptoms (“IGA=0” or “IGA=1,” respectively), and (iv) changes in the Dermatology Life Quality Index (“DLQI,” which is a questionnaire designed to measure the health-related quality of life of adult patients suffering from a skin disease). There would be two stages in this trial, including an induction therapy period of 12 weeks (stage 1) and a maintenance therapy period of 36 weeks (stage 2). We planned to enroll a total of 508 subjects, who would be assigned to an active treatment group receiving QX001S (45 mg/0.5 mL) and a control group receiving ustekinumab (45 mg/0.5 mL) equally. The subjects would receive a dose of either QX001S or ustekinumab at 45 mg on the first day of trial (day 0) and another injection of the same dose at week 4. The PK, immunogenicity, efficacy and safety evaluation would be conducted at week 12, which would be reviewed by an IDMC. The trial would be terminated if the IDMC concludes that the trial results at week 12 cannot show clinical equivalence between QX001S and ustekinumab. If the trial proceeds to stage 2, the subjects would receive another dose of either QX001S or ustekinumab at 45 mg on the first day of week 16 and then a dose every 12 weeks (Q12W) until week 40, followed by the efficacy and safety evaluation at week 52. The diagram below illustrates the design of this trial.

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Trial status: This trial was initiated in June 2021 and completed in June 2023. A total of 508 subjects were enrolled in the study, with 253 and 255 subjects in the QX001S and ustekinumab groups, respectively.

Efficacy results: In this trial, the primary endpoint, *i.e.*, the proportion of subjects responding to the treatment as measured by PASI-75 at week 12, was 70.4% and 64.3% in the QX001S and ustekinumab groups, respectively, indicating a similar efficacy of QX001S and ustekinumab. In addition, the QX001S and ustekinumab groups showed similar improvement trends and magnitudes in terms of secondary efficacy parameters. For example, both groups showed improvements in PASI and DLQI scores at week 4 in comparison with baseline, which were maintained during the subsequent treatment. The proportion of subjects achieving PASI-50, PASI-75, PASI-90 and PASI-100 in the QX001S and ustekinumab groups also increased and maintained as drug administration time prolonged. The proportion of subjects achieving IGA score (0 or 1) in both groups increased gradually after drug administration and stabilized at week 40, which then experienced a slight decrease after week 40.

Safety results: In this trial, QX001S was well-tolerated and overall its safety profile was good and comparable to ustekinumab. 216 of the 253 (85.4%) subjects in the QX001S group and 206 of the 255 (80.8%) subjects in the ustekinumab group reported TEAEs, including 16 (6.3%) incidents in the QX001S group and 30 (11.8%) incidents in the ustekinumab group being Grade 3 or higher under CTCAE. Additionally, 141 of the 253 (55.7%) subjects in the QX001S group and 111 of the 255 (43.5%) subjects in the ustekinumab group reported drug-related AEs, including 6 (2.4%) incidents in the QX001S group and 8 (3.1%) incidents in the ustekinumab group being Grade 3 or higher under CTCAE. Furthermore, 10 of the 253 (4.0%) subjects in the QX001S group and 13 of the 255 (5.1%) subjects in the ustekinumab group reported TESAEs. Only one TESAE, of abnormal liver function, in the QX001S group was considered related to the treatment. There were 2 (0.8%) subjects in the QX001S group and 3 (1.2%) subjects in the ustekinumab group that discontinued treatment and withdrew from the study due to TEAEs occurred in this trial. No death was observed in this trial.

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Immunogenicity: In this trial, the proportion of ADA-positive subjects was overall not higher in the QX001S group than in the ustekinumab group, with 48 and 78 ADA-positive subjects observed in the QX001S and ustekinumab groups, respectively. Neutralizing antibody (NAb) was also tested in this trial, which is often a required indicator of a clinical trial if immunogenicity is observed in subjects, because ADAs have the potential to neutralize the effects of a drug. The QX001S and ustekinumab groups had a similar NAb-positive rate in this trial, with 25 NAb-positive subjects in each of the groups.

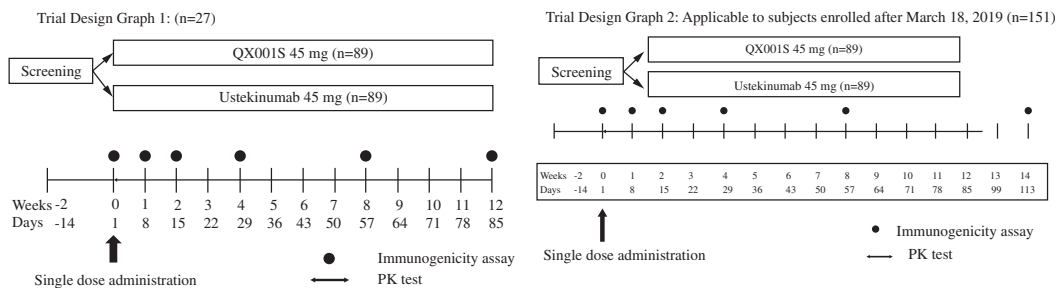
PK: In this trial, QX001S and ustekinumab showed comparable PK profile with similar trends and no significant difference in drug concentration. Additionally, drug concentration is considered to have stabilized at week 16 with no significant accumulation under a drug administration frequency of Q12W.

Conclusion: In this trial, QX001S demonstrated a clinical equivalence to ustekinumab as measured by the proportion of subjects achieving PASI-75 at week 12. Additionally, similar clinical efficacy, safety, immunogenicity and PK characteristics were observed in the QX001S and ustekinumab groups for long-term use, further supporting the clinical equivalence of QX001S and ustekinumab.

Phase I Clinical Trial

The Phase I clinical trial in China was a randomized, double-blind, single-dose, parallel and comparison clinical study in healthy male subjects to evaluate the PK profile of QX001S versus ustekinumab.

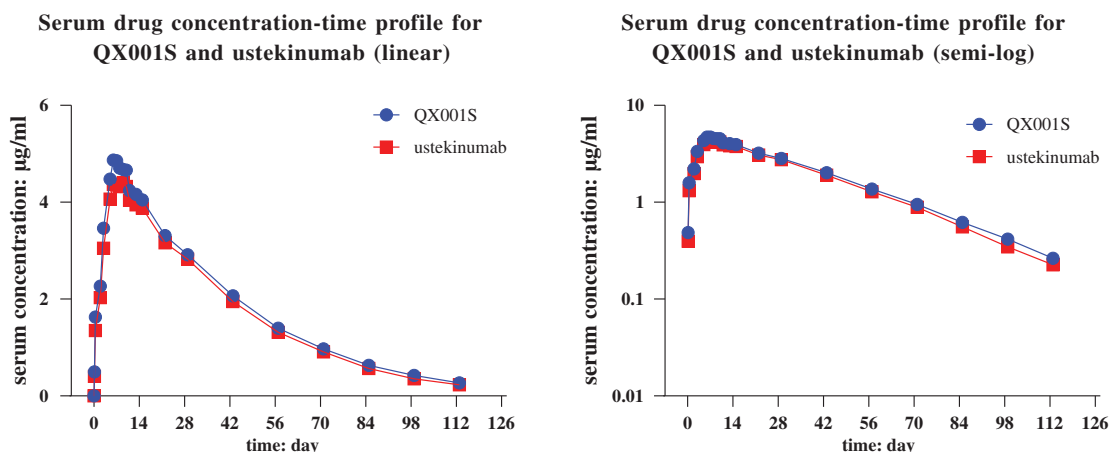
Trial design: The primary endpoints included PK parameters for evaluating the PK similarity of a single dose of QX001S (45 mg/0.5 mL) versus ustekinumab (45 mg/0.5 mL) in healthy male subjects. The secondary endpoints included safety parameters and immunogenicity. We planned to enroll a total of 178 subjects, who would be assigned to two groups with 89 subjects in each group. The active treatment group and control group would receive a single subcutaneous injection of QX001S (45 mg/0.5 mL) and ustekinumab (45 mg/0.5 mL), respectively, under fasting conditions. The trial would include a screening period of 14 days and an evaluation period of 85 days. The evaluation period was later amended to 113 days for subjects enrolled after March 18, 2019. The diagrams below illustrate the design of this trial.



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Trial status: This trial was initiated in November 2018 and completed in May 2020. A total of 178 subjects were enrolled in the study with 177 subjects included in the safety, PK and immunogenicity analysis sets as one subject withdrew from the study for personal reasons. 89 and 88 subjects were assigned to the QX001S and ustekinumab groups, respectively.

PK: In this trial, QX001S and ustekinumab showed comparable PK profile in healthy male subjects, as indicated by their ratios of the adjusted geometric means (90% confidence intervals) for the main PK parameters (C_{max} , AUC_{0-t} and AUC_{0-inf}), which were all within the range of 80% to 125% (the predefined bioequivalence limits). The mean serum concentration-time curves are shown below.



Immunogenicity: In this trial, the proportion of ADA-positive patients was overall lower in the QX001S group than in the ustekinumab group, as shown in the table below.

Time	QX001S group (n = 89)	Ustekinumab group (n = 88)	
hour (day)	n (%)	n (%)	p
Pre-dose	2 (2.2)	3 (3.4)	0.64
168 (8)	1 (1.1)	15 (17)	<0.05
336 (15)	3 (3.4)	14 (15.9)	<0.05
672 (29)	3 (3.4)	11 (12.5)	<0.05
1,344 (57)	11 (12.4)	15 (17)	0.37
2,688 (113)	11 (12.4)	21 (23.8)	<0.05

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Safety results: In this trial, QX001S was well-tolerated and its safety profile was good and comparable to ustekinumab. 98 of the 177 (55.4%) subjects in the safety analysis set reported a total of 228 AEs, all of which were treatment-emergent adverse events (TEAEs). 143 of those AEs were adverse drug reactions (ADRs), reported by 75 (42.4%) subjects. Most TEAEs were of mild or moderate severity. There were no serious adverse events (SAEs) and no subjects discontinued treatment or withdrew from the study due to safety issues in this trial. The following table summarizes the AEs occurred in this trial.

	QX001S group (n = 89)		Ustekinumab group (n = 88)		Total (n = 177)		p
	n (%)	Number of reactions	n (%)	Number of reactions	n (%)	Number of reactions	
Total	38 (42.7)	88	37 (42.0)	55	75 (42.4)	143	0.93
Upper respiratory infection	9 (10.1)	9	6 (6.8)	6	15 (8.5)	15	0.43
Elevated triglyceride level	3 (3.4)	4	6 (6.8)	6	9 (5.1)	10	0.29
Elevated leukocyte count	5 (5.6)	6	3 (3.4)	3	8 (4.5)	9	0.47
Elevated alanine aminotransferase	12 (13.5)	14	4 (4.5)	4	16 (9.0)	18	0.04
Elevated aspartate aminotransferase	8 (9.0)	9	0 (0.0)	0	8 (4.5)	9	NA
Elevated neutrophil counts	5 (5.6)	6	3 (3.4)	3	8 (4.5)	9	0.47

Conclusion: In this trial, QX001S demonstrated a good PK and safety profile in healthy male subjects comparable to that of ustekinumab. In addition, the rate of ADA-positive subjects in the QX001S group was lower than that in the ustekinumab group. Based on the trial results, we have initiated a Phase III clinical trial in China to further evaluate QX001S for the treatment of moderate-to-severe plaque Ps.

Material Communications and Next Steps

We received an IND approval of QX001S for the treatment of moderate-to-severe plaque Ps from the NMPA in January 2018. Zhongmei Huadong, a subsidiary of Huadong Medicine and our commercialization partner for QX001S, and we completed the Phase III clinical trial for this indication in June 2023. Zhongmei Huadong submitted a BLA in China in July 2023, which was accepted by the NMPA in August 2023 and under review as of the Latest Practicable Date. According to Frost & Sullivan, QX001S was the first and only ustekinumab biosimilar candidate that had been submitted for a BLA in China as of the Latest Practicable Date. Zhongmei Huadong and we plan to initiate the commercial launch of QX001S in China for the treatment of Ps upon expected BLA approval in the fourth quarter of 2024. As of the Latest Practicable Date, we had not received any relevant regulatory agency’s concerns or objections to our clinical development plans and no material adverse changes had occurred since we obtained the IND approval.

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Inflammatory Bowel Disease

Ustekinumab, the reference drug of QX001S, was first approved by the FDA for the treatment of CD in 2016 and for the treatment of UC in 2019. We, together with our commercialization partner Zhongmei Huadong, plan to develop QX001S, an anti-IL-12/IL-23p40 antibody and an ustekinumab biosimilar, for the treatment of UC/CD. During our joint development with Zhongmei Huadong of QX001S in China for indications other than Ps, Zhongmei Huadong shall be responsible for any expenses related to the clinical trials and regulatory communication and registration for QX001S; we shall be responsible for expenses related to the sample production and process development and optimization prior to the commercialization of QX001S. See “—Collaboration with Zhongmei Huadong—QX001S Framework Agreement” for details of our collaboration with Zhongmei Huadong. See “—QX004N—Inflammatory Bowel Disease” below for details of UC and CD.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET QX001S SUCCESSFULLY.

QX004N

QX004N, a recombinant humanized IgG1 monoclonal antibody targeting the p19 subunit of IL-23, is an innovative drug candidate indicated for Ps and CD. IL-23p19 has emerged as a key target associated with superior efficacy for Ps patients with more severe symptoms or inadequate response to existing treatments and has a more dominant role than IL-12 in causing CD. Specifically, blocking the signaling of IL-23 may lead to better clinical benefits than blocking the signaling of both IL-23 and IL-12, primarily because the immune response and surveillance mediated by IL-12 are preserved. Additionally, it has been reported to be a target with favorable safety profile that is suitable for long-term use.

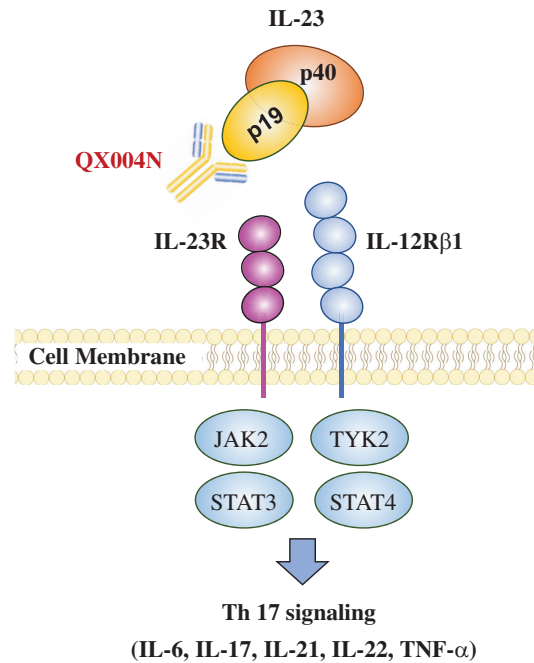
We obtained an IND approval for QX004N for the treatment of Ps and CD from the NMPA in August 2021 and November 2022, respectively. We completed a Phase Ia clinical trial of QX004N in healthy subjects for the Ps indication in China in September 2023 and QX004N showed a good safety profile. As of the Latest Practicable Date, we also commenced a Phase Ib clinical trial and a Phase II clinical trial in China to evaluate QX004N for this indication and expect to complete them in the second quarter of 2024 and the first half of 2025, respectively. As of the Latest Practicable Date, we also commenced a Phase Ia clinical trial in healthy subjects for the treatment of CD in China, which we expect to complete in the first quarter of 2024. In addition, we may investigate QX004N for further indication expansion to UC.

Mechanism of Action

IL-23 drives Th17 cell differentiation by binding and signaling through its receptor complex composed of two subunits, *i.e.*, IL-12R β 1, which binds to the p40 subunit of IL-23, and IL-23R, which binds to the p19 subunit of IL-23. Th17 cells are characterized by the production of a group of cytokines, such as IL-6, IL-17A, IL-17F, IL-21 and IL-22. Particularly, IL-17A and IL-17F signal through the IL-17 receptor (IL-17R) complex to induce

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the production of pro-inflammatory cytokines, which drives the inflammatory response in psoriasis lesions. This suggests that the IL-23/IL-17 pathway plays an important role in the pathogenesis of psoriasis. By binding to the p19 subunit of IL-23, QX004N blocks the binding between IL-23 and IL-23R and the corresponding signal transduction, which inhibits the development of Th17 cells and leads to reduced production of IL-17 cytokines. The diagram below illustrates the mechanism of action of QX004N, which is designed to bind to IL-23p19 and block the binding between IL-23 and IL-23R.



Source: the Company

Psoriasis

Due to the chronic and relapsing nature of Ps, there is an unmet medical need for new Ps drugs with a superior efficacy and safety profile suitable for long-term disease management. We believe QX004N will be a promising alternative for Ps patients as drugs targeting IL-23p19 are expected to show an improved efficacy profile with higher potency than those targeting IL-12/IL-23p40. Additionally, it has been reported to be a target with favorable safety profile that is suitable for long-term use. Together with QX001S, we hope to improve accessibility of the two drug candidates and establish a comprehensive coverage of Ps patients who experience different levels of disease severity and have different abilities to pay.

We completed a Phase Ia clinical trial of QX004N in healthy subjects for the Ps indication in China in September 2023 and QX004N showed a good safety profile. As of the Latest Practicable Date, we had commenced a Phase Ib clinical trial and a Phase II clinical trial in China to evaluate QX004N for this indication and expect to complete them in the second quarter of 2024 and the first half of 2025, respectively.

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Market Opportunity and Competition

For details of the prevalence of Ps in China and its current treatments, as well as the competitive landscape of biologic drugs for Ps, see “Industry Overview—Overview of the Autoimmune Disease Drug Market—Major Autoimmune Diseases—Psoriasis” and “—QX001S—Market Opportunity and Competition” above.

Our Advantages

We believe QX004N has the following potential advantages in comparison with the approved drugs and drug candidates targeting Ps:

- Potentially better efficacy profile. The IL-12/IL-23 axis is one of the many proposed mechanistic pathways of Ps, with IL-23 reported to be the key player in the alleviation of inflammation. IL-23p19 inhibitors have shown favorable efficacy results in clinical studies. For example, in the PsO-1 and PsO-2 clinical trials in 406 and 392 adult patients with plaque Ps, respectively, subjects receiving risankizumab, an IL-23p19 inhibitor, achieved PASI 90 (75% and 75%, respectively) and static Physician’s Global Assessment (sPGA, which is used to determine the overall severity of a patient’s disease at a given point in time) level of 0 or 1 (88% and 84%, respectively) at week 16. Additionally, IL-23p19 inhibitors have been reported to maintain effective in long-term use. In the VOYAGE 1 and VOYAGE 2 clinical trials in 837 and 992 patients with moderate-to-severe Ps, respectively, response rates as measured by the proportions of subjects achieving PASI 75, PASI 100, IGA level of 0 or 1 and IGA level of 0 were maintained in subjects receiving guselkumab, another IL-23p19 inhibitor, from week 52 through week 204. QX004N showed a good safety profile based on preliminary results from our Phase Ia clinical trial. In addition, as IL-23 promotes differentiation of naïve T helper cells to Th17 cells, a subset of effector Th cells characterized by the production of multiple pro-inflammatory cytokines, including IL-17, IL-21, IL-22 and IL-26, selective blockade of the specific p19 subunit of IL-23 is able to act upstream in the IL-23/IL-17 cytokine pathway as compared to the more distant blockade of IL-17A or its receptor. For example, the ECLIPSE trial in 1,048 patients with moderate-to-severe plaque Ps showed that guselkumab had superior long-term efficacy in comparison with secukinumab, an IL-17A inhibitor, in terms of the proportion of patients with a PASI90 response at week 48.
- Commercialization synergy between QX001S and QX004N. We plan to rapidly develop and commercialize QX001S in collaboration with Huadong Medicine. In doing so, we expect to create development and commercialization synergy for QX004N as both are indicated for Ps. We believe that QX004N, as a promising drug candidate for Ps with a potentially improved efficacy and safety profile, could also benefit from the commercialization network and market acceptance that we will establish for QX001S.

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Summary of Clinical Trial Results

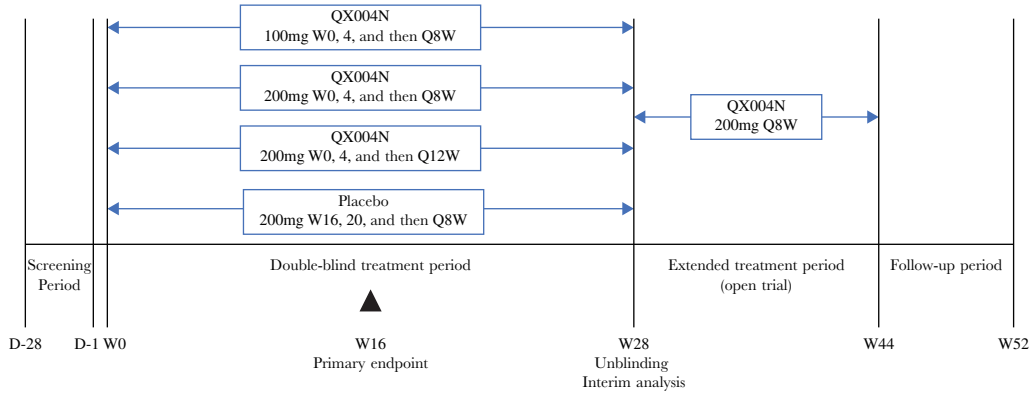
We commenced a Phase Ia clinical trial in healthy subjects, a Phase Ib clinical trial in adult patients with moderate-to-severe plaque Ps and a Phase II clinical trial in adult patients with moderate-to-severe plaque Ps to evaluate QX004N for the Ps indication in China in November 2021, February 2023 and September 2023, respectively. We completed the Phase Ia clinical trial in September 2023. The Phase Ib trial and Phase II trial were ongoing as of the Latest Practicable Date and we expect to complete them in the second quarter of 2024 and the first half of 2025, respectively.

Ongoing Phase II Clinical Trial

The Phase II clinical trial in China is a multi-center, randomized, double-blind and placebo-controlled clinical study in adult patients with moderate-to-severe plaque Ps to evaluate the efficacy, safety, PK and PD profile of QX004N.

Trial design: The primary endpoint of this trial is the proportion of subjects who experience PASI90 at week 16. The secondary endpoints include safety and tolerability, PK, immunogenicity, PD and efficacy parameters, including (i) the proportion of subjects who experience PASI75 at week 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44, 48 and 52; (ii) the proportion of subjects who experience PASI90 at week 4, 8, 12, 20, 24, 28, 32, 36, 40, 44, 48 and 52; (iii) the proportion of subjects who experience PASI100 at week 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44, 48 and 52; (iv) the proportion of subjects who achieve IGA level of 0 or 1 at week 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44, 48 and 52; (v) the proportion of subjects who achieve IGA level of 0 at week 8, 16, 28, 40 and 52; (vi) improvement in BSA assessments at week 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44, 48 and 52; and (vii) improvement in DLQI score at week 4, 8, 12, 16, 28, 40 and 52. We plan to enroll a total of 160 patients, who will be assigned to 4 groups (including 3 treatment groups and 1 control group) with 40 patients in each group. There will be two treatment periods in this trial, including the double-blind treatment period (from week 0 to week 28) and extended treatment period (from week 28 to week 44). During the double-blind treatment period, the first treatment group will receive QX004N at 100 mg at week 0 and 4 and then Q8W until week 28; the second treatment group will receive QX004N at 200 mg at week 0 and 4 and then Q8W until week 28; the third treatment group will receive QX004N at 200 mg at weeks 0 and 4 and then Q12W until week 28; and the control group will receive placebo at week 0, 4 and 12 and then receive QX004N at 200 mg at week 16, 20 and 28. During the extended treatment period, all four groups will receive QX004N at 200 mg Q8W until week 44. After week 44, there will be a follow-up period of eight weeks. The chart below summarizes the design of this trial.

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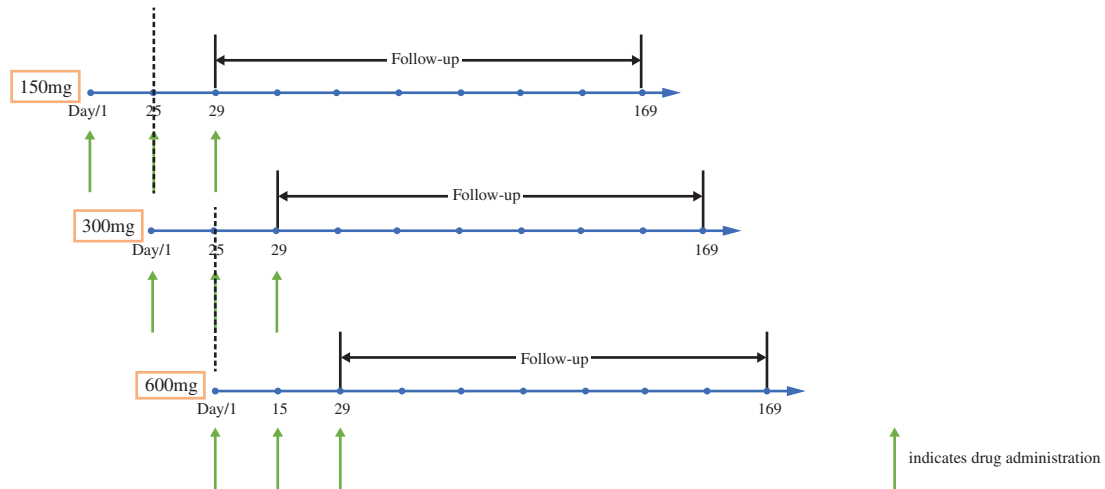
Trial status: Subject enrollment commenced in September 2023 and was completed in January 2024. A total of 160 subjects were enrolled, including 40 in each of the three treatment groups and the control group. We expect to complete this trial in the first half of 2025.

Ongoing Phase Ib Clinical Trial

The Phase Ib clinical trial in China is a multi-center, randomized, double-blind, multi-ascending-dose and placebo-controlled clinical study in adult patients with moderate-to-severe plaque Ps to evaluate the safety, tolerability, efficacy and PK profile of QX004N.

Trial design: The primary endpoints of this trial included safety and tolerability of QX004N in adult patients with moderate-to-severe plaque Ps. The secondary endpoints included PK parameters, immunogenicity and efficacy parameters, including (i) the proportion of subjects who experience PASI75 at week 12 as the primary efficacy measure, (ii) average improvement in PASI at week 2, 4, 8, 12, 16, 20 and 24, (iii) the proportion of subjects who experience PASI75, PASI50, PASI90 and PASI100 at week 2, 4, 8, 12, 16, 20 and 24, (iv) the proportion of subjects who achieve IGA level of 0 or 1 at week 2, 4, 8, 12, 16, 20 and 24, (v) improvement in BSA (body surface area affected by Ps) assessments at week 2, 4, 8, 12, 16, 20 and 24, and (vi) improvement in DLQI score at week 2, 4, 8, 12, 16, 20 and 24. We planned to enroll a total of 30 patients, who would be assigned to three groups with ten patients in each group (eight receiving QX004N and two receiving placebo). Each group would receive three doses of either QX004N or placebo at their designated dose level (150 mg, 300 mg and 600 mg, respectively), to be administered on day 1, day 15 and day 29, followed by safety follow-up until day 169. The trial would proceed from one dose level to the next only if the evaluation of tolerability and safety on the previous dose level group on day 15 has been completed. In the event where termination may be warranted, the sponsor and investigator would determine whether to terminate the trial or resume the trial with the median level of the previous and current dose levels. The chart below summarizes the design of this trial.

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Trial status: Subject enrollment commenced in February 2023 and was completed in June 2023. We enrolled a total of 30 subjects, including 10 subjects (8 receiving QX004N and 2 receiving placebo) in each of the 150 mg, 300 mg and 600 mg groups. We expect to complete the Phase Ib clinical trial in the second quarter of 2024.

Phase Ia Clinical Trial

The Phase Ia clinical trial in China was a single-center, randomized, double-blind, single-ascending-dose and placebo-controlled clinical study in healthy subjects to evaluate the PK profile, safety, tolerability and immunogenicity of QX004N.

Trial design: The primary endpoints of this trial included safety and tolerability of QX004N in healthy subjects. The secondary endpoints included PK parameters and immunogenicity. We planned to enroll a total of 45 subjects, who would be assigned to five groups with five subjects in the first group (four receiving QX004N and one receiving placebo) and ten subjects in each of the other four groups (eight receiving QX004N and two receiving placebo). The trial would start with the first group receiving a single subcutaneous injection of 10 mg and the subsequent four groups each receiving an increased single dose of 50 mg, 100 mg, 300 mg and 600 mg, respectively. Each subject would receive only one corresponding dose of QX004N (or placebo). The trial would proceed from one dose level to the next only if safety of the previous dose level is confirmed after a two-week evaluation period upon drug administration. In the event where termination may be warranted, the sponsor and the investigator would determine whether to terminate the trial or resume the trial with the median level of the previous and current dose levels.

Trial status: This trial was initiated in November 2021 and completed in September 2023. We enrolled a total of 55 subjects. In the 10 mg group, we enrolled five subjects with four receiving QX004N and one receiving placebo. In each of the 50 mg, 100 mg and 600 mg group, we enrolled ten subjects with eight receiving QX004N and two receiving placebo. For the 300 mg group, we enrolled 20 subjects with 16 receiving QX004N and four receiving placebo, as the initial data collection of this dose level halted due to the COVID-19 pandemic and it was later reassessed to meet the requirements for this trial.

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Safety results: In this trial, QX004N was well-tolerated and its safety profile was good. 43 (78.2%) subjects in the safety analysis set reported AEs, among which 34 (61.8%) subjects reported ADRs. One AE of CTCAE Grade 3 was reported in the 10 mg group that was possibly unrelated to the drug. The subject was reported to have elevated blood triglycerides and later recovered without treatment. All other AEs observed in this trial were of CTCAE Grade 1 or 2. There was one SAE reported in the 300 mg group that was possibly unrelated to the drug. The subject was reported to have a miscarriage and later physically recovered. No other SAEs or death were observed in this trial. No significant difference was observed in terms of safety between the QX004N groups and the control group and there was no significant correlation between the incidence of AEs and ascending dosage levels.

PK: The plasma exposure of QX004N in healthy subjects showed an increasing trend as the dose level increased from 10 mg to 600 mg following a single subcutaneous administration, suggesting a linear PK.

Immunogenicity: In this trial, seven (15.9%) subjects in the QX004N groups were reported ADA-positive after treatment. Subjects who were ADA-positive before treatment did not experience increases in antibody levels after treatment. No impact of immunogenicity on safety was found in this trial.

Conclusion: In this trial, QX004N was safe and well-tolerated in healthy subjects in the dose range from 10 mg to 600 mg. The plasma exposure of QX004N in healthy subjects also showed an increasing trend as the dose level increased, suggesting a linear PK.

Summary of Preclinical Study Results

As of the Latest Practicable Date, we had conducted a series of preclinical studies to characterize the PD, PK and toxicity of QX004N. Overall, QX004N has demonstrated high potency, comparable to risankizumab and better than guselkumab. Our *in vivo* studies in a Ps mouse model showed that QX004N (10 mg/kg, 3 mg/kg and 1 mg/kg) could effectively reduce ear thickness, ear weight and protein level of IL-17 and IL-22 in the mice. QX004N (10 mg/kg and 3 mg/kg) could also effectively decrease epidermal thickness, lymphocyte infiltration and the comprehensive pathological score. The effective dose of QX004N in this study was 1 mg/kg and there was a dose-dependent relationship within the dose range from 1 mg/kg to 10 mg/kg. At the same dose level (10 mg/kg), risankizumab and QX004N had comparable PD effects.

Material Communications and Next Steps

We obtained an IND approval for QX004N for the treatment of Ps from the NMPA in August 2021. We expect to complete the ongoing Phase Ib clinical trial and Phase II clinical trial in China in the second quarter of 2024 and the first half of 2025, respectively. As of the Latest Practicable Date, we had not received any relevant regulatory agency's concerns or objections to our clinical development plans and no material adverse changes had occurred since we obtained the IND approval.

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Inflammatory Bowel Disease

Inflammatory bowel disease (IBD) is a broad term that describes conditions characterized by chronic inflammation of the gastrointestinal tract. The two most common types of IBD are UC and CD. UC is characterized by mucosal inflammation limited to the colon which involves the rectum in approximately 95% of cases and may extend to parts or all of the large intestine. In contrast, CD is characterized by full thickness inflammation that can occur anywhere in the digestive tract but most typically involves the terminal ileum and colon. Symptoms for UC and CD can vary, depending on the location and severity of inflammation, but some of the most common are diarrhea, abdominal cramps and rectal bleeding. IBD is a chronic inflammatory condition that requires lifelong treatment, which usually involves either drug therapy, including anti-inflammatory drugs, immunomodulators and biologics, or surgery.

Ulcerative Colitis

Aminosalicylic acids, also known as 5-ASA, are the standard of care for the first-line treatment of adult UC. Aminosalicylic acids, which control the inflammatory process and thus allow damaged tissue to heal, are largely effective for mild-to-moderate disease. Corticosteroids are often effective for patients with moderate-to-severe UC, but safety concerns preclude their long-term use. Moderate-to-severe UC patients in the United States are provided with more treatment options, including biologic therapies, compared to patients in China, where there remains significant unmet need. As of the Latest Practicable Date, vedolizumab, infliximab and infliximab biosimilars were the only biologic therapies that had been approved for treating UC in China.

Crohn’s Disease

Choice of treatment for CD is based on the overall evaluation of the disease condition, such as infection status. For patients with mild disease, treatment options include aminosalicylic acids and budesonide. For patients with moderate disease, corticosteroids are the primary systemic treatment option, while immunosuppressants can be used for maintenance therapy. For severe disease, biologics are the primary treatment options.

We are developing QX004N for the treatment of moderate-to-severe CD. Similar to the case of psoriasis, IL-23 has a more dominant role than IL-12 in causing CD. Specifically, blocking the signaling of IL-23 may lead to better clinical benefits than blocking the signaling of both IL-23 and IL-12, primarily because the immune response and surveillance mediated by IL-12 are preserved. We commenced a Phase Ia clinical trial in February 2023.

In addition to QX004N, to address the vast and underserved market demand for more effective, safe and affordable drugs for moderate-to-severe UC/CD, we are also developing QX001S, an anti-IL-12/IL-23p40 antibody with different mechanism and benefit from QX004N, for the treatment of UC/CD. See “—QX001S—Inflammatory Bowel Disease” above for details.

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Market Opportunity and Competition

The number of CD patients in China increased from 120,400 in 2018 to 173,500 in 2022 at a CAGR of 9.6%, and is estimated to reach 271,700 in 2030, at a CAGR of 5.8% from 2022 to 2030. The significantly overlapping UC/CD drugs market in China grew rapidly in recent years, from US\$594.3 million in 2018 to US\$1,051.2 million in 2022, representing a CAGR of 15.3%, and is estimated to reach US\$5,490.1 million in 2030, representing a CAGR of 23.0% from 2022 to 2030. Biologic drugs accounted for 13.7% of the UC/CD drugs market in China in 2022, which is estimated to increase to 55.9% in 2030.

Medications indicated for moderate-to-severe CD mainly include corticosteroids, immunosuppressants and biologics. However, a large portion of the patients who initially respond to corticosteroid therapy develop a dependency on corticosteroids or have a relapse within 1 year. In addition, use of corticosteroids is often limited by a relatively high risk of serious adverse effects including bone loss, metabolic complications, increased intraocular pressure and glaucoma and potentially lethal infections. While both biologics and immunosuppressants are particularly useful when patients are not responsive to corticosteroid for induction or relapse prevention, biologics have been demonstrated in studies to achieve higher response rate with less flare up and side effect rates compared to immunosuppressants. As of the Latest Practicable Date, biologics have been recommended as a main treatment option for UC/CD by prevailing clinical guidelines.

There are three types of approved biologic drugs in China for the treatment of CD, namely, TNF- α inhibitors, integrin α 4 (ITGA4)/integrin β 7 (ITGB7) inhibitors and IL-12/IL-23 inhibitors. TNF- α inhibitors block the binding of TNF to TNF receptors, thereby suppressing their biological effects. Integrin α 4/integrin β 7 inhibitors bind to the surface of white blood cells so they cannot pass through tissue layers and exacerbate inflammation. However, use of certain integrin α 4/integrin β 7 inhibitors carries an increased risk of progressive multifocal leukoencephalopathy, a severe brain condition. In contrast, IL-23 inhibitors have exhibited strong safety profile while maintaining satisfactory efficacy. However, all such classes of biologics are likely to result in drug-resistance, forcing CD patients to switch between such types of biologics to prolong treatment.

As of the Latest Practicable Date, there were 12 biologic drugs for CD approved in China, including ten TNF- α inhibitors (including infliximab, adalimumab, three infliximab biosimilars and five adalimumab biosimilars), one integrin α 4/integrin β 7 inhibitor and one IL-12/IL-23 inhibitor, namely, ustekinumab. See “—QX001S—Background of Reference Drug” for details of ustekinumab. The TNF- α inhibitors, integrin α 4/integrin β 7 inhibitors and IL-12/IL-23 inhibitors are expected to continue to be mainstream biologic treatments for CD in the near future. As of the same date, there were eight biologic drug candidates for CD in the clinical stage in China, five of which are IL-12/IL-23 inhibitors or IL-23 inhibitors. The following tables set forth details of QX004N as well as the approved biologic drugs and biologic drug candidates for CD in clinical stage in China as of the Latest Practicable Date.

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Marketed Targeted Biologics for CD in China						
Target	Brand Name	INN	Company	Median Price ⁽¹⁾	NMPA Approval Time	NRDL Inclusion
IL-12/IL-23	Stelara	Ustekinumab	Janssen (J&J)	4,318	2020	Yes
	Remicade	Infliximab	Janssen (J&J)	2,007	2006	Yes
TNF- α	QLETLI (格乐立)	Adalimumab-BAT1406	Bio-Thera	1,080	2019	Yes
	Anjianning (安健宁)	Adalimumab-HS016	Hisun	1,148	2019	Yes
	Humira	Adalimumab	AbbVie	1,290	2020	Yes
	SULINNO (苏立信)	Adalimumab-IBI303	Innovent	1,088	2020	Yes
	Leiting (类停)	Infliximab-CMAB008	MabPharm	1,268	2021	Yes
	Anbaite (安佰特)	Infliximab-HS626	Hisun	1,268	2021	Yes
	Jiayoujian (佳佑健)	Infliximab-GB242	Yuxi Genor Biotechnology	1,280	2022	Yes
	Junmaikang (君迈康)	Adalimumab-UBP1211	Junshi Bioscience	998	2022	Yes
Integrin α 4/ Integrin β 7	安佳润®	Adalimumab-SCT630	SinoCelltech	N/A	2023	No
	Entyvio	Vedolizumab	Takeda	4,980	2020	Yes

Note:

- (1) Reflects the NRDL median price per minimum formulation unit in 2022 in RMB.

Clinical-Stage Biologic Drug Candidates for CD Treatment in China				
Target	Drug Code	Company	Status	First Posted Date
IL-12, IL-23	Ustekinumab-BAT2206	Bio-Thera	Phase I	2020-05-06
	Risankizumab	AbbVie	BLA submission ⁽¹⁾	2023-07-06
IL-23	LY3074828	Eli Lilly	Phase III	2020-04-24
	Guselkumab	Janssen (J&J)	Phase III	2020-06-08
	QX004N	the Company	Phase I	2022-12-28
TNF- α	Adalimumab-TQZ2301	Chia Tai Tianqing	Phase I	2018-11-13
TNFSF15	PF-06480605	Pfizer	Phase I	2021-11-17
Undisclosed	HZBio2	Grand pharma	Phase I	2022-05-16

Source: Frost & Sullivan Report (based on annual reports of relevant companies and information published by the NMPA)

Note:

- (1) AbbVie has not announced the specific indication for BLA submission of Risankizumab for UC/CD.

Our Advantages

CD is a chronic inflammatory condition that requires lifelong treatment. The demand for biologic drugs is increasing as a result of rising disease prevalence. With the first IL-12/IL-23 inhibitor approved for treating CD in China 2020, IL-12/IL-23 inhibitors have emerged as an important modality for treating CD, leveraging their important roles in the regulation of tissue inflammation. With its potentially better efficacy profile, we expect that our QX004N will become a favorable option for patients with moderate-to-severe CD. See “—Psoriasis—Our Advantages.”

Summary of Clinical Trial

We commenced a Phase Ia clinical trial of QX004N for CD through intravenous injection in China in February 2023, which was ongoing as of the Latest Practicable Date and is expected to be completed in the second quarter of 2024.

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Trial design: The Phase Ia clinical trial is a single-center, randomized, double-blinded, placebo-controlled and single ascending-dose clinical study to evaluate the PK, safety, tolerability and immunogenicity of intravenous injection of QX004N in healthy subjects. The primary endpoints of this trial include safety and tolerability of intravenous injection of QX004N in healthy subjects. The secondary endpoints include PK parameters and immunogenicity of intravenous injection of QX004N and to recommend dosing regimens for the Phase II clinical trials. The exploratory endpoints include PD parameters of intravenous injection of QX004N in these subjects. We plan to enroll a total of 40 participants, who will be assigned to 5 groups with 8 participants in each group (6 receiving QX004N and 2 receiving placebo). The trial will start with the first group receiving a single intravenous injection of 300 mg and the subsequent four groups each receiving an increased single dose of 600 mg, 900 mg, 1200 mg and 1600 mg, respectively. Each participant will receive only one corresponding dose of QX004N (or placebo). The trial will proceed from one dose level to the next only if the safety of such previous dose level is confirmed after a 15-day follow-up period. In the event where termination may be warranted, the sponsor and the investigator will determine whether to terminate the trial or resume the trial with the median level of the previous and current dose levels.

Trial status: Subject enrollment commenced in February 2023 and was completed in August 2023. A total of 41 subjects were enrolled, including 6 receiving QX004N and 2 receiving placebo in each of the 300 mg, 600 mg, 900 mg, 1200 mg and 1600 mg groups and one withdrawn from the study. We had completed drug administration for all subjects as of the Latest Practicable Date.

Summary of Preclinical Study Results

We conducted a series of preclinical studies to characterize the PD, PK and toxicity of QX004N, which demonstrated that QX004N has potency comparable to risankizumab and superior to guselkumab. See “—Psoriasis—Summary of Preclinical Study Results.”

Material Communications and Next Steps

We obtained the IND approval of the Phase I, Phase II and Phase III clinical trials of QX004N for treatment of CD from the NMPA in November 2022. As of the Latest Practicable Date, we were conducting the Phase Ia clinical trial of QX004N for CD in China and had completed drug administration of all subjects. We plan to complete the Phase Ia clinical trial in China in the second quarter of 2024 and initiate a Phase Ib clinical trial in China depending the data from the Phase Ia clinical trial to evaluate the safety, efficacy, PK and tolerability of multiple intravenous injections of QX004N in adult patients with CD. As of the Latest Practicable Date, we had not received any relevant regulatory agency’s concerns or objections to our clinical development plans. No material adverse changes had occurred since we obtained the IND approval and up to the Latest Practicable Date.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET QX004N SUCCESSFULLY.

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QX006N

QX006N is one of the only two IFNAR1 inhibitors developed by Chinese domestic companies that had entered the clinical stage for SLE in China as of the Latest Practicable Date. Clinical research in SLE therapeutics has been met with limited success in recent years. SAPHNELO (anifrolumab), a first-in-class IFNAR1 inhibitor, was approved by the FDA in 2021, making it the only new SLE treatment in more than 10 years. The type I IFNs are a group of pleiotropic (having multiple traits) cytokine affecting a wide variety of immune cells. They are involved in multiple aspects of lupus etiology and pathogenesis and exert their bioeffect by binding to their common receptor. Anifrolumab had demonstrated clear clinical benefit in patients with moderate-to-severe SLE in previous studies. As of the Latest Practicable Date, there was no IFN receptor antibody approved by the NMPA for SLE treatment and only one such drug approved by the FDA, indicating a huge market potential for such drugs.

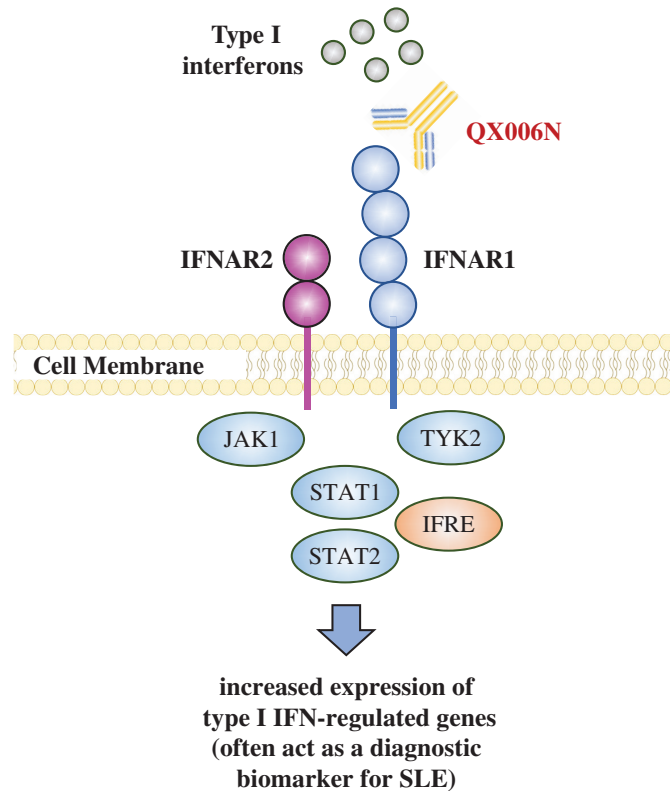
We received IND approval of QX006N for SLE from the NMPA in September 2021. We completed our Phase Ia clinical trial in healthy subjects in July 2023. As of the Latest Practicable Date, we had initiated a Phase Ib clinical trial in SLE patients.

Mechanism of Action

SLE is a highly heterogeneous, multiorgan autoimmune disease characterized by the overproduction of diverse autoantibodies. Autoantibodies attack one’s own body tissues and form antigen-antibody complexes that could be deposited to multiple organs or tissues throughout the body, triggering a complex chain reaction leading to local inflammatory responses. Although the etiology of SLE is not fully understood and likely to be multifactorial, Type I IFNs, particularly IFN- α , have been established to be pivotal to the disease pathogenesis. In SLE patients, IFN- α could amplify the inflammatory responses and fuel autoimmunity through its interactions with a host of immune cells, including, among others, facilitating the differentiation of B cells into autoantibody-producing plasma cells and promoting the maturation of dendritic cells (DCs) as the key antigen-presenting cells that help activate autoreactive T helper cells and B cells.

Type I IFNs signal through their common receptor complex, comprised of subunits IFNAR1 and IFNAR2, on the cell surface, resulting in the activation of the pro-inflammatory Janus kinase-signal transducers and activators of transcription (JAK/STAT) signaling pathway. QX006N is a humanized IgG4 mAb that is designed to specifically bind to the type I IFN receptor, in particular, IFNAR1, thereby blocking the signal pathway and biological functions of IFNs. The following diagram illustrates the mechanism of action of QX006N.

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Source: the Company

Systemic Lupus Erythematosus

Systemic lupus erythematosus (SLE) is an autoimmune disease associated with substantial morbidity and mortality. It is the most common type of lupus, characterized by widespread inflammation and tissue damage in the affected organs. SLE patients may experience a variety of symptoms such as fatigue, skin rashes, fevers and pain or swelling in the joints. The severity of symptoms varies from patient to patient, ranging from mild to life-threatening. SLE could also affect multiple organs in the patient, including the brain, lungs and, most commonly, the kidneys. Lupus nephritis (LN) is the most common severe complication of SLE.

There is no cure for SLE and currently available treatments aim to provide symptom relief. We are developing QX006N, a humanized mAb targeting the receptor for type I interferons (IFNs), a key mediator of the human immune system, for the treatment of SLE.

Market Opportunity and Competition

According to Frost & Sullivan, the SLE patient population in China reached approximately 1 million in 2022 and is expected to remain relatively stable over the next decade.

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The types of drugs that have been used to treat SLE mainly include corticosteroids, traditional DMARDs (such as hydroxychloroquine), NSAIDs and biologic drugs. Corticosteroids are recommended as initial treatment for SLE patients. Low-dose corticosteroids, hydroxychloroquine or NSAIDs are recommended for patients with mild symptoms. For SLE patients with more severe conditions, combined therapies of corticosteroids, biologic drugs and traditional DMARDs are recommended. High doses of corticosteroids can be helpful in severe cases of SLE, but the patients face considerable risk of disease progression, relapse over time and serious side effects, including osteoporosis (weak bones), high blood pressure and diabetes. In addition, treatment with traditional DMARDs may result in an increased risk of serious infections and certain types of cancer. Hydroxychloroquine may offer relief for SLE-related symptoms, such as arthritis, fatigue and rashes, but is associated with increased risk of retinopathy. There remain significant unmet needs for new therapeutics for SLE that effectively control disease activity, have a favorable safety profile and improve the patients’ quality of life.

Over the past decades, there has been growing interest in the development of biologic drugs indicated for SLE, including, most importantly, B cell depletion therapies aiming to inhibit autoreactive B cell activation and autoantibody production, and IFN receptor inhibitors. According to Frost & Sullivan, the market for biologic drugs for SLE in China is estimated to increase from US\$111.5 million in 2022 to US\$2.4 billion in 2030, representing a CAGR of 46.5%. We believe QX006N will primarily compete with IFNAR1 inhibitors and other biologic drugs in China.

As of the Latest Practicable Date, there were two approved B cell depletion therapies in China indicated for SLE, namely, belimumab and telitacept. Belimumab is a human monoclonal antibody that inhibits B lymphocyte stimulator (BLyS), also known as B cell activating factor (BAFF), a member of the TNF cytokine family produced by myeloid lineage cells, such as DCs and macrophages, and a key factor in the differentiation and survival of B cells. Telitacept targets two cell-signaling molecules critical for B cell development: BLyS and a proliferation inducing ligand (APRIL). Belimumab was approved by the FDA in 2011, making it the first new drug approved for SLE treatment in more than 50 years.

However, studies have found that the survival of certain types of B cells involved in the autoimmune responses, such as memory B cells and long-lived plasma cells, are independent of BLyS or APRIL, suggesting potential limits in the depletion effect of BLyS or APRIL inhibitors. Patients under BLyS or APRIL inhibition therapies showed considerable variability in their responses in several clinical trials. Considering the substantial heterogeneity of SLE pathogenesis, BLyS or APRIL inhibitors may be effective in certain subsets of patients while ineffective in others and there is no reliable objective marker to predict patients’ response.

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As of the Latest Practicable Date, only one IFN receptor inhibitor, anifrolumab, had been approved by the FDA for SLE and no drug of the same target had been approved for SLE by the NMPA. As of the same date, in addition to our QX006N, there were 15 biologic drug candidates for SLE in the clinical stage in China, two of which were IFNAR1 inhibitors. Other targets under investigation include BAFF and various membrane/transmembrane proteins, such as CD38 and CD22. The following table sets forth details of QX006N and biologic drugs and drug candidates in the clinical stage for SLE in China as of the Latest Practicable Date.

Marketed Targeted Biologics for SLE in China

Target	Brand Name	INN	Company	NMPA Approval Time	Median Price ⁽¹⁾	NRDL Inclusion
BAFF	Benlysta	Belimumab	GSK	2019	727.5	Yes
BAFF/APRIL	Tai'ai (泰愛)	Telitacicept	Remegen	2021	818.8	Yes

Clinical-Stage Biologic Drug Candidates for SLE in China

Target	Drug Code	Company	Status	First Posted Date
IFNAR1	Anifrolumab	AstraZeneca	Phase III	2021-08-09
	GR1603	Genrix Bio	Phase I/II	2021-12-03
	QX006N	the Company	Phase I	2021-11-23
BAFF	UBP1213sc	Junshi Bioscience	Phase I	2022-02-18
BAFFR	VAY736	Novartis	Phase III	2023-01-09
CLEC4C	BIIB059	Biogen; Vetter Pharma-Fertigung	Phase III	2022-06-07
CD20	Obinutuzumab	Roche	Phase III	2022-10-27
	MIL62	Mabworks	Phase II/III	2023-02-08
CD40L	Dapirolizumab Pegol	UCB Pharma	Phase III	2022-11-07
	IBI355	Innovent Bio	Phase I	2023-10-19
CD38	CM313	Keymed Bioscience	Phase I/II	2022-07-08
	SG301	Shangjian Biotech	Phase I	2023-11-06
CD22	SM03	Longrui	Phase I	2015-01-07
CD79B, FCGR2B	PRV-3279	Zhongmei Huadong	Phase II	2023-08-02
Undisclosed	SHR-2001	Hengrui	Phase I	2023-07-10
APRIL, BAFF	ALPN-303	Ajinomoto Bio-Pharma	Phase I	2023-12-22

Source: Frost & Sullivan Report (based on annual reports of relevant companies and information published by the NMPA)

Note:

(1) Reflects the NRDL median price for minimum formulation unit in 2022 in RMB.

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Our Advantages

Taking into account the significant unmet needs for new therapeutics for SLE, we believe our QX006N, as an IFNAR1 antibody, has the potential to be a favorable option for SLE patients with a promising efficacy and safety profile. Anifrolumab, the FDA-approved IFNAR1 inhibitor, demonstrated clear clinical benefit in patients with moderate-to-severe SLE in a Phase III study (TULIP-2) and a Phase IIb study (MUSE). QX006N showed a good safety profile based on results from our Phase Ia clinical trial, and potency and affinity comparable to those of an internally prepared anifrolumab analog in our preclinical studies. See “—Summary of Clinical Trials” below for more details.

In addition, a large population of SLE patients in China have an urgent need for more affordable medical treatments as the currently available biologic treatments impose significant economic burden on patients with moderate income. According to Frost & Sullivan, in 2022, the estimated annual treatment cost of belimumab and telitacicept in China was around RMB49,000 to RMB52,000 and RMB85,000, respectively. However, leveraging our integrated R&D and manufacturing platform and cost control measures, we aim to provide QX006N at a competitive price.

Summary of Clinical Trials

We commenced a Phase Ia clinical trial in healthy subjects in December 2021 and completed such trial in July 2023. We also initiated a Phase Ib clinical trial in SLE patients in March 2023, which was ongoing as of the Latest Practicable Date.

Ongoing Phase Ib Clinical Trial

Trial design: The Phase Ib clinical trial in China is a multi-center, randomized, double-blind and placebo-controlled multiple-dose escalation trial in moderate-to-severe SLE patients. The primary objective of this trial is to evaluate the safety, tolerability and PK properties of multiple doses of QX006N in moderate-to-severe SLE patients. The secondary objectives are to evaluate the PD characteristics and immunogenicity of QX006N, and to determine a recommended dose for a Phase II clinical trial. A total of 30 patients are expected to be enrolled and assigned to three dose groups (150 mg group, 300 mg group and 600 mg group) with ten patients in each group. Within each group, eight patients would receive QX006N and two patients would receive placebo. Patients in each group would receive intravenous infusion of QX006N of the designated dose level (or placebo) on day 1, day 15 and day 29, and then proceed to a follow-up period till day 85. The trial will proceed from one dose level to the next only if the safety and tolerability of the previous dose level is confirmed by the evaluation on day 15.

Trial status: The Phase Ib clinical trial was initiated in March 2023. As of the Latest Practicable Date, we had enrolled 22 patients and we expect to complete patient enrollment in the first quarter of 2024.

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Phase Ia Clinical Trial

Trial design: The Phase Ia clinical trial in China was a single-center, randomized, double-blind and placebo-controlled single-dose escalation trial in healthy subjects. The primary objective of this trial was to evaluate the safety and tolerability of single escalating dose of QX006N in healthy subjects. The secondary objectives were to evaluate the PK and immunogenicity of QX006N, and to determine the recommended dose for a Phase Ib clinical trial. A total of 45 subjects would be assigned to five groups receiving single intravenous infusions of 0.3 mg/kg, 1.0 mg/kg, 3.0 mg/kg, 6.0 mg/kg and 10.0 mg/kg QX006N or placebo, respectively. Five subjects would be assigned to the 0.3 mg/kg group and ten subjects would be assigned to each of the remaining four dose groups. Within each dose group, the ratio of subjects receiving QX006N to those receiving placebo would be 4:1.

Trial status: The Phase Ia clinical trial was initiated in December 2021. We completed patient enrollment for the trial in August 2022, with a total of 55 subjects enrolled. Ten extra subjects were enrolled for the 3.0 mg/kg group as the data collection for the initially enrolled subjects were interrupted due to the COVID-19 pandemic. We completed the Phase Ia clinical trial in July 2023.

Safety results: QX006N was well-tolerated and showed a good safety profile in healthy subjects in all dose groups. No death, SAE or TEAE of grade 3 (severe or medically significant but not immediately life-threatening as defined in CTCAE 5.0) or above were reported. 27 (out of 44, 61.4%) subjects in QX006N groups and 6 (out of 11, 54.5%) subjects in the placebo group reported 63 TEAEs, none of which led to a subject's withdrawal from the trial. Most subjects recovered from such TEAEs without medical intervention. The overall incidence rate of TEAE in the QX006N groups (61.4%) was close to that of the placebo group (54.5%).

PK: In the dose range from 0.3mg/kg to 10.0mg/kg, with the increase of the dose level, the $T_{1/2}$ of QX006N showed an increasing trend before reaching a stable level. The clearance (L/h) gradually decreased with the increasing dose level. The C_{max} increased in a proportional manner with the increasing dose level, while AUC_{0-t} and AUC_{0-inf} increased in a greater-than-proportional manner with the increasing dose level.

Immunogenicity: for all groups (except the 0.3 mg/kg group and the placebo group), the ADA positive rates gradually increased with time, reaching their peak at D57 (62.5% to 87.5%). The ADA positive rates were similar across such dose groups. The 0.3 mg/kg dose group and the placebo group showed no significant increase in their ADA positive rates over time and had lower positive rates. Overall, QX006N exhibited certain immunogenicity compared to the placebo group.

Conclusion: The trial met its primary and secondary endpoints. In this trial, QX006N was well-tolerated in healthy subjects in all dose groups, and demonstrated a good safety profile, non-dose-proportional PK and certain level of immunogenicity compared to the placebo group.

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Summary of Preclinical Study Results

We conducted a series of preclinical studies in order to characterize the PD, PK and toxicity profile of QX006N. In our *in vitro* PD studies, QX006N demonstrated potency and affinity comparable to those of an internally prepared anifrolumab analog. In particular, in whole blood and THP-1 cells (a commonly used model for human monocytes), QX006N demonstrated suppressing effects comparable to that of anifrolumab analog on IFN- α -induced secretion of IP-10, which plays an important role in the pathological process of SLE. In our preclinical PK studies, QX006N exhibited nonlinear PK in cynomolgus monkeys over a dose range from 1 mg/kg to 30 mg/kg following single subcutaneous or intravenous administration. Systemic exposure (as measured by AUC) of QX006N increased in a greater-than-proportional manner with increasing dose. In our preclinical toxicological studies, QX006N demonstrated no obvious systemic toxicity. The MTD in single-dose intravenous-administration toxicity study of QX006N in cynomolgus monkeys was at least 600 mg/kg.

Material Communications and Next Steps

We received IND approval of the Phase I, Phase II and Phase III clinical trials of QX006N for SLE from the NMPA in September 2021. As of the Latest Practicable Date, we were conducting the Phase Ib clinical trial of QX006N for the treatment of SLE in China. We plan to complete the ongoing Phase Ib clinical trial in the fourth quarter of 2024. We have not received any relevant regulatory agency’s concerns or objections to our clinical development plans as of the Latest Practicable Date. No material adverse changes had occurred since we obtained the IND approval and up to the Latest Practicable Date.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET QX006N SUCCESSFULLY.

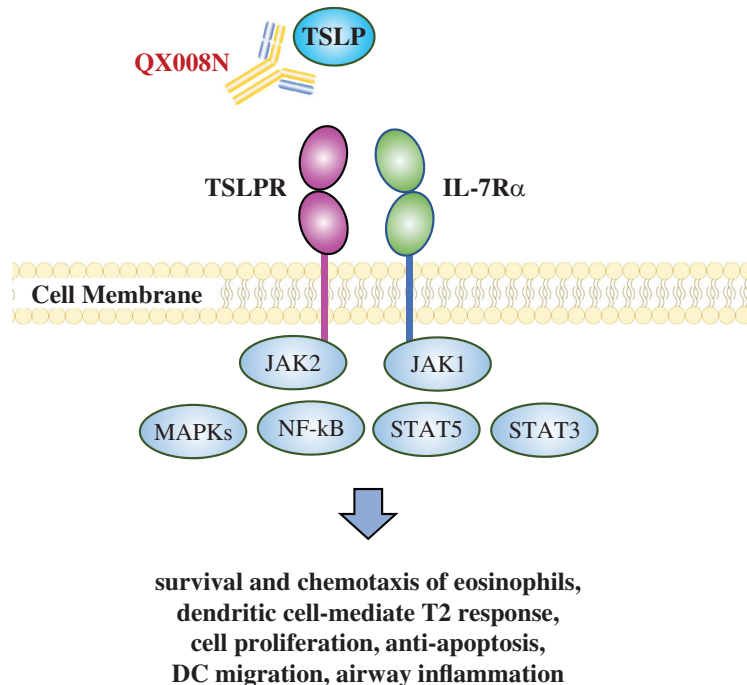
QX008N

QX008N is a humanized IgG1 monoclonal antibody targeting thymic stromal lymphopoietin (TSLP). TSLP plays a critical role as an upstream cytokine mediating multiple inflammatory pathways. While the efficacy of non-TSLP targeting biologics have shown to be correlated to the levels of certain type 2 biomarkers, TSLP inhibitors can be a treatment for patients with low-level or no expression of type 2 biomarkers. We are developing QX008N for the treatment of asthma and moderate-to-severe COPD, including those with low-level or no type 2 inflammation biomarkers. We obtained IND approvals of QX008N for treatment of asthma and moderate-to-severe COPD from the NMPA in May 2022. We also obtained an IND approval of QX008N for treatment of severe asthma from the FDA in September 2022. We entered into a technology transfer agreement in January 2024 to grant Joincare Pharmaceutical Group Industry Co., Ltd. an exclusive license to develop, manufacture and commercialize QX008N in mainland China, Hong Kong and Macau. See “—Licenses, Rights and Obligations” below for details.

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Mechanism of Action

The epithelial cell-derived cytokine TSLP is a pleiotropic cytokine that acts on multiple cell lineages, including dendritic cells, T cells, B cells, neutrophils, mast cells, eosinophils and innate lymphoid cells, affecting their maturation, survival and recruitment. TSLP initiates intracellular signaling by establishing a complex with its specific receptor, TSLP receptor (TSLPR), and IL-7R α . The TSLP complex can transduce pro-inflammatory signals which promote the maturation and differentiation of DCs and naïve CD4⁺ T cells into allergen-specific Th2 cells, and the secretion of IL-4, IL-5 and IL-13. TSLP has also been shown to enhance cytokine production from multiple types of innate immune cells and to promote the development and function of a subset of basophils. Finally, TSLP may have effects on both Th1 and Th17 cells, although likely to a much lesser extent than observed effects on Th2 cells. Given its position at the top of the inflammatory cascade, TSLP can exert broad influence over airway inflammation through its impact on multiple cell types and pathways. TSLP/TSLPR/IL-7R α pathway has been implicated in the initiation and persistence of inflammatory responses in airway diseases. QX008N is designed to specifically bind to TSLP and block the binding of TSLP to its receptor TSLPR-IL-7R α , thus inhibiting the activation of its signaling pathway for the treatment of allergic diseases, including asthma and COPD. The following diagram illustrates the mechanism of action of QX008N.



Source: the Company

BUSINESS

Licenses, Rights and Obligations

We entered into a technology transfer agreement with Joincare Pharmaceutical Group Industry Co., Ltd. (“Joincare”) in January 2024 (the “QX008N Agreement”), to grant Joincare an exclusive license of the know-how and patents controlled by us to develop, manufacture and commercialize QX008N in mainland China, Hong Kong and Macau. For the avoidance of doubt, we retain the exclusive rights to develop, manufacture and commercialize QX008N outside the licensed territory.

Pursuant to the QX008N Agreement, Joincare will be responsible for the clinical development (including certain preclinical studies required for BLA approval), regulatory activities, manufacturing and commercialization of QX008N in the licensed territory at its own costs and expenses (other than a part of the Phase Ib clinical trial in China that we have already initiated). Joincare will be the MAH of QX008N in the licensed territory, once QX008N is approved.

Pursuant to the QX008N Agreement, we shall be responsible for the supplemental study required for the Phase Ia clinical trial of QX008N in China and supplemental preclinical studies, if any. We shall also provide Joincare with our existing sample products of QX008N and relevant placebo for the clinical development of QX008N. If additional QX008N sample products and placebo are required for the clinical development of QX008N, we may manufacture and provide such sample and/or placebo to Joincare at cost plus a reasonable profit margin. In addition, we shall transfer to Joincare relevant manufacturing process know-how.

Under the QX008N Agreement, we are entitled to receive (i) two non-refundable upfront payments; (ii) payments upon achievement of certain development and regulatory approval milestones with respect to QX008N’s first approved indication; (iii) payment(s) upon subsequent marketing approvals for up to two indication expansions of QX008N; (iv) payment(s) upon reaching certain sales targets; and (v) tiered royalties on the net sales of QX008N in the licensed territory. As of the Latest Practicable Date, we had received the first upfront payment.

Pursuant to the QX008N Agreement, we shall exclusively own all intellectual property that we developed, owned or controlled prior to entering into the QX008N Agreement and any intellectual property solely invented or developed by or on behalf of us after entering into the QX008N Agreement. Joincare is licensed to use the patents and know-how of QX008N solely for the purpose of developing, manufacturing and commercializing QX008N in the licensed territory. For any patents we obtained in the process of commercializing QX008N outside the licensed territory, we shall grant exclusive license of such patents to Joincare for its use within the licensed territory at no extra cost.

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Asthma

We are developing QX008N for the treatment of moderate-to-severe asthma. We entered into a technology transfer agreement in January 2024 to grant Joincare Pharmaceutical Group Industry Co., Ltd. an exclusive license to develop, manufacture and commercialize QX008N in mainland China, Hong Kong and Macau. See “—Licenses, Rights and Obligations” above for details. We commenced a Phase Ib clinical trial of QX008N for the treatment of moderate-to-severe asthma in China in August 2023. In addition to QX008N, to address the unmet medical needs of a broad asthma patient population, we are also developing (i) QX005N, an anti-IL-4R α antibody, as an alternative drug candidate aiming to reach a major portion of asthma patient population and (ii) QX007N, an anti-IL-33 antibody, as another alternative drug candidate for asthma patients. See “—Our Core Products—QX005N—Asthma” and “—Our Other Product Candidates—QX007N—Asthma” for details.

Market Opportunity and Competition

Biologic drugs and candidates for asthma in China primarily include IgE inhibitors, IL-5 inhibitors, IL-4R α inhibitors and TSLP inhibitors. While current antibodies targeting IL-5/IL-5R, IL-4R and IgE are shown to reduce exacerbations and improve symptoms and quality of life in patients with asthma, the efficacy of these biologic treatment has shown to be correlated to the levels of certain type 2 biomarkers, such as blood eosinophil counts and IgE. According to Frost & Sullivan, approximately 50% of patients with severe asthma are estimated to have low-level or no expression of type 2 biomarkers and classified as having type 2-low or non-type 2 allergic diseases. For patients without the elevation of those biomarkers, there continue to be important and unmet medical needs. As TSLP is at the top of multiple inflammatory cascades and involved in over-reactive immune response in multiple allergic disorders, TSLP inhibitors can be a treatment for patients with low-level or no expression of type 2 biomarkers. Based on published clinical data, asthma patients receiving anti-TSLP antibody treatment of experienced significantly fewer exacerbations irrespective of their type 2 biomarker status. Thus, the development of TSLP-targeting biologic treatment may be a promising strategy for addressing the clinical needs of patients with type 2-low allergic diseases. As of the Latest Practicable Date, no TSLP-targeting biologics had been approved in China and there were ten anti-TSLP candidates in the clinical stage in China. See “—Our Core Products—QX005N—Asthma—Market Opportunity and Competition” above for details of the approved biologic drug and biologic drug candidates in the clinical stage in China as of the Latest Practicable Date.

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Our Advantages

We believe our QX008N has the following potential advantages in comparison with the approved drugs and drug candidates indicated for asthma:

- Key target with great potential. Treatment of asthma is modified in a continuous cycle of assessment, treatment, adjustment and review response. Growing incidence of asthma and chronic disorders are expected to further drive the growth of the asthma treatment market. According to Frost & Sullivan, approximately 50% of patients with severe asthma are estimated to have low-level or no expression of type 2 biomarkers and classified as having type 2-low or non-type 2 allergic diseases. QX008N, as a TSLP-targeting biologic drug candidate, can be a promising candidate to address the clinical needs of such patients. In addition, the prevalence of asthma-COPD overlap (ACO) accounted for approximately 26.5% of the asthma patient population, according to Frost & Sullivan. As QX008N is designed for the treatment of both asthma and COPD, we expect QX008N to address the clinical needs of ACO patients.
- Promising preclinical efficacy profile. Based on our preclinical studies, QX008N has high affinity and a potency superior to an internally prepared analog of tezepelumab, the only FDA-approved TSLP targeting biologic drug.
- Good safety profile. QX008N exhibited a good safety profile in our Phase Ia clinical trial and in our preclinical studies where no significant systemic toxic reaction was observed. The NOAEL observed in our preclinical studies was 300 mg/kg, which was higher than its proposed clinical maximum dose, thus leaving a wide safety window. We believe that such feature will enable QX008N to bring clinical benefits to patients without severe side effects.
- Promising accessibility. As of the Latest Practicable Date, tezepelumab was the only FDA-approved TSLP-targeting biologic drug and no TSLP-targeting biologics had been approved in China. The high costs of tezepelumab as well as other biologics may in turn limit patients’ access. We aim to make QX008N more accessible to patients in China, especially those with low-level or no expression of type-2 biomarkers.

Summary of Clinical Trials

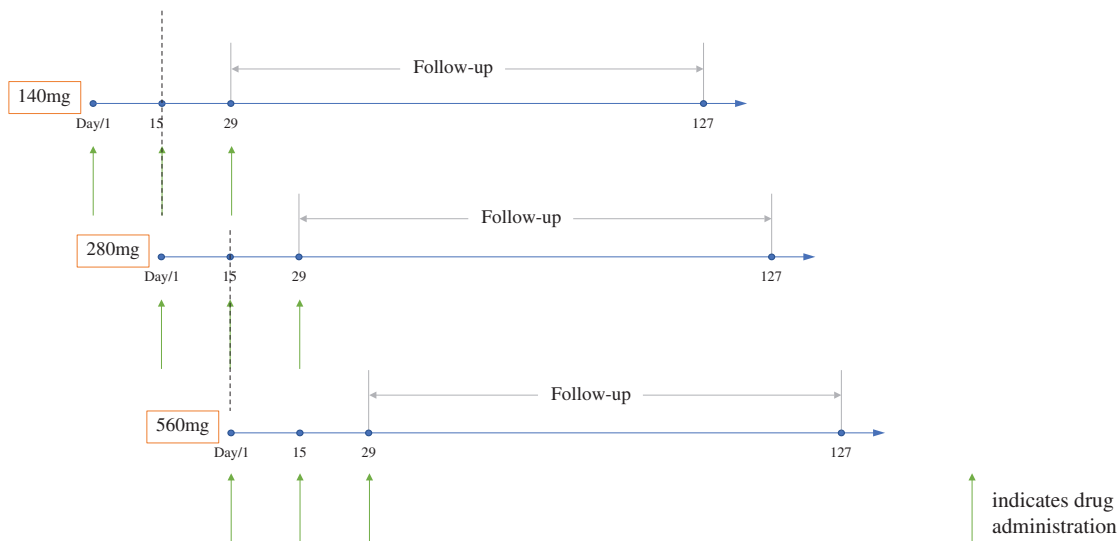
We commenced the Phase Ia clinical trial of QX008N in healthy subjects in China in August 2022 and completed such trial in July 2023. We commenced a Phase Ib clinical trial of QX008N in adult patients with moderate-to-severe asthma in China in August 2023. Pursuant to the QX008N Agreement, Joicare will continue with the remainder of the Phase Ib clinical trial.

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Ongoing Phase Ib Clinical Trial

We have designed the Phase Ib clinical trial in China to be a multi-center, randomized, double-blind, placebo-controlled and multiple-ascending-dose clinical study to evaluate the efficacy, safety, tolerability, immunogenicity and PK profile of QX008N in adult patients with moderate-to-severe asthma. In January 2024, we entered into a technology transfer agreement with Joincare, pursuant to which, among other things, Joincare will conduct the remainder of the Phase Ib clinical trial and subsequent trials. The design of the Phase Ib clinical trial will therefore be subject to any modifications that Joincare may choose to pursue.

Trial design: The primary objective of this trial is to evaluate the safety and tolerability of multiple subcutaneous injections of QX008N in adult patients with moderate-to-severe asthma. The secondary objectives of this trial are to evaluate the efficacy, PK and immunogenicity of multiple subcutaneous injections of QX008N in adult patients with moderate-to-severe asthma, and to determine the recommended dose for a Phase II clinical trial. We planned to enroll a total of 30 patients, who would be assigned to 3 groups with 10 patients in each group (8 receiving QX008N and 2 receiving placebo). Each group would receive three doses of either QX008N or placebo at their designated dose level (140 mg, 280 mg and 560 mg, respectively), to be administered on day 1, day 15 and day 29, followed by safety follow-up until day 127. The trial would proceed from one dose level to the next only if the safety evaluation on the previous dose level group on day 15 has been completed. In the event where termination may be warranted, the sponsor and investigator would determine whether to terminate the trial or resume the trial with the median level of the previous and current dose levels. The chart below summarizes the design of this trial.



Trial status: As of the Latest Practicable Date, we had enrolled seven subjects for this clinical trial. Joincare will continue with the remainder of the trial pursuant to the QX008N Agreement.

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Phase Ia Clinical Trial

The Phase Ia clinical trial in China was a single-center, randomized, double-blind, placebo-controlled, single-dose escalation clinical study to evaluate the safety, tolerability, PK and immunogenicity of QX008N in healthy subjects.

Trial design: The primary endpoints include safety and tolerability of a single subcutaneous injection of QX008N in healthy subjects. The secondary endpoints include PK and immunogenicity of a single subcutaneous injection of QX008N and to recommend dosing regimens for the Phase II clinical trials. The exploratory endpoints include PD parameters of QX008N in these subjects. We planned to enroll 44 healthy subjects, who will be assigned to five groups with four participants in the first group (three receiving QX008N and one receiving placebo) and ten participants in each of the other four groups (eight receiving QX008N and two receiving placebo). The trial will start with the first group receiving a single subcutaneous injection of 42 mg and the subsequent four groups each receiving an increased single dose of 140 mg, 280 mg, 560 mg and 840 mg, respectively. Each participant will receive only one corresponding dose of QX008N (or placebo). The trial will proceed from one dose level to the next only if the safety of such previous dose level is confirmed after a two-week follow-up period. In the event where termination may be warranted, the sponsor and investigator will determine whether to terminate the trial or resume the trial with the median level of the previous and current dose levels.

Trial status: We commenced the Phase Ia clinical trial in August 2022 and completed such trial in July 2023. A total of 44 subjects were enrolled and 42 subjects completed the trial as two subjects withdrew from the study for personal reasons.

Safety results: In this trial, QX008N had a good safety profile in healthy subjects. 29 (82.9%) subjects in QX008N groups reported a total of 81 AEs and 8 (88.9%) subjects in the placebo groups reported 21 AEs, none of which led to a subject's withdrawal from the trial. One subject in the placebo groups reported an SAE (grade 3 AE as defined in the CTCAE version 5.0), which had no relationship with the drug. All other AEs observed in this trial were of Grade 1 (mild) or 2 (moderate) using CTCAE version 5.0. Most of the subjects fully recovered from the AEs at the end of the study. No significant difference was observed in the incidence of AEs between the QX008N groups and the control group.

PK: QX008N exhibited dose-proportional PK in healthy subjects over a dose range from 42 mg to 840 mg following single subcutaneous administration.

Immunogenicity: In this trial, four subjects (one in the 42 mg group, one in the 280 mg group and two in the 560 mg group) showed positive ADA responses on day 85, but no negative impact on QX008N's PK was observed.

Conclusion: In this trial, QX008N demonstrated a good safety profile and dose-proportional PK. Based on the trial results, we have initiated a Phase Ib clinical trial to further evaluate QX008N for the treatment of moderate-to-severe asthma in China.

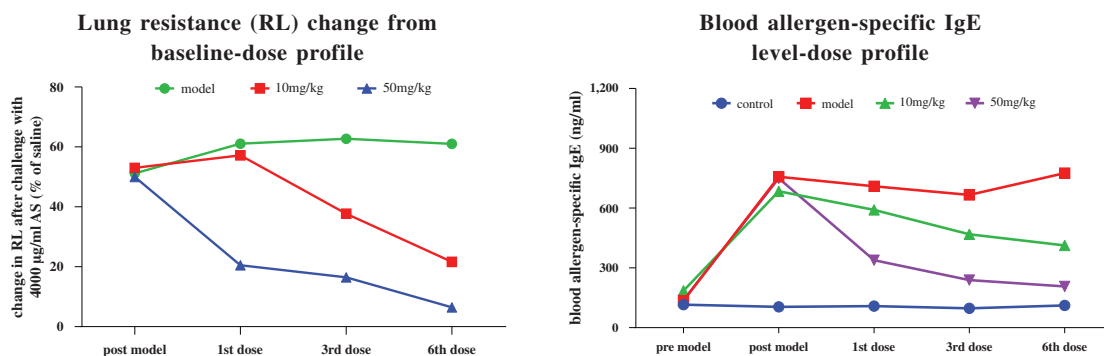
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Summary of Preclinical Study Results

We conducted preclinical studies to evaluate the PD, PK and toxicity of QX008N and achieved favorable results to support clinical development. The major preclinical studies were summarized as below:

PD: In our *in vitro* studies, QX008N demonstrated a high affinity comparable to and a potency superior to an internally prepared tezepelumab analog.

In the *in vivo* studies, QX008N demonstrated a potency comparable to tezepelumab analog. We established an asthma model in cynomolgus monkeys, which is characterized by typical type 2 immune responses, specifically, elevated levels of serum IgE, TSLP and eosinophils. In such studies, QX008N significantly improved respiratory functions and reduced eosinophils, TSLP and IgE levels at the dose levels of 10 mg/kg and 50 mg/kg in a dose-dependent manner. The charts below illustrate the improvement of lung function and reduction of IgE level by QX008N *in vivo* at the dose levels of 10 mg/kg and 50 mg/kg in our preclinical studies.



Toxicity: Toxicological studies showed that QX008N had no obvious systemic toxicity. The MTD observed in a study of single administration (subcutaneous or intravenous) of QX008N in cynomolgus monkeys were at least 700 mg/kg. In the toxicity studies of repeated subcutaneous administrations of QX008N in cynomolgus monkeys once a week for 4 and 26 consecutive weeks, respectively, the NOAEL was 300 mg/kg and 100mg/kg, respectively. In another study of repeated intravenous administrations of QX008N in cynomolgus monkeys (once a week for 26 consecutive weeks), the NOAEL was 30mg/kg.

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Material Communications and Next Steps

We obtained an IND approval of the Phase I, Phase II and Phase III clinical trials of QX008N for treatment of asthma from the NMPA in May 2022 and obtained an IND approval of the Phase I clinical trial of QX008N for treatment of severe asthma from the FDA in September 2022. We commenced a Phase Ia clinical trial in August 2022, which was completed in July 2023. We commenced a Phase Ib clinical trial for the treatment of moderate-to-severe asthma in August 2023, the remainder of which will be completed by Joincare. We plan to formulate a clinical development plan in the United States depending on the data from our Phase Ia and Phase Ib clinical trials in China. As of the Latest Practicable Date, we had not received any relevant regulatory agency’s concerns or objections to our clinical development plans. No material adverse changes had occurred since we obtained the IND approval and up to the Latest Practicable Date.

Chronic Obstructive Pulmonary Disease

We are developing QX008N for the treatment of moderate-to-severe COPD. We entered into a technology transfer agreement in January 2024 to grant Joincare Pharmaceutical Group Industry Co., Ltd. an exclusive license to develop, manufacture and commercialize QX008N in mainland China, Hong Kong and Macau. See “—Licenses, Rights and Obligations” above for details. Similar to the pathogenesis of asthma, high levels of TSLP were also detected in bronchial mucosa of COPD patients, suggesting a potential for TSLP inhibitors to become a biologic treatment for COPD. In addition to QX008N, to address the unmet medical needs of a broad COPD patient population, we are also developing (i) QX005N, an anti-IL-4R antibody, as a drug candidate for patients with eosinophilic COPD; and (ii) QX007N, an anti-IL-33 antibody, as a drug candidate with particular promising efficacy for patients with prior smoking history. See “—Our Core Product—QX005N—Chronic Obstructive Pulmonary Disease” and “—Our Other Product Candidates—QX007N—Chronic Obstructive Pulmonary Disease” for details.

Market Opportunity and Competition

As of the Latest Practicable Date, no biologics had been approved for the treatment of COPD. As of the same date, there were seven biologic drug candidates for COPD in the clinical stage in China and none of such candidates targets TSLP. See “Industry Overview—Overview of the Allergic Disease Drug Market—Major Allergic Diseases—Chronic Obstructive Pulmonary Disease” for details.

Our Advantages

We believe QX008N, as an anti-TSLP antibody, can be a promising treatment for COPD patients with or without expression of type 2 biomarkers, given its promising preclinical efficacy profile, good safety profile and promising accessibility. See “—Asthma—Our Advantages” for more details.

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Summary of Clinical Trial and Preclinical Studies

We completed a single-center, randomized, double-blind, placebo-controlled, single-dose escalation Phase Ia clinical trial evaluating the safety, tolerability, PK and anti-drug antibody of QX008N in healthy subjects in July 2023. See “—Asthma—Summary of Clinical Trials—Phase Ia Clinical Trial.”

We conducted a series of preclinical studies on the PD, PK and toxicity of QX008N. See “—Asthma—Summary of Preclinical Study Results” for more details.

Material Communications and Next Steps

We obtained an IND approval of the Phase I, Phase II and Phase III clinical trials of QX008N for treatment of moderate-to-severe COPD from the NMPA in May 2022. As of the Latest Practicable Date, we had not received any relevant regulatory agency’s concerns or objections to our clinical development plans. No material adverse changes had occurred since we obtained the IND approval and up to the Latest Practicable Date.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET QX008N SUCCESSFULLY.

Our Other Product Candidates

QX007N

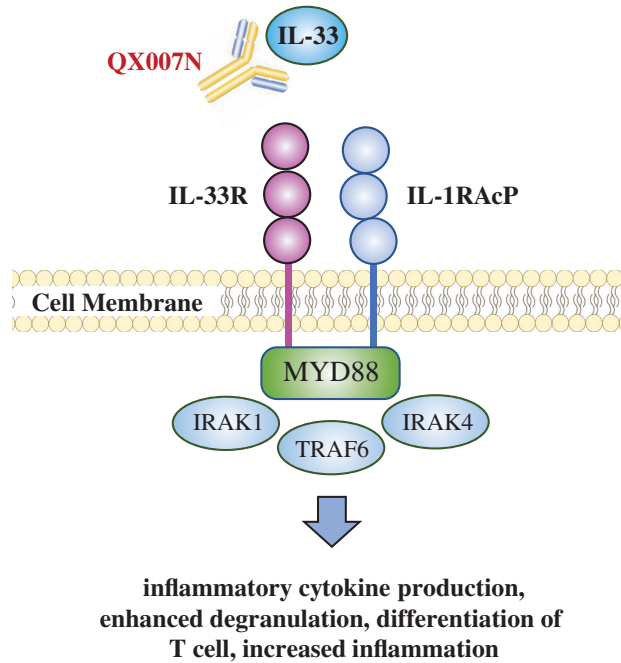
QX007N is a humanized IgG1 monoclonal antibody targeting IL-33, one of the recently discovered members of the IL-1 family. We are developing QX007N for the treatment for moderate-to-severe COPD and asthma. As of the Latest Practicable Date, we had submitted the IND applications for QX007N for such indications. On February 19, 2024, we obtained an IND approval of the Phase I, Phase II and Phase III clinical trials of QX007N for the treatment of COPD from the NMPA.

Mechanism of Action

IL-33, an alarmin and pleotropic cytokine involved in type 2 immune responses, can cause the activation, migration and recruitment of immune cells and drive allergic airway disease pathogenesis by binding to its receptor, consisting of IL-33R and IL-1RAcP (IL-1 receptor accessory protein). Abundantly expressed in lung epithelial cells, IL-33 plays a critical role in both innate and adaptive immune responses in mucosal organs. In innate immune responses, IL-33 and group 2 innate lymphoid cells (ILC2s) provide an essential axis for rapid immune responses and tissue homeostasis. In adaptive immune responses, IL-33 interacts with dendritic cells, Th2 cells, follicular T cells and regulatory T cells, where IL-33 influences the development of chronic airway inflammation and tissue remodeling. Smoking is a key inducer of COPD and it not only activates IL-33 production by epithelial and endothelial cells, but also induces the expression of IL-33 in peripheral blood mononuclear cells. IL-33 is one of the inflammatory mediators involved in pathogenesis of COPD. QX007N, as a recombinant

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humanized IgG1 monoclonal antibody, is designed to bind to IL-33 and block the interaction of IL-33 with its receptor, thus inhibiting inflammatory responses in COPD. The following diagram illustrates the mechanism of action of QX007N.



Source: the Company

Chronic Obstructive Pulmonary Disease

We are developing QX007N for the treatment of COPD. Studies have shown that smoking promotes an amplified IL-33 cytokine response and progression of COPD. We believe that QX007N, as an IL-33 inhibitor, has particular promising efficacy for patients with prior smoking history. We obtained an IND approval of the Phase I, Phase II and Phase III clinical trials of QX007N for the treatment of COPD from the NMPA in February 2024.

In addition to QX007N, to address the unmet medical needs of a broad COPD patient population, we have two other drug candidates in our COPD pipeline, namely: (i) QX005N, an anti-IL-4R antibody, as a drug candidate for patients with eosinophilic COPD; and (ii) QX008N, an anti-TSLP antibody, as a drug candidate for COPD patients, including those with low-level or no expression of type 2 inflammation biomarkers. See “—Our Core Product—QX005N—Chronic Obstructive Pulmonary Disease” and “—Our Other Key Product Candidates—QX008N—Chronic Obstructive Pulmonary Disease” for details.

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Market Opportunity and Competition

As of the Latest Practicable Date, no biologics had been approved for treatment of COPD and there were seven biologic drug candidates for COPD in the clinical stage in China, two of which targets IL-33. See “Industry Overview—Overview of the Allergic Disease Drug Market—Major Allergic Diseases—Chronic Obstructive Pulmonary Disease” for details.

Our Advantages

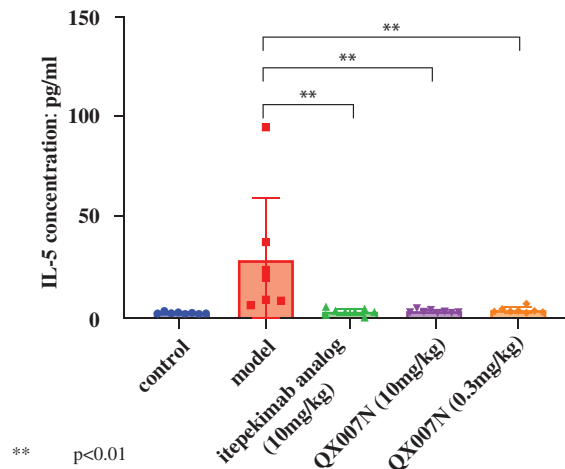
Itepekimab, one of the few IL-33 targeting biologic drug candidates for the treatment of COPD, have demonstrated in its Phase IIa clinical trial efficacy in improving lung functions of COPD patients with prior smoking history. Accordingly, we expect QX007N, as an IL-33 inhibitor, to be a drug candidate with promising efficacy for COPD patients, especially those with prior smoking history.

Summary of Preclinical Study Results

We have conducted a series of preclinical studies to assess the PD, PK and toxicity of QX007N. The major preclinical studies are summarized below:

PD: In our *in vivo* studies, QX007N significantly reduced human IL-33-induced inflammation in mice. In such studies, 56 mice (including eight in the model group, eight in each of the five QX007N dose groups and eight in the 10 mg/kg itepekimab analog group.) were administered with human IL-33 daily for seven consecutive days. The model group exhibited increased serum IL-5 content compared to the control group and the QX007N groups exhibited significant reduction of IL-5 concentration in mouse serum at the dose levels of 0.3 mg/kg, 1 mg/kg, 3 mg/kg, 5 mg/kg and 10 mg/kg. The chart below illustrates the PD profile of QX007N *in vivo* at dose levels of 0.3 mg/kg and 10 mg/kg in comparison with itepekimab analog at dose level of 10 mg/kg in our preclinical studies.

IL-5 level comparison between QX007N and itepekimab analog



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PK: In our studies of single subcutaneous or intravenous administration of QX007N in 24 cynomolgus monkeys (six in the 5 mg/kg intravenous administration group and six in each of the three subcutaneous administration dose groups), QX007N exhibited dose-proportional pharmacokinetics over a dose range of 0.5 mg/kg, 5 mg/kg and 50 mg/kg. The mean $T_{1/2}$ of QX007N ranged from 9.73 days to 12.3 days. The bioavailability after subcutaneous administration ranged from 81.1% to 99.2%.

Toxicity: Our toxicological studies showed that QX007N had no obvious systemic toxicity. The MTD observed in a toxicity study of single administration (subcutaneous or intravenous) of QX007N in cynomolgus monkeys were at least 750 mg/kg. In another study of repeated administrations (subcutaneous or intravenous) of QX007N in cynomolgus monkeys (once a week over 4 consecutive weeks), the NOAEL was 300 mg/kg.

Asthma

We are developing QX007N for the treatment of asthma. Similar to the pathogenesis of COPD, IL-33 is one of the inflammatory mediators involved in pathogenesis of asthma, suggesting a potential for IL-33 inhibitors to become a biologic treatment for asthma. In addition to QX007N, to address the unmet medical needs of a broad asthma patient population, we have two other drug candidates in our asthma pipeline, namely: (i) QX005N, an anti-IL-4R α antibody, as an alternative drug candidate aiming to reach a major portion of asthma patient population; and (ii) QX008N, an anti-TSLP antibody, as a drug candidate for asthma patients, including those with low-level or no expression of type 2 inflammation biomarkers. See “—Our Core Product—QX005N—Asthma” and “—Our Other Key Product Candidates—QX008N—Asthma” for details.

As of the Latest Practicable Date, no biologics targeting IL-33 had been approved for the treatment of asthma in China and none of the biologic drug candidates in China targets IL-33. See “Industry Overview—Overview of the Allergic Disease Drug Market—Major Allergic Diseases—Asthma” for details.

We conducted a series of preclinical studies on the PD, PK and toxicity of QX007N. See “—Chronic Obstructive Pulmonary Disease—Summary of Preclinical Study Results” for more details.

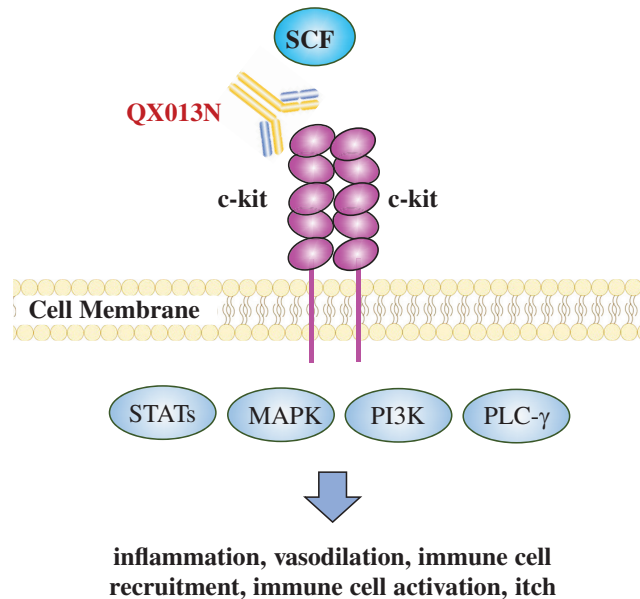
WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET QX007N SUCCESSFULLY.

QX013N

QX013N is a humanized IgG1 mAb targeting c-kit (a type III receptor tyrosine kinase) and indicated for CSU. In February 2024, we submitted an IND application to the NMPA for QX013N for the treatment of CSU, which was under formal review as of the Latest Practicable Date. For details of the pathogenesis and unmet clinical need of CSU, see “—Our Core Products—QX005N—Chronic Spontaneous Urticaria.” QX013N is designed to bind to c-kit to

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block the interaction between a stem cell growth factor (SCF) and c-kit, which activates the SCF/c-kit signal transduction pathway and causes the differentiation, maturation, survival, proliferation and degranulation of mast cells that lead to the release of histamine and other mediators. As urticaria is considered a disease driven mainly by mast cell degranulation, QX013N is designed to downregulate the downstream signaling and inhibit the development of CSU. The diagram below illustrates the mechanism of action of QX013N.



Source: the Company

Summary of Preclinical Study Results

As of the Latest Practicable Date, we had conducted a series of preclinical studies to characterize the PK, toxicity and PD of QX013N and assessed its potency in comparison to an internally prepared barzolvolimab analog. Barzolvolimab is another humanized anti-c-kit IgG1 monoclonal antibody at the Phase II clinical trial stage with positive topline Phase II clinical trial results for patients with antihistamine–refractory CSU (characterized by uncontrolled symptoms of patients treated with antihistamines in combination with other standard therapies). QX013N demonstrated good and comparable potency to the barzolvolimab analog in terms of inhibition of SCF-c-kit–induced activities in our preclinical studies.

PK: QX013N exhibited nonlinear PK in cynomolgus monkeys over a dose range from 3 mg/kg to 30 mg/kg following a single subcutaneous administration. Systemic exposure (as measured by AUC) of QX013N increased in a greater-than-proportional manner with the increasing dose level.

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Toxicity: QX013N did not show any obvious systemic toxicity in our preclinical toxicity studies. The MTD of QX013N in cynomolgus monkeys was 100 mg/kg through the subcutaneous injection. QX013N was repeatedly administered through subcutaneous injections in cynomolgus monkeys every two weeks for four consecutive weeks, with the NOAEL of 75 mg/kg.

PD: Our *in vivo* study in an urticaria mouse model showed that QX013N (3 mg/kg, 10 mg/kg and 30 mg/kg) effectively reduced the leakage of Evan's Blue Concentration (a common selective dye marker for measuring microvascular leakage in animal models) in the ear tissue of the model, with an effective dose of 3 mg/kg and demonstrating a dose-dependent relationship within the dose range from 3 mg/kg to 30 mg/kg.

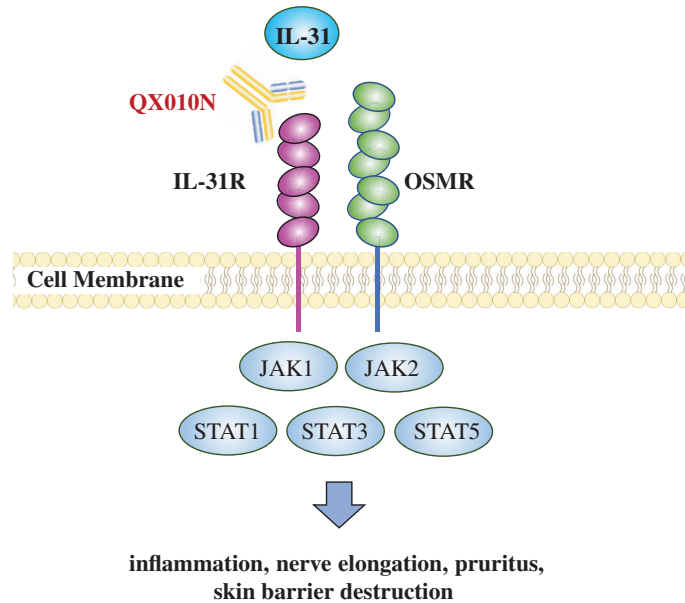
WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET QX013N SUCCESSFULLY.

QX010N

QX010N is a humanized IgG1 mAb targeting IL-31R and indicated for pruritus, which was in the preclinical stage as of the Latest Practicable Date. Pruritus, which means itchy skin, is an uncomfortable, irritating sensation that makes the patient want to scratch. The itch-scratch cycle is difficult to break and may lead to skin injury, infection and scarring. Severe or chronic pruritus could affect the patients' quality of life, interrupt their daily routine and sleep, or even cause mental illness such as anxiety or depression. Pruritus is the clinical manifestation of many diseases, which means it can be difficult to diagnose the underlying causes and there has been no effective long-term treatment strategy, indicating a huge market potential for this condition, according to Frost & Sullivan. Biologic drugs are a relatively new class of drugs under investigation for treating pruritus, which have not yet been recommended as a main treatment option by prevailing clinical guidelines. In addition, we may investigate QX010N for indication expansion to PN.

IL-31 is induced mainly by IL-4 and IL-33 activated CD4⁺ T cells and plays an important role in the development of pruritus. By binding to its receptor, a heterodimer consisting of IL-31R and OSMR, IL-31 activates downstream JAK-STAT pathways that cause inflammation, nerve elongation, itch and skin barrier destruction. QX010N is designed to bind to IL-31R to block the interaction between IL-31 and IL-31R to downregulate the downstream signaling, thus inhibiting the development of pruritus. The diagram below illustrates the mechanism of action of QX010N.

BUSINESS



Source: the Company

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET QX010N SUCCESSFULLY.

RESEARCH AND DEVELOPMENT

We are a clinical-stage biotech company exclusively focused on biologic therapies for autoimmune and allergic diseases, with a self-developed drug pipeline. We have built a broad pipeline that covers the four major disease areas in the field, including skin, rheumatic, respiratory and digestive diseases. We believe research and development is critical to our ability to grow into a biopharmaceutical company and remain competitive in the industry. We have developed all of our innovative biologic drug candidates in-house, with proprietary know-how across the entire process, and are dedicated to continuing to expand our innovative product pipeline. Our R&D also includes selected biosimilar product.

We conduct our R&D activities through an in-house team as well as engagement of external CROs, as is in line with industry practice. We have established an integrated R&D platform to support our drug development from discovery to clinical trial. We believe that our R&D activities have laid a solid foundation for the future regulatory approval, manufacturing and commercialization of our drug candidates. We incurred research and development expenses of RMB151.9 million, RMB257.2 million and RMB263.3 million in the years ended December 31, 2021 and 2022 and the nine months ended September 30, 2023, respectively. During the Track Record Period, our R&D expenses increased significantly, primarily as a result of the advancement and expansion of preclinical and clinical studies of our drug candidates. For details, see “Financial Information—Description of Certain Key Items of the Consolidated Statement of Profit or Loss and Other Comprehensive Income—Research and Development Expenses.”

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Our Rabbit Antibody Development Platform

Early development of therapeutic antibodies normally includes three stages: (i) antibody screening to get mAbs with high affinity and specificity to a specific target human antigen, (ii) antibody engineering of the screened antibodies to get humanized antibody leads with strong bioactivity and good physical/chemical and PK/PD properties, and (iii) pre-clinical *in vivo* studies including pharmacodynamic, toxicology, *etc.*, to determine an antibody molecule for further CMC development and clinical studies. At present, the majority of mAbs designed to target human antigens are murine mAbs, based on mice. However, in recent decades, there have been growing interest in the industry toward the development of rabbit mAbs as many studies have shown that the unique features of B-cell ontogeny and antibody repertoire make rabbits a valuable source for antibodies that have high affinity and specificity, which could potentially translate into strong bioactivity, and are easier to humanize, leading to lower risk of immunogenicity.

Our rabbit antibody discovery platform covers the development stages (i) and (ii) described above, and integrates nine technical steps as illustrated by the diagram below. It begins with immunizing rabbits with a target immunogen using our specific immunization strategy. With B-cell isolation and culture techniques, a wider range of antigen-specific B cells can be isolated and high titer of antibodies in culture can be reached, which permit high-throughput screening using functional assays to get rabbit mAbs with strong bioactivity in the early development stage. It significantly increases efficiency of antibody screening and the following humanization and antibody engineering of the selected rabbit antibodies.



Our platform not only facilitates the selection of rabbit mAbs with strong bioactivity, but also helps evaluate their viability to be further developed into commercial-grade biological drugs, aiming to avoid excessive modifications to reduce uncertainties in subsequent CMC process development, and assess immunogenicity as early as possible to reduce the risk of high immunogenicity during clinical development. In general, we can complete the screening and evaluation of the lead antibody in about one year and complete the humanization of the lead antibody and the initial druggability evaluation within three months. Moreover, we do not need additional time for affinity maturation due to the innate high affinity features of rabbit antibodies. The average time leading from cell line development to IND approval for our drug candidates is approximately 20 months.

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Supported by the platform and a research team with extensive experience in rabbit mAb research and development, we are able to discover and develop new antibodies with novel targets. As of the Latest Practicable Date, we had developed all of our eight innovative mAb drug candidates through our rabbit antibody development platform, among which five had proceeded to clinical development stage (*i.e.*, QX002N, QX005N, QX004N, QX006N and QX008N). For details, see “—Our Drug Candidates” above. We engage qualified CROs for animal studies involved in the discovery and development of antibodies and require them to carry out such studies in strict compliance with our protocol and relevant laws and regulations regarding laboratory practice, including animal studies.

In-house R&D capabilities

Our in-house R&D team consisted of 122 members as of the Latest Practicable Date, including 20 for new drug discovery, 4 for technological development, 10 for translational medicine, 37 for clinical development, 6 for pharmaceutical affairs, 3 for quality management and 42 for CMC-related research and development. Our R&D team is led by senior management members with a proven track record in drug R&D, including Ms. Fang Min (our deputy general manager, who is primarily responsible for clinical development) and Dr. Li Jianwei (the chief operating officer and deputy general manager of our Company and the general manager of Cellularforce, who is primarily responsible for CMC-related research and development), both of which have extensive experience in their respective field of work. See “Directors, Supervisors and Senior Management—Senior Management” for further details on their past experience. As of the Latest Practicable Date, approximately 60% of our R&D team members had a master’s degree or above in biology/pharmacy or related field.

The development of our Core Products, QX002N and QX005N, involved core members from each function of our R&D team, such as Ms. Fang Min (head of clinical development), Mr. Kong Yong (director of new drug discovery), Mr. Chen Wei (director of antibody engineering), Mr. Chen Tao (director of pharmacology) and Mr. Qiao Huaiyao (senior director of CMC-related research and development), all of whom have strong academic background and professional experience for R&D of biologic drugs and joined our Group early on. In particular, 42, 66 and 85 employees in our R&D team participated in the development of QX002N in 2021 and 2022 and the nine months ended September 30, 2023, respectively. The development of QX002N incurred research and development expenses of RMB18.0 million, RMB49.5 million and RMB57.2 million in 2021 and 2022 and the nine months ended September 30, 2023, respectively, representing 11.9%, 19.3% and 21.7% of our total research and development expenses in the respective periods. 49, 83 and 109 employees in our R&D team participated in the development of QX005N in 2021 and 2022 and the nine months ended September 30, 2023, respectively. The development of QX005N incurred research and development expenses of RMB37.5 million, RMB66.2 million and RMB88.5 million in 2021 and 2022 and the nine months ended September 30, 2023, respectively, representing 24.7%, 25.7% and 33.6% of our total research and development expenses in the respective periods.

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During the Track Record Period, we engaged one external individual consultant for the preclinical development of our drug candidates and another for the clinical development of our drug candidates. Both consultants are experts with extensive experience in their respective fields, *i.e.*, preclinical/clinical evaluation of innovative drugs, and have worked in various entities in the industries, including regulatory agencies, hospitals and/or pharmaceutical companies. We entered into a one-year consultancy agreement with our preclinical consultant and a two-year consultancy agreement with our clinical consultant. Pursuant to such agreements, the responsibilities of the external consultants primarily include assisting our preclinical/clinical team in formulating preclinical/clinical evaluation strategies, reviewing study designs, organizing preclinical/clinical expert communication and providing related personnel training. Under the consultancy agreements, we have the ownership and may fully and freely utilize or transfer to third parties within the scope of our business any intellectual property rights or other rights related to inventions or creations resulting from the performance of duties by the consultants or the direct or indirect use of our materials, technologies and business information during the period of engagement of the consultants. For the determination of consultancy fees, we took into account various factors, including the academic qualifications, professional experience and reputation of the consultants, their expected responsibilities and the market fee levels. In 2021 and 2022 and the nine months ended September 30, 2023, we have incurred consultancy fees of nil, RMB60,000 and RMB180,000, respectively, relating to our preclinical consultant and RMB144,000, RMB144,000 and RMB183,000, respectively, relating to our clinical consultant. To the best of our knowledge, neither of the two consultants have any past or present relationships with our Group, our shareholders, directors or senior management, or any of their respective associates, except in their capacity as external consultants.

Drug Discovery and Preclinical Development

Our drug discovery team is dedicated to the discovery of novel biologic drug candidates indicated for autoimmune and allergic diseases to address unmet clinical needs. Multiple departments, covering R&D, manufacturing and commercialization, participate early in our research and development process, ensuring the implementation of our differentiated strategy in target and indication selection and perform in-house market forecasts and financial analysis for the potential product. We aim to maintain our exclusive focus on autoimmune and allergic diseases, solidifying and expanding our comprehensive coverage of the four major disease areas, namely, skin diseases, rheumatic diseases, respiratory diseases and digestive diseases.

Our antibody discovery and development capabilities are driven by innovative technologies and guided by our expertise in immunology and structural biology. Leveraging our rabbit antibody development platform, our team can accurately screen for antigen-specific monoclonal antibodies, analyze their biological function and determine their viability to be further developed as therapeutics. Our team has developed a series of *in vitro* functional assay platforms to examine the biological function of selected antibodies and employs structure-based antibody engineering to ensure efficient antibody humanization. Our internal research and development team takes a leading role in the design and management of the research projects and outsources certain daily execution tasks, such as pharmacologic, pharmacokinetic and toxicologic evaluation, to multiple CROs. For details, see “—Collaboration with CROs” below.

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Clinical Development

Our clinical development department is comprised of the following functional teams: (i) clinical operation team, which is responsible for the overall execution and supervision of clinical trials, (ii) medical team, which is responsible for providing medical support and addressing medical-related problems in clinical trials, (iii) quality control team, which is responsible for monitoring clinical trials and conducting self-inspection of our in-house R&D activities to ensure the authenticity, accuracy and completeness of our clinical trial data, (iv) pharmacovigilance (PV) team, which is responsible for ensuring our compliance with applicable regulations and standard operating procedures in drug safety management and clinical trials, and (v) statistics team, which is responsible for managing statistic issues during clinical studies. We have set up two clinical development centers in Beijing and Shanghai, managed by our clinical development department. As of the Latest Practicable Date, the Beijing center had 15 clinical staff members, while the Shanghai center had 11 clinical staff members. The primary functions of the development centers revolve around the management of clinical projects, providing support for medical inquiries and medical monitoring of clinical projects, and offering quality control assistance throughout the progression of clinical trials. The development centers in Beijing and Shanghai play a crucial role in ensuring the smooth operation and successful execution of our clinical research endeavors. Our clinical development department manages all stages of clinical trials, including clinical trial design, implementation and the collection and analysis of trial data. The department also cooperates with top-notch research institutions, such as well-known hospitals and CROs, and experienced experts (as leading PIs) for our clinical trials.

Chemistry, Manufacturing and Controls (CMC)

CMC is an integral part of our R&D and manufacturing process. Our CMC team performs vital roles including process development, scale-up and optimization. It provides technical support and analysis from druggability and production perspective during lead screening and selection, and works closely with our clinical development department to manage the supply of tested drugs during preclinical and clinical development. In addition, our CMC team is also responsible for the commercial-scale manufacturing of our drug candidates at our manufacturing facility in Taizhou, Jiangsu. To address anticipated increase in demand after future commercialization of our drug candidates and achieve competitive pricing, our CMC team also focuses on process scale-up and optimization, with an aim to increase the yield of our production line, ensure large-scale delivery of biologic drugs and drug candidates and reduce unit manufacturing costs. We have completed the manufacturing of multiple batches of drug substance and drug products. For further details, see “—Manufacturing” below.

Our CMC team is led by Dr. Li Jianwei, our chief operating officer and deputy general manager and the general manager of Cellularforce, who has over 14 years of experience in the R&D and manufacturing of recombinant protein drugs. Prior to joining us, Dr. Li worked in a number of global biopharmaceutical companies, where his responsibilities included process development and manufacturing of recombinant protein therapeutics.

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Collaboration with CROs

In line with industry practice, we engage reputable CROs to support our preclinical and clinical studies from time to time. We proactively seek well-known CROs with good reputation in the industry, and evaluate self-recommendations from CROs offering services to us. We also select CROs through tenders for projects with high value and typically evaluate three to four CROs for a specific preclinical or clinical study. When selecting CROs, we consider a number of factors, including their past experience in biologics-related preclinical and clinical studies, their reputation and influence in the industry, their qualifications, professional experience of their employees and pricing. When determining service fees for CROs, we would discuss with the CRO and set the pricing based on various factors, including the academic and professional qualifications of its team, its experience in the industry and market fee levels. The involvement and roles of CROs in the development of novel biologic drug candidates are typically standardized and similar among different projects. The work scope of these third parties in the development of our drug candidates may vary, subject to our overall management and instructions. We engaged 28, 37 and 31 CROs in 2021, 2022 and the nine months ended September 30, 2023, respectively, all of which were Independent Third Parties to the best of our knowledge.

With respect to preclinical studies, CROs typically provide us with services related to preclinical PK, PD and toxicity evaluations, both *in vitro* and *in vivo*, of our drug candidates in accordance with our study design and under our supervision. We engaged CROs to conduct preclinical PK, PD and toxicity studies for both QX002N and QX005N. With respect to clinical studies, CROs typically provide us with a comprehensive suite of services required in complex clinical trials in accordance with our trial design and under our supervision. We engaged CROs for all completed and ongoing clinical trials of QX002N and QX005N. CROs generally assist us in the implementation and management of clinical trials, including day-to-day site management, trial preparation, source data verification, clinical safety management, data management and report preparation.

After we select a CRO to support our clinical trial, we will sign an agreement with the CRO, which sets out, among other things, the purpose and content of the clinical trial, responsibilities of each party, research procedures and the payment schedule. We have set in place various procedures regarding the management and monitoring of the performance by CROs. Our clinical development department is responsible for managing the overall clinical trial process and overseeing CROs' work. We hold regular progress meetings with CROs and provide specific directions to ensure the quality and efficiency of the trial execution. We conduct regular and *ad hoc* on-site audits of CROs, including interviewing their employees, reviewing documentations and records, such as relevant trial data and reports. We would keep formal records of such audits and follow up regarding issues discovered in the process. For clinical CROs, we would also refer to the NMPA compliance record of their previous clinical trials. Our CROs are also required to fully cooperate with our monitoring and inspection activities and rectify any issue identified during such inspections. If the CROs fail to conduct the studies in compliance with the relevant laws and regulations, we may be subject to liability. See “Risk Factors—Risks Relating to Our Operations—Our employees, CROs, collaboration

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partners and others with whom we deal may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements, which could harm our reputation and subject us to penalties and significant expenses that have a material adverse effect on our business, financial condition and results of operations” for further details. Under the agreements, we own all intellectual property and trial results and the CROs must maintain strict confidentiality with respect to the information they acquire during clinical trials. There was no material non-compliance incidence during our cooperation with CROs and we did not have any material disputes or disagreements with the engaged CROs during the Track Record Period and up to the Latest Practicable Date.

On December 20, 2022, we entered into a five-year collaboration framework agreement (the “Tigermed Framework Agreement”) with Hangzhou Tigermed Consulting Co., Ltd. (“Tigermed”) for the future development of our drug candidates, including QX002N, QX005N and others, in China. Tigermed is one of the industry-leading CROs in China, whose business covers the development and registration of innovative pharmaceutical candidates. It is listed on the Shenzhen Stock Exchange (stock code: 300347) and the Stock Exchange (stock code: 03347). Pursuant to the Tigermed Framework Agreement, we will treat Tigermed as a preferred CRO service provider and Tigermed will set up a strategic service group responsible for future coordination. We and Tigermed will further enter into independent service contracts governing the development of specific drug candidates. As of the Latest Practicable Date, we had entered into service contracts with Tigermed with respect to the Phase III clinical trial of QX002N for AS and the Phase II clinical trials of QX005N for PN and CRSwNP. We also expect to enter into contracts with Tigermed with respect to relevant CRO services for future Phase III clinical trials of QX005N for AD, PN and CRSwNP, among others. The Tigermed Framework Agreement sets forth an overall service fee range agreed upon by both parties, which was determined based on a series of variables including the phase of the clinical trial, the number of trial sites/subjects involved and Tigermed’s customary fee levels. We also took into account the market fee level, Tigermed’s experience in the industry and our own budget when negotiating the fee range. The service fee for a specific development project will be set forth in the relevant service contract and within the determined fee range, unless the aforementioned variables (such as the number of trial sites/subjects) deviate significantly from contemplated scenarios, in which case the parties will negotiate separately for the service fee for such project. Service fees incurred pursuant to the Tigermed Framework Agreement shall be recorded as third-party contracting costs under the research and development expenses in our consolidated statements of profit or loss and other comprehensive income. We believe this framework agreement with Tigermed will enable us to leverage its extensive experience in clinical trial execution and help ensure smooth development and registration of our drug candidates.

REGULATORY AFFAIRS

Our regulatory affairs team is responsible for the regulatory approval process of our drug candidates from clinical research to commercialization stage, including assembling application dossiers for IND applications and BLAs, addressing inquiries from relevant regulatory authorities and monitoring ongoing R&D projects to ensure compliance with relevant laws and

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regulations. Our regulatory team members are deeply familiar with regulatory processes of relevant governmental agencies, such as the NMPA, and had successfully obtained 18 IND approvals (17 from the NMPA and 1 from the FDA) for our drug candidates as of February 20, 2024. We believe our team’s extensive experience in navigating the regulatory process will be critical for our commercial success.

MANUFACTURING

Manufacturing Facility

We are one of only a few Chinese biotech companies that are focused on autoimmune and allergic diseases and have an established commercial-scale in-house manufacturing capability, according to Frost & Sullivan. Cellularforce, our CMC-focused subsidiary, is equipped with a manufacturing facility established according to the cGMP standards of China, the United States and the EU (although not GMP-certified due to the termination of the certification mechanism by relevant government agencies in China since 2019). Our manufacturing facility is located at our headquarters in Taizhou, Jiangsu and occupies 57,977 sq.m. of land (the “Taizhou Manufacturing Facility”). In April 2021, we received a Drug Manufacturing Certificate from Jiangsu Medical Products Administration for the production of QX001S at Taizhou Manufacturing Facility.

We have a CMC team of more than 150 members at our Taizhou Manufacturing Facility, covering the full-cycle development of monoclonal antibodies, including cell-line development, process development, formulation development, analytical development, drug substance manufacturing, drug product manufacturing, quality control (QC) and quality assurance (QA). Our drug substance manufacturing site has four 2,000L single-use bioreactors and one downstream purification/production line with an annual manufacturing capacity of 40 batches of drug products (approximately 300 kg therapeutic antibodies). Our drug product manufacturing site has one vial fill-finish and packaging production line for 2 ml, 10 ml and 30 ml vials, with a manufacturing capacity of 18,000 vials/hour, and one prefilled syringe production line for 1 ml and 2 ml syringes, with a manufacturing capacity of 9,000 syringes/hour. We have manufactured more than 30 batches of drug substance, including seven batches of 2,000L of QX001S for scale-up research, Phase III clinical trial and BLA-required process validation, four batches of 2,000L of QX002N for Phase III clinical trial and three batches of 2,000L of QX005N for Phase II clinical trial, as well as other batches for various clinical trials. We have completed the manufacturing of more than 30 batches of drug products in vials (with 2,000 to 5,000 vials per batch) and more than 10 batches of drug products in prefilled syringes (with 3,000 to 30,000 syringes per batch) for various clinical trials and BLA-required process validation for QX001S drug products. With production of 15 batches in 2023, the utilization rate of our Taizhou Manufacturing Facility was 37.5%, including the manufacturing of our own drug candidates under development (11 batches, or 27.5% of our manufacturing capacity), the expected commercial production of QX001S (2 batches, or 5.0% of our manufacturing capacity) and CDMO services provided to Zhongmei Huadong (2 batches, or 5.0% of our manufacturing capacity) pursuant to relevant service contract. The anticipated commercial production of QX001S will be a small portion of our manufacturing activities and we do not expect it to have a material impact on the utilization of our manufacturing capacities.

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To satisfy anticipated market demand for our products, assure stable production in a cost-effective measure and meet the requirements of regulatory authorities for quality control, we plan to continuously optimize our drug substance manufacturing process to improve production efficiency. We could achieve a competitive drug substance production yield of 5-9 g/L for different antibodies.

Additionally, we have successfully developed a new drug substance upstream process, which starts a production run with high cell-density and large volume of working cell bank, and therefore could significantly shorten the production time required for each batch, improve capacity utilization and lower unit manufacturing costs. Additionally, in order to ensure the stability of the supply chain and further reduce manufacturing costs, we have established strategic cooperations with domestic suppliers of cell culture media and disposables, which we expect to reduce related one-off costs significantly. We also plan to further expand our Taizhou Manufacturing Facility after we officially launch the commercial productions of our products.

While prioritizing internal R&D and commercialization demands, we plan to further enhance the utilization of our production capacity through retaining the manufacturing rights of drug candidates for which we established strategic collaborations. We will also continue to develop external CDMO services to diversify our source of revenue and better utilize our manufacturing capacity. Through Cellularforce, we intend to provide comprehensive CDMO services, including molecular design and evaluation, process development, analysis and quality management, registration application and commercial production of antibody drugs, to external clients, primarily Chinese biopharmaceutical companies. We entered into a service contract with Zhongmei Huadong in February 2023 as part of our strategic cooperation with it regarding CDMO services, pursuant to which Cellularforce will provide a series of development and manufacturing services to Zhongmei Huadong, covering cell line and cell banking services, formulation development and process development, scale-up and validation. Cellularforce will provide such services in accordance with the cGMP standards and further requirements or procedures set out by Zhongmei Huadong. See “Connected Transactions—(B) Continuing Connected Transactions subject to the Reporting, Annual Review and Announcement Requirements but Exempt from the Circular and Independent Shareholders’ Approval Requirements—CDMO Services Framework Agreement” for further details. We do not expect CDMO services offered to external parties to affect the manufacturing of our own products because we have sufficient manufacturing capacity to accommodate the production plans of our own products. With the estimated utilization rate of our manufacturing facility for 2023 at approximately 40% (taking into account the manufacturing of our own drug candidates under development, the expected commercial production of QX001S and CDMO services to be provided to Zhongmei Huadong pursuant to relevant service contract), we are able to provide CDMO services to external parties as a measure to improve the utilization rate of our spare manufacturing capacity on the premise of ensuring the production plans of our own products. We have built an efficient project management system to allocate our manufacturing capacity and review/prioritize our manufacturing plans monthly.

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Quality Management

We have established QA and QC teams to oversee the development, manufacturing, and commercialization quality systems of our drug candidates. Our QA team ensures that our products and procedures meet regulatory standards and guidelines, while our QC team implements comprehensive testing and analysis to ensure that our materials and products meet the preset quality standards and the relevant testing methods are stable and reliable.

We have established an internal quality management system that covers the entire lifecycle of our drug candidates in accordance with cGMP standards of the NMPA, FDA and EMA. We continually review and update our quality management system through ongoing monitoring of our laboratory control system, production system, materials system, facilities and equipment system and packaging and labeling system to ensure compliance with regulatory requirements. We utilize advanced information management systems such as the Warehouse Management System (WMS) and Document Management System (DMS) to implement dynamic control over materials and products throughout the entire process, ensuring reliable and traceable data.

Our QC function comprises seven components: physical and chemical analysis, instrumental analysis, materials analysis, biochemical analysis, microbiological analysis, environmental monitoring and cGMP laboratory operations. Cellularforce has an industry-standard Laboratory Information Management System and a comprehensive analysis system covering the lifecycle of our drug candidates, which has supported multiple batch release testing, method verification and audit inspections. Our large molecule drug quality control platform is in compliance with the requirements of both the FDA and the NMPA for the production of biological drugs and drug candidates at the clinical and commercial stages. However, additional clinical trials and/or regulatory approval would be required before any manufactured products could be sold in overseas markets, including the U.S. We conduct quality testing on materials in accordance with the drug quality system principles outlined in the Q10 Guideline issued by the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) and strictly follow cGMP requirements for the release testing and stability studies of drug substance and drug products.

COMMERCIALIZATION

We currently do not have any products approved yet. However, we are in the process of formulating our commercialization plans in anticipation of multiple potential product launches within the next few years. Leveraging our management team's accumulated knowledge of and extensive experience in the biopharmaceutical industry in China, especially in the field of autoimmune and allergic diseases, we expect to develop our commercialization strategies for each close-to-market drug candidate reflecting its market positioning, taking into consideration of key factors such as pricing, dose regimen, economic, social and demographic characteristics of patients, market access and reimbursement policies.

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Based on the indication coverage of our product pipeline and the current development status, we have adopted a practical commercialization model, first cooperating with established pharmaceutical companies on the commercialization of our future drugs for diseases with patients located in vast, geographically dispersed areas, and then establishing a relatively small, indication-specialized in-house commercialization team.

External Partnerships

We are seeking partnerships with well-known companies in the pharmaceutical industry that can offer access to established distribution channels, recognized branding, an experienced sales force and longstanding connections with target physicians and hospitals. When selecting commercialization partners, we will also consider their expertise in the relevant therapeutic area and their regulatory know-how.

The patients of autoimmune and allergic diseases are scattered geographically and many of them are of moderate income. According to Frost & Sullivan, a significant proportion of autoimmune and allergic disease patients (*e.g.*, Ps patients) in China initially receive treatment in local hospitals, so an extensive sales network providing robust coverage of local sales channels is essential. However, as we are at an early stage of preparation for future commercialization of our drug candidates, building a large commercialization team would be time-consuming and expensive, which would increase our commercial risk and distract us from our R&D efforts. To address this conundrum, we choose to cooperate with well-known pharmaceutical companies to promote the commercialization of our drugs in a cost-effective manner. In August 2020, we entered into a strategic cooperation agreement with Zhongmei Huadong, a subsidiary of Huadong Medicine, with regard to the joint development and exclusive commercialization of QX001S in mainland China. See “—Collaboration with Zhongmei Huadong” for further details on the key terms of our agreement. Huadong Medicine has established and comprehensive commercialization capabilities, with a sales team of more than 7,000 members experienced in the management of chronic diseases, such as diabetes and autoimmune diseases, an area it has focused on for over 30 years. According to Frost & Sullivan, Huadong Medicine has top-tier commercialization capabilities for autoimmune drugs in China, covering over 3,000, or more than 90% of all, Grade IIIA hospitals in China and over 15,500 hospitals of Grade II and below. We believe this collaboration with Huadong Medicine will enable us to leverage its nationwide sales and marketing network targeting the autoimmune and allergic disease field as well as its extensive experience in chronic disease management to ensure effective and efficient commercialization of QX001S.

We will continue to explore our commercialization partnerships with recognized pharmaceutical companies once we develop and start commercialization of more approved drugs and for additional indications. In addition, we also plan to seek cooperation opportunities, which include, but are not limited to, co-promotion and product out-licensing with global and domestic industry players, to commercialize subsequent pipeline products in other countries outside China.

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In-house Commercialization Capability

In the future, leveraging our accumulated knowledge of autoimmune and allergic diseases and China’s biopharmaceutical market, we also plan to build a relatively small, indication-specialized in-house commercialization team with medical and scientific background. The in-house team would be responsible for the commercialization of a few selected drug candidates and indications, beginning with those for which the patient population is relatively small and the clinical centers are relatively concentrated and therefore do not require a huge marketing network covering expansive geographic areas. We believe an internal commercialization team will be sufficient for patient management and effective market coverage for such indications. In addition, biological therapies have limited awareness in such specialized indications and more customer education is needed before marketing our biologic drugs. We believe we are well-positioned to provide such education given our deep knowledge in the relevant diseases and their respective biological therapies.

Our commercialization team will market our future approved biologic drug candidates to physicians and hospitals using a physician-targeted, academic marketing model, focusing on promoting the clinical benefits and accessibility of our products. We will also focus on long-term patient management. For example, we plan to host medical lectures or seminars for patients to promote their awareness of autoimmune diseases and allergic diseases, as means to increase the rate of diagnosis and treatment, through patient advocacy. In addition, we intend to track and follow the treatment and improvement of patients using our drugs, and procure potential patients through the referrals and word of mouth.

COLLABORATION WITH ZHONGMEI HUADONG

QX001S Framework Agreement

On August 14, 2020, we entered into a collaboration agreement (as supplemented on December 7, 2023, the “QX001S Framework Agreement,” and together with the QX001S Production Quality Agreement and the QX001S Supply Agreement (as defined below), the “QX001S Agreements”) with Zhongmei Huadong, a subsidiary of Huadong Medicine, with respect to the joint development and exclusive commercialization of QX001S in China. As of the Latest Practicable Date, Zhongmei Huadong and Cellularforce had also entered into the QX001S Production Quality Agreement and the QX001S Supply Agreement for the Product Supply (as defined below) as individual agreements under the QX001S Framework Agreement based on the principles provided in the QX001S Framework Agreement. During our ordinary course of business, we became acquainted with China Grand through its business development department. We then became acquainted with Zhongmei Huadong through introduction by China Grand. China Grand holds approximately 41.67% interest in Huadong Medicine and is its controlling shareholder. Huadong Medicine is a leading PRC pharmaceutical company listed on the Shenzhen Stock Exchange, whose business covers the whole pharmaceutical industrial chain, integrating R&D, manufacturing and sales of medicine. Zhongmei Huadong is one of our [REDACTED] Investors and a wholly owned subsidiary of Huadong Medicine. See “Connected Transactions—(A) Continuing Connected Transactions Fully Exempt from the Reporting, Annual Review, Announcement, Circular and Independent Shareholders’ Approval Requirements—QX001S Framework Agreement” for details. This collaboration reflected the

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parties’ mutual interest in the commercialization of new drug candidates targeting autoimmune and allergic diseases in China. We believe this collaboration with Huadong Medicine will enable us to leverage its market access, nationwide sales and marketing network targeting the autoimmune and allergic disease field as well as its extensive experience in chronic disease management, which will be crucial to ensure rapid commercialization of QX001S.

The respective contributions and responsibilities of our Company, Zhongmei Huadong and Jiangsu Cellularforce Biopharma Co., Ltd. (“Cellularforce”), our CMC-focused subsidiary, in China under the QX001S Framework Agreement are summarized as follows:

<u>Contributions and responsibilities</u>		<u>Commencement and completion of preclinical and clinical trials</u>	<u>Responsible party</u>	<u>Party bearing related expenses</u>	<u>Whether related expenses are deductible from pre-tax profit</u>
	Upfront payment and milestone payment	–	Zhongmei Huadong	Zhongmei Huadong, who paid the upfront payment and milestone payment on August 28, 2020 and July 16, 2021, respectively	Non-deductible
R&D	Preclinical	October 2016-May 2017	Our Company	Our Company	Non-deductible
	Phase I	November 2018-May 2020	Our Company	Our Company	Non-deductible
	Phase III ⁽¹⁾	June 2021-June 2023 (for Ps treatment)	Joint development committee (the “JDC”)	Zhongmei Huadong	Non-deductible
Manufacturing	Sample production for clinical trials and process optimization	–	Cellularforce	Our Company	Non-deductible
	Commercial production and quality control	–	Cellularforce	Zhongmei Huadong	Deductible
Regulatory communication and registration	Preclinical	–	Our Company	Our Company	Non-deductible
	Phase I	–	Our Company	Our Company	Non-deductible
	Phase III and post clinical trials	–	JDC	Zhongmei Huadong	Non-deductible
Commercialization (plan and decision)	–		Joint sales committee (the “JSC”)	N/A	N/A
Sales and marketing	–		Zhongmei Huadong	Zhongmei Huadong	Deductible

BUSINESS

Note:

- (1) A Phase III clinical trial of QX001S for Ps was commenced after completion of the Phase I clinical trial as Phase II clinical trials are not required for biosimilars such as QX001S.

We consider all costs and expenses incurred for commercialization of QX001S deductible, which is reflected in the deductible items on the table above. Particularly, it was understood by the parties that the upfront payment and the milestone payment made by Zhongmei Huadong are to recover part of our development expenses incurred before the joint development. During the joint development, we will be responsible for the CMC expenses while Zhongmei Huadong bears the costs associated with the Phase III clinical trial, which allows both parties to share the development expenses. It is also consistent with our profit sharing arrangement as the parties will share profit after deduction of the relevant commercialization expenses incurred for QX001S.

Key terms of the QX001S Framework Agreement are summarized as follows:

Scope of Collaboration The parties agree to conduct joint development and exclusive commercialization of QX001S for the diagnosis, prevention and treatment of human diseases, including but not limited to, psoriasis, active psoriatic arthritis, Crohn's disease and ulcerative colitis, in China.

We agree to grant Zhongmei Huadong joint clinical development, manufacturing and exclusive commercialization rights of QX001S in China, which shall not be sub-licensed to a third party without written approval from us. Cellularforce shall be solely responsible for the commercial production of QX001S. We retain the full development and commercialization rights of QX001S outside China.

Term The QX001S Framework Agreement has a term of 15 years commencing from August 14, 2020 and ending on August 13, 2035, which can be extended for a further term of five years unless terminated earlier in accordance with the terms of the QX001S Framework Agreement. It may be terminated by mutual agreement of the parties or other triggering events, such as one party's uncured material breach, bankruptcy, liquidation or receivership, as stipulated in the QX001S Framework Agreement.

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Development Costs

Zhongmei Huadong shall make an upfront payment of RMB30 million to us within ten days upon the execution of the QX001S Framework Agreement. Zhongmei Huadong shall also make a milestone payment of RMB20 million to us within ten days after we complete the sample production of QX001S for a Phase III clinical trial and have, upon a consultation with the CDE, obtained consent to proceed with such trial. Pursuant to the QX001S Framework Agreement, both the upfront payment and the milestone payment are non-refundable, and Zhongmei Huadong paid us the upfront payment and the milestone payment on August 28, 2020 and July 16, 2021, respectively, totaling RMB50 million. The upfront payment and the milestone payment under the QX001S Framework Agreement were determined after arm’s-length negotiations between our Group and Zhongmei Huadong, having taken into account various factors, including but not limited to the expenses incurred and to be incurred for the development of QX001S, expected prospects of the development and commercialization of QX001S in the PRC, rights and obligations of both parties under the QX001S Framework Agreement and the reasons and benefits of the transactions contemplated under the QX001S Framework Agreement. In particular, during the Track Record Period, for supporting the development of QX001S, the Group incurred total expenses of approximately RMB31.0 million, RMB32.3 million and RMB13.8 million in 2021, 2022 and the nine months ended September 30, 2023, respectively. It was understood by the parties that the upfront payment and the milestone payment are to recover part of these development expenses incurred before the completion of production of sample drugs for the Phase III clinical trial of QX001S, and our Directors are of the view that the upfront payment and the milestone payment in a total of RMB50 million under the QX001S Framework Agreement are fair and reasonable.

In addition, during the parties’ joint development, Zhongmei Huadong shall be responsible for any expenses related to the clinical trials and regulatory communication and registration for QX001S; we shall be responsible for expenses related to the sample production and process development and optimization prior to the commercialization of QX001S.

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Joint Clinical Development The parties agree to establish a JDC to manage the joint clinical development of QX001S, which shall be responsible for overseeing the development, clinical trials and registrational matters of QX001S before its commercial launch, within which, the JDC's detailed authorities include (i) determining when a development project shall be carried out; (ii) reviewing and approving modifications of development plans; (iii) monitoring and updating the implementation progress of development plans; (iv) discussing and making decisions on the application, maintenance and protection of intellectual property rights; and (v) any other matters that either us or Zhongmei Huadong considers necessary for discussion. The JDC shall contain six representatives, including three representatives from each of us and Zhongmei Huadong, who shall have comprehensive experience and knowledge in drug development and work experience of at least five years in the medicine development industry. We and Zhongmei Huadong each shall have one vote (*i.e.*, collectively one vote for the three representatives from us and the three representatives from Zhongmei Huadong, respectively) when making decisions within the JDC's responsibility scope. Any decisions made by the JDC must be subject to its unanimous consent, and when such consent is not reached, the relevant issue shall be submitted to the senior management of both us and Zhongmei Huadong for consideration. If consent is still not achieved upon review by the senior management, an independent third party agency may be engaged to resolve such dispute.

In addition to the aforementioned development costs that each party is responsible for, we shall be responsible for completing the relevant ongoing preclinical studies and the Phase I clinical trial of QX001S for the treatment of Ps before the date of execution of the QX001S Framework Agreement as well as conducting any subsequent supplemental preclinical and clinical studies that the NMPA may require prior to the Phase III clinical trial for this indication at our cost.

The parties agree to jointly register the Phase III clinical trial of QX001S with the relevant regulatory authorities, with us being the clinical trial sponsor.

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Product Supply

During the term of the QX001S Framework Agreement, we and Cellularforce will exclusively manufacture and supply QX001S to Zhongmei Huadong in the PRC (the “Product Supply”) and relevant quality control. Except when Cellularforce is unable to meet the manufacturing demand, Zhongmei Huadong cannot engage other manufacturers. Cellularforce shall supply QX001S to Zhongmei Huadong at a unit supply price which will be determined by taking into account our actual costs expected to be incurred for manufacturing of QX001S and a cost-plus margin of 25% for such manufacturing (the “Markup”), and on a priority basis. When registering QX001S for commercial manufacturing, Zhongmei Huadong shall be the applicant for the drug registration certificate and Cellularforce shall be the drug manufacturer. For further details, see “—QX001S Supply Agreement” below.

Except for being the manufacturer of QX001S, Cellularforce does not have control over QX001S in any other material aspects, including its R&D development plan and execution, clinical trials, commercialization and intellectual property (including technical know-how).

Commercialization

The parties agree to establish a JSC for the commercialization of QX001S, which shall be responsible for overseeing the commercialization, manufacturing and marketing expense proposal of QX001S and other commercialization-related work, within which, the JSC’s detailed authorities include (i) discussing and communicating on marketing and production plans; (ii) reviewing disputes arising from deductible expenses in the pre-tax profit sharing arrangement; and (iii) any other matters that either us or Zhongmei Huadong considers necessary for discussion. The JSC shall contain six representatives, including three representatives from each of us and Zhongmei Huadong, who shall have comprehensive experience and knowledge in drug production or commercialization as well as work experience of at least five years in the medicine production or commercialization industry. We and Zhongmei Huadong each shall have one vote (*i.e.*, collectively one vote for the three representatives from us and the three representatives from Zhongmei Huadong, respectively) when making decisions within the JSC’s responsibility scope. Any decisions made by the JSC must be subject to its unanimous consent, and when such consent is not reached, the relevant issue shall be submitted to the senior management of both us and Zhongmei Huadong for consideration. If consent is still not achieved upon review by the senior management, Zhongmei Huadong shall have the right of spontaneous decision making, provided that both parties’ mutual interests are protected.

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- Commercialization in China

Zhongmei Huadong shall be the MAH of QX001S for the treatment of Ps and for any potential expansion of indications in China to exclusively conduct marketing activities and commercialization of QX001S. Zhongmei Huadong shall make commercially reasonable efforts to promote such commercialization. We plan to establish a development and commercialization plan of QX001S in China with Zhongmei Huadong at a later stage in accordance with the QX001S Framework Agreement and depending on the regulatory approval progress of QX001S after completion of the Phase III clinical trial for Ps.

- Commercialization overseas

We retain the exclusive commercialization rights of QX001S outside China and are entitled to use any intellectual property and other proprietary information associated with the QX001S Framework Agreement outside China. As of the Latest Practicable Date, we did not have any concrete plan for the overseas expansion of QX001S.

Termination

The QX001S Framework Agreement may be terminated by either party in writing if (i) a party fails to perform, refuses to perform or delays its performance overdue under the QX001S Framework Agreement, which constitutes a major breach, and the breaching party fails to remedy within 30 days after the no-fault party demands remedy in writing; (ii) a party undergoes restructuring, winding-up, takeover, dissolution, suspension or cancellation of operation permits or insolvency; (iii) the parties mutually agree to termination; (iv) the commercialization of QX001S is interrupted due to its infringement of a third party's legal rights or its intellectual property being challenged; and (v) a party undergoes a change of control.

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We may terminate the QX001S Framework Agreement with 30-day written notice if (i) Zhongmei Huadong fails to make relevant payments to us pursuant to the QX001S Framework Agreement; (ii) Zhongmei Huadong's breach causes the projects to fail; or (iii) during the term of the QX001S Framework Agreement, Zhongmei Huadong develops other biologics targeting IL-12/IL-23p40 or provide clinical data and other trade secrets under the QX001S Framework Agreement to third parties.

In addition, Zhongmei Huadong may terminate the QX001S Framework Agreement with 30-day written notice if (i) the Phase III clinical trial of QX001S cannot be commenced before June 30, 2021 due to disapproval of the clinical trial or request of additional information from the NMPA; (ii) the Phase III clinical trial of QX001S fails to reach its primary endpoint and its clinical data is insufficient to support an application for marketing approval; (iii) the NMPA refuses the marketing approval application of QX001S; (iv) Cellularforce fails to provide Zhongmei Huadong with a sufficient quantity of drug samples qualified for clinical studies by June 30, 2021; or (v) we fail to transfer the MAH to Zhongmei Huadong pursuant to the QX001S Framework Agreement.

Dispute Resolution

In the event of a dispute due to execution of the QX001S Framework Agreement, the disputing party shall send a written notice to the other party and state the nature of the dispute. Within 14 days after receiving the dispute notice, the parties shall organize a meeting at a mutually agreed time and place to resolve the dispute. If the dispute is not resolved within 30 days of a mutually agreed time or within 60 days after first receiving the dispute notice, either party may file the dispute with a court with jurisdiction at the filing party's place of residence.

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Profit Sharing

The parties agree that the accumulative pre-tax profit generated from sales of QX001S in China (as calculated pursuant to the QX001S Framework Agreement), after setting off the accumulative losses attributable to the commercialization of QX001S incurred in prior years (if any), shall be shared by the two parties on a 50:50 basis, provided that 50% of the Markup for the manufacturing of QX001S will be further deducted from our portion of the pre-tax profit receivable and attributed to Zhongmei Huadong's portion instead. Our Directors are of the view that the basis of the profit sharing ratio, having taken into account various factors, including but not limited to the expenses incurred and to be incurred for the development of QX001S borne by both parties, expected prospects of the development and commercialization of QX001S in the PRC, rights and obligations of both parties under the QX001S Framework Agreement and the reasons and benefits of the transactions contemplated under the QX001S Framework Agreement, is fair and reasonable. In addition, the parties are entitled to engage an independent certified public accountant mutually agreed upon to audit and verify items included in the calculation of the profit sharing, whose audit results shall be the final basis for determining the profit sharing within 30 days after the end of each calendar year. The fees incurred in engaging such third party auditor shall be included in the expenses to be set off from the accumulative pre-tax profit. Zhongmei Huadong shall pay us the corresponding profit share within 10 days after the audit results are issued.

Intellectual Property

We are the sole owner of all intellectual property rights (including trade secrets) associated with QX001S that were developed by us independently before the date of the QX001S Framework Agreement. We and Zhongmei Huadong shall be the co-owners of any intellectual property rights (including trade secrets) (the "Co-Developed IP rights") associated with QX001S that are developed since the date of the QX001S Framework Agreement. Any of the aforementioned intellectual property rights (including trade secrets) may be used at no cost by both parties in China and solely by us outside China.

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With respect to the Co-Developed IP rights, Zhongmei Huadong shall be primarily responsible for the relevant application and registrational matters in China while we shall be responsible for such application and registrational matters outside China. If a party decides to abandon any intellectual property (including trade secrets) mentioned therein, the other party shall be entitled to a priority transfer.

Our PRC Legal Advisors are of the view that (i) we and Zhongmei Huadong will co-own the clinical data developed since the date of the QX001S Framework Agreement, and either party shall provide the other party with preclinical and clinical research protocols and reports, complete production process and formula reports as well as any raw data in a timely manner; (ii) we are the sole owner of any intellectual property (including trade secrets) associated with QX001S developed before the date of the QX001S Framework Agreement, while we and Zhongmei Huadong will co-own the Co-Developed IP rights; and (iii) in an event of a major breach of the QX001S Framework Agreement by a party, the other party is entitled to request remedy within a specified time period, and may terminate the agreement and demand compensation for all of its loss due to the breach, if the breaching party fails to remedy.

Non-competition

During the term of the QX001S Framework Agreement, neither party shall develop any other biologics targeting IL-12/IL-23p40 without the other party's consent.

Confidentiality

Both parties are under strict confidentiality with respect to any information that is received from the other party under the QX001S Framework Agreement and may reasonably be considered confidential.

Since the date of the QX001S Framework Agreement and up to the Latest Practicable Date, we had not had any disputes in relation to the development of QX001S with Zhongmei Huadong.

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QX001S Production Quality Agreement

On June 16, 2022, to ensure that the Product Supply is in compliance with the relevant regulations and technical specifications, Zhongmei Huadong and Cellularforce entered into a production quality agreement (as amended on October 25, 2022, March 16, 2023 and April 26, 2023, the “QX001S Production Quality Agreement”). The key terms of the QX001S Production Quality Agreement are summarized below:

<i>Term</i>	The QX001S Production Quality Agreement shall be effective from June 16, 2022 to at least one year after the expiration date of the last commercial batch of QX001S if the parties terminate the commissioned production arrangement.
<i>Purpose</i>	To ensure that the Product Supply shall stay compliant with relevant drug laws and regulations and technical standards; and each party shall be responsible for carrying out respective duties as required by the relevant law or regulation.
<i>Zhongmei Huadong’s responsibilities</i>	Zhongmei Huadong shall assume the corresponding legal responsibilities as the MAH with respect to the R&D application, production, distribution and use of QX001S.
<i>Cellularforce’s responsibilities</i>	Cellularforce shall assume the relevant legal responsibilities as the drug manufacturer with respect to the drug production process.
<i>Personnel and facilities</i>	Cellularforce shall ensure that (i) relevant personnel are trained and qualified in accordance with GMP requirements; and (ii) the facilities, equipment and internet system related to the Product Supply and its inspection are in working conditions and verified.
<i>Raw materials</i>	Zhongmei Huadong shall be responsible for the selection, management, review and approval of suppliers for raw materials and the procurement of raw materials for the Product Supply. Cellularforce shall be responsible for quality control of the procured raw materials.
<i>Verification</i>	Cellularforce shall be responsible for verification work as specified in the QX001S Production Quality Agreement.

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<i>Documentation</i>	Cellularforce shall be responsible for documentation and recording of the production activities as specified in the QX001S Production Quality Agreement.
<i>Non-compliance</i>	In an event of non-compliance with the relevant law or regulation, the responsible party shall bear the corresponding responsibility pursuant to such law or regulation.

QX001S Supply Agreement

On September 28, 2022, Zhongmei Huadong and Cellularforce entered into a supply agreement (the “QX001S Supply Agreement”) with respect to the Product Supply. The key terms of the QX001S Supply Agreement are summarized below:

<i>Scope</i>	<p>As the MAH of QX001S, Zhongmei Huadong may place production orders of QX001S with Cellularforce after Zhongmei Huadong completes the onsite assessment and verification of Cellularforce’s manufacturing facility and obtains approval for the Product Supply as required by the relevant regulatory authorities.</p> <p>As of the Latest Practicable Date, Zhongmei Huadong has completed the onsite assessment and verification of the manufacturing facility.</p>
<i>Production facilities</i>	Cellularforce shall provide certain designated manufacturing facility, quality control lab and storage center for the Product Supply to Zhongmei Huadong as specified in the QX001S Supply Agreement.
<i>Term</i>	The term of the QX001S Supply Agreement is one year from the first batch of commercial production and may be renewed automatically for another year if the parties agree.
<i>Zhongmei Huadong’s responsibilities</i>	Zhongmei Huadong shall be responsible for the commercial release of final products.
<i>Zhongmei Huadong’s rights</i>	Zhongmei Huadong is entitled to examine the production and inspection process of Cellularforce from time to time and request Cellularforce to immediately terminate production or take remedial or rectification measures in the event of Cellularforce’s breach or violation of the QX001S Supply Agreement, GMP requirements or operation procedures.

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*Cellularforce’s
responsibilities*

Cellularforce shall ensure that the Product Supply is in compliance with GMP requirements and other regulatory requirements.

Cellularforce shall also complete sampling, inspection and production release within 30 days upon completion of a production instruction.

Cellularforce’s rights

Cellularforce is entitled to commission fees per orders completed, the calculation and settlement of which shall be determined in subsequent supplemental agreements between the parties.

Information about Zhongmei Huadong

While Huadong Medicine (including Zhongmei Huadong) is a large comprehensive pharmaceutical company with strong sales networks for autoimmune and allergic drugs, we do not consider it to be our competitor primarily because (i) for the same skin disease indications, such as Ps and AD, Huadong Medicine’s focus is primarily on developing systematic topical drugs that are more commonly used for mild diseases, which would not directly compete with our biologic drug candidates that are intended for more severe cases and instead are complementary to our business; (ii) while Zhongmei Huadong had a biologic drug candidate for SLE in the clinical trial stage as of the Latest Practicable Date, we do not consider it to be a direct competitor to QX006N as these two drug candidates have different mechanisms of action and both are still in early clinical trial stage with considerable time before their commercialization (if at all); and (iii) in 2022, Huadong Medicine obtained the commercialization right of etanercept (a TNF inhibitor) and tofacitinib (a JAK inhibitor), both developed by Pfizer, for the treatment of AS in China, but we believe they will primarily cover a different patient population from QX002N as QX002N targets IL-17A, a promising target that has shown clear clinical benefit in AS patients who are intolerant to or fail to achieve adequate disease control with TNF- α inhibitors and there still remain concerns over the safety profile of JAK inhibitors.

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TERMINATION OF NEGOTIATIONS WITH SENECA

On August 5, 2019, we entered into a mutual non-disclosure agreement (the “Seneca NDA”) with Neuralstem, Inc., a Delaware corporation that later changed its name to Seneca Biopharma, Inc. (“Seneca”), to engage in discussions regarding and to evaluate Seneca’s potential exclusive licensing of certain product candidates developed by us, including QX005N, QX002N, QX004N and QX006N. On October 31, 2019, we further entered into a term sheet with Seneca, which outlined the proposed terms of the potential licensing, which were non-binding and conditioned upon the execution of a definitive licensing agreement between the parties. In addition, the term sheet contained certain binding terms, including terms detailing the establishment of an interim working group and the initial development plan for the potential licensing, as well as confidentiality and exclusivity clauses. On January 6, 2020, the parties ceased negotiations as a result of not being able to reach agreement on certain terms of the potential license.

During the negotiations and before the termination, we disclosed early-stage clinical data of certain projects for relevant product candidates (*i.e.*, QX005N, QX002N, QX004N and QX006N) to Seneca, which shall be protected pursuant to the Seneca NDA, which provides that a party’s obligation to protect the confidential information disclosed by another party under the Seneca NDA shall survive the termination or expiration of the Seneca NDA for a period of five years and no license with respect to confidential information is granted by the disclosing party for any purpose. Furthermore, pursuant to the binding confidentiality clause in the term sheet, the contents of the term sheet and all confidential information (as defined in the Seneca NDA) disclosed by the parties in relation to the term sheet or the potential license will be subject to the Seneca NDA.

Under the exclusivity clause in the term sheet, during the 180-day period commencing on the execution of the term sheet (which has since expired), we shall not, directly or indirectly, through any affiliate, officer, director, agent or otherwise, make, solicit, initiate or encourage submission of any proposal or offer from any third party relating to a sale or license of the rights to any relevant product candidates, or any other transaction that would effectively prohibit Seneca from negotiating the proposed license. We do not bear any liability nor have incurred any payable compensation to Seneca as a result of the termination.

INTELLECTUAL PROPERTY

Intellectual property rights are the basis for the success of our business, and we are committed to the development and protection of our intellectual property. Our success depends in part on our ability to obtain and maintain patents and other intellectual property and proprietary protections for commercially important technologies, inventions and know-how. Our success also depends in part on our ability to defend and enforce our patents, preserve the confidentiality of our trade secrets and operate without infringing, misappropriating or otherwise violating the valid, enforceable intellectual property rights of third parties.

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As of the Latest Practicable Date, we held 37 patents in China, including 31 invention patents and 6 utility models, as well as 9 patents overseas. As of the same date, we also had 44 patent applications pending in China and overseas. In particular, with respect to our Core Products, we had eight registered patents and two pending patent applications for QX002N and five registered patents and four pending patent applications for QX005N.

We conduct our business under the brand name of “Qyuns (“荃信”).” As of the Latest Practicable Date, we had registered 83 trademarks in the PRC and Hong Kong. As of the same date, we were also the registered owner of 21 domain names in the PRC. See “Appendix VIII—Statutory and General Information” to this document for further information.

The actual protection provided by a patent varies on a claim-by-claim and country-by-country basis and depends upon many factors, including the type of patent, the scope of its coverage, the availability of any patent term extensions or adjustments, the availability of legal remedies in a particular country and the validity and enforceability of the patent. We cannot provide any assurance that patents will be issued with respect to any of our owned or licensed pending patent applications or any such patent applications that may be filed in the future, nor can we provide any assurance that any of our owned or licensed issued patents or any such patents that may be issued in the future will be commercially useful in protecting our biologic drug candidates and methods of manufacturing the same. See “Risk Factors—Risks Relating to Our Intellectual Property Rights” for further details. During the Track Record Period and up to the Latest Practicable Date, we had not been involved in any material proceeding in respect of, and we had not received notice of any material claim of infringement of, any intellectual property rights that may be threatened or pending, in which we may be a claimant or a respondent that may have a material adverse impact on us.

The table below lists the material patents and patent applications of our Core Products, QX002N and QX005N, as of the Latest Practicable Date. Inventors of each of the QX002N patents or patent applications listed below include Mr. Qiu, Dr. Qiu Zhihua, Mr. Chen Wei, Mr. Kong Yong, Mr. Wu Yiliang and other key members of our R&D team. Inventors of each of the QX005N patents or patent applications listed below include Mr. Qiu, Dr. Qiu Zhihua, Mr. Chen Wei, Mr. Wu Yiliang, Mr. Qiao Huaiyao and other key members of our R&D team. We do not expect there to be material legal impediments in obtaining approval for our pending patent applications.

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Product	Patent/Application Number	Type of Patent	Patent/Application Name	Scope of Patent/ Application		Status	Application Date	Expected Approval Date	Expiration Date
				Protection	Jurisdiction				
QX002N	201810473679.4	Invention	Anti-human interleukin 17A monoclonal antibody and application thereof (抗人白介素17A単克隆抗体及其應用)	Molecular Entity	China	Granted	May 17, 2018	Granted	May 17, 2038
QX002N	US17/055,789	Invention	Anti-human interleukin 17A monoclonal antibody and application thereof	Molecular Entity	US	Pending	May 17, 2018	December 31, 2024	NA
QX002N	CA3100092	Invention	Anti-human Interleukin 17A monoclonal antibody and application thereof	Molecular Entity	Canada	Pending	May 17, 2018	December 31, 2025	NA
QX002N	EP18919093.7	Invention	Anti-human Interleukin 17A monoclonal antibody and application thereof	Molecular Entity	Europe	Granted	May 17, 2018	Granted	May 17, 2038
QX002N	AU2018423921	Invention	Anti-human interleukin 17A monoclonal antibody and application thereof	Molecular Entity	Australia	Granted	May 17, 2018	Granted	May 17, 2038
QX002N	JP2020565275	Invention	Anti-human Interleukin 17A monoclonal antibody and application thereof (抗ヒトインターロイキン17Aモノクローナル抗体およびその使用)	Molecular Entity	Japan	Granted	May 17, 2018	Granted	May 17, 2038
QX005N	201811592427.X	Invention	Anti-human interleukin-4 receptor α monoclonal antibody and application thereof (抗人白介素4受體 α 単克隆抗体及其應用)	Molecular Entity	China	Granted	December 25, 2018	Granted	December 25, 2038
QX005N	US 17/418,571	Invention	Monoclonal antibody against human interleukin-4 receptor alpha and use thereof	Molecular Entity	US	Pending	December 25, 2019	December 31, 2025	NA
QX005N	CA3124726	Invention	Monoclonal antibody against human interleukin-4 receptor alpha and use thereof	Molecular Entity	Canada	Pending	December 25, 2019	December 31, 2026	NA
QX005N	EP19902812.7	Invention	Monoclonal antibody against human interleukin-4 receptor alpha and use thereof	Molecular Entity	Europe	Pending	December 25, 2019	December 31, 2024	NA
QX005N	AU2019416486	Invention	Monoclonal antibody against human interleukin-4 receptor alpha and use thereof	Molecular Entity	Australia	Granted	December 25, 2019	Granted	December 25, 2039
QX005N	JP2021537939	Invention	Monoclonal antibody against human interleukin-4 receptor alpha and use thereof (抗ヒトインターロイキン-受容體のモノクローナル抗体およびその使用)	Molecular Entity	Japan	Granted	December 25, 2019	Granted	December 25, 2039

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RAW MATERIALS AND SUPPLIERS

Our Raw Materials

We procure raw materials from both domestic and overseas suppliers according to our drug development plans. Our raw materials for our biologic drug candidates primarily include biological and chemical materials, such as chromatography media and culture media, as well as disposable consumables, such as buffer preparation bags and filters.

For the selection and management of raw material suppliers, we maintain a list of qualified suppliers and review their qualifications on an annual basis by taking into consideration their production capacity, production quality, product delivery and feedback efficiency, pricing, reputation and compliance with relevant regulations and industry standards. Our functional departments will initiate the purchase plan of raw materials based on the status of research and development activities and our inventory level. Our procurement department is responsible for placing orders with qualified suppliers and managing suppliers. Our clinical development department and QA and QC teams are also involved in the procurement process and participate in raw material quality control. To monitor the quality of supplies, we implemented a standardized operating system, setting out the procedures and guidelines for the procurement and acceptance of raw materials, quality control inspection, warehousing, testing and storage.

Our Suppliers

During the Track Record Period, our suppliers primarily consisted of suppliers of third-party contracting services for preclinical and clinical studies of our drug candidates, as well as raw materials, consumables and equipment. We have established stable collaboration relationships with qualified suppliers for raw materials and R&D services, which we believe have sufficient capacity to meet our demand. We also believe that adequate alternative sources for such supplies exist.

During the Track Record Period, we did not encounter any material dispute with our suppliers or any material breach of our purchase agreements, nor did we experience any material shortage, delay or price fluctuation in the supply of our raw materials. For risks related to supply of our raw materials, see “Risk Factors—Risks Relating to the Manufacturing and Commercialization of Our Drug Candidates—Scarcity of available raw materials or increases in our raw material costs may negatively impact our business, financial condition and results of operations.”

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For each of the years ended December 31, 2021 and 2022 and the nine months ended September 30, 2023, our purchases from our five largest suppliers were RMB39.4 million, RMB55.0 million and RMB54.9 million, respectively, accounting for approximately 26.3%, 27.4% and 25.2%, respectively, of our total purchases for the respective periods. In the same periods, purchases from our largest supplier were RMB12.4 million, RMB24.3 million and RMB25.9 million, respectively, accounting for approximately 8.3%, 12.1% and 11.9%, respectively, of our total purchases for the respective periods.

The following table sets forth details of our five largest suppliers during each year/period of the Track Record Period.

Supplier*	Principal Business	Products purchased	Credit terms	Commencement of business relationship	Purchase amount	% of total purchases in same period
					<i>(Renminbi in thousands)</i>	
<i>For the nine months ended September 30, 2023</i>						
A	Product development for pharmaceutical-related industries and health-related industries	Clinical and discovery CRO services	Settle in accordance with the milestones in the contract	2016	25,898	11.9
B	New drug research, development and production services, inspection and testing services, technology development, clinical and consulting services for the biomedical industry	Clinical and discovery CRO services	Settle in accordance with the milestones in the contract	2018	12,570	5.8
C	Develop ability research, process scale-up optimization, quality research and pilot and commercial production for global innovative drug R&D institutions	Preclinical service	Settle in accordance with the milestones in the contract	2016	6,371	2.9
D	Biotechnology development and technical consulting	Sample-testing service	Settle in accordance with the milestones in the contract	2018	5,131	2.4
E	Medical and nursing care services	Clinical trial services	Settle in accordance with the milestones in the contract	2021	4,949	2.3
Total					<u>54,919</u>	<u>25.2</u>

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<u>Supplier*</u>	<u>Principal Business</u>	<u>Products purchased</u>	<u>Credit terms</u>	<u>Commencement of business relationship</u>	<u>Purchase amount</u> <i>(Renminbi in thousands)</i>	<u>% of total purchases in same period</u>
<i>For the year ended December 31, 2022</i>						
F	Non-clinical efficacy, pharmacokinetics, toxicology evaluation and clinical sample testing for pharmaceutical enterprises	Preclinical service	Settle in accordance with the milestones in the contract	2015	24,303	12.1
B	New drug research, development and production services, inspection and testing services, technology development, clinical and consulting services for the biomedical industry	Clinical and discovery CRO services	Settle in accordance with the milestones in the contract	2018	9,464	4.7
G	R&D services for biological products, R&D technical consultation for biological products and biochemical drugs, technical detection services for medical devices	Sample test service and raw materials	Settle in accordance with the milestones in the contract	2016	7,837	3.9
H	Medical and nursing care services	Clinical trial services as trial site	Settle in accordance with the milestones in the contract	2018	6,719	3.4
I	Laboratory filling services and distribution services as an imported filler distributor	Raw materials	30 days	2021	6,656	3.3
Total					<u>54,979</u>	<u>27.4</u>

BUSINESS

<u>Supplier*</u>	<u>Principal Business</u>	<u>Products purchased</u>	<u>Credit terms</u>	<u>Commencement of business relationship</u>	<u>Purchase amount</u> <i>(Renminbi in thousands)</i>	<u>% of total purchases in same period</u>
<i>For the year ended December 31, 2021</i>						
F	Non-clinical efficacy, pharmacokinetics, toxicology evaluation and clinical sample testing for pharmaceutical enterprises	Preclinical service	Settle in accordance with the milestones in the contract	2015	12,410	8.3
B	New drug research, development and production services, inspection and testing services, technology development, clinical and consulting services for the biomedical industry	Clinical and discovery CRO services	Settle in accordance with the milestones in the contract	2018	10,427	7.0
J	Sales of biological devices, raw materials and consumables, and the distribution of related imported products	Raw materials and equipment	30 days after invoice date	2020	7,421	5.0
K	Power generation, transmission, and power supply	Electricity	N/A	2015	4,763	3.2
L	Medical and nursing care services	Clinical trial services as trial site	Settle in accordance with the milestones in the contract	2020	4,340	2.9
Total					<u>39,361</u>	<u>26.3</u>

Note:

* We have masked the identities of the suppliers because we believe that the information disclosed above, including the suppliers’ principal businesses, purchased products, credit terms, commencement of business relationship, purchase amount and the corresponding percentage of the total purchase in the same period, is sufficient to enable an understanding of the background of such suppliers and the nature/significance of our transactions with them.

To the best of our knowledge, all of our five largest suppliers during each year/period of the Track Record Period are independent third parties. As of the Latest Practicable Date, none of our Directors, their close associates or any Shareholders which, to the best knowledge of our Directors, owned more than 5% of our share capital, had any interest in any of our five largest suppliers during each year/period of the Track Record Period.

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COMPETITION

The development and commercialization of innovative biologic drugs are highly competitive and subject to rapid and significant changes. We believe that our comprehensive portfolio, deep knowledge of key therapeutic pathways, commercial-scale in-house manufacturing capacity and practical commercialization model provide us with strong competitive advantages. We face potential competition from many different sources working to develop therapies targeting the same indications for which we develop our drug candidates, in particular in the autoimmune and allergic disease areas. These include major pharmaceutical companies as well as specialty pharmaceutical companies of various sizes. Our Core Products and key drug candidates face competition from approved and clinical-stage drug candidates that focus on similar indications and target patient population with us, and these competing products may have significant competitive strengths and advantages when compared to our drug candidates. For competitive landscape of our products and products candidates, see “—Our Drug Candidates” and “Industry Overview” in this document.

EMPLOYEES

As of September 30, 2023, we had 323 employees in total. The following table sets forth the details of our employees by function:

<u>Function</u>	<u>Number of employees</u>	<u>Percentage</u>
R&D	119	36.8%
Manufacturing	155	48.0%
Management and administrative	49	15.2%
Total	323	100.0%

All of our employees are based in China. In compliance with the applicable labor laws, we enter into individual employment contracts with our employees covering matters such as wages, employee benefits, workplace safety and grounds for termination. Our standard employment contract also contains a confidentiality clause and an assignment clause, under which we own all the rights to all inventions, technologies, know-how and trade secrets derived during the course of our employee’s work. We also enter into standard non-compete agreements with our key personnel, including all employees in our R&D team and employees of manager level or above in other departments.

To maintain a stable workforce and retain key personnel in our Company, we offer our employee competitive remuneration packages. Our employees’ remuneration comprises salaries, legally required welfare, such as social insurance, paid annual leave and high-temperature subsidies, and additional welfare, such as supplementary medical insurance for employees and their families, lunch subsidies, annual physical examinations and annual trip.

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We offer remuneration packages based on individuals' qualifications and experiences and generally match the market rate for salary to stay competitive in the labor market. We also take into consideration the long-term growth and advancement of our employees and offer opportunities for both job promotion and technical development. We have a triple-tier internal training system, covering company, department and post level policies, procedures and professional knowledge. We also provide opportunities for external trainings, such as industry forums/summits, special skills training and various job qualification trainings. Additionally, we established an Employee Share Incentive Scheme to better retain and motivate our employees, with eligible participants comprising core management members and key technical/business personnel of our Group. During the Track Record Period and up to the Latest Practicable Date, we did not experience any strikes or labor disputes which had a material effect on our business. Some of our employees are currently represented by labor unions, and we consider our relations with our employees to be good.

In accordance with PRC laws and regulations, we are obliged to contribute to social insurance and housing provident funds for our employees. During the Track Record Period, we did not make full contribution to social insurance and housing provident funds for some of our employees and engaged third-party agents to make the payment of social insurance and housing provident fund on behalf of us for certain employees. We made full provisions for the total amount of such shortfall of RMB3.8 million, RMB5.4 million and RMB3.9 million to our consolidated statements of profit or loss and other comprehensive income for the years ended December 31, 2021 and 2022 and the nine months ended September 30, 2023, respectively. As advised by our PRC Legal Advisors, according to the relevant PRC laws and regulations in respect of social insurance and housing provident funds contribution, if the relevant government authorities are of the view that our contribution did not satisfy the requirements under the relevant PRC laws and regulations, we may be ordered to rectify the shortfall in our contribution within a prescribed period and if we fail to do so within the prescribed period, we could be subject to related fines, the potential maximum amount of which equals three times the amount of our outstanding social insurance contribution and a late fee of 0.05% of the outstanding amount for each day of delay. As advised by our PRC Legal Advisors, the risk of us being penalized for such shortfall is remote, provided that we rectify such shortfall in a timely manner after receiving notices from the relevant PRC authorities.

During the Track Record Period and up to the Latest Practicable Date, we had not received any notifications from the relevant government authorities requiring us to rectify the shortfall or pay related late payment fees. Our Company and all of our subsidiaries which did not make full contribution and/or engaged third parties for such contribution had obtained written confirmations from competent local government authorities, which confirmed that no penalties had been imposed on us with respect to social insurance and housing provident funds during the Track Record Period. During the Track Record Period and up to the Latest Practicable Date, we were not aware of any material employee complaints nor involved in any material labor disputes with our employees with respect to social insurance and housing provident fund contributions. In addition, we have implemented relevant internal control measures to strengthen our oversight and management in relation to the social insurance and housing provident funds, including studying official rules and regulations promulgated by the

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government, organizing relevant personnel to participate in related training provided by government agencies and reviewing the social insurance and housing provident funds contribution for all eligible employees on an annual basis. For further details on the risks associated with the shortfall in our contribution, see “Risk Factors—Risks Relating to Our Operations—We may be required to pay late payment fines or other penalties in connection with our failure to contribute to social insurance and housing provident funds.”

INSURANCE

We maintain insurance policies that are required under PRC laws and regulations as well as based on our assessment of our operational needs and industry practice. In line with industry practice in China, we maintain different types of insurance policies, such as personal accident insurance and clinical trials liability insurance. Considering that we have not commercialized our products, we have not purchased certain types of insurance, such as product liability insurance, except for product candidates in clinical trials. Our Directors consider that our existing insurance coverage is generally in line with the industry practice in China. See “Risk Factors—Risks Relating to Our Operations—Our insurance coverage may not sufficiently cover the risks related to our business operations.” for risks relating to our insurance coverage.

SOCIAL, HEALTH, WORK SAFETY AND ENVIRONMENTAL MATTERS

We are subject to various social, health, safety and environmental laws and regulations and our operations are regularly inspected by local government authorities. We believe we have adequate policies ensuring compliance with all social, health, safety and environmental protection regulations. Particularly, we believe our continued growth rests on integrating social values into our business. We intend to create a lasting positive environmental, social and governance (“ESG”) impact on our customers, suppliers and the broader community whom our operation may impact. We acknowledge our responsibilities on environmental protection, social responsibilities and are aware of the climate-related issues that may have impact on our business. We are committed to complying with ESG reporting requirements upon [REDACTED].

Our core management team is responsible for adopting and adjusting our overall ESG vision and principle and our Administrative, Human Resources and Operational Support (under Cellularforce) departments are collectively responsible for assessing and managing our ESG-related risks and monitoring the compliance of our operations with environment, health and safety laws and regulations. We have adopted company-wide environmental, health and safety (EHS) manuals and standard operating procedures in relation to waste treatment, process safety management, worker health and safety requirements and emergency planning and response, and provide regular trainings to our employees on related issues.

As a biotech company, we face a variety of environmental, health or safety-related risks associated with our operations over the short-, medium- and long-term. For example, our operations involve the use of hazardous materials, including chemicals, and may produce hazardous waste products to the environment. If we fail to process the hazardous materials in

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compliance with relevant laws and regulation, cause injury to persons involved or contaminate the environment, we could incur significant costs associated with administrative, civil or criminal fines and penalties, lose our permit/certificate or be ordered to make substantial alternation to our business operations. See “Risk Factors—Risks Relating to Our Operations—If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could materially and adversely affect our business” for more details on the potential impact of such risks. Additionally, we are also subject to potential risks arising from changes in social trends and political policies related to ESG issues. See “Risk Factors—Risks Relating to Our Operations—Changes in social trends and political policies related to environmental, social, and governance issues may adversely affect our business operation” for further details.

To better identify, assess and manage ESG-related risks, we use the LEC (likelihood, exposure and consequences) method to evaluate potential impact of the risks. In the short term, we will endeavor to manage these risks by (i) ensuring strict compliance with existing laws and regulations, including the environmental impact assessment requirements and pollutant discharge permit reviews, (ii) engaging qualified third parties for the disposal of hazardous waste from our operations and (iii) further improving our internal monitoring of ESG-related operations through advanced technical systems, such as the sewage online monitoring system. In the medium- and long-term, as a company that is committed to sustainability and responsible business practices, we will keep abreast of the regulatory standards and advancements in scientific and technical solutions to environmental issues and update our related policies, procedures and resources accordingly.

Resource Consumption and Emissions

We rely on various metrics to measure the impact of our business on the environment, which are broadly aligned with industry standards. Such metrics include the amount of resource consumption, amount of waste (including wastewater and solid waste) generated and greenhouse gas emissions. We have also set various goals to reduce our environmental impact, and we continue to take significant steps toward these targets. The following table sets forth our resource use and emission-related indicators during the Track Record Period.

	Nine months ended		
	Year ended December 31,		September 30,
	2021	2022	2023
Resource consumption			
Electricity (MWh)			
— Total amount	7,645	8,355	6,115
— Intensity* (MWh/sq.m.)	0.175	0.192	0.140
Water (tons)			
— Total amount	78,658	77,055	59,136
— Intensity* (t/sq.m.)	1.805	1.768	1.357

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	Year ended December 31,		Nine months ended
			September 30,
	2021	2022	2023
Emission			
Wastewater (tons)			
— Total amount	8,829	6,541	8,647
— Intensity* (t/sq.m.)	0.203	0.150	0.198
Hazardous solid waste (tons)			
— Total amount	10	26	27
— Intensity* (kg/sq.m.)	0.22	0.61	0.63
Greenhouse gas emissions (tons of CO2 equivalent)			
— Scope 1 (direct emissions)	248	204	103
— Scope 2 (indirect emissions)	7,429	8,144	5,848

Note:

* Calculated as the total amount of resource consumption or emission divided by the gross floor area of our manufacturing facility

The total amount of discharged wastewater in 2021 was higher than that in 2022, primarily because we conducted wastewater treatment procedure testing in 2021 in the early stage of our manufacturing to ensure the quality of discharged wastewater, which caused additional wastewater discharge. The total amount of discharged wastewater in the nine months ended September 30, 2023 was higher than that in 2022, primarily because of the relatively heavy rainfall during this period, which led to an increased inflow of rainwater into the sewage network, and an increase in our manufacturing activities. The total amount of discharged hazardous solid waste increased in 2022 and the nine months ended September 30, 2023, primarily due to increase in our manufacturing activities.

Resource Consumption

We incorporate the concept of resource conservation into our corporate culture and the daily operation of our laboratories and offices, monitor our resource consumption and established internal resource consumption management systems for laboratories and offices. We actively implement energy-saving measures in our daily operation, such as installing energy-efficient devices (*e.g.*, variable frequency air conditioners), timely turning off idle equipment and lighting in laboratories and offices and adjusting the operation load of air conditioners and switching the heating mode of air-conditioning water heater systems between single and double plates.

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We focus on water resources issue and actively shoulder the social responsibility of protecting water resources. Municipal water supply networks are the main incoming source of our Company’s water, and we did not encounter major difficulties seeking suitable water sources during the Track Record Period. Since we have not yet started commercial-scale production, our water resources are mainly used for laboratories and manufacturing facilities to support our in-house research and development activities, and daily use in offices during the Track Record Period.

Emissions

The waste we produce is divided into hazardous waste (such as chemical waste and liquid) and non-hazardous waste (such as waste from general office operations). The hazardous waste generated in our in-house research and development process are processed by qualified third-party waste treatment companies. We have set up an online monitoring system to monitor real-time wastewater discharge and a water treatment system to pre-treat concentrated wastewater for collection. We use single-use bioreactors in our manufacturing facilities, which can significantly reduce the need for sterilization. With respect to exhaust gas emission, we utilize natural gas boilers with low-nitrogen combustion technology to reduce greenhouse gas emissions. Additionally, we installed various gas collection devices such as ventilation hoods and range hoods to collect exhaust gas, which would be treated with activated carbon adsorbents before being discharged.

Our greenhouse gas emissions primarily consist of Scope 1 and Scope 2 emissions. Scope 1 direct emissions include the direct greenhouse gas emissions from our own manufacturing and other facilities. Scope 2 energy indirect emissions primarily include the greenhouse gas emissions from our usage of purchased electricity, calculated based on the “Accounting Methods and Reporting Guidelines for Greenhouse Gas Emissions of Enterprises in Other Industries” (Trial) issued by the National Development and Reform Commission. In response to the national target of carbon neutrality, we actively focus on reducing the greenhouse gas emissions generated during our operations. Other indirect emissions that occur outside of our operation but are related to our activities and ESG goals are categorized as Scope 3 indirect emissions. Such emissions include both upstream and downstream emissions, such as emissions by our suppliers in their production of raw materials or disposables and in product transport, emissions from business travels by our employees and emissions due to electricity used for sewage processing by the relevant government agency. While we have limited control over the activities that directly contribute to Scope 3 emissions, we firmly believe in the positive impact by fostering an environmentally conscious operational culture in our own operation. This includes opting for qualified domestic suppliers to minimize energy consumption and greenhouse gas emissions during product transport, prioritizing virtual meetings over unnecessary business trips, as well as upgrading our manufacturing facilities/methods as appropriate to reduce waste production and thereby reduce downstream emissions.

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Measures and Targets

With the expansion of our business and anticipated commercialization of our drug candidates, we endeavor to curb the increase in our resource consumption and emissions and aim to keep them relatively stable. We will continue to adopt a wide range of environment-conservation measures to limit resource consumption and emissions. With respect to resource consumption, we will (i) install energy efficient facilities for our daily office operation and manufacturing process; (ii) limiting business air travels and replacing long-journey in-person meetings with virtual conferences where possible; and (iii) cultivate a corporate culture of environmental protection through employee training and office policies, such as switching off certain equipment or setting up automatic power shutdown for certain systems and devices when not in use. With respect to waste generation and greenhouse gas emissions, we will (i) regularly monitor and assess sources of hazardous waste generation and update to more environment-friendly manufacturing processes and facilities when appropriate; and (ii) continue to work with qualified professional waste processors and enhance our on-site waste treatment capacities.

In 2023, we aim to control our (i) total amount and intensity of resource consumption (primarily electricity and water) at approximately 90% to 95% of that recorded in 2022, (ii) total amount and intensity of wastewater and solid waste generation at approximately 170% to 180% and 145% to 150% of those recorded in 2022, respectively, and (iii) greenhouse gas emission at 90% to 95% of that recorded in 2022.

Our Board will set targets for each material KPIs at the beginning of each financial year in accordance with the disclosure requirements of the Listing Rules and other relevant rules and regulations upon [REDACTED]. The relevant targets on material KPIs will be reviewed on an annual basis to ensure that they remain appropriate to the needs of our Group. In setting targets for the ESG-related KPIs, we will take into account our respective historical consumption or discharge levels during the Track Record Period, and our future business expansion in a thorough and prudent manner with a view of balancing business growth and environmental protection to achieve sustainable development.

Social Responsibilities

In respect of social responsibilities, we are committed to offering a fair and caring working environment to our employees. We have transparent policies on recruitment, compensation, dismissal, equal opportunities, diversity and anti-discrimination. We hire employees based on their merits and it is our corporate vision to offer equal opportunities to our employees. We encourage our employees who encounter any discrimination to seek immediate assistance, which also allows us to conduct timely investigation and follow up as needed. In addition, we provide training programs on industry and regulatory developments to our employees.

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In light of the COVID-19 pandemic, we have endeavored to provide a safe work environment by implementing company-wide self-protection policies for employees, including providing protective masks and sanitization to our employees.

Work Safety

To ensure our compliance with applicable EHS laws and regulations and to maintain a healthy and safe environment for our employees, we (i) inspect our equipment and facility regularly to identify and eliminate safety hazards, (ii) assign designated personnel to manage EHS issues during daily operations, (iii) provide regular safety awareness training to our employees, (iv) conduct annual health examinations for all employees, and (v) conduct regular fire safety inspections, maintenance of fire-fighting equipment and regular emergency drills.

Environmental Matters

We are concerned about the impact of our business on climate and environment. We strive to take measures to protect the ecological environment during our business operation, with an aim of minimizing adverse environmental impact.

Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials, and may also produce hazardous waste such as wastewater and biological solid waste. All waste generated during our operations will be stored in accordance with our internal policies and applicable laws and regulations and discharged following harmless treatment by qualified service providers. See “Regulatory Overview—Principal Regulatory Provisions—Laws and Regulations on Environmental Protection” for details on relevant PRC environmental laws and regulations. We also actively monitor our resource consumption for our manufacturing function.

We believe we have maintained good relationships with the communities surrounding our manufacturing facility. During the Track Record Period and up to the Latest Practicable Date, we complied with the relevant environmental and occupational health and safety laws and regulations in all material aspects, and we did not have any incidents or complaints which had a material and adverse effect on our business, financial condition or impact on the operations of our business during the period. For the years ended December 31, 2021 and 2022 and the nine months ended September 30, 2023, our expenses in relation to environmental protection amounted to RMB0.6 million, RMB0.4 million and RMB0.4 million, respectively. We expect our costs of complying with current and future environmental protection laws to increase in the future, as we further our R&D efforts and commence commercial manufacturing of our products after regulatory approval. We incorporate a sustainable development approach in our daily business operation decisions.

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PROPERTIES

We are headquartered in Taizhou, Jiangsu province. As of the Latest Practicable Date, we owned the buildings of our Taizhou Manufacturing Facility of 43,571 sq.m. in gross floor area and the parcel of land housing our Taizhou Manufacturing Facility of 57,977 sq.m. As advised by our PRC Legal Advisors, during the Track Record Period and up to the Latest Practicable Date, we had obtained the real estate title certificate for such land parcel and properties. For further details with respect to our property interests, see “Appendix IV—Valuation Report” to this document. As of the Latest Practicable Date, we leased eight properties with an aggregate gross floor area of 3,969 square meters in Shanghai, Beijing and Taizhou for our daily business operations, R&D functions and staff dormitory.

As of the Latest Practicable Date, we had not completed lease registrations for seven of our leases, with an aggregate gross floor area of 1,229 sq.m., with the relevant regulatory authorities due to the inaction of the landlords to cooperate with the registration procedure. As advised by our PRC Legal Advisors, the non-registration of lease agreements will not affect the validity of such lease agreements, but the relevant local housing administrative authorities can require us to complete registrations within a specified timeframe and we may be subject to a fine between RMB1,000 and RMB10,000 per lease for any delay in making these registrations, which we do not believe would have a material adverse impact on our operation. However, we will consult with our legal advisors and aim to address the issue appropriately during the lease negotiation process in the future. As of the Latest Practicable Date, we were not subject to any penalties arising from the non-registration of the lease agreements. See “Risk Factors—Risks Relating to Our Operations—We may be required to pay administrative fines for our failure to register some of our lease agreements with housing administration authorities.”

AWARDS AND RECOGNITIONS

The following table sets out a summary of the major awards and recognitions we have received.

<u>Year</u>	<u>Award or Recognition</u>	<u>Issuing Authority</u>
2023	China Biopharmaceutical Industry Value List Top 10 Most Promising CDMO Enterprises (Cellularforce) (中國生物醫藥產業價值榜最具成長性CDMO企業TOP10 (賽孚士))	Huayi Research Institution (華醫研究院)
2023	China Biopharmaceutical Science and Technology Innovation Value List Top 10 Most Promising Biopharmaceutical Enterprises (中國生物醫藥科技創新價值榜最具成長性生物藥企業TOP10)	Shanghai Biopharmaceutical Industry Association (上海市生物醫藥行業協會); Yiyun Technology (醫耘科技)

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Year	Award or Recognition	Issuing Authority
2022-2023	Top 50 Chinese Enterprises in terms of biopharmaceutical R&D capability (中國生物藥研發實力排行榜50強)	China Pharmaceutical Industry Journal Publisher (中國藥業雜誌社); Yaozhi Web (藥智網)
2022-2023	Top 100 Chinese Enterprises in terms of comprehensive pharmaceutical R&D capability (中國藥品研發綜合實力排行榜100強)	China Pharmaceutical Industry Journal Publisher (中國藥業雜誌社); Yaozhi Web (藥智網)
2022	China Biopharmaceutical Technology Innovation Rank – Top 20 Most Influential Antibody Biotech Companies (中國生物醫藥科技創新價值榜“最具影響力抗體藥企業TOP20”)	Shanghai Biopharmaceutical Industry Association (上海市生物醫藥行業協會); Yiyun Technology (醫耘科技)
2022	Top 50 Chinese Innovative Biotech Enterprises (生物科技創新50企業)	KPMG China
2021-2022	Top 100 Chinese Seed Enterprises in terms of Pharmaceutical Innovation (中國醫藥創新種子企業100強)	Healthcare Executive (E藥經理人)
2021-2022	Potential Unicorn Enterprise of Jiangsu Provincial High-Tech Industrial Development Area (江蘇省高新技術產業開發區潛在獨角獸企業)	Productivity Center of Jiangsu Province (江蘇省生產力促進中心)
2021-2022	Top 30 Most Innovative Chinese Antibody Therapeutics Enterprises (中國抗體藥物企業創新力TOP30)	Menet (米內網)
2021	Jiangsu Autoimmune Diseases Antibody Engineering Research Center (江蘇省免疫性疾病抗體工程研究中心)	Jiangsu Provincial Development and Reform Commission (江蘇省發展和改革委員會)
2021	High and New Tech Enterprise (高新技術企業)	Jiangsu Science and Technology Department (江蘇省科學技術廳)
2021	Top 10 Most Promising Enterprises of Antibody Innovative Drugs (年度最具發展潛力的抗體創新藥企TOP10)	CHUJIETECH (觸界科技)

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LICENSES, PERMITS AND APPROVALS

During the Track Record Period and up to the Latest Practicable Date, we had obtained all requisite licenses, approvals and permits from relevant authorities that are material to our operations. The table below sets forth the relevant details of the material license we hold for our operations in China.

<u>License/Permit</u>	<u>Holder</u>	<u>Issuing Authority</u>	<u>Issue Date</u>	<u>Expiration Date</u>
Drug Manufacturing Certificate (藥品生產許可證)	Cellularforce	Jiangsu Medical Products Administration	April 15, 2021 (last renewed on October 18, 2023)	March 27, 2026

LEGAL PROCEEDING AND COMPLIANCE

During the Track Record Period and up to the Latest Practicable Date, we had not been involved in any litigation, arbitration or administrative proceedings which could have a material adverse impact on our business, financial condition or results of operations. As of the Latest Practicable Date, we were not aware of any pending or threatened litigation, arbitration or administrative proceedings against us which may have a material and adverse impact on our business, financial condition or results of operations.

During the Track Record Period and as of the Latest Practicable Date, we had not had any non-compliance incidents which our Directors believe would, individually or in the aggregate, have a material operational or financial impact on our company as a whole.

RISK MANAGEMENT AND INTERNAL CONTROL

We are subject to various risks during our operations. See “Risk Factors—Risks Relating to Our Operations.” We have established a consolidated risk management system and relevant policies and procedures which we consider suitable for our business operations. Our policies and procedures are aimed at managing and monitoring our business performance.

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To monitor the continuous implementation of risk management policies and corporate governance measures after the [REDACTED], we have adopted or will continue to adopt, among other things, the following risk management measures:

- establish an audit committee to review and supervise our financial reporting process and internal control system. Our audit committee consists of three members: Mr. Fung Che Wai, Anthony, chairman of the committee, Mr. Wu Zhiqiang and Dr. Ling Jianqun. For the qualifications and experiences of these members, see “Directors, Supervisors and Senior Management”;
- adopt various policies to ensure the compliance with the Listing Rules, including but not limited to policies in respect of risk management, connected transactions and information disclosure;
- provide regular anti-corruption and anti-bribery compliance training for senior management and employees in order to enhance their knowledge of and compliance of applicable laws and regulations; and
- arrange our Directors and senior management to attend training seminars on Listing Rules requirements and the responsibilities as directors of a Hong Kong-listed company.

We have appointed an internal control consultant to review the effectiveness of our internal control measures related to our major business processes, to identify the deficiencies for improvement, advise on the rectification measures and review the implementation of such measures. During the review process of our internal control consultant, certain internal control matters were identified, and we have adopted corresponding internal control measures to improve on these matters. We have adopted the recommendations made by the internal control consultant and our internal control consultant has completed the follow-up procedures on our internal control system and have not identified any material deficiencies in our internal control system.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

BOARD OF DIRECTORS

Our Board of Directors comprises nine Directors, including three executive Directors, three non-executive Directors and three independent non-executive Directors. The powers and duties of our Board include determining our business and investment plans, preparing our annual financial budgets and final reports, and exercising other powers, functions and duties as conferred by the Articles. We have entered into a service agreement with each of our executive Directors and a letter of appointment with each of our non-executive Directors and independent non-executive Directors.

The table below sets out the key information of our Directors, Supervisors and senior management:

Our Directors

Name	Age	Date of joining our Group	Date of appointment as Director	Existing position(s) in our Group	Roles and responsibilities	Relationship with other Directors, Supervisors and senior management
<i>Executive Directors</i>						
Mr. Qiu Jiwan (裘霽宛)	52	June 5, 2015	June 5, 2015	Executive Director, chairman of our Board, chief executive officer and general manager of our Company	Responsible for the strategic planning, business direction and operational management of our Group	None
Mr. Wu Yiliang (吳亦亮)	42	June 16, 2015	April 10, 2019	Executive Director and executive deputy general manager of Cellularforce	Responsible for the process development and production of our Group	None
Mr. Lin Weidong (林偉棟)	41	August 23, 2021	March 16, 2022	Executive Director and deputy general manager of our Company	Responsible for the financial management, financing and capital market affairs of our Group	None

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Name	Age	Date of joining our Group	Date of appointment as Director	Existing position(s) in our Group	Roles and responsibilities	Relationship with other Directors, Supervisors and senior management
<i>Non-executive Directors</i>						
Mr. Yu Xi (余熹)	50	August 14, 2020	August 14, 2020	Non-executive Director	Responsible for providing guidance for the strategy and business development of our Group	None
Mr. Wu Zhiqiang (吳志強)	42	September 17, 2021	September 17, 2021	Non-executive Director	Responsible for providing guidance for the strategy and business development of our Group	None
Dr. Xue Mingyu (薛明宇)	37	March 29, 2021	March 29, 2021	Non-executive Director	Responsible for providing guidance for the strategy and business development of our Group	None
<i>Independent non-executive Directors</i>						
Dr. Zou Zhongmei (鄒忠梅)	59	January 4, 2024	January 4, 2024	Independent non-executive Director	Responsible for providing independent advice to our Board	None
Dr. Ling Jianqun (凌建群)	55	January 4, 2024	January 4, 2024	Independent non-executive Director	Responsible for providing independent advice to our Board	None
Mr. Fung Che Wai, Anthony (馮志偉)	55	January 4, 2024	January 4, 2024	Independent non-executive Director	Responsible for providing independent advice to our Board	None

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Our Supervisors

Name	Age	Date of joining our Group	Date of appointment as Supervisor	Existing position(s) in our Group	Roles and responsibilities	Relationship with other Directors, Supervisors and senior management
Mr. Ye Xiang (葉翔)	51	September 17, 2021	September 17, 2021	President of the Supervisory Committee and Supervisor	Responsible for presiding the work of the Supervisory Committee, supervising and providing independent advice to our Board	None
Dr. Ding Chao (丁超)	36	September 15, 2022	September 15, 2022	Supervisor	Responsible for supervising and providing independent advice to our Board	None
Ms. Wang Yujiao (王玉姣) ^(Note)	42	June 5, 2015	September 17, 2021	Employee representative Supervisor and assistant to general manager of our Company	Responsible for supervising and providing independent advice to our Board	None

Our senior management

Name	Age	Date of joining our Group	Date of appointment as senior management	Existing position(s) in our Group	Roles and responsibilities	Relationship with other Directors, Supervisors and senior management
Mr. Qiu Jiwan (裘霽宛)	52	June 5, 2015	June 16, 2015	Executive Director, chairman of our Board, chief executive officer and general manager of our Company	Responsible for the strategic planning, business direction and operational management of our Group	None
Mr. Wu Yiliang (吳亦亮)	42	June 16, 2015	June 16, 2015	Executive Director and executive deputy general manager of Cellularforce	Responsible for the process development and production of our Group	None

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Name	Age	Date of joining our Group	Date of appointment as senior management	Existing position(s) in our Group	Roles and responsibilities	Relationship with other Directors, Supervisors and senior management
Mr. Lin Weidong (林偉棟)	41	August 23, 2021	August 23, 2021	Executive Director and deputy general manager of our Company	Responsible for the financial management, financing and capital market affairs of our Group	None
Dr. Li Jianwei (李建偉)	63	October 14, 2020	October 14, 2020	Chief operating officer and deputy general manager of our Company and general manager of Cellularforce	Responsible for the R&D, good manufacturing practice (“GMP”) manufacturing, quality management and general operation of our Group	None
Mr. Wu Shenglong (吳生龍)	50	February 13, 2023	February 13, 2023	Chief business officer and deputy general manager of our Company	Responsible for the business development, equity investment and financing of our Group	None
Ms. Fang Min (房敏)	48	December 24, 2017	December 24, 2017	Deputy general manager of our Company	Responsible for the management of clinical strategy and operation of our Group	None
Mr. Hu Yanbao (胡衍保)	36	November 2, 2020	August 30, 2022	Board secretary and joint company secretary of our Company	Responsible for business development, financing, corporate governance and company secretarial matters of our Group	None

Note: Ms. Wang Yujiao served as our Supervisor from June 5, 2015 to August 14, 2020 and was re-appointed as our Supervisor on September 17, 2021.

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Executive Directors

Mr. Qiu Jiwan (裘霽宛), aged 52, is the founder of our Group. He was appointed as our Director on June 5, 2015 and was re-designated as our executive Director on March 23, 2023. Mr. Qiu has been serving as our chief executive officer since June 2015, the general manager since September 2021 and the chairman of our Board since February 2022. He is primarily responsible for the strategic planning, business direction and operational management of our Group.

Mr. Qiu also holds various directorships and management positions in our Group companies, including (i) the executive director of Saifu Juli since July 2018, where he has been primarily responsible for the overall management of Saifu Juli; and (ii) the general manager of Cellularforce from August 2018 to March 2023, where he was primarily responsible for the overall management of Cellularforce.

As an industry veteran, Mr. Qiu has nearly 30 years of experience in the biotechnology and pharmaceutical industries, where he started as a biotechnology specialist, gradually extended his role as a leader supervising the discovery, technology and manufacturing platform and accumulated management experience in the R&D and manufacturing of biotech companies, and eventually became a serial entrepreneur with various entrepreneurial achievements. From July 1993 to January 2004, Mr. Qiu served at Hangzhou Jiuyuan Gene Engineering Co., Ltd. (杭州九源基因工程有限公司) (“Hangzhou Jiuyuan”), a biotech company primarily engaged in the production of injections and active pharmaceutical ingredients (APIs), with his last position being a director of research institute. During his tenure at Hangzhou Jiuyuan, he was primarily responsible for: (i) leading the development of Human Interleukin-11 for Injection (hIL-11) (formerly known as Recombinant Human Interleukin-11 for Injection (Yeast)); and (ii) leading the research on the recombinant human serum albumin production method and the stabilizing agents containing ciliary neurotrophic factor analogs, and obtained the relevant invention patents. From February 2004 to June 2005, Mr. Qiu served as a deputy general manager at Epitomics (Hangzhou) Biotechnology Co., Ltd. (宜康(杭州)生物技術有限公司) (“Hangzhou Epitomics”), a biotech company primarily engaged in the R&D and manufacturing of antibody reagents. During his tenure at Hangzhou Epitomics, he was primarily responsible for: (i) the establishment of a technology platform for mass production of high affinity rabbit monoclonal antibodies; and (ii) the production of hundreds of high quality rabbit monoclonal antibodies which are currently on sale in the European and American markets. From December 2005 to January 2015, Mr. Qiu founded Jiangsu T-mab and its two subsidiaries, Hangzhou Genewave Biotechnology Co., Ltd. (杭州基偉生物技術有限公司) (“Hangzhou Genewave”) and Taizhou Beijin Biotechnology Co., Ltd. (泰州貝今生物技術有限公司) (“Taizhou Beijin”), all being companies principally engaged in the R&D and production of genetically engineered drugs, where Mr. Qiu served as (i) the general manager at Hangzhou Genewave beginning from July 2005 to January 2015; (ii) the general manager at Taizhou Beijin beginning from August 2007 to January 2015; and (iii) the general manager at Jiangsu T-mab from July 2008 to January 2015. During his tenure at Jiangsu T-mab, he was primarily responsible for: (i) the establishment of long-lasting protein technology platform and the development of two innovative recombinant protein drugs for the treatment of white blood cell hypoplasia after tumor radiotherapy and type 2 diabetes; (ii) the introduction of rabbit

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

monoclonal antibody platform technology and the development of one innovative monoclonal antibody drug for the treatment of ophthalmic wet age-related macular degeneration; (iii) the development of one biological drug targeted RANKL for the treatment of tumor bone metastasis and osteoporosis; and (iv) leading the co-establishment of China Pharmaceutical City Large Molecule Drug Public Service Platform (中國醫藥城大分子藥物公共服務平台) with Torch High Technology Industry Development Center, Ministry of Science and Technology (科技部火炬高技術產業開發中心) and Department of Science and Technology of Jiangsu Province (江蘇省科學技術廳), both being government institutions. In June 2009, he was appointed as a non-executive director nominated by Hangzhou Genewave at Jiangsu Stanford Biotechnology Co., Ltd. (江蘇斯坦福生物技術有限公司) (“Jiangsu Stanford”), a company established in the PRC with limited liability principally engaged in R&D of reagents and consumables required in the process of stem cell, where he was primarily responsible for providing strategic guidance and was not involved in its day-to-day management and operations.

Mr. Qiu graduated from Fudan University (復旦大學) in the PRC in July 1993 with a bachelor’s degree in genetics and genetic engineering. He also obtained a master’s degree in business administration (MBA) from Zhejiang University (浙江大學) in the PRC in June 2005. Mr. Qiu was awarded the Third Prize of Zhejiang Province Science and Technology Award (浙江省科學技術三等獎) by the People’s Government of Zhejiang Province (浙江省人民政府) in 2005 and the Second Prize of Hangzhou Science and Technology Progress Award (杭州市科技進步二等獎) by Hangzhou Municipal People’s Government (杭州市人民政府) in February 2006.

Mr. Wu Yiliang (吳亦亮), aged 42, was appointed as our Director on April 10, 2019 and was re-designated as our executive Director on March 23, 2023. Mr. Wu joined our Group in June 2015 and has been serving as the executive deputy general manager of Cellularforce since March 2023. He is primarily responsible for the process development and production of our Group.

Mr. Wu has over 15 years of experience in biopharmaceutical industry, specialized in process development, quality control and commercial manufacturing of recombinant protein drugs. Mr. Wu joined our Group in June 2015 and served as the director of our department of process research and development from June 2015 to January 2019, where he led the establishment of platforms for antibody drug process development, quality research and pilot production, and was mainly responsible for the preclinical research of our biosimilar antibody drug candidate QX001S. From February 2019 to February 2023, Mr. Wu served as the chief operating officer of our Company and was primarily responsible for assisting the president with the overall operational management of our Company. During his tenure, we successfully completed pharmacology, preclinical pharmacology and toxicology studies for QX002N, QX005N, QX004N, QX006N and QX008N, which are currently in Phase I or II clinical research. Mr. Wu also served as the vice president of production at Cellularforce from March 2019 to February 2023, where he was primarily responsible for the design, construction, testing and confirmation of manufacturing facilities, and assisted in the establishment of quality management system.

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Prior to joining our Group, from July 2007 to March 2015, Mr. Wu worked at Hangzhou Genewave which is a subsidiary of Jiangsu T-mab. Mr. Wu successively served various positions at Jiangsu T-mab, including as: (i) a purification researcher in protein drug department from July 2008 to May 2010, where he was primarily responsible for the purification process development of two long-acting recombinant cytokine-based drugs; and (ii) a deputy manager of the antibody drugs department from May 2010 to May 2015, where he was involved in establishing the antibody drugs department and was responsible for its process research and pilot scale-up (500L scale) production system for antibody drugs.

Mr. Wu graduated from Xiamen University (廈門大學) in the PRC in July 2003 with a bachelor’s degree in biotechnology. He also obtained a master’s degree in cytobiology from Xiamen University in September 2006. He was certified as a senior engineer (高級工程師) by Human Resources and Social Security Department of Jiangsu Province (江蘇省人力資源和社會保障廳) in December 2013.

Mr. Lin Weidong (林偉棟), aged 41, was appointed as our Director on March 16, 2022 and was re-designated as our executive Director on March 23, 2023. Mr. Lin joined our Group in August 2021 and served as the vice president of finance of our Company from August 2021 to September 2021. He has been serving as the deputy general manager of our Company since September 2021. He is primarily responsible for the financial management, financing and capital market affairs of our Group.

Mr Lin has over 13 years of experience in auditing and corporate financial management. Prior to joining our Group, Mr. Lin served as an auditor at Shanghai De’An Certified Public Accountants (上海德安會計師事務所有限公司) from October 2004 to June 2005 and worked at KPMG Huazhen LLP (Shanghai Branch) (畢馬威華振會計師事務所上海分所) from November 2005 to December 2009 with his last position being an assistant audit manager. Since 2010, Mr. Lin has accumulated extensive experience in corporate financial management by serving as the senior management at various enterprises, including as: (i) a financial manager of Shanghai Arkema Gaoyuan Chemical Co., Ltd. (上海阿科瑪高遠化工有限公司), a company primarily engaged in production of high quality engineering polyamides and a subsidiary of Arkema S.A., a specialty chemicals and advanced materials company whose shares are listed on Euronext Paris (stock code: AKE), from May 2010 to May 2012, where he was primarily responsible for the overall financial management; (ii) a regional financial manager for Asia Pacific operation at Imerys (Shanghai) Investment Management Co., Ltd. (益瑞石(上海)投資管理有限公司) and Imerys (Shanghai) Filtering Minerals Trading Co., Ltd. (益瑞石(上海)過濾礦物貿易有限公司), both of which are primarily engaged in non-metallic minerals processing and trading and are subsidiaries of Imerys S.A., a specialty minerals company whose shares are listed on Euronext Paris (stock code: NK), from December 2013 to June 2015, where he was primarily responsible for the financial reporting, analysis and management; (iii) a vice president of finance at Shanghai Muhe Network Technology Co., Ltd. (上海慕和網絡科技有限公司), a company primarily engaged in mobile games development and operation, from February 2016 to October 2016, where he was mainly responsible for the overall financial management; (iv) the co-founder and chief financial officer at Ifenqu Network Technology Shanghai Co., Ltd. (愛分趣網絡技術(上海)有限公司), a company primarily engaged in online

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insurance business, from November 2016 to March 2018, where he was primarily responsible for financial management and financing; (v) worked at Shanghai Yiguo E-commerce Co., Ltd. (上海易果電子商務有限公司), an e-commerce platform primarily engaged in online sales of fresh agricultural products, from September 2018 to March 2019; and (vi) a financial director at Harbour BioMed (Shanghai) Co., Ltd. (和鉅醫藥(上海)有限責任公司) (“HBM Shanghai”), a company mainly engaged in the R&D of biomedical product and an indirect wholly owned subsidiary of HBM Holdings Limited, a biopharmaceutical company whose shares are listed on the Stock Exchange (stock code: 02142), from June 2019 to December 2020, where he was primarily responsible for financial management.

Mr. Lin received a bachelor’s degree in English from Tongji University (同濟大學) in the PRC in July 2004 and a master’s degree in business administration (MBA) from Shanghai Jiao Tong University (上海交通大學) in the PRC in June 2016. He was qualified as a Certified Public Accountant non-practicing member (中國註冊會計師協會非執業會員) by The Chinese Institute of Certified Public Accountants (中國註冊會計師協會) in February 2013.

Non-executive Directors

Mr. Yu Xi (余熹), aged 50, was appointed as our Director on August 14, 2020 and was re-designated as our non-executive Director on March 23, 2023. He is primarily responsible for providing guidance for the strategy and business development of our Group.

Mr. Yu Xi has extensive professional experience in business development, consulting and investment in the biopharmaceutical industry. Mr. Yu Xi once served as an alliance management director of business strategy and development department at Xi’an Janssen Pharmaceutical Ltd. (西安楊森製藥有限公司), a pharmaceutical company which is the subsidiary of Johnson & Johnson whose shares are listed on NASDAQ (stock code: JNJ), and served as a director of business development at Sanofi-Aventis China Investment Co., Ltd. (賽諾菲(中國)投資有限公司) (“Sanofi China”), a company mainly engaged in investments in the pharmaceutical and biological sectors and a subsidiary of Sanofi S.A. whose shares are listed on Euronext Paris (stock code: SAN) and NASDAQ (stock code: SYN). From September 2018 to December 2019, Mr. Yu Xi served as a vice president of business development and strategy at HBM Shanghai, where he was primarily responsible for product licensing and mergers and acquisitions. Since January 1, 2020, Mr. Yu Xi has been serving as the general manager of investment department at Huadong Medicine, a pharmaceutical company whose shares are listed on the Shenzhen Stock Exchange (stock code: 000963) and the parent company of Zhongmei Huadong which is our substantial shareholder, where he is primarily responsible for department affairs.

Mr. Yu Xi graduated from East China University of Science and Technology (華東理工大學) in the PRC in July 1997 with a bachelor’s degree in English for Science and Technology.

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Our Directors are of the view that there is no actual conflict of interest among Mr. Yu Xi, Zhongmei Huadong and our Group for the following reasons:

- (i) the negotiations for the Series B+ Financing and the QX001S Framework Agreement between Zhongmei Huadong and our Group were conducted between May to August 2020, when Mr. Yu Xi had not yet been appointed as our Director and Zhongmei Huadong had not yet become our Shareholder. Mr. Yu Xi has been serving as the general manager of investment department at Huadong Medicine since January 1, 2020, where he is primarily responsible for sourcing suitable biotech companies with R&D potential to invest in and promising drug products with market prospects for marketing and commercialization collaboration. He was involved in the business matchmaking and negotiation for the Series B+ Financing and the QX001S Framework Agreement;
- (ii) each of our Directors (including Mr. Yu Xi) is aware of his/her fiduciary duties as a Director, which require, among other things, that he/she does not allow any conflict between his/her duties as a Director and his/her personal interests. Since Mr. Yu Xi became our Director, he has declared his potential conflict of interest at the relevant Board meetings in respect of the transactions between Zhongmei Huadong and our Group and abstained from voting on such matters;
- (iii) since Zhongmei Huadong became our Shareholder, it has abstained from voting at the relevant Shareholders’ meetings in respect of the transactions between Zhongmei Huadong and our Group; and
- (iv) Mr. Yu Xi was nominated by Zhongmei Huadong as our non-executive Director. He has not and will not be involved in the daily management and operation of our Group and does not enjoy any special rights as one of our non-executive Directors.

Mr. Wu Zhiqiang (吳志強), aged 42, was appointed as our Director on September 17, 2021 and was re-designated as our non-executive Director on March 23, 2023. He is primarily responsible for providing guidance for the strategy and business development of our Group.

Mr. Wu has over 13 years of experience in the investment and financing industry. From December 2007 to June 2010, Mr. Wu worked at Industrial Securities Co., Ltd. (興業證券股份有限公司), a state-controlled securities company whose shares are listed on the Shanghai Stock Exchange (stock code: 601377). From May 2011 to November 2017, Mr. Wu successively served as a financial manager of financing and investment department, an assistant to the director, a deputy director of investment department, a deputy director of office, an assistant to general manager at Taizhou Oriental, a state-owned company primarily engaged in pharmaceutical promotion and financial services and a substantial shareholder of Taizhou Huayin, where he was primarily responsible for its administrative management, investment and financing strategy management. Mr. Wu also served various positions at certain subsidiaries of Taizhou Huayin, including (i) an assistant to general manager primarily responsible for the financing guarantee business from January 2012 to May 2012 and a deputy general manager

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primarily responsible for the operation and management from November 2015 to December 2016 at Taizhou Medical City Hongtai Financing Guarantee Co., Ltd. (泰州醫藥城鴻泰融資擔保有限公司), a state-owned company primarily engaged in financing guarantee business; (ii) a deputy general manager at Taizhou Huajian Venture Capital Co., Ltd. (泰州華健創業投資有限公司) (“Taizhou Huajian”), a state-owned venture capital company, from May 2013 to July 2018, primarily responsible for the investment management; and (iii) a general manager at Jiangsu Huatairong Supply Chain Management Co., Ltd. (江蘇華泰融供應鏈管理有限公司), a state-owned investment company, from November 2015 to December 2016, primarily responsible for the operation and management. Since September 2019, Mr. Wu has been serving as the general manager at Taizhou Huayin, where he is mainly responsible for the overall operations and management. In August 2014, he was appointed as a non-executive director nominated by Taizhou Huajian at Jiangsu Stanford, a company established in the PRC with limited liability principally engaged in R&D of reagents and consumables required in the process of stem cell, where he was primarily responsible for providing strategic guidance and was not involved in its day-to-day management and operations.

Mr. Wu received a bachelor’s degree in finance from Zhongnan University of Economics and Law (中南財經政法大學) in the PRC in June 2004.

Dr. Xue Mingyu (薛明宇), aged 37, was appointed as our Director on March 29, 2021 and was re-designated as our non-executive Director on March 23, 2023. He is primarily responsible for providing guidance for the strategy and business development of our Group.

Dr. Xue has extensive professional experience in the management consulting, business development and venture fund investment in healthcare industry. From October 2016 to July 2018, Dr. Xue worked at Bain & Company China, Inc. (貝恩創效管理諮詢(上海)有限公司), a global management consulting firm, with his last position as a senior consultant. From July 2018 to September 2020, he served as an associate director of global business development and licensing at Sanofi China. Since September 2020, Dr. Xue has been serving as a vice president at Matrix Partners China, where he is primarily responsible for the investment in healthcare sector.

Dr. Xue graduated from the University of Hong Kong with his bachelor’s degree of science in November 2008. He further obtained a doctoral degree in chemistry and chemical biology from Harvard University in the United States. Dr. Xue conducted post-doctorate research at Weill Cornell Medicine biochemistry department in the United States until January 2016.

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Independent non-executive Directors

Dr. Zou Zhongmei (鄒忠梅), aged 59, was appointed as our independent non-executive Director on January 4, 2024. Dr. Zou is responsible for providing independent advice to our Board.

Dr. Zou has over 32 years of experience in natural products chemistry and R&D of new drugs. Dr. Zou worked at the teaching and research laboratory of Chinese medicine chemistry of Hubei College of Chinese Medicine (湖北中醫學院中藥化學教研室) from July 1984 to September 1987 and also served as its teaching assistant from August 1990 to July 1992. From July 1992 to September 1995, she served as an assistant professor at the Chinese medicine research institute of Hubei College of Chinese Medicine (湖北中醫學院中藥研究所). From July 1998 to February 2005, she successively served as an assistant professor and an associate professor at the Institute of Medicinal Plant Development of Chinese Academy of Medical Sciences (中國醫學科學院藥用植物研究所) (“IMPLAD”), a national research institution of public service specializing in protection, development and utilization of medicinal plant resources. Dr. Zou successively served as a deputy director and associate professor of the research center of natural medicine chemistry of IMPLAD from February 2005 to November 2021 and has been serving as its professor since September 2005 and its director since November 2021.

Dr. Zou graduated from Hubei University of Chinese Medicine (湖北中醫藥大學) (formerly known as Hubei College of Chinese Medicine (湖北中醫學院)) in the PRC with a bachelor’s degree in Chinese medicine in July 1984. Dr. Zou graduated from Peking Union Medical College (北京協和醫學院) (formerly known as Peking Union Medical College (中國協和醫科大學)) in the PRC with a master’s degree in biopharmacology in August 1990 and a doctoral degree (Ph.D.) in pharmaceutical chemistry in July 1998, respectively. She was awarded as the National Candidate of New Century Hundred Million Talents Project (新世紀百千萬人才工程國家級人選) by the Ministry of Human Resources and Social Security of the PRC (中華人民共和國人力資源和社會保障部) in 2009. She was granted the Government Special Allowance of the State Council (國務院政府特殊津貼) by the State Council of the PRC (中華人民共和國國務院) in February 2013.

Dr. Ling Jianqun (凌建群), aged 55, was appointed as our independent non-executive Director on January 4, 2024. Dr. Ling is responsible for providing independent advice to our Board.

Dr. Ling has over 23 years of experience in the biopharmaceuticals industry. From August 1994 to September 1999, he served as a lecturer at Zhejiang University Biotechnology Institute (浙江大學生物技術研究所) in the PRC, where he was primarily responsible for teaching courses of biology and genetic engineering. From 2004 to 2011, Dr. Ling successively served as a post-doctoral fellow, a research scientist and a senior research scientist at Stanford University Department of Medicine in the United States. From April 2011 to January 2023, Dr. Ling served as the chairman of the board of directors and the general manager of Genloci Biotechnologies Inc. (江蘇吉銳生物技術有限公司), a high-tech biological enterprise, where he has been primarily responsible for its strategic planning and operational management.

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Dr. Ling obtained a college diploma in biology from Zhejiang Normal University (浙江師範大學) in the PRC in July 1988. Dr. Ling graduated from Peking University (北京大學) in the PRC in July 1994 with a master’s degree in botany. He also obtained a doctoral degree (Ph.D.) in agronomy from Tokyo University of Agriculture and Technology in Japan in March 2004. Dr. Ling was awarded the Second Prize of Army Science and Technology Progress Award (軍隊科學技術進步獎二等獎) by the Science and Technology Commission of Central Military Commission (中央軍委科學技術委員會) in December 2020.

Mr. Fung Che Wai, Anthony (馮志偉), aged 55, was appointed as our independent non-executive Director on January 4, 2024. Mr. Fung is responsible for providing independent advice to our Board.

Mr. Fung has over 29 years of experience in accounting and financial management. From August 1992 to September 1999, he successively served as a staff accountant, a semi senior accountant, a senior accountant and a manager at Deloitte Touche Tohmatsu, an accounting firm, where he was primarily responsible for audit planning and control. From October 1999 to August 2007, he served as a director at Winsmart Consultants Limited (弘陞投資顧問有限公司), where he was primarily responsible for advising the client on corporate finance and investor relations. From January 2008 to August 2010, he served as a vice president of investor relations department at NagaCorp Limited (金界控股有限公司), a hotel, gaming and leisure operator in Cambodia whose shares are listed on the Stock Exchange (stock code: 3918), where he was primarily responsible for the development of investor relations and liaison with existing and potential investors as well as analysts. From January 2011 to December 2022, Mr. Fung served as the chief financial officer and the company secretary at various listed companies, where he was primarily responsible for the overall financial operations, company secretarial matters, investor relations and compliance matters, including at: (i) Zall Smart Commerce Group Ltd. (卓爾智聯集團有限公司) (formerly known as Zall Development (Cayman) Holding Co., Ltd. (卓爾發展(開曼)控股有限公司)), a developer and operator of large-scale consumer product focused wholesale shopping malls in the PRC whose shares are listed on the Main Board of the Stock Exchange (stock code: 2098), from January 2011 to July 2014; (ii) Kong Sun Holdings Limited (江山控股有限公司), a solar power plants investor and operator whose shares are listed on the Main Board of the Stock Exchange (stock code: 0295), from July 2014 to April 2017; and (iii) Beijing Enterprises Urban Resources Group Limited (北控城市資源集團有限公司), an integrated waste management solution provider whose shares are listed on the Main Board of the Stock Exchange (stock code: 3718), from May 2017 to December 2022.

Since April 2017, Mr. Fung has been serving as an independent non-executive director primarily responsible for supervising and providing independent advice to the board of directors at various listed companies, including at: (i) FY Financial (Shenzhen) Co., Ltd. (富銀融資租賃(深圳)股份有限公司), a financial services provider whose shares are listed on the GEM Board of Stock Exchange (stock code: 8452), from April 2017 to August 2023; (ii) S&P International Holding Limited (椰豐集團有限公司), a Malaysian coconut food manufacturer and seller whose shares are listed on the Main Board of the Stock Exchange (stock code: 1695), from June 2017 to October 2021; (iii) KWG Living Group Holdings Limited (合景悠活集團控股有限公司), a comprehensive property management service provider whose shares are listed

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on the Main Board of the Stock Exchange (stock code: 3913), since October 2020; (iv) Zhong An Group Limited (眾安集團有限公司), a real estate development company whose shares are listed on the Main Board of the Stock Exchange (stock code: 0672), since November 2021; (v) XXF Group Holdings Limited (喜相逢集團控股有限公司), an automobile retailer providing automobile finance lease service whose shares are listed on the Main Board of the Stock Exchange (stock code: 2473), since October 2023; and (vi) Dekon Food and Agriculture Group (四川德康農牧食品集團股份有限公司), a livestock and poultry breeding and farming enterprise whose shares are listed on the Main Board of the Stock Exchange (stock code: 2419), since December 2023.

Mr. Fung obtained his bachelor’s degree in accountancy from The Hong Kong Polytechnic University (formerly known as Hong Kong Polytechnic) in Hong Kong in October 1992. Mr. Fung was admitted as a fellow member of the Association of Chartered Certified Accountants (ACCA) in October 2001 and as a fellow member of the Hong Kong Institute of Certified Public Accountants (HKICPA) in September 2005, respectively.

Save as disclosed above and in this document, each of our Directors has confirmed that he/she has no other relationship with any other Directors, senior management, substantial shareholders or controlling shareholders of our Company and none of our Directors has held any other directorships in listed companies during the three years immediately preceding the date of this document.

Each of Mr. Qiu and Mr. Wu Zhiqiang (吳志強) was a director of Jiangsu Stanford. The business license of Jiangsu Stanford was revoked on September 29, 2020 because it had ceased its business operation voluntarily for at least six consecutive months and there were no personnel responsible for its daily operation (including annual inspection matters) after its cessation of business. As such, it failed to conduct annual inspection on a timely basis pursuant to the regulations under PRC laws. According to the Regulation of the PRC on the Administration of the Registration of Market Entities (《中華人民共和國市場主體登記管理條例》), an enterprise shall publish its annual report in accordance with the relevant PRC laws and regulations. The Interim Regulation on Enterprise Information Disclosure (《企業信息公示暫行條例》) further provides that in the event an enterprise fails to publish its annual report timely, the competent local counterparts of SAMR shall list such enterprise into a category of enterprises with abnormal operations or impose punishments on such enterprise in serious cases. According to the PRC Company Law, the business license of an enterprise may be revoked by the competent company registration authority if such business entity ceases its business operation voluntarily for at least six consecutive months. Mr. Qiu and Mr. Wu Zhiqiang confirmed that, (i) they were nominated by Hangzhou Genewave and Taizhou Huajian, both being minority shareholders of Jiangsu Stanford, to be their respective board representatives at Jiangsu Stanford and the directorship they held at Jiangsu Stanford was non-executive in nature; (ii) as a non-executive director, they were not involved in the daily management or company secretarial matters of Jiangsu Stanford; (iii) after their departure from Hangzhou Genewave and Taizhou Huajian in January 2015 and July 2018, respectively, they tendered their resignation at Jiangsu Stanford but did not receive any response from Jiangsu Stanford; (iv) they were not aware of any non-compliance involved leading to the cessation of

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business operations in Jiangsu Stanford; and (v) they were not aware of any failure of conducting annual inspection before the revocation. Each of Mr. Qiu and Mr. Wu also confirmed that, as of the Latest Practicable Date, no claims had been made against him and he was not aware of any threatened or potential claims made against him and there were no outstanding claims and/or liabilities as a result of the revocation of the business license of such company.

Mr. Wu Zhiqiang (吳志強) was a director of Jiangsu Meide Biotech Pharmaceutical Co., Ltd. (江蘇美德生技醫藥有限公司) (“Jiangsu Meide”), a company established in the PRC with limited liability principally engaged in pharmaceutical and medical device R&D. The business license of Jiangsu Meide was revoked on May 31, 2017 because Jiangsu Meide ceased its business operation and failed to conduct annual inspection on a timely basis under PRC laws. Mr. Wu confirmed that, as of the Latest Practicable Date, no claims had been made against him and he was not aware of any threatened or potential claims made against him and there was no outstanding claims and/or liabilities as a result of the revocation of the business license of such company.

Save as disclosed above, each of our Directors has confirmed that there are no other matters relating to his/her appointment as a Director that need to be brought to the attention of our Shareholders and there is no other information in relation to his/her appointment which is required to be disclosed pursuant to Rule 13.51(2) of the Listing Rules.

Each of our Directors has confirmed that he/she obtained the legal advice on March 22, 2023 with regards to the requirements under the Listing Rules that are applicable to him/her as a director of a listed issuer and the possible consequences of making a false declaration or giving false information to the Stock Exchange as set out in Rule 3.09D of the Listing Rules and he/she understood his/her obligations as a director of a listed issuer.

Each of our independent non-executive Directors has confirmed his/her independence with regards to each of the factors as set out in Rule 3.13(1) to (8) of the Listing Rules and that there are no other factors that may affect his/her independence at the time of his/her appointment.

SUPERVISORS

In accordance with the PRC Company Law, all joint stock companies are required to establish a supervisory committee, responsible for supervising the board of directors and senior management on fulfilling their respective duties, financial performance, internal control management and risk management of the corporation. The Supervisory Committee consists of three members comprising one employee representative Supervisor, and two Supervisors representing Shareholders.

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Mr. Ye Xiang (葉翔), aged 51, was appointed as our Supervisor and the president of the Supervisory Committee on September 17, 2021. He is primarily responsible for presiding the work of the Supervisory Committee, supervising and providing independent advice to our Board.

Mr. Ye has extensive professional experience in the investment management industry. From December 2014 to January 2020, Mr. Ye successively served as the deputy general manager and general manager at Rongjianda, which is one of our [REDACTED] Investors, where he was primarily responsible for its investment matters and overall management. Since January 2020, Mr. Ye has been serving as a director of risk management at Suzhou Rongshi, an investment management company and the general partner of Suzhou Guanhong, where he is mainly responsible for its risk control.

Mr. Ye graduated from Xiamen University (廈門大學) in the PRC with a bachelor’s degree in biochemistry in July 1995 and a master’s degree in management in June 2002. He obtained the Bar Admission Certificate (律師資格證書) issued by Bar Admissions Committee of the Ministry of Justice of the PRC (中華人民共和國司法部律師資格審查委員會) in May 1999.

Dr. Ding Chao (丁超), aged 36, was appointed as our Supervisor on September 15, 2022. He is primarily responsible for supervising and providing independent advice to our Board.

Dr. Ding has extensive professional experience in the investment in biopharmaceuticals. From February 2017 to March 2019, Dr. Ding served as an investment manager at Beijing 3E Investment Management Co., Ltd. (北京三益投資管理有限公司), a company mainly engaged in the investment in new drug development, medical devices, clinical diagnostics and medical services, where he was primarily responsible for equity investments in biopharmaceuticals. Since April 2019, he has been successively serving as the vice president of investment, the senior vice president of investment and the executive director at Hongtai Aplus, an investment fund company focusing on private equity investment in consumption, healthcare, finance, TMT (technology, media, telecommunications) and education industries and the general partner of Hongtai Health which is one of our [REDACTED] Investors, where he was mainly responsible for the equity investment and post-investment management in the biopharmaceutical sector. Since September 2022, he has been serving as a director of Jiangsu Zechen Biotech Co., Ltd. (江蘇澤成生物技術有限公司), a company mainly engaged in R&D, production and sales of medical devices and *in vitro* diagnostic reagents and instruments, where he was nominated by Hongtai Aplus and has primarily been responsible for the post-investment management.

Dr. Ding graduated from China University of Geosciences (中國地質大學) in the PRC in July 2009 with a bachelor’s degree in material chemistry. He also obtained a doctoral degree (Ph.D.) of science from Tsinghua University (清華大學) in the PRC in January 2017.

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Ms. Wang Yujiao (王玉姣), aged 42, was appointed as our Supervisor on September 17, 2021. She served as our director of human resources and management from April 2018 to April 2021 and has been serving as the assistant to general manager since April 2021. She is primarily responsible for supervising and providing independent advice to our Board.

Ms. Wang joined our Group in June 2015 and has successively served various positions within our Group, including as: (i) our Supervisor from June 2015 to August 2020, where she was mainly responsible for supervising and providing independent advice to the Company; (ii) a deputy director of our integrated affairs department from June 2015 to April 2018 and a director of human resources and management from April 2018 to April 2021 and she has been mainly responsible for the management of human resources and administrative affairs; and (iii) an assistant to general manager since April 2021 and has been mainly responsible for the daily affairs management of the board of directors and shareholders’ meeting, and the management of human resources and administrative affairs.

Prior to joining our Group, from July 2006 to March 2015, Ms. Wang worked at Hangzhou Genewave which is a subsidiary of Jiangsu T-mab. From July 2008 to March 2015, Ms. Wang served as the registration manager at Jiangsu T-mab, where she was primarily responsible for drug registration, preclinical animal testing project management, regulatory filing and survey research.

Ms. Wang graduated from Zhejiang University of Technology (浙江工業大學) in the PRC with a bachelor’s degree in biopharmaceutical science in June 2003 and a master’s degree in biochemical engineering in June 2006. She was qualified as a senior engineer (高級工程師) by Human Resources and Social Security Department of Jiangsu Province (江蘇省人力資源和社會保障廳) in September 2015.

Save as disclosed above and in this document, each of our Supervisors has confirmed that he/she has no other relationship with any Directors, senior management, substantial shareholders or controlling shareholders of our Company and none of our Supervisors has held any other directorships in listed companies during the three years immediately preceding the date of this document.

Mr. Ye Xiang (葉翔) was a director and legal representative of Shanghai Geqin Biotechnology Co., Ltd. (上海格沁生物科技有限公司) (“Shanghai Geqin”), a company established in the PRC with limited liability principally engaged in biochemistry R&D, sales of pharmaceutical intermediates and biochemical reagents. The business license of Shanghai Geqin was revoked on May 27, 2011 because Shanghai Geqin ceased its business operation and failed to conduct annual inspection on a timely basis under PRC laws. Mr. Ye confirmed that, as of the Latest Practicable Date, no claims had been made against him and he was not aware of any threatened or potential claims made against him and there was no outstanding claims and/or liabilities as a result of the revocation of the business license of such company.

Save as disclosed above, each of our Supervisors has confirmed that there are no other matters relating to his/her appointment as a Supervisor that need to be brought to the attention of our Shareholders and there is no other information in relation to his/her appointment which is required to be disclosed pursuant to Rule 13.51(2) of the Listing Rules.

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SENIOR MANAGEMENT

Mr. Qiu Jiwan (裘霽宛), aged 51, our executive Director, chairman of our Board, chief executive officer and general manager. For his biography, see “—Board of Directors—Executive Directors—Mr. Qiu Jiwan” in this section.

Mr. Wu Yiliang (吳亦亮), aged 42, our executive Director and executive deputy general manager of Cellularforce. For his biography, see “—Board of Directors—Executive Directors—Mr. Wu Yiliang” in this section.

Mr. Lin Weidong (林偉棟), aged 41, our executive Director and deputy general manager. For his biography, see “—Board of Directors—Executive Directors—Mr. Lin Weidong” in this section.

Dr. Li Jianwei (李建偉), aged 63, joined our Group on October 14, 2020 and served as our chief technology officer and the chief operating officer of Cellularforce from October 2020 to February 2023. He has been serving as the chief operating officer and deputy general manager of our Company and general manager of Cellularforce since March 2023. He is mainly responsible for the R&D, GMP manufacturing, quality management and general operation of our Group.

Dr. Li has over 14 years of experience in biotechnology and pharmaceutical industries, leading the R&D and GMP manufacturing of therapeutic recombinant proteins. Prior to joining our Group, he once worked at Symyx Technologies Inc., a company mainly engaged in developing high-throughput technologies for screening catalysts and API leads whose shares are listed on NASDAQ (stock code: SMMX). He once worked at Syagen Technology Inc., a subsidiary of Smiths Group plc, a company mainly engaged in developing portable mass spectrometers for fast field detection of bio-organic weapons and drugs whose shares are listed on the London Stock Exchange (stock code: SMIN), where he was primarily responsible for the research and development of methods based on photoionization mass spectrometry to rapidly screen water samples for the presence of chemical weapons. From August 2007 to November 2014, Dr. Li served as the principal scientist at Allergan, Inc. (currently known as AbbVie Inc.), a global pharmaceutical company whose shares are listed on NASDAQ (stock code: ABBV), where he was primarily responsible for the research and development of biologics. From April 2016 to August 2020, Dr. Li served as a vice president of process development and manufacturing department at Sorrento Therapeutics Inc., a clinical-stage antibody-centric biopharmaceutical company whose shares are listed on NASDAQ (stock code: SRNE), where he was primarily responsible for the overall management of process development and manufacturing department.

Dr. Li graduated from Shanghai University of Technology (上海工業大學) (currently known as Shanghai University (上海大學)) in the PRC with a bachelor’s degree in metallurgical engineering in October 1982 and a master’s degree in applied chemistry in May 1988. He further received his doctoral degree (PH.D.) of Philosophy from University of Berne in Switzerland in December 1993.

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Mr. Wu Shenglong (吳生龍), aged 50, joined our Group as the chief business officer and deputy general manager of our Company on February 13, 2023. He is primarily responsible for the business development, equity investment and financing of our Group.

Mr. Wu has extensive experience in business development, investment and financing, M&A and consulting in pharmaceutical industry. Prior to joining our Group, beginning from January 2013, he served as a business development manager at Pfizer Investment Co., Ltd. (輝瑞投資有限公司), a subsidiary of Pfizer Inc., a pharmaceutical and biotechnology company mainly engaged in R&D, production and distribution of innovative drugs, healthcare products and vaccines, whose shares are listed on NASDAQ (stock code: PFE). Beginning from December 2014, he served as an associate director of intelligence and portfolio management department at Beijing Fresenius-Kabi Pharmaceutical Co., Ltd. (北京費森尤斯卡比醫藥有限公司), a company mainly engaged in R&D and production in the fields of infusion, blood transfusion, clinical nutrition, pharmaceuticals and medical devices. From January 2017 to September 2018, he served as a director of corporate M&A at SPH KDL Health (Shanghai) Pharmaceutical Co., Ltd. (上藥康德樂(上海)醫藥有限公司), a medical supply chain service provider mainly engaged in the import, distribution and delivery of drugs, medical devices, specialty products and health products, where he was primarily responsible for its investment and M&A. He once worked at Roland Berger Enterprise Management (Shanghai) Co., Ltd. (羅蘭貝格企業管理(上海)有限公司), a consulting firm. From June 2020 to August 2022, he worked at KPC Pharmaceuticals, Inc. (昆藥集團股份有限公司), a pharmaceutical company whose shares are listed on the Shanghai Stock Exchange (stock code: 600422).

Mr. Wu graduated from Nanjing University (南京大學) in the PRC in July 1995 with a bachelor’s degree in biology. He further obtained a master’s degree in business administration from Simon Fraser University in Canada in September 2007.

Ms. Fang Min (房敏), aged 48, joined our Group as a senior director to set up our clinical medicine department on December 24, 2017 and served as a vice president of clinical medicine from April 2021 to February 2023. Since March 2023, she has been serving as the deputy general manager of our Company. She is mainly responsible for the management of clinical strategy and operations of our Group.

Ms. Fang has extensive experience in clinical drug R&D, clinical trials and related management. Prior to joining our Group, she once worked at Schering-Plough China Co., Ltd. (先靈葆雅(中國)有限公司), a subsidiary of Schering-Plough Corporation (currently known as Merck & Co., Inc.), a global pharmaceutical company engaged in the production, sales and wholesale of anti-allergy and skin care drugs whose shares are listed on NASDAQ (stock code: MRK). From November 2012 to June 2014, she served as a senior clinical research associate manager at GlaxoSmithKline (China) R&D Company Limited (葛蘭素史克(上海)醫藥研發有限公司), a wholly owned subsidiary of GSK plc, a company engaged in the R&D and production of prescription drugs, vaccines and healthcare products whose shares are listed on the London Stock Exchange (stock code: GSK), where she was primarily responsible for the establishment and management of clinical research team and the overall management of clinical key programs. From January 2015 to September 2015, Ms. Fang served as the director

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of global clinical operations and project management at BeiGene (Beijing) Co., Ltd. (百濟神州(北京)生物科技有限公司), a subsidiary of BeiGene, Ltd. (百濟神州有限公司), a global biotechnology company focused on developing and commercializing innovative and affordable oncology medicines whose shares are listed on the Stock Exchange (stock code: 6160), where she was mainly responsible for the management of clinical program team and various international multicenter clinical trials. From October 2015 to April 2017, Ms. Fang served as a director of Product Development Service and Partnership (PDSP) at WuXi AppTec (Shanghai) Co., Ltd. (上海藥明康德新藥開發有限公司), a company mainly engaged in the R&D of new drugs and drug intermediates and is a wholly owned subsidiary of WuXi AppTec Co., Ltd. (無錫藥明康德新藥開發股份有限公司) whose shares are listed on both the Stock Exchange (stock code: 02359) and the Shanghai Stock Exchange (stock code: 603259), where she was primarily responsible for the planning, coordination, and management of cross-functional product development projects throughout the corresponding development process to ensure seamless execution according to the defined timeline, budget and deliverables. From April 2017 to October 2017, Ms. Fang served as a clinical medicine director at Centaurus BioPharma Co., Ltd. (北京賽林泰醫藥技術有限公司), a company primarily engaged in oncology and diabetes drug development, where she was primarily responsible for the overall management of medicine team, clinical operations team and the clinical trials of drug candidates.

Ms. Fang graduated from Xi’an Jiaotong University (西安交通大學) in the PRC in July 2000 with a bachelor’s degree in clinical medicine. She further obtained a master’s degree in educational and training systems design from University of Twente in the Netherlands in August 2003.

Mr. Hu Yanbao (胡衍保), aged 36, joined our Group as a senior manager of business development department in November 2020 and was appointed as our Board secretary and joint company secretary in August 2022 and March 22, 2023, respectively. He is primarily responsible for business development, financing, corporate governance and company secretarial matters of our Group.

Prior to joining our Group, from August 2012 to September 2018, Mr. Hu served as the a member and bureau chief of investment promotion bureau at China Medical City, a government institution that focus on promoting the pharmaceutical industry, where he was responsible for investment promotion and business expansion. From October 2018 to October 2020, Mr. Hu served as a deputy general manager at Rongjianda VC, a state-owned investment company, where he was mainly responsible for equity investment and post-investment services.

Mr. Hu graduated from Beijing University of Chinese Medicine (北京中醫藥大學) in the PRC in June 2009 with a bachelor’s degree in pharmaceutical engineering. He also obtained a master’s degree of pharmacognosy from Peking Union Medical College (北京協和醫學院) in the PRC in July 2012.

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JOINT COMPANY SECRETARIES

Mr. Hu Yanbao (胡衍保), aged 36, our Board secretary and joint company secretary. For his biography, see “—Senior Management—Mr. Hu Yanbao” in this section.

Ms. Tang King Yin (鄧景賢), was appointed as our joint company secretary on March 22, 2023.

Ms. Tang is a senior manager of corporate services of Tricor Services Limited, a global professional services provider specializing in integrated business, corporate and investor services. Ms. Tang has over 10 years of experience in the corporate secretarial field. She has been providing professional corporate services to Hong Kong listed companies as well as multinational, private and offshore companies.

Ms. Tang is currently serving as the company secretary or joint company secretary of three companies listed on the Main Board of the Stock Exchange, namely, Tuya Inc. (塗鴉智能) (stock code: 2391), Yum China Holdings, Inc. (百勝中國控股有限公司) (stock code: 9987) and Changjiu Holdings Limited (長久股份有限公司) (stock code: 6959).

Ms. Tang obtained a bachelor’s degree in business administration from Hong Kong Shue Yan University in July 2011 and a master’s degree in corporate governance and compliance from the Hong Kong Baptist University in November 2021. Ms. Tang is a Chartered Secretary, a Chartered Governance Professional and an Associate of both The Hong Kong Chartered Governance Institute and The Chartered Governance Institute in the United Kingdom, respectively.

BOARD COMMITTEES

Our Board has established the Audit Committee, the Remuneration and Appraisal Committee, the Nomination Committee, and the Strategy and Development Committee and delegated various responsibilities to these committees, which assist our Board in discharging its duties and overseeing particular aspects of our Group’s activities.

Audit Committee

We have established the Audit Committee on January 4, 2024 pursuant to Rule 3.21 of the Listing Rules with written terms of reference in compliance with paragraph D.3 of Part 2 of the Corporate Governance Code as set out in Appendix C1 to the Listing Rules (the “CG Code”). The Audit Committee consists of Mr. Fung Che Wai, Anthony, Mr. Wu Zhiqiang and Dr. Ling Jianqun. Mr. Fung Che Wai, Anthony is the chairman of the audit committee. Mr. Fung Che Wai, Anthony has the appropriate professional qualifications or accounting or related financial management expertise as required under Rule 3.10(2) of the Listing Rules.

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The primary duties of the Audit Committee include, but not limited to (i) reviewing and monitoring the external auditors’ audit process; (ii) giving guidance to our internal audit work; (iii) overseeing the effectiveness of our financial reporting system, risk management and internal control systems; (iv) reviewing and providing advice and comments on our financial reports; (v) performing our corporate governance functions; (vi) coordination among our management team, internal audit department and related departments and external auditors; and (vii) performing other duties and responsibilities as assigned by our Board and/or required by the relevant laws and regulations.

Remuneration and Appraisal Committee

We have established the Remuneration and Appraisal Committee on January 4, 2024 pursuant to Rule 3.25 of the Listing Rules with written terms of reference in compliance with paragraph E.1 of Part 2 of the CG Code. The Remuneration and Appraisal Committee consists of Dr. Ling Jianqun, Dr. Zou Zhongmei and Mr. Qiu Jiwan. Dr. Ling Jianqun is the chairman of the Remuneration and Appraisal Committee.

The primary duties of the Remuneration and Appraisal Committee include, but not limited to (i) making recommendations to our Board on our policy and structure for remuneration of our Directors and senior management and on the establishment of a formal and transparent procedure for developing remuneration policies; (ii) reviewing and approving the management team’s remuneration proposals with reference to corporate goals and objectives; (iii) determining the remuneration packages of each Director and senior management; (iv) making recommendations to our Board on the remuneration of non-executive Directors and Supervisors; (v) considering salaries paid by comparable companies, time commitment and responsibilities and employment conditions for other employees of our Group; (vi) reviewing and approving the compensation payable to executive Directors and senior management for any loss or termination of office or appointment to ensure that it is consistent with contractual terms and is otherwise fair and not excessive; (vii) reviewing and approving compensation arrangements relating to dismissal or removal of Directors for misconduct to ensure that they are consistent with contractual terms and are otherwise reasonable and appropriate; (viii) ensuring that no Director or any of his/her associates is involved in deciding that Director’s own remuneration; (ix) evaluating the performance of executive Directors and including in the annual work summary; (x) reviewing the terms of service agreements or appointment letters for Directors and Supervisors; (xi) reviewing and/or approving matters relating to share schemes under Chapter 17 of the Listing Rules; and (xii) performing other duties and responsibilities as assigned by our Board.

Nomination Committee

We have established the Nomination Committee on January 4, 2024 pursuant to Rule 3.27A of the Listing Rules with written terms of reference in compliance with paragraph B.3 of Part 2 of the CG Code. The Nomination Committee consists of Mr. Qiu Jiwan, Dr. Zou Zhongmei and Dr. Ling Jianqun. Mr. Qiu Jiwan is the chairman of the Nomination Committee.

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The primary duties of the Nomination Committee are to (i) reviewing the structure, size and composition (including the skills, knowledge, experience and diversity of perspectives) of our Board at least annually and making recommendations on any proposed changes to our Board to complement our corporate strategy; (ii) identifying individuals suitably qualified to become Directors and selecting or making recommendations to our Board on the selection of individuals nominated for directorships; (iii) assessing the independence of independent non-executive Directors; (iv) making recommendations to our Board on the appointment or re-appointment of Directors and succession planning for Directors, in particular the chairman and the chief executive; (v) reviewing our board diversity policy, any measurable objectives for implementing such board diversity policy as may be adopted by our Board from time to time, the progress on achieving the objectives and disclose the board diversity policy or its summary in the corporate governance report; (vi) proposing the resolutions to elect independent non-executive Director at the general meeting and setting out the selection processes and reasons in the circular to Shareholders and/or explanatory statement accompanying the notice of the relevant general meeting; (vii) reviewing the implementation and effectiveness of our mechanism(s) to ensure independent views and opinions are available to our Board; (viii) reporting to our Board on decisions or recommendations, except where legal or regulatory restrictions prevent such reporting; and (ix) performing other duties and responsibilities as assigned by our Board.

Strategy and Development Committee

We have established the Strategy and Development Committee on January 4, 2024, which consists of Mr. Qiu Jiwan, Mr. Yu Xi and Dr. Xue Mingyu. Mr. Qiu Jiwan is the chairman of the Strategy and Development Committee. The primary duties of the Strategy and Development Committee are to study and advise on the long term strategy and major development and financing plans of our Group.

BOARD DIVERSITY POLICY

Our Board has adopted a board diversity policy which sets out the approach to achieve diversity on our Board. Our Company recognizes and embraces the benefits of having a diverse Board and sees increasing diversity at the Board level as an essential element in supporting the attainment of our Company’s strategic objectives and sustainable development. Our Company seeks to achieve Board diversity through the consideration of a number of factors, including but not limited to talent, skills, gender, age, cultural and educational background, ethnicity, professional experience, independence, knowledge and length of service. We will select potential Board candidates based on merit and his/her potential contribution to our Board while taking into consideration our own business model and specific needs from time to time. All Board appointments will be based on meritocracy and candidates will be considered against objective criteria, having due regard to the benefits of diversity on our Board.

Our Board has a balanced mix of knowledge, skills and experience, including but without limitation to biotechnology and pharmaceutical R&D and production, auditing, consulting, corporate operation management, corporate financial management, investment management, business development, sales and marketing, securities and derivatives and financing guarantee. Members of our board have obtained degrees in various majors including biotechnology,

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cytobiology, botany, biology, Chinese medicine, biopharmacology, pharmaceutical chemistry, agronomy, chemistry, chemical biology, genetics and genetic engineering, finance, accountancy, business administration and English. We have three independent non-executive Directors from different backgrounds, including accounting, biotechnology and pharmaceutical industries. Furthermore, our Directors are of a wide range of age, from 37 years old to 59 years old.

With regards to gender diversity on the Board, we recognize the particular importance of gender diversity. Our Board currently comprises one female Director and eight male Directors and expects to maintain the same gender mix in the Board upon [REDACTED]. We have taken and will continue to take steps to promote and enhance gender diversity at all levels of our Company, including but without limitation at our Board and senior management levels. Our board diversity policy provides that our Board should aim to increase the proportion of female members over time after [REDACTED] where possible when selecting and making recommendations on suitable candidates for Board appointments. We will also ensure that there is gender diversity when recruiting staff at mid to senior level so that we will have a pipeline of female senior management and potential successors to our Board going forward. It is our objective to maintain an appropriate balance of gender diversity with reference to the expectations of stakeholders and international and local recommended best practices.

Our Nomination Committee is responsible for ensuring the diversity of our Board members. After [REDACTED], our Nomination Committee will review our board diversity policy and its implementation from time to time to monitor its continued effectiveness and we will disclose the implementation of our board diversity policy, including any measurable objectives set for implementing the board diversity policy and the progress on achieving these objectives, in our corporate governance report on an annual basis.

CORPORATE GOVERNANCE

Our Company aims to achieve high standards of corporate governance which are crucial to the development and safeguard the interests of our Shareholders. To accomplish this, our Company expects to comply with the CG Code and the associated Listing Rules after the [REDACTED] save for the deviation as mentioned below. Any deviation from the code provisions shall be carefully considered, and the reasons for any deviation and explanation of how good corporate governance was achieved by means other than strict compliance with the code provisions shall be given in the interim report and the annual report in respect of relevant period.

According to code provision C.2.1 of Part 2 of the CG Code, the roles of chairman and chief executive should be separate and should not be performed by the same individual. Mr. Qiu is currently the chairman and chief executive officer of our Company. In view of the fact that Mr. Qiu is our founder and has been assuming the responsibilities in the overall management, R&D and business strategy of our Group since our establishment, our Board believes that it is in the best interest of our Group to have Mr. Qiu taking up both roles for effective management and operations. Therefore, our Directors consider that the deviation from such code provision is appropriate. Notwithstanding such deviation, our Directors are of the view that our Board is able to work efficiently and perform its responsibilities with all key and

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appropriate issues discussed in a timely manner. In addition, as all major decisions will be made in consultation with members of our Board and the relevant Board committees, and there are three independent non-executive Directors on our Board offering independent perspective, our Board is therefore of the view that there are adequate safeguards in place to ensure sufficient balance of powers within our Board. Our Board shall nevertheless review the structure and composition of our Board and senior management from time to time in light of prevailing circumstances to maintain a high standard of corporate governance practices of our Company.

COMPENSATION OF DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Our Directors, Supervisors and members of our senior management receive compensation from our Group in the form of fees, salaries and other benefits and contribution to pension scheme.

The aggregate remuneration (including salaries, allowances, benefits in kind, discretionary bonuses, retirement scheme contributions and share-based payments) paid or payable to our Directors and Supervisors for the two years ended December 31, 2022 and the nine months ended September 30, 2023 was approximately RMB11.86 million, RMB32.66 million and RMB61.03 million, respectively. Save as disclosed above, no other amounts have been paid or are payable by any member of our Group to our Directors or Supervisors for each of the two years ended December 31, 2022 and the nine months ended September 30, 2023.

The aggregate amount of salaries, allowances, benefits in kind, discretionary bonuses, retirement scheme contributions and share-based payments paid or payable to our five highest paid individuals in respect of the two years ended December 31, 2022 and the nine months ended September 30, 2023 was approximately RMB14.61 million, RMB36.40 million and RMB70.42 million, respectively.

No remuneration was paid by us to our Directors, Supervisors or the five highest paid individuals as an inducement to join or upon joining us or as a compensation for loss of office in respect of the two years ended December 31, 2022 and the nine months ended September 30, 2023. Further, none of our Directors or Supervisors had waived or agreed to waive any remuneration during the same periods.

Under the arrangement currently in force, the aggregate remuneration (including salaries, allowances, benefits in kind, discretionary bonuses, retirement scheme contributions and share-based payments) of our Directors and Supervisors for the year ending December 31, 2024 is estimated to be no more than approximately RMB55 million.

Our Board will review and determine the remuneration and compensation packages of our Directors, Supervisors and senior management and will, following the Listing, receive recommendation from the remuneration and appraisal committee which will take into account salaries paid by comparable companies, time commitment and responsibilities of our Directors and performance of our Group.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

COMPETITION

As of the Latest Practicable Date, two of our non-executive Directors held management role or directorship in some companies which are principally engaged in production and sales of pharmaceutical products. These companies do not form part of our Group and details of which are set out below:

Mr. Yu Xi, our non-executive Director, was nominated by Zhongmei Huadong, one of our [REDACTED] Investors, to be its representative in our Board. Mr. Yu Xi is the general manager of investment and business development at Huadong Medicine, a pharmaceutical company whose shares are listed on the Shenzhen Stock Exchange (stock code: 000963) and the parent company of Zhongmei Huadong. According to the annual report issued by Huadong Medicine published on April 14, 2023, its operating revenue for the year ended December 31, 2022 amounted to approximately RMB37.7 billion.

Mr. Wu Zhiqiang, our non-executive Director, was nominated by Taizhou Jianxin and Rongjianda, two of our [REDACTED] Investors, to be their representative in our Board. He is currently serving as a director of Jiangsu Durui Pharmaceutical Co., Ltd. (江蘇杜瑞製藥有限公司) (“Jiangsu Durui”), a company principally engaged in the R&D and production of small-molecule chemical generics. As confirmed by Mr. Wu, (i) he was nominated by Taizhou Jianxin and Rongjianda to be their board representative in Jiangsu Durui following their investments; and (ii) Taizhou Jianxin and Rongjianda are investors with minority interests in Jiangsu Durui as of the Latest Practicable Date and Mr. Wu’s role in Jiangsu Durui is non-executive in nature where he has never been involved in the daily management and operation of Jiangsu Durui.

Our Directors are of the view that there is no material competition between each of Huadong Medicine and Jiangsu Durui and our Group arising from Mr. Yu Xi or Mr. Wu’s management role or directorship for the following reasons:

- (a) we are a clinical-stage biotech company exclusively focused on biologic therapies for autoimmune and allergic diseases. In comparison, (i) Huadong Medicine is a pharmaceutical company deeply engaged in the R&D, manufacturing and sales of specialty medication, chronic disease medication and special medication, and has formed a core product line focusing on chronic kidney disease, transplant immunity, endocrine, digestive system and anti-tumor fields; and (ii) Jiangsu Durui is principally engaged in the R&D and production of small-molecule chemical generics;
- (b) the management and operational decisions of our Group are made by our executive Directors and senior management. As our non-executive Directors, Mr. Yu Xi and Mr. Wu are not and will not be involved in the daily management and operation of our Company;

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

- (c) our independent non-executive Directors constitute one third of our Board upon [REDACTED] and none of them has any relationship with Mr. Yu Xi, Mr. Wu or their respective associates. We believe that our independent non-executive Directors will bring independent judgment to the decision-making process of our Board and possess relevant experience to allow the proper functioning of our Board; and
- (d) in case of conflict of interest between our Group and each of Huadong Medicine and Jiangsu Durui, Mr. Yu Xi and Mr. Wu will exercise their duties in accordance with relevant constitutional documents, applicable laws and regulations and corporate governance measures adopted by our Group as set out in the “Relationship with our Controlling Shareholders—Corporate Governance Measures” in this document.

Save as disclosed above, each of our Directors confirms that as of the Latest Practicable Date, he/she did not have any interest in a business, apart from the business of our Group, which competes or is likely to compete, either directly or indirectly, with our business, which would require disclosure under Rule 8.10 of the Listing Rules.

From time to time our non-executive Directors may serve on the boards of both private and public companies within the broader healthcare and biopharmaceutical industries. However, as these non-executive Directors are neither our controlling shareholders nor members of our executive management team, we believe that their interests in such companies as directors would not render us incapable of carrying on our business independently from the other companies in which they may hold directorships from time to time.

As of the Latest Practicable Date, Dr. Yu Guoliang, our former non-executive Director during the period from June 2015 to February 2022 and our current consultant, is interested in 1,500,000 Shares granted to him (among which 1,000,000 Shares were granted pursuant to the Original Share Option Scheme and 500,000 Shares were granted pursuant to the Employee Share Incentive Scheme). Save for the 500,000 incentive Shares granted to Dr. Yu Guoliang on October 15, 2022 pursuant to the Employee Share Incentive Scheme, there is no other remuneration or reward to him as our consultant for a term of office of three years from October 15, 2022. Apart from the shareholding interests in our Company, Dr. Yu Guoliang also held directorships and/or shareholding interests in other businesses which mainly include development of oncology drugs, medical testing, medical devices, pharmaceutical R&D of treatment of autoimmune and inflammatory diseases and CDMO services (“Dr. Yu’s Other Businesses”).

Among Dr. Yu’s Other Businesses, (a) in respect of the businesses of development of oncology drugs, medical testing and medical devices, they are clearly delineated from our business as we are not engaged in such businesses; (b) in respect of the pharmaceutical R&D of treatment of autoimmune and inflammatory diseases, Dr. Yu Guoliang is currently serving as a non-executive director of Inmagene Biopharmaceuticals (“Inmagene”) and is interested in approximately 1.1% shareholding interest in Inmagene, a clinical-stage biotech company principally engaged in the pharmaceutical R&D of treatment of autoimmune and inflammatory diseases. Inmagene has four pipeline products at the clinical stage targeting IL-17A, OX40,

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Bruton tyrosine kinase and IL-36R for the treatment of autoimmune and inflammatory diseases including psoriatic arthritis, psoriasis and atopic dermatitis, which may compete with our business; and (c) in respect of the CDMO services, (i) Dr. Yu Guoliang is currently serving as the legal representative and chairman of the board of directors of Zhejiang Innoforce Pharmaceuticals Co. Ltd. (浙江健新原力製藥有限公司) (“Innoforce”) and indirectly interested in approximately 33.5% shareholding interest in Innoforce, a CDMO focusing on process development and GMP manufacturing of plasmid DNA, viral vectors, cell therapies and mRNA products which could be delineated from the CDMO business of our Group focusing on antibody drugs; and (ii) Innoforce is holding 49% equity interest (as the minority shareholder) in Thermo Fisher Biopharma Services (Hangzhou) Ltd. (賽默飛生物製藥(杭州)有限公司) (“Thermo Fisher Hangzhou”), a CDMO whose businesses include CDMO services for antibody drugs and recombinant protein drugs which may compete with our business to the extent that Cellularforce may provide CDMO services to external parties to improve the utilization of its facilities where capacity allows.

Notwithstanding the potential competition as stated above, our Directors are of the view that the potential competition, if exists, will not be material, due to the following reasons: (i) Dr. Yu Guoliang had never participated in the operational management and R&D of the products of our Group and was or is not able to exert significant influence over the operations or R&D of our products before or after his resignation as the non-executive Director; (ii) his current role of consultant of our Company does not offer him any voting rights in our Board or Shareholders’ meetings; and (iii) as a non-executive director of Inmagene holding approximately 1.1% of its issued share capital and the minority shareholder of Thermo Fisher Hangzhou, he could not exert significant influence over Inmagene or Thermo Fisher Hangzhou. Dr. Yu Guoliang has good reputation in the industry and is interested in 1,500,000 Shares granted to him pursuant to the Original Share Option Scheme and the Employee Share Incentive Scheme. Nevertheless, to avoid conflict of interest in light of Dr. Yu Guoliang’s exposure to competing businesses, the Company will adopt the following measures to ensure that the advice provided by Dr. Yu Guoliang and adopted by our Company will be in the best interest of our Company and Shareholders as whole: (i) Dr. Yu Guoliang shall make full disclosure in respect of his completing business that may have conflict or potentially conflict with any of our interest before providing his advice to our Group; and (ii) the advice provided by Dr. Yu Guoliang will be scrutinized independently by our Company and all major decisions will be made in consultation with members of our Board, including our independent non-executive Directors who will offer independent advice to our Board.

KEY TERMS OF EMPLOYMENT CONTRACTS

We normally enter into employment contracts, confidentiality agreements and non-competition agreements with our senior management members and other key personnel. Below sets forth the key terms of these contracts we have entered into with our senior management and other key personnel.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Confidentiality

The employee shall keep in confidence and shall not disclose our trade secrets, until we or a third party in legal possession of the trade secret declares that it has been declassified or that the trade secret is actually in the public domain. If a part or individual element is disclosed and becomes public knowledge, but other parts or the whole of the information has not yet become public knowledge, the employee shall still fulfill the obligation of confidentiality for the undisclosed part of the information or trade secret.

Non-competition

Within two years from the date of the employee's departure (the "Non-compete Period"), without our prior written consent, the employee shall not, directly or indirectly, with or without compensation, (i) accept or acquire any interest or position from our competitors; (ii) participate in the business of our competitors, including but not limited to, serving as their shareholder, dormant shareholder, partner, dormant partner, beneficiary, director, supervisor, manager, employee, consultant, agent or providing services of any kind to them; assist or cooperate with other person or business entities to carry out business that competes or may constitute competition with the business that we are engaged in or intend to engage in; (iii) invest directly or indirectly in our competitors in any way (whether in one's own name or in the name of another person), except where the competitor is a company listed on any stock exchange and the employee's shareholding does not exceed one thousandth of the voting shares; (iv) cause, assist or encourage any of our employees to take a position with or perform services of any kind for our competitors; (v) hinder or attempt to hinder our customers, business partners or any potential customers from doing business with us; (vi) provide any of our former, existing and potential customers any products or services that compete with us; or (vii) engage in any business that competes with us or serves our competitors in any other way.

Invention for Hire

The rights and interests in any invention, discovery, utility model, design and technical solution, including but not limited to those: (i) produced by the employee during his/her employment or developed mainly using our resource; or (ii) produced by the employee within two years from the date of the employee's departure, mainly using the confidential information related to our main business known by virtue of his/her employment, shall belong to us, be assigned to us or licensed to us free of charge in perpetuity in accordance with our instructions. The invention for hire produced by the employee shall not infringe on the legal rights and interests of his/her former employers or other intellectual property rights holders.

Non-solicitation

The employee agrees that he/she shall not in any form, (i) solicit, induce, recruit or encourage any of our employees to leave our Group; and (ii) solicit our clients, after his/her termination of employment with our Group.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

COMPLIANCE ADVISOR

We have appointed Somerley Capital Limited as our compliance advisor pursuant to Rule 3A.19 of the Listing Rules. Pursuant to Rule 3A.23 of the Listing Rules, our compliance advisor will advise our Company in the following circumstances:

- before the publication of any regulatory announcement, circular and financial report;
- where a transaction, which might be notifiable or connected transaction under the Listing Rules, is contemplated including shares issues and share repurchases;
- where our Company proposes to use the [REDACTED] from the [REDACTED] in a manner different from that detailed in this document or where our business activities, developments or results deviate from any forecast, estimate or other information in this document; and
- where the Stock Exchange makes an inquiry of our Company regarding unusual movements in the [REDACTED] or [REDACTED] of our Shares under Rule 13.10 of the Listing Rules.

The term of the appointment shall commence on the [REDACTED] and end on the date on which our Company distribute our annual report in respect of our financial results for the first full financial year commencing after the [REDACTED].

RELATIONSHIP WITH OUR CONTROLLING SHAREHOLDERS

OVERVIEW

Immediately upon completion of the [REDACTED], Mr. Qiu will, directly or through Hangzhou Quanyi, Shanghai Quanyou and Xinfu Tongxin, control the voting rights of approximately [REDACTED]% of the total share capital of our Company.

Hangzhou Quanyi is an investment holding general partnership owned as to 50% by Mr. Qiu and 50% by Mr. Yu Guo’an as its general partners. Pursuant to the supplemental partnership agreement of Hangzhou Quanyi entered into between Mr. Qiu and Mr. Yu Guo’an on February 5, 2022, Mr. Qiu and Mr. Yu Guo’an agreed and confirmed, among others, that since the date of establishment of our Company, they have been and would continue to be parties acting in concert and they have agreed to consult with each other and reach a consensus between themselves before making the decisions and exercising their voting rights through Hangzhou Quanyi at the Board and Shareholders’ meetings and in the event that they are unable to reach consensus on any matter presented, the decisions of Mr. Qiu shall prevail. Shanghai Quanyou is an investment holding limited partnership whose general partner is Mr. Qiu. Xinfu Tongxin is one of our employee share incentive platforms whose general partner is Mr. Qiu. Accordingly, Mr. Qiu, Mr. Yu Guo’an, Hangzhou Quanyi, Shanghai Quanyou and Xinfu Tongxin constitute a group of our Controlling Shareholders under the Listing Rules.

Mr. Qiu is our founder, executive Director, chairman of the Board, chief executive officer and general manager of our Company. For further background of Mr. Qiu, see “Directors, Supervisors and Senior Management” in this document. Mr. Yu Guo’an is our founding investor who has nearly 20 years of working experience in the biotech industry, including as: (i) the founder and general manager of Hangzhou Epitomics, a biotech company principally engaged in the R&D and manufacturing of antibody reagents, from May 2003 to March 2014; and (ii) a deputy general manager of Hangzhou Liangkang Technology Co., Ltd. (杭州量康科技有限公司), a health monitoring service provider, since June 2014. Mr. Qiu and Mr. Yu Guo’an have a long-term cooperation relationship prior to the establishment of our Company. They first became acquainted in February 2004 when Mr. Qiu joined Hangzhou Epitomics as its deputy general manager. In July 2008, Mr. Qiu as the founder and Mr. Yu Guo’an as one of the investors established Jiangsu T-mab, a biotech company principally engaged in the R&D and production of genetically engineered drugs which was subsequently acquired by Shenzhen Langrun Investment Co., Ltd. (深圳市朗潤投資有限公司) (“Shenzhen Langrun”), a company focusing on investment in biotech and pharmaceutical projects which was owned as to approximately 88.29% by Mr. Tang Chunshan (唐春山) and 11.71% by Ms. Chen Shanna (陳珊娜), both being Independent Third Parties. Immediately prior to such acquisition, Jiangsu T-mab was owned as to 18.23% by Mr. Qiu, 32.94% by Mr. Yu Guo’an and 48.83% by other three Independent Third Parties. On January 26, 2015, Mr. Qiu and Mr. Yu Guo’an transferred their 18.23% and 32.94% equity interest in Jiangsu T-mab to Shenzhen Langrun at a consideration of RMB45,575,000 and RMB82,350,000, respectively. Jiangsu T-mab is currently a wholly owned subsidiary and manufacturing base of Mabwell (Shanghai) Biotechnology Co., Ltd. (邁威(上海)生物科技股份有限公司) (“Mabwell”), a company mainly engaged in the R&D, manufacturing and sales of biopharmaceuticals in oncology, metabolism, ophthalmology and infection and whose shares are listed on the Shanghai Stock Exchange (stock code: 688062). Having taken into account (i) the past successful achievement of Jiangsu T-mab in the R&D of its drug candidates led by Mr. Qiu and the recognition of the R&D and management capabilities of our management team; and (ii) Mr. Yu’s various directorships and

RELATIONSHIP WITH OUR CONTROLLING SHAREHOLDERS

management roles in his other businesses and his anticipation that he would not be able to devote sufficient time to our Company should he be appointed as our Director, Mr. Yu Guo’an, through Hangzhou Quanyi, made his investment in our Company as a founding investor. He has not been involved in our day-to-day management and business operation since the commencement of our business. Mr. Yu Guo’an also has no intention of serving as our Director or a member of our senior management after [REDACTED].

DELINEATION OF BUSINESS

Business of our Group

We are a clinical-stage biotech company exclusively focused on biologic therapies for autoimmune and allergic diseases.

Other business invested by Mr. Yu Guo’an

As of the Latest Practicable Date, apart from our business, Mr. Yu Guo’an had invested as a minority shareholder in other businesses which mainly include health monitoring, sales of health food, medical testing, *in vitro* diagnostics, medical devices, clothing design and sales and investment management (“Mr. Yu’s Other Businesses”). Given the differences between the business of our Group and Mr. Yu’s Other Businesses, there is clear delineation between our business and Mr. Yu’s Other Businesses. In addition, Mr. Yu Guo’an is also serving as a director of Triastek, Inc. (南京三迭紀醫藥科技有限公司) (“Triastek”), a biotech company principally engaged in the R&D of small-molecule drugs using 3D printing technology. Mr. Yu’s role in Triastek is non-executive in nature where he has never been involved in its daily management and operations. Mr. Yu Guo’an has no control and is unable to exert substantial influence over Triastek.

As of the Latest Practicable Date, the board of directors of Triastek consisted of eight directors, namely Dr. Cheng Senping (成森平), Mr. He Sun, Dr. Li Xiaoling (李霄凌), Ms. Wu Jing (吳晶), Dr. Yu Zhiyun (喻志雲), Mr. Sun Qi (孫琦), Mr. Xue Wenyu (薛文煜) and Mr. Yu Guo’an. Triastek has a broad and diverse base of shareholders and its shareholding structure as of the Latest Practicable Date was as follows:

Name of shareholders of Triastek	Approximate equity interest percentage held
Dr. Cheng Senping	14.98%
Dr. Li Xiaoling	8.99%
Shiyao Biomedical Technology (Shanghai) Co., Ltd. (世耀生物醫藥技術(上海)有限公司)	6.63%
Nanjing Yapei Culture Communication Co., Ltd. (南京雅培文化傳播有限公司)	6.08%
Nanjing Jingqian No.2 Equity Investment Partnership (Limited Partnership) (南京經乾二號股權投資合夥企業(有限合夥))	5.91%

RELATIONSHIP WITH OUR CONTROLLING SHAREHOLDERS

Name of shareholders of Triastek	Approximate equity interest percentage held
Suzhou Dalton Chunhui Venture Capital Partnership (Limited Partnership) (蘇州道彤淳輝創業投資合夥企業(有限合夥))	5.60%
Shanghai Volcanic Stone Phase I Equity Investment Partnership (Limited Partnership) (上海火山石一期股權投資合夥企業(有限合夥))	5.11%
Nanjing Da Sheng Guan Management Consulting Partnership (Limited Partnership) (南京大勝關管理諮詢合夥企業(有限合夥))	4.74%
CPE 3D Pharmaceutical Limited	4.63%
Nanjing Tianyin Management Consulting Partnership (Limited Partnership) (南京天印管理諮詢合夥企業(有限合夥))	4.26%
Mr. Zheng Xiaodong (鄭效東)	4.14%
Tasly Pharmaceutical Group Co., Ltd. (天士力醫藥集團股份有限公司)	3.84%
HealthCare Asia Bio Tech Limited (亞洲保康生物技術有限公司)	3.76%
Shanghai Guoxin Investment Development Co., Ltd. (上海國鑫投資發展有限公司)	3.51%
Nanjing Yunzhou Venture Capital Investment Center (Limited Partnership) (南京雲周創業投資中心(有限合夥))	3.33%
Jiangsu Honrts Medical Technology Co., Ltd. (江蘇泓睿醫療科技有限公司)	2.03%
Tianjin Kangchen Ruixin Pharmaceutical Group Co., Ltd. (天津康晨瑞信醫藥集團有限公司)	1.70%
Tianjin Huaxin Pharmaceutical Venture Capital Partnership (Limited Partnership) (天津華新醫藥創業投資合夥企業(有限合夥))	1.70%
Mr. Yu Guo'an	1.69%
Shenzhen Triwise Kangzhi Venture Capital Partnership (Limited Partnership) (深圳勤智康智創業投資合夥企業(有限合夥))	1.44%
Shanghai Science and Technology Creation Center No.1 Equity Investment Fund Partnership (Limited Partnership) (上海科創中心壹號股權投資基金合夥企業(有限合夥))	1.39%
Dalton Inc.	1.05%
Gongqingcheng Gaomai Yuanhang Zhiyi Investment Partnership (Limited Partnership) (共青城高脈元航智醫投資合夥企業(有限合夥))	1.05%
New Dimension Ventures Limited Liability Company	0.77%
Triwise Huisheng	0.59%
Gongqingcheng Triwise Hecheng No.1 Venture Capital Partnership (Limited Partnership) (共青城勤智和成壹號創業投資合夥企業(有限合夥))	0.55%
Triwise Detai	0.37%
Nanjing Yuncheng Equity Investment Center (Limited Partnership) (南京雲成股權投資中心(有限合夥))	0.18%
Total	100%

Note: To the best of our Directors' knowledge, information and belief, save for (i) Triwise Huisheng and Triwise Detai being two of our Shareholders; and (ii) Shenzhen Triwise Kangzhi Venture Capital Partnership (Limited Partnership) (深圳勤智康智創業投資合夥企業(有限合夥)) and Gongqingcheng Triwise Hecheng No.1 Venture Capital Partnership (Limited Partnership) (共青城勤智和成壹號創業投資合夥企業(有限合夥)) being limited partnerships controlled by Triwise Capital, the other shareholders of Triastek has no past or present relationships (business, employment, family, financing, trust or otherwise) with Mr. Yu Guo'an or our Group or their respective associates.

RELATIONSHIP WITH OUR CONTROLLING SHAREHOLDERS

Based on the list of suppliers provided by Triastek, for the two years ended December 31, 2022 and the nine months ended September 30, 2023, we had 10, 14 and 16 overlapping suppliers with Triastek, respectively, and the total transaction amount with the overlapping suppliers accounted for approximately 5.2%, 0.9% and 1.5% of our total procurement for the corresponding periods. Given the difference on product characteristics and R&D technology between our Group and Triastek and Mr. Yu’s non-executive role in Triastek, our Directors are of the view that there is no material competition between Triastek and our Group arising from Mr. Yu’s directorship in Triastek.

Save as disclosed above, as of the Latest Practicable Date, none of our Controlling Shareholders and their close associates had any interest in a business, apart from our business, which competes or is likely to compete, either directly or indirectly, with our business, which would require disclosure under Rule 8.10 of the Listing Rules.

INDEPENDENCE FROM OUR CONTROLLING SHAREHOLDERS AND THEIR CLOSE ASSOCIATES

We believe that we are capable of carrying on our business independently from our Controlling Shareholders and their respective close associates (other than our Group) after the [REDACTED] for the following reasons:

Management Independence

Our Board comprises three executive Directors, three non-executive Directors and three independent non-executive Directors. Mr. Qiu is one of our executive Directors, chief executive officer, general manager and chairman of our Board. He has been involved in the management of our Group since he founded our Group. With the support of our experienced management team, Mr. Qiu is expected to continuously devote a sufficient portion of his time to the day-to-day operations of our Group upon [REDACTED]. Mr. Qiu is also serving as the general partner of each of Hangzhou Quanyi, Shanghai Quanyou and Xinfu Tongxin. As of the Latest Practicable Date, save for Mr. Qiu, none of our Directors or members of our senior management held any position at our Controlling Shareholders or their close associates.

Despite the overlapping roles assumed by Mr. Qiu as mentioned above, when performing his duties in our Group, Mr. Qiu has been and will continue to be supported by the separate and independent Board which comprises eight other Board members and senior management of our Group. Moreover, each of Hangzhou Quanyi and Shanghai Quanyou is merely an investment holding platform and Xinfu Tongxin is one of our employee share incentive platforms and do not engage in other business activities. On such basis, Mr. Qiu confirmed that his involvement in the aforementioned entities will not affect the discharge of his duties in our Group.

RELATIONSHIP WITH OUR CONTROLLING SHAREHOLDERS

Each of our Directors is aware of his/her fiduciary duties as a Director, which require, among other things, that he/she acts for the benefit and in the best interests of our Company and does not allow any conflict between his/her duties as a Director and his/her personal interests. In the event that there is an actual or potential conflict of interest arising out of any transaction to be entered into between our Group and any of the Directors or their respective close associates, the interested Director(s) shall abstain from voting at the relevant Board meetings of our Company in respect of such transactions and shall not be counted in the quorum.

Our Board comprises nine Directors, including three independent non-executive Directors, which represent one-third of the members of our Board. Our independent non-executive Directors have extensive experience in corporate management and governance, and they are appointed to ensure that our Board will only make decisions after due consideration of independent and impartial opinions. Certain matters of our Company must always be referred to the independent non-executive Directors for review.

We have adopted a series of corporate governance measures to manage conflicts of interest, if any, between our Group and our Controlling Shareholders that would support our independent management. For details, see “Corporate Governance Measures” in this section.

Based on the reasons above, our Directors are of the view that our Group is capable of managing our business independently from our Controlling Shareholders and their respective close associates after the [REDACTED].

Operational Independence

We have full rights to make all decisions on, and carry out, our own business operations independently from our Controlling Shareholders and their respective close associates and will continue to do so after the [REDACTED]. Our Group is able to operate without reliance on our Controlling Shareholders and their respective close associates.

Research and development

We have our own R&D platform, personnel and production facilities which are independent from our Controlling Shareholders and their respective close associates. As of the Latest Practicable Date, our R&D platforms had employed 122 members, who were all full-time employees of our Group and did not hold any position in our Controlling Shareholders or their respective close associates. We, through our CMC-focused subsidiary, Cellularforce, have established an in-house manufacturing capability which seamlessly supports our R&D activities from laboratory-scale trial, clinical trial to commercial scale production. In addition, our Group owns over 40 registered patents in the PRC and other countries which are necessary for our R&D and operations. With such independent R&D platforms, an experienced and independent R&D team, independent supporting manufacturing capabilities and self-owned patents, our Directors believe that we have all the requisite resources to carry on our R&D process independently.

RELATIONSHIP WITH OUR CONTROLLING SHAREHOLDERS

Access to suppliers and business partners

We have independent access to our suppliers as well as our business partners. Our suppliers and business partners bases are diversified and unrelated to our Controlling Shareholders and their respective close associates.

Operational facilities and administration

We have independent R&D platform office and manufacturing facilities. In addition, we have a full-time management team and staff to carry out our own administration and operation independently from our Controlling Shareholders and their respective close associates. All key administrative functions have been and will be carried out by our own without reliance or the support of our Controlling Shareholders and their respective close associates.

Employees

As of the Latest Practicable Date, all of our full-time employees were independent from our Controlling Shareholders and their respective close associates and were primarily recruited through both internal referrals and external sources such as campus recruitment, recruiting websites and third-party recruiters.

Based on the reasons above, our Directors are of the view that we have full rights to make all decisions on, and to carry out, our own business operations independently from our Controlling Shareholders and their respective close associates and will continue to do so after the [REDACTED].

Financial Independence

We have an independent financial system and make financial decisions according to our own business needs. We also have our own internal control and accounting systems, accounting and finance department for discharging the treasury function, which all are independent from our Controlling Shareholders and their respective close associates.

As of the Latest Practicable Date, our Group did not have any outstanding loans, advances or balances due to or from our Controlling Shareholders or their respective close associates which were not arising out of the ordinary course of business. All guarantee provided by our Controlling Shareholders or their respective close associates on the borrowings of our Group had been released as of the Latest Practicable Date. We are capable of obtaining financing from Independent Third Parties without relying on any guarantee or security provided by our Controlling Shareholders or their respective close associates and we received a series of [REDACTED] Investments from Independent Third Party investors as of the Latest Practicable Date. For details of the [REDACTED] Investments, see “History and Corporate Structure—[REDACTED] Investments” in this document.

RELATIONSHIP WITH OUR CONTROLLING SHAREHOLDERS

Based on the above, our Directors believe that we are able to conduct our business independently from our Controlling Shareholders and their respective close associates from a financial perspective and are able to maintain financial independence and would not place undue reliance on our Controlling Shareholders or their respective close associates.

CORPORATE GOVERNANCE MEASURES

Each of our Controlling Shareholders has confirmed that it/he has fully comprehended its/his obligations to act in our Shareholders’ best interests as a whole. Our Directors recognize the importance of good corporate governance in protecting our Shareholders’ interests. We would adopt the following measures to safeguard good corporate governance standards and to avoid potential conflict of interests between our Group and our Controlling Shareholders:

- (a) as part of our preparation for the [REDACTED], we have amended our Articles of Association to comply with the Listing Rules. In particular, our Articles of Association provided that, unless otherwise provided, a Director shall not vote on any resolution approving any contract or arrangement or any other proposal in which such Director or any of his/her associates have a material interest nor shall such Director be counted in the quorum present at the meeting;
- (b) a Director with himself/herself or his/her close associates having material interests shall make full disclosure in respect of matters that may have conflict or potentially conflict with any of our interest at the meeting of our Board, shall abstain from voting on such matters and not be counted in the quorum, unless the attendance or participation of such Director at such meeting of the Board is permitted under the Listing Rules;
- (c) we are committed that our Board should include a balanced composition with not less than one-third of independent non-executive Directors to ensure that our Board is able to effectively exercise independent judgment in its decision-making process and provide independent advice to our Shareholders. We have appointed three independent non-executive Directors and we believe our independent non-executive Directors possess sufficient experience and they are free of any business or other relationship which could interfere in any material manner with the exercise of their independent judgment and will be able to provide an impartial, external opinion to protect the interests of our public Shareholders. For details of our independent non-executive Directors, see “Directors, Supervisors and Senior Management—Board of Directors—Independent non-executive Directors” in this document;
- (d) we have appointed Somerley Capital Limited as our compliance advisor pursuant to Rule 3A.19 of the Listing Rules, which will provide advice and guidance to us in respect of compliance with the applicable laws and the Listing Rules including various requirements relating to Directors’ duties and corporate governance;

RELATIONSHIP WITH OUR CONTROLLING SHAREHOLDERS

- (e) our Company has established internal control mechanisms to identify connected transactions. Upon and after the [REDACTED], if our Company enters into connected transactions with our Controlling Shareholders or any of their associates, our Company will comply with the applicable Listing Rules; and
- (f) as required by the Listing Rules, our independent non-executive Directors shall review any continuing connected transaction annually and confirm in our annual report that such transactions have been entered into in our ordinary and usual course of business, are either on normal commercial terms or on terms no less favorable to us than those available to or from independent third parties and on terms that are fair and reasonable and in the interests of our Shareholders as a whole.

Based on the above, our Directors believe that there are sufficient and adequate corporate governance measures in place to manage existing and potential conflicts of interest that may arise between our Group and our Controlling Shareholders, and to protect minority shareholders’ interests after the [REDACTED].

CONNECTED TRANSACTIONS

OVERVIEW

Pursuant to Chapter 14A of the Listing Rules, the directors, substantial shareholders and chief executive of our Company and our subsidiaries (other than the directors, substantial shareholders and chief executive of insignificant subsidiaries), any person who was a director of our Company or our subsidiaries within 12 months preceding the Listing Date and any of their respective associates will be connected persons of our Company upon [REDACTED].

We have entered into certain agreements with Zhongmei Huadong, one of our substantial shareholders, who will become a connected person of our Company upon [REDACTED] and the transactions contemplated under such agreements will constitute continuing connected transactions of our Company under Chapter 14A of the Listing Rules upon [REDACTED]. As our Company is eligible for [REDACTED] on the Stock Exchange under Chapter 18A of the Listing Rules as a pre-revenue biotech company, the revenue ratio under Rule 14.07 of the Listing Rules would not be an appropriate measurement of the size of relevant continuing connected transactions as set out in this section. Accordingly, we have applied a percentage ratio test based on the total expenses for R&D and administrative matters of our Group as an alternative size test.

(A) CONTINUING CONNECTED TRANSACTIONS FULLY EXEMPT FROM THE REPORTING, ANNUAL REVIEW, ANNOUNCEMENT, CIRCULAR AND INDEPENDENT SHAREHOLDERS’ APPROVAL REQUIREMENTS

QX001S Framework Agreement

Principal terms

Our Company entered into a collaboration agreement and a supplemental agreement to the collaboration agreement (the “QX001S Framework Agreement”) with Zhongmei Huadong on August 14, 2020 and December 7, 2023, respectively, pursuant to which we agreed to (i) grant an exclusive right to Zhongmei Huadong to promote and commercialize QX001S in the PRC and Zhongmei Huadong shall be the MAH of QX001S in the PRC to exclusively conduct marketing activities and commercialization of QX001S; (ii) together with Zhongmei Huadong, jointly engage in the R&D of QX001S, including but not limited to its clinical trials and regulatory communication and registration; and (iii) bear the expenses of sample production and process development and optimization prior to the commercialization of QX001S. In addition, our Company and Zhongmei Huadong also agreed to engage Cellularforce to manufacture and supply all quantities of QX001S for commercial use in the PRC (the “Product Supply”), by entering into individual agreement. Except when Cellularforce is unable to meet the manufacturing demand, the parties shall not engage other manufacturers for the commercial production of QX001S. As of the Latest Practicable Date, Zhongmei Huadong and Cellularforce had entered the QX001S Production Quality Agreement and the QX001S Supply Agreement as individual agreements under the QX001S Framework Agreement based on the principles provided in the QX001S Framework Agreement. For details of the QX001S Production Quality Agreement and the QX001S Supply Agreement, see “Business—Collaboration with Zhongmei Huadong—QX001S Production Quality Agreement” and “Business—Collaboration with Zhongmei Huadong—QX001S Supply Agreement.”

CONNECTED TRANSACTIONS

In consideration of our Company agreeing to the above arrangement, pursuant to the QX001S Framework Agreement, Zhongmei Huadong agreed to (i) make an upfront payment of RMB30.0 million (the “Upfront Payment”) to us within ten days after the execution of the QX001S Framework Agreement and a milestone payment of RMB20.0 million (the “Milestone Payment”) to us within ten days after we complete the sample production of QX001S for the Phase III clinical trial and have, upon a consultation with the CDE, obtained consent to proceed with such Phase III clinical trial; (ii) bear the expenses of clinical trials and regulatory communication and registration for QX001S during the term of the QX001S Framework Agreement; and (iii) after setting off accumulative losses attributable to the commercialization of QX001S incurred in prior years (if any), share with us the accumulative pre-tax profit (as calculated pursuant to the QX001S Framework Agreement) derived from sales of QX001S in the PRC on a 50:50 basis, provided that 50% of the markup for the manufacturing of QX001S under the Product Supply corresponding to the sales of QX001S by Zhongmei Huadong will be further deducted from our portion of the pre-tax profit receivable and attributed to Zhongmei Huadong’s portion instead (the “Profit Sharing”). Pursuant to the QX001S Framework Agreement, Zhongmei Huadong paid the Upfront Payment and the Milestone Payment to us on August 28, 2020 and July 16, 2021, respectively.

Product Supply

The payment to be received by our Group from Zhongmei Huadong for the Product Supply pursuant to the QX001S Framework Agreement will be determined in accordance with the following formula:

Amount receivable by us = unit supply price⁽¹⁾ × amount of QX001S supplied under the Product Supply

Note:

1. The unit supply price will be determined by taking into account our actual costs expected to be incurred for manufacturing of QX001S and a cost-plus margin of 25% for such manufacturing.

Profit Sharing

The payment to be received by our Group from Zhongmei Huadong for the Profit Sharing pursuant to the QX001S Framework Agreement will be determined in accordance with the following formula:

Amount of pre-tax profit receivable by us under the Profit Sharing = (net sales revenue of QX001S by Zhongmei Huadong⁽¹⁾ – amount received and receivable by our Group under the Product Supply corresponding to the sales of QX001S by Zhongmei Huadong – marketing and sales and other operating costs of QX001S by Zhongmei Huadong – taxes and surcharges incurred by Zhongmei Huadong for the sales of QX001S⁽²⁾) × 50% – the markup for the manufacturing of QX001S under the Product Supply corresponding to the sales of QX001S by Zhongmei Huadong × 50%

CONNECTED TRANSACTIONS

Notes:

1. Net sales revenue shall be the results of gross sales (net of value-added taxes) minus sales returns, allowances and discounts.
2. Such taxes and surcharges include but not limited to consumption tax, urban maintenance and construction tax, urban land use tax, resource tax, education surcharge, real estate tax, land use tax, vehicle and vessel tax and stamp duty (if applicable).
3. When calculating the accumulative pre-tax profit, (i) amount received and receivable by our Group under the Product Supply; (ii) marketing and sales and other operating costs of QX001S; (iii) taxes and surcharges for the sales of QX001S; and (iv) the markup for the manufacturing of QX001S under the Product Supply corresponding to the sales of QX001S by Zhongmei Huadong are listed as cost items. If the formula produces negative results, it constitutes a loss attributable to the commercialization of QX001S of the current year. The accumulative pre-tax profit to be shared by Zhongmei Huadong and us shall net off the accumulative losses attributable to the commercialization of QX001S incurred in prior years (if any).

The fees paid and payable under the QX001S Framework Agreement, including the Upfront Payment, the Milestone Payment and the amount to be received by us under the Product Supply and Profit Sharing were determined after arms’ length negotiations between our Group and Zhongmei Huadong, having taken into account various factors, including but not limited to the expenses incurred and to be incurred for the development of QX001S, expected prospects of the development and commercialization of QX001S in the PRC, rights and obligations of both parties under the QX001S Framework Agreement and the reasons and benefits of the transactions contemplated under the QX001S Framework Agreement. The QX001S Framework Agreement and the overall arrangements thereunder, including the Upfront Payment, Milestone Payment, Product Supply and Profit Sharing, as a whole, are generally in line with the market practice, as confirmed by Frost & Sullivan.

The QX001S Framework Agreement has a term of 15 years commencing from August 14, 2020 and ending on August 13, 2035, which can be automatically extended for a further term of five years unless terminated earlier in accordance with the terms of the QX001S Framework Agreement. Frost & Sullivan has confirmed that it is market practice in the pharmaceutical industry for similar collaboration agreements to be entered into for a long term, primarily due to the substantial amount of capital committed by the collaboration partners and the risks involved.

For further details of the QX001S Framework Agreement, see “Business—Collaboration with Zhongmei Huadong—QX001S Framework Agreement.” The Company will comply at all time with the applicable provisions under Chapter 14A of the Listing Rules in respect of the transactions contemplated under the QX001S Framework Agreement.

CONNECTED TRANSACTIONS

Reasons for and benefits of the transaction

We entered into the QX001S Framework Agreement with Zhongmei Huadong for the following reasons:

- (a) the primary purpose of this collaboration is to leverage Zhongmei Huadong’s market access, nationwide sales and marketing network targeting the autoimmune and allergic disease field as well as its extensive experience in chronic disease management, which will be crucial to help achieve rapid commercialization of QX001S in the PRC. Considering that patients with autoimmune and allergic diseases are largely scattered at county-level hospitals in the PRC, we believe it would be in the best interest of our Group to find a business partner that is a large pharmaceutical company with strong R&D and commercialization capabilities nationwide to ensure the successful commercialization of QX001S in the PRC. Zhongmei Huadong is wholly owned by Huadong Medicine, a leading PRC pharmaceutical company whose shares are listed on the Shenzhen Stock Exchange (stock code: 000963). Having considered Huadong Medicine’s active role in the PRC pharmaceutical market for more than 30 years, the business of Huadong Medicine covers the whole pharmaceutical industrial chain, integrating R&D, production and sales of medicine and has established strong expert resources and sales and marketing network in the PRC, with its annual operating revenue of more than RMB37.7 billion in 2022 according to its annual report published on April 14, 2023. We believe this collaboration will enable us to leverage Zhongmei Huadong and Huadong Medicine’s market access, nationwide sales and marketing network targeting the autoimmune and allergic disease field as well as its extensive experience in chronic disease management;
- (b) the QX001S Framework Agreement allows both our Group and Zhongmei Huadong to leverage respective strength and share value of QX001S reasonably commensurate with their respective contribution in R&D and sales and marketing. Our Group expects to focus our resources on the ongoing R&D of QX001S and other drug candidates as a late clinical-stage biotech company, while Zhongmei Huadong has robust commercial network and experienced sales and marketing team for sales and distribution of QX001S in hospitals in the PRC. It is in line with industry practice and commercially beneficial for our Group and Zhongmei Huadong to enter into the QX001S Framework Agreement so that we can continue to focus on drug R&D while Zhongmei Huadong would be compensated fairly for its R&D efforts in the Phase III clinical trial and commercialization efforts in respect of QX001S. In addition, our Group will exclusively manufacture and supply QX001S to Zhongmei Huadong under the Product Supply, which allows us to utilize our in-house manufacturing capability and ensure quality control while providing such services at arm’s length. Therefore, through leveraging the respective resources and established capabilities of our Group and Zhongmei Huadong, we believe such collaboration agreement will bring commercial benefits to both our Group and Zhongmei Huadong; and

CONNECTED TRANSACTIONS

- (c) the QX001S Framework Agreement allows both our Group and Zhongmei Huadong to share the risks and costs associated with the advancement of clinical trials and commercialization of QX001S and to leverage their respective resources and established capabilities to expeditiously establish an advantageous position in relevant markets.

Taking into consideration of the above and the evaluation procedures in place as set out below, we believe that the QX001S Framework Agreement is in the interest of our Company and our Shareholders as a whole.

Procedures in evaluation of collaboration arrangements

During the ordinary and usual course of our business, we evaluate potential collaboration opportunities from time to time. When such opportunity arises, we would normally focus on well-known companies in the pharmaceutical industry that can offer access to established distribution channels, recognized branding, an experienced sales force and longstanding connections with well-known physicians and hospitals. When selecting potential business partners, we will also consider their expertise in the relevant therapeutic area and their regulatory know-how. In parallel, prior to a decision of developing a particular product, our R&D, manufacturing, financial and business development teams perform in-house market forecasts and financial analysis for such potential products, and project competitive landscape of the products for the territory of interest. Furthermore, our business development team routinely evaluates collaboration arrangements with potential partners in respect of drug products with similar mechanism of action for deal benchmarking and for term sheet evaluation purposes.

In addition, the commercial negotiations with potential business partners are led by our chief executive officer and/or certain members of our senior management, who will independently evaluate the terms taking into account all relevant factors as we consider necessary. A decision on whether to establish collaborations with another company will be made purely based on commercial considerations and only if we consider it is in the best interest of our Company and our Shareholders to enter into such collaboration arrangement.

Term of the QX001S Framework Agreement

Rule 14A.52 of the Listing Rules provides that the period for the agreement of a continuing connected transaction must not exceed three years except in special circumstances where the nature of the transaction requires a longer period. Our Directors are of the view that the nature of the collaboration under the QX001S Framework Agreement requires a longer period commencing from August 14, 2020 to August 13, 2035 (the “Initial Term”), which can be automatically extended for a further term of five years unless terminated earlier in accordance with the terms the QX001S Framework Agreement, on the following grounds:

- (i) the nature of the collaboration requires a longer period. The QX001S Framework Agreement is a strategic collaboration between our Group and Zhongmei Huadong with respect to the joint development and exclusive commercialization of QX001S in the PRC, which allows our Group and Zhongmei Huadong to (a) share the risks

CONNECTED TRANSACTIONS

and costs associated with the R&D and marketing and sales of QX001S following the market practice and share the value of QX001S reasonably commensurate with their respective contributions in R&D and sales and marketing of QX001S; and (b) leverage their respective resources and established capabilities to expeditiously establish an advantageous position in relevant market, both of which are long term in nature. According to Frost & Sullivan, it is market practice in the pharmaceutical industry for similar collaboration agreements to be entered into for a long term, primarily due to the substantial amount of capital and contributions committed by the collaboration partners and the risks involved;

- (ii) a contractual arrangement of long term is necessary and critical to the development of our business and to ensure stable revenue and cash flows from the future commercialization of QX001S. Our primary purpose of this collaboration is to leverage Zhongmei Huadong’s market accessibility, nationwide sales and marketing network targeting the autoimmune and allergic disease field as well as its extensive experience in chronic disease management, which will be crucial to help achieve rapid commercialization of QX001S in the PRC and accordingly, Zhongmei Huadong will be the MAH of QX001S in the PRC to exclusively conduct marketing activities and commercialization of QX001S. If the QX001S Framework Agreement is determined at a short term, our Company may face the unnecessary and substantial risks of failing to renew such agreement upon expiry of a relatively short term and losing its competitive advantages. Imposing an arbitrary three-year term of the QX001S Framework Agreement will also be contrary to the business intention of the parties to have a long term collaboration and the commercial objective of such strategic collaboration to allow both parties to leverage respective strength and share value of QX001S reasonably commensurate with their respective contribution in R&D and sales and marketing;
- (iii) such long-term collaboration is in the interest of our Company and our Shareholders as a whole; and
- (iv) immediately before the expiry of the Initial Term, our Company will re-comply with the provisions of Chapter 14A of the Listing Rules applicable to such transactions, including seeking independent shareholders’ approval where the case may so require.

The Sole Sponsor is of the view that, taking into consideration (i) the reasons for entering into the QX001S Framework Agreement as set out above; (ii) the market practice in the pharmaceutical industry for similar collaboration agreement and the confirmation from Frost & Sullivan as set out above; and (iii) the fact that the relevant arrangements were negotiated on an arm’s length basis and in accordance with the procedures in evaluation of collaboration arrangements of our Group as set forth above, it is reasonable for QX001S Framework Agreement to be entered into for a term of 15 years commencing from August 14, 2020 and ending on August 13, 2035, which can be extended for a further term of five years unless terminated earlier in accordance with the terms the QX001S Framework Agreement, and it is normal business practice for agreements of this type to be of such duration.

CONNECTED TRANSACTIONS

Historical transaction amounts

As QX001S has not yet been approved for commercialization by the relevant authorities in the PRC, there was no historical amount received by our Group from Zhongmei Huadong in relation to the Product Supply and Profit Sharing during the Track Record Period.

Annual caps

There will be no transaction amount under the QX001S Framework Agreement from the [REDACTED] to the commercialization of QX001S in the PRC.

Immediately before the commercialization of QX001S in the PRC, our Company will, based on specific circumstances at that time, set monetary annual caps for the purpose of Rule 14A.53 of the Listing Rules and will re-comply with the provisions of Chapter 14A of the Listing Rules applicable to such transactions, including seeking independent shareholders’ approval where the case may so require.

Listing Rules implications

As there will be no transaction amount under the QX001S Framework Agreement from the [REDACTED] to the commercialization of QX001S in the PRC, the transactions contemplated under the QX001S Framework Agreement for the corresponding period will be within the *de minimis* threshold provided under Rule 14A.76 of the Listing Rules and will, upon the [REDACTED], be fully exempt from the reporting, annual review, announcement, circular and independent shareholders’ approval requirements under Chapter 14A of the Listing Rules.

(B) CONTINUING CONNECTED TRANSACTIONS SUBJECT TO THE REPORTING, ANNUAL REVIEW AND ANNOUNCEMENT REQUIREMENTS BUT EXEMPT FROM THE CIRCULAR AND INDEPENDENT SHAREHOLDERS’ APPROVAL REQUIREMENTS

CDMO Services Framework Agreement

Principal terms

On January 16, 2024, Cellularforce, our CMC-focused subsidiary, entered into a CDMO services framework agreement (the “CDMO Services Framework Agreement”) with Zhongmei Huadong, pursuant to which Zhongmei Huadong and/or its subsidiaries (“Zhongmei Huadong Group”) may from time to time commission Cellularforce to provide CDMO services for their drug substance and drug products and in return Zhongmei Huadong Group shall agree to pay service fees to Cellularforce for such CDMO services. The CDMO Services Framework Agreement has a term commencing from the [REDACTED] to December 31, 2025, which may be renewed for a further term not exceeding three years from time to time, as the parties may mutually agree, subject to compliance with the requirements under Chapter 14A of the Listing Rules and all other applicable laws and regulations. Relevant members of both parties will enter into separate CDMO services agreements setting out the specific terms and conditions based on the principles provided in the CDMO Services Framework Agreement.

CONNECTED TRANSACTIONS

The service fees chargeable by Cellularforce will be determined after arm’s length negotiations between Cellularforce and Zhongmei Huadong Group on a cost-plus basis, with the cost-plus margin ranging from approximately 5% to 30% of our cost depending on the nature, scope and complexity of services to be provided, the expected cost and expenses for provision of the required services.

Reasons for and benefits of the transaction

The provisions of CDMO services under the CDMO Services Framework Agreement are in the ordinary and usual course of business of our Group and on normal commercial terms. The transactions under the CDMO Services Framework Agreement can enhance the utilization of our in-house, commercial-scale biologic drug manufacturing capability, fulfill our business needs and diversify our source of revenue, which in turn can also support our R&D activities. Taking into consideration of the above and the corporate governance procedures in place as set out below, we believe that the transactions contemplated under the CDMO Services Framework Agreement are in the interest of our Company and our Shareholders as a whole.

Procedures in determination of price and terms of the transaction

In determining the price and terms of the transactions contemplated under the CDMO Services Framework Agreement, we follow our internal procedures which are applicable to all clients engaging Cellularforce for similar services. Such internal procedures cover the execution of confidentiality agreements with potential clients, discussions with potential clients to understand service needs and demands, preparation of work proposal and fee quote, arm’s length negotiations with clients on the terms of transactions, preparation and internal review of written agreements and execution of the same.

In addition to the above business procedures, we have promulgated the guidelines for establishing pricing for different kinds of services applicable for all clients and the business development department of Cellularforce shall conduct market analysis on specific service and making pricing proposal to our senior management after considering a number of factors as they consider necessary, including but not limited to service cost, profit margin, market pricing, capacity utilization and marketing perception. The business development department of Cellularforce shall review the reasonableness of pricing of relevant services on regular basis and ensure that the terms for the transactions under the CDMO Services Framework Agreement will not be more favorable than terms available to Independent Third Parties, and report to our senior management, if necessary, for their approval for any adjustment. Our independent non-executive Directors will also conduct annual review on the transactions under the CDMO Services Framework Agreement to ensure that such transactions have been entered into on normal commercial terms, are fair and reasonable, and conducted according to the terms of the CDMO Services Framework Agreement.

CONNECTED TRANSACTIONS

Historical transaction amounts

As Cellularforce commenced the provision of CDMO services to Zhongmei Huadong Group in February 2023, there was only an upfront payment of approximately RMB2 million received by Cellularforce from Zhongmei Huadong Group under the CDMO Services Framework Agreement during the Track Record Period.

Annual caps

Our Directors estimate that the maximum amount of service fees payable by Zhongmei Huadong Group to Cellularforce under the CDMO Services Framework Agreement for each of the two years ending December 31, 2025 will not exceed RMB10.0 million and RMB12.0 million, respectively.

In arriving at the above annual caps, our Directors have considered: (i) the volume, work order and estimated schedule of CDMO services we expect to provide to Zhongmei Huadong Group for the two years ending December 31, 2025. Based on the current status of the project under the existing contract, it is anticipated that all major milestones under such project will be completed in 2023 save for the stability study of drug substance, and approximately RMB11.0 million of the transaction amount of such project will be recorded in 2023. The stability study of drug substance under such project carries a study period of five years with the remaining transaction amount to be recorded in 2027; (ii) the projected transaction amount of our CDMO services from other new projects under the CDMO Services Framework Agreement as a result of our plan to develop external CDMO services through our manufacturing facility in Taizhou and the demand for such services from Zhongmei Huadong Group for the clinical development of their pipeline drug candidates. It is anticipated that Cellularforce may, in each year, be engaged in one new project with similar size and completion schedule that save for its stability study which will be a five-year study, each project is expected to be completed within twelve months from its commencement; and (iii) the expected year-on-year increase in related fees charged by Cellularforce due to the estimated increase in operational costs of approximately 5% to 10% (including labor costs, material costs and administrative costs) for the provision of CDMO services.

Listing Rules implications

As each of the applicable percentage ratios (other than the profits ratio) in respect of the annual caps under the CDMO Services Framework Agreement is expected to be more than 0.1% but less than 5% on an annual basis, the transactions contemplated under the CDMO Services Framework Agreement constitute continuing connected transactions for our Company which will, upon [REDACTED], be subject to the reporting, annual review and announcement requirements but exempt from the circular and independent shareholders' approval requirements under Chapter 14A of the Listing Rules.

CONNECTED TRANSACTIONS

WAIVER APPLICATION FOR NON-EXEMPT CONTINUING CONNECTED TRANSACTIONS

By virtue of Rule 14A.76(2) of the Listing Rules, the transactions contemplated under the CDMO Services Framework Agreement will constitute non-exempt continuing connected transactions subject to the reporting, annual review and announcement requirements but exempt from the circular and independent shareholders’ approval requirements under Chapter 14A of the Listing Rules.

As the above non-exempt continuing connected transactions are expected to continue on a recurring, continuing basis and will extend over a period of time after [REDACTED], our Directors consider that compliance with the above announcement, circular and independent shareholders’ approval requirements would be impractical, unduly burdensome and would impose unnecessary administrative costs on our Company. Accordingly, pursuant to Rule 14A.105 of the Listing Rules, we have applied to the Stock Exchange for, and the Stock Exchange [has granted] us, a waiver exempting us from strict compliance with the announcement requirement under Chapter 14A of the Listing Rules in respect of the continuing connected transactions as disclosed in “—(B) Continuing Connected Transactions Subject to the Reporting, Annual Review and Announcement Requirements but exempt from the Circular and Independent Shareholders’ Approval Requirements” in this section, on the condition that the Company will re-comply with the provisions of Chapter 14A of the Listing Rules applicable to such transactions upon the expiry of the term of the CDMO Services Framework Agreement.

In addition, we confirm that our Company will comply at all time with the other applicable provisions under Chapter 14 and Chapter 14A of the Listing Rules in respect of the notifiable and non-exempt continuing connected transactions. In the event of any future amendments to the Listing Rules imposing more stringent requirements than those applicable as of the Latest Practicable Date on the continuing connected transaction referred to in this document, our Company will take immediate steps to ensure compliance with such new requirements within a reasonable time.

CONFIRMATION FROM THE DIRECTORS

Our Directors, including the independent non-executive Directors, are of the view that the non-exempt continuing connected transactions as set out above have been and will be entered into: (i) in the ordinary and usual course of business of our Group; (ii) on normal commercial terms or better and in accordance with the respective terms that are fair and reasonable and in the interest of our Company and our Shareholders as a whole; and (iii) the proposed annual caps for the non-exempt continuing connected transactions described in this section are fair and reasonable and in the interest of our Company and our Shareholders as a whole.

CONNECTED TRANSACTIONS

CONFIRMATION FROM THE SOLE SPONSOR

The Sole Sponsor has reviewed the relevant information prepared and provided by our Company in relation to the continuing connected transactions described in this section. Based on the above, the Sole Sponsor is of the view that the non-exempt continuing connected transactions have been entered into: (i) in the ordinary and usual course of business of our Group; (ii) on normal commercial terms or better and in accordance with the respective terms that are fair and reasonable and in the interests of our Company and our Shareholders as a whole; and (iii) the proposed annual caps for the non-exempt continuing connected transactions described in this section are fair and reasonable and in the interests of our Company and our Shareholders as a whole.

SUBSTANTIAL SHAREHOLDERS

So far as our Directors are aware, the following persons will, immediately prior to and following the completion of the [REDACTED] and conversion of [REDACTED] Shares into H Shares, have interests or short positions in our Shares or underlying Shares which would be required to be disclosed to us under the provisions of Divisions 2 and 3 of Part XV of the SFO, or who is, directly or indirectly, interested in 10% or more of the nominal value of any types of our issued voting shares of any member of our Group:

LONG POSITIONS IN SHARES OF OUR COMPANY

Name of Shareholder	Nature of interest	Shares held as of the date of this document and immediately prior to the completion of the [REDACTED] and conversion of [REDACTED] Shares into H Shares ⁽¹⁾			Shares held immediately following the completion of the [REDACTED] and conversion of [REDACTED] Shares into H Shares ⁽¹⁾			
		Type of Shares ⁽²⁾	Number	Percentage of shareholding in the relevant type of Shares (<i>approx.</i>)	Type of Shares ⁽²⁾	Number	Percentage of shareholding in the relevant type of Shares (<i>approx.</i>)	Percentage of shareholding in the total issued share capital (<i>approx.</i>)
Hangzhou Quanyi ⁽³⁾	Beneficial owner	[REDACTED] Shares	40,000,000 (L)	19.05%	H Shares	[REDACTED] (L)	[REDACTED]%	[REDACTED]%
Xinfu Tongxin ⁽⁴⁾	Beneficial owner	[REDACTED] Shares	15,550,000 (L)	7.40%	H Shares	[REDACTED] (L)	[REDACTED]%	[REDACTED]%
Mr. Qiu ⁽³⁾⁽⁴⁾⁽⁵⁾⁽⁶⁾	Beneficial owner	[REDACTED] Shares	70,550,000 (L)	33.59%	[REDACTED] Shares	[REDACTED] (L)	[REDACTED]%	[REDACTED]%
	Interest in controlled corporations				H Shares	[REDACTED] (L)	[REDACTED]%	
Ms. Xu Qiu (許秋) ⁽⁷⁾	Interest of spouse	[REDACTED] Shares	70,550,000 (L)	33.59%	[REDACTED] Shares	[REDACTED] (L)	[REDACTED]%	[REDACTED]%
					H Shares	[REDACTED] (L)	[REDACTED]%	
Mr. Yu ⁽³⁾	Interest in a controlled corporation	[REDACTED] Shares	40,000,000 (L)	19.05%	H Shares	[REDACTED] (L)	[REDACTED]%	[REDACTED]%
Ms. Zhu Jing (朱靜) ⁽⁸⁾	Interest of spouse	[REDACTED] Shares	40,000,000 (L)	19.05%	H Shares	[REDACTED] (L)	[REDACTED]%	[REDACTED]%
Zhongmei Huadong ⁽⁹⁾	Beneficial owner	[REDACTED] Shares	35,900,000 (L)	17.09%	H Shares	[REDACTED] (L)	[REDACTED]%	[REDACTED]%
Huadong Medicine ⁽⁹⁾	Interest in a controlled corporation	[REDACTED] Shares	35,900,000 (L)	17.09%	H Shares	[REDACTED] (L)	[REDACTED]%	[REDACTED]%

SUBSTANTIAL SHAREHOLDERS

Name of Shareholder	Nature of interest	Shares held as of the date of this document and immediately prior to the completion of the [REDACTED] and conversion of [REDACTED] Shares into H Shares ⁽¹⁾			Shares held immediately following the completion of the [REDACTED] and conversion of [REDACTED] Shares into H Shares ⁽¹⁾			
		Type of Shares ⁽²⁾	Number	Percentage of shareholding in the relevant type of Shares (<i>approx.</i>)	Type of Shares ⁽²⁾	Number	Percentage of shareholding in the relevant type of Shares (<i>approx.</i>)	Percentage of shareholding in the total issued share capital (<i>approx.</i>)
China Grand Enterprises Incorporation (中國遠大集團有限責任公司) (“China Grand”) ⁽⁹⁾	Interest in controlled corporations	[REDACTED] Shares	35,900,000 (L)	17.09%	H Shares	[REDACTED] (L)	[REDACTED]%	[REDACTED]%
Beijing Grand Huachuang Investment Co., Ltd. (北京遠大華創投資有限公司) (“Beijing Grand”) ⁽⁹⁾	Interest in controlled corporations	[REDACTED] Shares	35,900,000 (L)	17.09%	H Shares	[REDACTED] (L)	[REDACTED]%	[REDACTED]%
Mr. Hu Kaijun (胡凱軍) ⁽⁹⁾	Interest in controlled corporations	[REDACTED] Shares	35,900,000 (L)	17.09%	H Shares	[REDACTED] (L)	[REDACTED]%	[REDACTED]%
Hongtai Health ⁽¹⁰⁾	Beneficial owner	[REDACTED] Shares	18,750,000 (L)	8.93%	H Shares	[REDACTED] (L)	[REDACTED]%	[REDACTED]%
Hongtai Aplus ⁽¹⁰⁾	Interest in controlled corporations	[REDACTED] Shares	18,750,000 (L)	8.93%	H Shares	[REDACTED] (L)	[REDACTED]%	[REDACTED]%
Qingdao Xinchun Sci-Tech Innovation Industrial Co., Ltd (青島鑫宸科創實業有限公司) (“Qingdao Xinchun”) ⁽¹⁰⁾	Interest in controlled corporations	[REDACTED] Shares	18,750,000 (L)	8.93%	H Shares	[REDACTED] (L)	[REDACTED]%	[REDACTED]%
Mr. Sheng Xitai (盛希泰) ⁽¹⁰⁾	Interest in controlled corporations	[REDACTED] Shares	18,750,000 (L)	8.93%	H Shares	[REDACTED] (L)	[REDACTED]%	[REDACTED]%

SUBSTANTIAL SHAREHOLDERS

Name of Shareholder	Nature of interest	Shares held as of the date of this document and immediately prior to the completion of the [REDACTED] and conversion of [REDACTED] Shares into H Shares ⁽¹⁾			Shares held immediately following the completion of the [REDACTED] and conversion of [REDACTED] Shares into H Shares ⁽¹⁾			
		Type of Shares ⁽²⁾	Number	Percentage of shareholding in the relevant type of Shares (<i>approx.</i>)	Type of Shares ⁽²⁾	Number	Percentage of shareholding in the relevant type of Shares (<i>approx.</i>)	Percentage of shareholding in the total issued share capital (<i>approx.</i>)
Zijin Trust ⁽¹⁰⁾	Interest in controlled corporations	[REDACTED] Shares	18,750,000 (L)	8.93%	H Shares	[REDACTED] (L)	[REDACTED]%	[REDACTED]%
Nanjing Zijin Investment Group Co., Ltd. (南京紫金投資集團有限責任公司) (“Nanjing Zijin”) ⁽¹⁰⁾	Interest in controlled corporations	[REDACTED] Shares	18,750,000 (L)	8.93%	H Shares	[REDACTED] (L)	[REDACTED]%	[REDACTED]%
Nanjing State-owned Assets Investment & Management Holding (Group) Co., Ltd. (南京市國有資產投資管理控股(集團)有限責任公司) (“Nanjing Assets”) ⁽¹⁰⁾	Interest in controlled corporations	[REDACTED] Shares	18,750,000 (L)	8.93%	H Shares	[REDACTED] (L)	[REDACTED]%	[REDACTED]%
Taizhou Huacheng ⁽¹⁰⁾	Interest in controlled corporations	[REDACTED] Shares	18,750,000 (L)	8.93%	H Shares	[REDACTED] (L)	[REDACTED]%	[REDACTED]%
Taizhou Jianxin ⁽¹¹⁾	Beneficial owner	[REDACTED] Shares	7,500,000 (L)	3.57%	[REDACTED] Shares H Shares	[REDACTED] (L) [REDACTED] (L)	[REDACTED]% [REDACTED]%	[REDACTED]%
Taizhou Huayin ⁽¹¹⁾⁽¹²⁾	Interest in controlled corporations	[REDACTED] Shares	15,000,000 (L)	7.14%	[REDACTED] Shares H Shares	[REDACTED] (L) [REDACTED] (L)	[REDACTED]% [REDACTED]%	[REDACTED]%
Taizhou Medical High-tech ⁽¹¹⁾⁽¹²⁾	Interest in controlled corporations	[REDACTED] Shares	15,000,000 (L)	7.14%	[REDACTED] Shares H Shares	[REDACTED] (L) [REDACTED] (L)	[REDACTED]% [REDACTED]%	[REDACTED]%

SUBSTANTIAL SHAREHOLDERS

Name of Shareholder	Nature of interest	Shares held as of the date of this document and immediately prior to the completion of the [REDACTED] and conversion of [REDACTED] Shares into H Shares ⁽¹⁾			Shares held immediately following the completion of the [REDACTED] and conversion of [REDACTED] Shares into H Shares ⁽¹⁾			
		Type of Shares ⁽²⁾	Number	Percentage of shareholding in the relevant type of Shares (<i>approx.</i>)	Type of Shares ⁽²⁾	Number	Percentage of shareholding in the relevant type of Shares (<i>approx.</i>)	Percentage of shareholding in the total issued share capital (<i>approx.</i>)
Taizhou Medicine ⁽¹⁰⁾⁽¹¹⁾⁽¹²⁾	Interest in controlled corporations	[REDACTED] Shares	33,750,000 (L)	16.07%	[REDACTED] Shares H Shares	[REDACTED] (L)	[REDACTED]% [REDACTED]%	[REDACTED]%
Matrix China Management VI, L.P. ⁽¹³⁾	Interest in controlled corporations	[REDACTED] Shares	10,920,000 (L)	5.20%	H Shares	[REDACTED] (L)	[REDACTED]%	[REDACTED]%
Matrix China VI GP, Ltd. ⁽¹³⁾	Interest in controlled corporations	[REDACTED] Shares	10,920,000 (L)	5.20%	H Shares	[REDACTED] (L)	[REDACTED]%	[REDACTED]%
Jiaxing Jiquan ⁽¹⁴⁾	Beneficial owner	[REDACTED] Shares	3,572,400 (L)	1.70%	[REDACTED] Shares	[REDACTED] (L)	[REDACTED]%	[REDACTED]%
Shanghai Jincheng Equity Investment Fund Management Co., Ltd (上海晉成股權投資基金管理有限公司) (“Shanghai Jincheng”) ⁽¹⁴⁾	Interest in controlled corporations	[REDACTED] Shares	3,572,400 (L)	1.70%	[REDACTED] Shares	[REDACTED] (L)	[REDACTED]%	[REDACTED]%
Mr. Xiong Yongxiang (熊永祥) ⁽¹⁴⁾	Interest in controlled corporations	[REDACTED] Shares	3,572,400 (L)	1.70%	[REDACTED] Shares	[REDACTED] (L)	[REDACTED]%	[REDACTED]%
Ms. Zheng Qing'ai (鄭青愛) ⁽¹⁴⁾	Interest in controlled corporations	[REDACTED] Shares	3,572,400 (L)	1.70%	[REDACTED] Shares	[REDACTED] (L)	[REDACTED]%	[REDACTED]%
Shanghai Jincheng Enterprise Development Group Co., Ltd (上海晉成企業發展集團有限公司) (“Shanghai Jincheng Group”) ⁽¹⁴⁾	Interest in controlled corporations	[REDACTED] Shares	3,572,400 (L)	1.70%	[REDACTED] Shares	[REDACTED] (L)	[REDACTED]%	[REDACTED]%

SUBSTANTIAL SHAREHOLDERS

Name of Shareholder	Nature of interest	Shares held as of the date of this document and immediately prior to the completion of the [REDACTED] and conversion of [REDACTED] Shares into H Shares ⁽¹⁾			Shares held immediately following the completion of the [REDACTED] and conversion of [REDACTED] Shares into H Shares ⁽¹⁾			
		Type of Shares ⁽²⁾	Number	Percentage of shareholding in the relevant type of Shares (<i>approx.</i>)	Type of Shares ⁽²⁾	Number	Percentage of shareholding in the relevant type of Shares (<i>approx.</i>)	Percentage of shareholding in the total issued share capital (<i>approx.</i>)
Jincheng (Shanghai) Industrial Co., Ltd (晉成(上海)實業有限公司) (“Jincheng Industrial”) ⁽¹⁴⁾	Interest in controlled corporations	[REDACTED] Shares	3,572,400 (L)	1.70%	[REDACTED] Shares	[REDACTED] (L)	[REDACTED]%	[REDACTED]%
Mr. Gu Dongchen (顧棟臣) ⁽¹⁴⁾	Interest in controlled corporations	[REDACTED] Shares	3,572,400 (L)	1.70%	[REDACTED] Shares	[REDACTED] (L)	[REDACTED]%	[REDACTED]%
Mr. Gu Zhiqiang (顧志強) ⁽¹⁴⁾	Interest in controlled corporations	[REDACTED] Shares	3,572,400 (L)	1.70%	[REDACTED] Shares	[REDACTED] (L)	[REDACTED]%	[REDACTED]%

Notes:

- (1) The letter “L” denotes the person’s long position in our Shares.
- (2) [REDACTED] Shares and H Shares are regarded as two different types of Shares. For the avoidance of doubt, both [REDACTED] Shares and H Shares are ordinary Shares in the share capital of our Company, and are considered as one class of Shares.
- (3) Hangzhou Quanyi is owned as to 50% by Mr. Qiu and 50% by Mr. Yu Guo’an, both being its general partners acting in concert pursuant to the supplemental partnership agreement of Hangzhou Quanyi. For details, see “Relationship with Our Controlling Shareholders—Overview” in this document. By virtue of the SFO, each of Mr. Qiu and Mr. Yu Guo’an is deemed to be interested in the Shares held by Hangzhou Quanyi.
- (4) Mr. Qiu is the general partner who holds approximately 7.20% interest in Xinfu Tongxin. By virtue of the SFO, Mr. Qiu is deemed to be interested in the Shares held by Xinfu Tongxin.
- (5) Mr. Qiu is the general partner who holds approximately 45.71% interest in Shanghai Quanyou. Shanghai Quanyou holds 5,000,000 Shares, representing approximately 2.38% and [REDACTED]% of our Shares in issue immediately prior to and following the completion of the [REDACTED]. By virtue of the SFO, Mr. Qiu is deemed to be interested in the Shares held by Shanghai Quanyou.
- (6) Mr. Qiu directly holds 10,000,000 Shares, representing approximately 4.76% and [REDACTED]% of our Shares in issue immediately prior to and following the completion of the [REDACTED].
- (7) Ms. Xu Qiu is the spouse of Mr. Qiu. By virtue of the SFO, Ms. Xu Qiu is deemed to be interested in the Shares held by Mr. Qiu.

SUBSTANTIAL SHAREHOLDERS

- (8) Ms. Zhu Jing is the spouse of Mr. Yu Guo’an. By virtue of the SFO, Ms. Zhu Jing is deemed to be interested in the Shares held by Mr. Yu Guo’an.
- (9) Zhongmei Huadong is wholly owned by Huadong Medicine. Huadong Medicine is owned as to approximately 41.66% by China Grand as its controlling shareholder. China Grand is owned as to approximately 92.97% by Beijing Grand, which is wholly owned by Mr. Hu Kaijun. By virtue of the SFO, each of Huadong Medicine, China Grand, Beijing Grand and Mr. Hu Kaijun is deemed to be interested in the Shares held by Zhongmei Huadong.
- (10) Hongtai Health is owned as to approximately 0.88% by Hongtai Aplus as its general partner, 55.07% by Taizhou Huacheng and 44.05% by Zijin Trust, both being its limited partners. Hongtai Aplus is wholly owned by Qingdao Xincheng, a company controlled by Mr. Sheng Xitai. Taizhou Huacheng is owned as to approximately 93.23% by Taizhou Medicine. Zijin Trust is owned as to approximately 50.67% by Nanjing Zijin, a company wholly owned by Nanjing Assets. By virtue of the SFO, each of Hongtai Aplus, Qingdao Xincheng, Mr. Sheng Xitai, Taizhou Huacheng, Taizhou Medicine, Zijin Trust, Nanjing Zijin and Nanjing Assets is deemed to be interested in the Shares held by Hongtai Health.
- (11) Taizhou Jianxin is an investment fund company managed by Taizhou Huaxin, a company owned as to approximately 91.25% by Taizhou Huayin. Taizhou Huayin is owned as to approximately 41.76% by Taizhou Medical High-tech, 31.50% by Taizhou Oriental (a company owned as to 90% by Taizhou Medicine), and 10.50% by Taizhou Huacheng (a company owned as to approximately 93.23% by Taizhou Medicine). Taizhou Jianxin holds 7,500,000 Shares, representing approximately 3.57% and [REDACTED]% of our Shares in issue immediately prior to and following the completion of the [REDACTED]. By virtue of the SFO, each of Taizhou Huaxin, Taizhou Huayin, Taizhou Medical High-tech and Taizhou Medicine is deemed to be interested in the Shares held by Taizhou Jianxin.
- (12) Rongjianda is an investment fund company managed by Rongjianda VC, which is owned as to 81% by Taizhou Huayin. Rongjianda is owned as to approximately 33.33% by Taizhou High-tech Industry Investment Development Co., Ltd. (泰州市高新產業投資有限公司) (“Taizhou High-tech”), 33.33% by Taizhou Huayin and 32.33% by Taizhou Huajian, a company wholly owned by Taizhou Huayin. Taizhou High-tech is a wholly owned subsidiary of Taizhou Financial Holding Group Co., Ltd. (泰州市金融控股集團有限公司) (“Taizhou Financial”), a company owned as to approximately 60.13% by Taizhou People’s Municipal Government State-owned Assets Supervision and Administration Commission (泰州市人民政府國有資產監督管理委員會). Taizhou Huayin is owned as to approximately 41.76% by Taizhou Medical High-tech, 31.50% by Taizhou Oriental (a company owned as to 90% by Taizhou Medicine), and 10.50% by Taizhou Huacheng (a company owned as to approximately 93.23% by Taizhou Medicine). Rongjianda holds 7,500,000 Shares, representing approximately 3.57% and [REDACTED]% of our Shares in issue immediately prior to and following the completion of the [REDACTED]. By virtue of the SFO, each of Rongjianda VC, Taizhou High-tech, Taizhou Financial, Taizhou Huayin, Taizhou Medical High-tech and Taizhou Medicine is deemed to be interested in the Shares held by Rongjianda.
- (13) The general partner of Matrix Partners China VI, L.P. and Matrix Partners China VI-A, L.P. is Matrix China Management VI, L.P.. The general partner of Matrix China Management VI, L.P. is Matrix China VI GP GP, Ltd.. Matrix Partners China VI, L.P. and Matrix Partners China VI-A, L.P. in aggregate hold 10,920,000 Shares, representing approximately 5.20% and [REDACTED]% of our Shares in issue immediately prior to and following the completion of the [REDACTED]. By virtue of the SFO, each of Matrix China Management VI, L.P. and Matrix China VI GP GP, Ltd. is deemed to be interested in the Shares held by Matrix Partners China VI, L.P. and Matrix Partners China VI-A, L.P..
- (14) Jiaying Jiquan is a limited partnership owned as to approximately 1.67% by Shanghai Jincheng as its general partner, 45% by Mr. Xiong Yongxiang and approximately 33.33% by Ms. Zheng Qing’ai, being two of its limited partners. Shanghai Jincheng is owned as to 90% by Shanghai Jincheng Group. Shanghai Jincheng Group is owned as to 99% by Jincheng Industrial, a company owned as to 50% by Mr. Gu Dongchen and 50% Mr. Gu Zhiqiang.

SUBSTANTIAL SHAREHOLDERS

LONG POSITIONS IN EQUITY INTEREST OF MEMBERS OF OUR GROUP

Name of Shareholder	Member of our Group	Nature of interest	Equity interest held immediately prior to the completion of the [REDACTED] <i>(approx.)</i>	Equity interest held immediately following the completion of the [REDACTED] <i>(approx.)</i>
Taizhou Huacheng ⁽¹⁾	Cellularforce	Beneficial owner	34.00%	[REDACTED]%
Taizhou Medicine ⁽¹⁾	Cellularforce	Interest in controlled corporation	34.00%	[REDACTED]%

Note:

- (1) Taizhou Huacheng is owned as to approximately 93.23% by Taizhou Medicine. By virtue of the SFO, Taizhou Medicine is deemed to be interested in the equity interest held by Taizhou Huacheng.

Except as disclosed above, our Directors are not aware of any person will, immediately prior to and following the completion of the [REDACTED] and conversion of [REDACTED] Shares into H Shares, have interests or short positions in any Shares or underlying Shares, which would be required to be disclosed to us under the provisions of Divisions 2 and 3 of Part XV of the SFO, or who is, directly or indirectly interested in 10% or more of the nominal value of any types of our issued voting shares of any member of our Group. Our Directors are not aware of any arrangement which may at a subsequent date result in a change of control of our Company.

SHARE CAPITAL

As of the Latest Practicable Date, the registered share capital of our Company was RMB210,025,200 divided into 210,025,200 [REDACTED] Shares, with a nominal value of RMB1.00 each.

Immediately after the completion of the [REDACTED] and conversion of [REDACTED] Shares into H Shares, the share capital of our Company will be as follows:

<u>Number of Shares</u>	<u>Description of Shares</u>	<u>Approximate percentage of total issued share capital</u>
[REDACTED]	[REDACTED] Shares ⁽¹⁾	[REDACTED]%
[REDACTED]	H Shares to be converted from [REDACTED] Shares ⁽²⁾	[REDACTED]%
[REDACTED]	H Shares to be issued under the [REDACTED]	[REDACTED]%
<u>[REDACTED]</u>		<u>100.00%</u>

Notes:

- (1) The [REDACTED] Shares refer to [REDACTED] Shares, [REDACTED] Shares and [REDACTED] Shares held by Mr. Qiu, Taizhou Jianxin and Jiaying Jiquan, respectively. As advised by Mr. Qiu, Taizhou Jianxin and Jiaying Jiquan, they currently have no plan or intention to convert the above [REDACTED] Shares into H Shares after [REDACTED].
- (2) For details of the identities of the Shareholders whose Shares will be converted into H Shares upon [REDACTED], see “History and Corporate Structure—[REDACTED]” in this document.

The above table assumes that the [REDACTED] has become unconditional and the H Shares are issued pursuant to the [REDACTED].

SHARE CAPITAL

RANKING

Upon the completion of the [REDACTED] and conversion of [REDACTED] Shares into H Shares, our Shares will consist of [REDACTED] Shares and H Shares. [REDACTED] Shares and H Shares are all ordinary Shares in the share capital of our Company and are regarded as the same class of Shares under the Articles of Association.

Apart from certain qualified domestic institutional investors in the PRC, the qualified PRC investors under the Shanghai-Hong Kong Stock Connect and the Shenzhen-Hong Kong Stock Connect and other persons who are entitled to hold our H Shares pursuant to relevant PRC laws and regulations or upon approvals of any competent authorities (such as our certain existing shareholders the [REDACTED] Shares held by whom will be converted into H Shares according to the filing with the CSRC), H Shares generally cannot be subscribed by or traded between legal or natural PRC persons.

[REDACTED] Shares and H Shares shall carry the same rights in all other respects and, in particular, will rank equally for dividends or distributions declared, paid or made. All dividend for H Shares will be denominated and declared in Renminbi, and paid in Hong Kong dollars or Renminbi, whereas all dividends for [REDACTED] Shares will be paid in Renminbi. Other than cash, dividends could also be paid in the form of shares or a combination of cash and shares.

CIRCUMSTANCES UNDER WHICH GENERAL MEETING AND CLASS MEETING ARE REQUIRED

Our Company will have only one class of Shares upon completion of the [REDACTED], namely ordinary shares, and each carry the same rights in all respects with the other Shares.

For details of circumstances under which our Shareholders’ general meeting and class Shareholders’ meeting are required, see “Appendix VII—Summary of Articles of Association” to this document.

CONVERSION OF OUR [REDACTED] SHARES INTO H SHARES

Pursuant to the regulations prescribed by the securities regulatory authorities of the State Council and the Articles of Association, the [REDACTED] Shares may be converted into overseas-listed Shares. Such converted Shares could be listed or traded on an overseas stock exchange, provided that prior to the conversion and trading of such converted Shares, any requisite internal approval process has been duly completed and all the filing procedures with the relevant regulatory authorities, including CSRC which requires administrative filing procedures for the conversion and trading of such converted Shares, have been obtained. In addition, such conversion and trading shall comply with the regulations, requirements and procedures prescribed by the relevant overseas stock exchange. If any of the [REDACTED] Shares are to be converted, [REDACTED] and [REDACTED] as H Shares on the Stock Exchange, such conversion, [REDACTED] and [REDACTED] will need to be filed with the relevant PRC regulatory authorities, including the CSRC, and the [REDACTED] of the Stock Exchange.

SHARE CAPITAL

[REDACTED] Approval by the Stock Exchange

We [have applied] to the Stock Exchange for the approval for the granting of [REDACTED] of, and permission to [REDACTED], our H Shares to be issued pursuant to the [REDACTED] and the H Shares to be converted from [REDACTED] Shares on the Stock Exchange, which is subject to the approval by the Stock Exchange. We will perform the following procedures for the conversion of [REDACTED] Shares into H Shares after receiving the approval of the Stock Exchange: (a) giving instructions to our [REDACTED] regarding relevant share certificates of the converted H Shares; and (b) enabling the converted H Shares to be accepted as eligible securities by [REDACTED] for deposit, clearance and settlement in the [REDACTED]. The Participating Shareholders may only [REDACTED] the Shares upon completion of following domestic procedures.

[REDACTED] Review and Filing with the CSRC

In accordance with the Guidelines for the “Full Circulation” Program for Domestic Unlisted Shares of H-share Listed Companies (《H股公司境内未上市股份申请「全流通」业务指引》) and the Overseas Listing Trial Measures announced by the CSRC, H-share listed companies which apply for the conversion of domestic shares and unlisted foreign shares into H shares for listing and circulation on the Stock Exchange shall file the application with the CSRC according to the administrative filing procedures necessary for the Overseas Listing Trial Measures. An H-share listed company may apply for a “Full Circulation” separately or when applying for refinancing overseas. An unlisted domestic joint stock company may apply for “Full Circulation” when applying for an overseas initial public offering.

Our Company shall file with the CSRC within three business days after our application for [REDACTED] is submitted to the Stock Exchange in relation to the filing of the overseas [REDACTED] and “Full Circulation” pursuant to which (i) our Company is supposed to issue no more than [REDACTED] H Shares with a nominal value of RMB1.00 each, which are all ordinary Shares, and upon such issuance our Company may be [REDACTED] on the Main Board of the Stock Exchange; (ii) a total of [REDACTED] Shares (with a nominal value of RMB1.00 each) held by Hangzhou Quanyi, Xinfu Tongxin, Shanghai Quanyou, Dr. Yu Guoliang, Dr. Li Jianwei, Dr. Qiu Zhihua, Mr. Guo Xinjun, Zhongmei Huadong, Hongtai Health, Matrix Partners China VI, L.P., Matrix Partners China VI-A, L.P., Rongjianda, Taizhou Jianxin, Suzhou Guanhong, Shanghai Shuo Chen, Lucky-source IV, Lucky-source III, Tongren Boda, Hefu Ruitai, Gongqingcheng Triwise Kangxin, Triwise Rozman, Shenzhen Triwise Kangxin, Triwise Detai, Triwise Huisheng, TWVC Panglin, Qianhai Efung, Shenzhen Kaitian, Nanjing Yuzhijia, Cowin Guosheng, Jiayin Lucky-source, Yuanzhi Fuhai, Everest No. 37 and Nanjing Talent (the “Participating Shareholders”) are supposed to be converted into H Shares after the completion of the filing procedures required by the CSRC, and the relevant Shares may be [REDACTED] on the Stock Exchange upon completion of the conversion.

SHARE CAPITAL

Domestic Procedures

The Participating Shareholders may only [REDACTED] the Shares upon completion of the following procedures for the registration, deposit and transaction settlement in relation to the conversion and [REDACTED]:

- (a) we will appoint China Securities Depository and Clearing Corporation Limited (中國證券登記結算有限責任公司) (“CSDC”) as the nominal holder to deposit the relevant securities at China Securities Depository and Clearing (Hong Kong) Company Limited (“CSDC (Hong Kong)”), which will then deposit the securities at [REDACTED] in its own name. CSDC, as the nominal holder of the Participating Shareholders, shall handle all custody, maintenance of detailed records, cross-border settlement and corporate actions, etc. relating to the converted H Shares for the Participating Shareholders;
- (b) we will engage a domestic securities company (the “Domestic Securities Company”) to provide services such as the transmission of [REDACTED] and [REDACTED] messages in respect of the converted H Shares. The Domestic Securities Company will engage a Hong Kong securities company (the “Hong Kong Securities Company”) for settlement of share transactions. We will make an application to CSDC Shenzhen Branch for the maintenance of a detailed record of the initial holding of the converted H Shares held by our Shareholders. Meanwhile, we will submit applications for a domestic transaction commission code and abbreviation, which shall be confirmed by CSDC Shenzhen Branch as authorized by the Shenzhen Stock Exchange;
- (c) the Shenzhen Stock Exchange shall authorize Shenzhen Securities Communication Co., Ltd. to provide services relating to transmission of [REDACTED] and [REDACTED] messages in respect of the converted H Shares between the Domestic Securities Company and the Hong Kong Securities Company, and the real-time market forwarding services of the H Shares;
- (d) according to the Notice of the SAFE on Issues Concerning the Foreign Exchange Administration of Overseas Listing (《國家外匯管理局關於境外上市外匯管理有關問題的通知》), the Participating Shareholders shall complete the overseas shareholding registration with the local foreign exchange administration bureau before the Shares are sold, and after the overseas shareholding registration, open a specified bank account for the holding of overseas shares by domestic investors at a domestic bank with relevant qualifications and open a fund account for the H Share “Full Circulation” at the Domestic Securities Company. The Domestic Securities Company shall open a securities trading account for the H Share “Full Circulation” at the Hong Kong Securities Company; and

SHARE CAPITAL

- (e) the Participating Shareholders shall submit trading orders of the converted H Shares through the Domestic Securities Company. Trading orders of the Participating Shareholders for the relevant Shares will be submitted to the Stock Exchange through the securities trading account opened by the Domestic Securities Company at the Hong Kong Securities Company. Upon completion of the transaction, settlements between each of the Hong Kong Securities Company and CSDC (Hong Kong), CSDC (Hong Kong) and CSDC, CSDC and the Domestic Securities Company, and the Domestic Securities Company and the Participating Shareholders, will all be conducted separately.

As a result of the conversion, the shareholding of the relevant Participating Shareholders in our [REDACTED] Share capital registered shall be reduced by the number of [REDACTED] Shares converted and the number of H Shares shall be increased by the number of converted H Shares.

A Shareholder holding [REDACTED] Shares can work with our Company according to the Articles of Association and follow the procedures set out in this document to convert the [REDACTED] Shares into H Shares after the [REDACTED] if they wish, provided that such conversion of [REDACTED] Shares into and [REDACTED] and [REDACTED] of H Shares will be subject to the completion of the filing procedures with the relevant PRC regulatory authorities, including the CSRC, the approval of the Stock Exchange and the satisfaction of the [REDACTED] requirement under the Listing Rules.

TRANSFER OF SHARES ISSUED PRIOR TO [REDACTED]

The PRC Company Law provides that in relation to the public offering of a company, the shares issued prior to the public offering shall not be transferred within a period of one year from the date on which the publicly offered shares are listed on any stock exchange. Accordingly, Shares issued by our Company prior to the [REDACTED] shall be subject to such statutory restriction and not be transferred within a period of one year from the [REDACTED].

For details of the lock-up undertaking given by our Controlling Shareholders to the Stock Exchange, see “[REDACTED]” in this document.

INCREASE IN SHARE CAPITAL

As advised by our PRC Legal Advisors, pursuant to the Articles of Association and subject to the requirements of relevant PRC laws and regulations, our Company, upon the [REDACTED] of our H Shares, is eligible to enlarge its share capital by issuing either new H Shares or new [REDACTED] Shares on the condition that such proposed issuance shall be approved by a special resolution of Shareholders in general meeting conducted in accordance with the provisions of the Articles of Association and that such issuance complies with the Listing Rules and other relevant laws and regulations of Hong Kong. To adopt a special resolution of Shareholders in general meeting, more than the two thirds votes represented by

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the Shareholders (including proxies) present at the general meeting must be exercised in favor of the resolution. Resolutions of a class of Shareholders shall be passed by votes representing more than two thirds of Shareholders with voting rights attending the class Shareholders’ meeting. See “—Ranking” in this section.

REGISTRATION OF SHARES NOT LISTED ON THE OVERSEAS STOCK EXCHANGE

According to the Notice of Centralized Registration and Deposit of Non-overseas Listed Shares of Companies Listed on an Overseas Stock Exchange (《關於境外上市公司非境外上市股份集中登記存管有關事宜的通知》) issued by the CSRC, an overseas listed company is required to register its shares that are not listed on the overseas stock exchange with China Securities Depository and Clearing Corporation Limited (中國證券登記結算有限責任公司) within 15 business days upon the listing and provide a written report to the CSRC regarding the centralized registration and deposit of its unlisted Shares as well as the current offering and listing of shares.

SHAREHOLDERS’ APPROVAL FOR THE [REDACTED]

Approval from holders of the Shares is required for the Company to issue H Shares and seek the [REDACTED] of H Shares on the Stock Exchange. The Company has obtained such approval at the Shareholders’ general meeting held on March 23, 2023.

FINANCIAL INFORMATION

You should read the following discussion and analysis in conjunction with our consolidated financial information included in “Appendix I—Accountants’ Report” to this document, together with the accompanying notes. Our consolidated financial information has been prepared in accordance with IFRSs. You should read the entire Accountants’ Report and not merely rely on the information contained in this section.

The following discussion and analysis contain forward-looking statements that reflect the current views with respect to future events and financial performance. These statements are based on assumptions and analyses made by us in light of our experience and perception of historical trends, current conditions and expected future developments, as well as other factors that we believe are appropriate under the circumstances. However, whether the actual outcome and developments will meet our expectations and predictions depends on a number of risks and uncertainties over which we do not have control. For details, see “Forward-looking Statements” and “Risk Factors.” Unless the content otherwise requires, reference to “2021” or “2022” refers to our financial year ended December 31 of such year.

OVERVIEW

We are a clinical-stage biotech company exclusively focused on biologic therapies for autoimmune and allergic diseases, with a self-developed drug pipeline and an established commercial-scale in-house manufacturing capability. To address significant unmet medical needs in the autoimmune and allergic disease drug market in China, we have built a broad pipeline that covers the four major disease areas in the field, including skin, rheumatic, respiratory and digestive diseases. Our mission is to pursue scientific innovation and deliver affordable and quality therapeutics.

As a pre-revenue biotech company, we were not profitable and incurred operating losses during the Track Record Period. In 2021, 2022 and the nine months ended September 30, 2022 and 2023, we had net losses of RMB426.5 million, RMB312.3 million, RMB205.9 million and RMB385.5 million, respectively. Our operating losses were primarily attributable to research and development expenses, changes in the carrying amount of financial instruments issued to investors, administrative expenses and finance costs.

BASIS OF PREPARATION AND PRESENTATION

Our Company was established in the PRC as a limited liability company on June 16, 2015 and was converted into a joint stock company with limited liability on September 2, 2021. See “History and Corporate Structure—Our Corporate Developments—Establishment and major shareholding changes of our Company.” We prepared our consolidated financial information in accordance with all applicable International Financial Reporting Standards (“IFRSs”) which collectively include all applicable individual International Financial Reporting Standards, International Accounting Standards and Interpretations issued by the International Accounting Standards Board (“IASB”).

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For the purposes of preparing our consolidated financial information, we have adopted all applicable new and revised IFRSs consistently for the Track Record Period. We have not adopted any new standards or interpretations that became effective for the accounting year beginning on or after January 1, 2024. See note 31 “Possible impact of amendments, new standards and interpretations issued but not yet effective for the relevant periods” to the Accountants’ Report in Appendix I to this document.

KEY FACTORS AFFECTING OUR RESULTS OF OPERATIONS

We believe that the most significant factors affecting our results of operations, financial condition and cash flow include the following:

Our Ability to Successfully Develop and Commercialize Our Biologic Drug Candidates

We are a clinical-stage biotech company specialized in biologic therapeutics for autoimmune and allergic diseases. Our results of operations will depend to a significant extent on the successful development and commercialization of our drug candidates. We entered into a collaboration agreement with a subsidiary of Huadong Medicine in August 2020 with respect to the joint development and exclusive commercialization of QX001S in China. See “Business—Collaboration with Zhongmei Huadong.” We completed a Phase III clinical trial of QX001S for Ps in June 2023 and Zhongmei Huadong submitted a BLA in China in July 2023, which was accepted by the NMPA in August 2023. We understand that Zhongmei Huadong plans to begin commercializing QX001S in the fourth quarter of 2024. In addition, we commenced a Phase III clinical trial to evaluate the efficacy and safety of QX002N for the treatment of AS in September 2023, which is expected to be completed in the second half of 2025. We are evaluating the safety and efficacy of QX005N for AD in adults in a Phase II clinical trial and expect to complete such trial in the first quarter of 2024. We are also conducting a Phase II clinical trial of QX005N for PN and expect to complete this trial in the first quarter of 2024. As of the Latest Practicable Date, including QX001S, QX002N and QX005N, we had six biologic drug candidates in various clinical stage and three biologic drug candidates in the preclinical stage. Whether our drug candidates can demonstrate favorable safety and efficacy in the clinical trial, whether we can obtain the requisite regulatory approvals for our drug candidates according to our plan and whether we can effectively implement our commercialization strategies are crucial for our business and results of operations.

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Our Operating Expenses

Our operating expenses during the Track Record Period primarily consisted of research and development expenses and administrative expenses, details of which are set out below.

- *Research and development expenses.* Our research and development expenses primarily consisted of third-party contracting costs, staff costs, cost of materials and consumables used and depreciation and amortization expenses. In 2021, 2022 and the nine months ended September 30, 2022 and 2023, our research and development expenses amounted to RMB151.9 million, RMB257.2 million, RMB189.7 million and RMB263.3 million, respectively. As a biotech company of innovative therapeutics, we have devoted significant resources on the research and development of our biologic drug candidates. We expect to continue to do so in the foreseeable future as we advance our drug development pipeline.
- *Administrative expenses.* Our administrative expenses primarily consisted of staff costs, [REDACTED] expenses, depreciation and amortization expenses, office and miscellaneous expense and other professional service fees. In 2021, 2022 and the nine months ended September 30, 2022 and 2023, our administrative expenses amounted to RMB48.8 million, RMB76.6 million, RMB33.2 million and RMB123.2 million, respectively. We anticipate increasing legal, compliance, accounting, insurance and investor and public relations expenses associated with being a public company in Hong Kong.

As we move from a clinical-stage company to a commercial-stage company, our cost structure will become more sophisticated with research and development expenses and administrative expenses continuing to increase in amount and complexity.

Carrying Amount of Financial Instruments Issued to Investors

During the Track Record Period, we conducted a series of equity financings. For details, see “History and Corporate Structure—Our Corporate Developments—Establishment and major shareholding changes of our Company.” We recognize the financial instruments issued to certain [REDACTED] Investors as financial liabilities because these financial instruments did not meet the definition of equity. The financial instruments issued to investors were measured by our Directors with reference to valuation reports prepared by an independent qualified professional valuer. We applied the discounted cash flow method to determine the underlying equity value of our Company and allocated a corresponding value to each share on a *pro rata* basis to determine the carrying amount of the financial instruments issued to investors as of the dates of issuance and at the end of each period of the Track Record Period. As a result, we recorded a non-cash charge of “changes in the carrying amount of financial instruments issued to investors” of RMB240.1 million in our statement of profit and loss in 2021. In July 2021, we entered into supplementary agreements with our [REDACTED] Investors, pursuant to which the [REDACTED] Investors waived certain preferred rights. Accordingly, we reclassified the financial liabilities recognized for the redemption obligations from financial liabilities to equity and no longer recognize fair-value changes in financial instruments issued to investors going forward.

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CRITICAL ACCOUNTING POLICIES AND ESTIMATES

Our material accounting policy information which are important for an understanding of our financial positions and results of operations are set forth in detail in note 2 to the Accountants' Report set out in Appendix I of this document. Some of the accounting policies involve subjective assumptions and estimates, as well as complex judgments relating to accounting items. In each case, the determination of these items requires management judgment based on information and financial data that may change in future periods. When reviewing our financial statements, you should consider (i) our selection of critical accounting policies, (ii) the judgments and estimates affecting the application of such policies, and (iii) the sensitivity of reported results to changes in conditions and assumptions.

Critical accounting judgments and estimates are those that are most important to the portrayal of our financial position and results of operations and require our management to make judgments, estimates and assumptions that affect the reported amounts of expenses, assets and liabilities and their accompanying disclosures during the Track Record Period, often as a result of the need to make estimates about the effect of matters that are inherently uncertain and may change in subsequent periods.

We continually evaluate these estimates based on our own historical experience, knowledge and assessment of current business and other conditions, our expectations regarding the future based on available information and our best assumptions, which together form our basis for making judgments about matters that are not readily apparent from other sources. Since the use of estimates is an integral component of the financial reporting process, our actual results could differ from those estimates and expectations. Some of our accounting policies require a higher degree of judgment than others in their application.

Material Accounting Policy Information

Employee Benefits

We incur staff costs, including salaries, annual bonuses and paid annual leave, contributions to defined contribution retirement plans and the cost of non-monetary benefits, in the period in which the associated services are rendered by employees. Where payment or settlement is deferred and the effect would be material, we state these amounts at their present values.

For equity-settled share-based payments, we recognize the fair value of equity-settled share-based payments awards granted to employees as an employee cost with a corresponding increase in a capital reserve within equity. We measure the fair value at grant date using customary valuation techniques, taking into account the terms and conditions upon which the equity-settled share-based payments awards were granted. Where the employees have to meet vesting conditions before becoming unconditionally entitled to the equity-settled share-based payment awards, we spread the total estimated fair value of the awards over the vesting period, taking into account the probability that they will vest.

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During the vesting period, we review the number of equity-settled share-based payments awards that is expected to vest. We charge/credit any resulting adjustment to the cumulative fair value recognized in prior years to the profit or loss for the period of the review, unless the original employee expenses qualify for recognition as an asset, with a corresponding adjustment to the capital reserve. On vesting date, we adjust the amount recognized as an expense to reflect the actual number of equity-settled share-based payments awards that vest (with a corresponding adjustment to the capital reserve) except where forfeiture is only due to not achieving vesting conditions that relate to the market price of our Shares. We recognize the equity amount in the capital reserve until either the equity-settled share-based payments award is exercised (when it is included in the amount recognized in share capital for the shares issued) or expires (when it is released directly to retained profits).

We account for modifications of an equity-settled share-based payment arrangement only if they are beneficial to the employee. If we modify the terms and conditions of the equity instruments granted in a manner that reduces the fair value of the equity instruments granted, or is not otherwise beneficial to the employee, we continue to recognize the services received measured as the grant date fair value of the equity instruments granted, unless those equity instruments do not vest because of failure to satisfy a vesting condition (other than a market condition) that was specified at grant date.

Property, Plant and Equipment

We state property, plant and equipment, including right-of-use assets arising from leases over leasehold properties, plant and equipment, at cost less accumulated depreciation and impairment losses. The cost of self-constructed items of property, plant and equipment includes the direct costs of construction and capitalized borrowing costs and any other costs directly attributable to bringing the asset to working condition for its intended use. We add subsequent expenditure relating to an recognized item of property, plant and equipment to the carrying amount of the asset when it is probable that the future economic benefits, in excess of the original assessed standard of performance of the existing asset, will flow to our Group or our Company. We recognize all other subsequent expenditure as an expense in profit or loss in the period in which it is incurred. We may produce items while bringing certain property, plant and equipment to the location and condition necessary for it to be capable of operating in the manner intended by management. We recognize the proceeds from selling any such produced items and the related costs in profit or loss. We determine gains or losses arising from the retirement or disposal of an item of property, plant and equipment as the difference between the net disposal proceeds and the carrying amount of the item and we recognize such gains or losses in profit or loss on the date of retirement or disposal.

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We calculate depreciation to write off the cost of items of property, plant and equipment, less their estimated residual value, if any, using the straight-line method over their estimated useful lives as follows:

Buildings	20 – 30 years
Equipment and Machinery	3 – 10 years
Other equipment, furniture and fixtures	3 – 5 years

Where parts of an item of property, plant and equipment have different useful lives, we allocate the cost on a reasonable basis between the parts and depreciate each part separately. We review the useful life and residual value of an asset annually.

Financial Instruments Issued to Investors with Preferred Rights

A contract that contains an obligation to repurchase our Company's equity instruments for cash or another financial asset gives rise to a financial liability even if our Company's repurchase obligation is conditional on the counterparty exercising a right to redeem. We reclassify the financial instruments issued to investors with preferred rights from equity to financial liability initially at the present value of the redemption amount. Subsequently, we recognize changes in the carrying amount of the liabilities in profit or loss.

We derecognize the financial liability when, and only when, our Group's obligations are discharged or canceled or have expired. Upon a termination of the redemption obligation, we credit the carrying amount of the financial instruments derecognized into the equity.

Critical Accounting Judgments and Estimates

Research and Development Expenses

We capitalize and defer the development costs incurred on any research and development project with respect to a certain drug candidate in our pipelines only when we can demonstrate the technical feasibility of completing the intangible asset so that it will be available for use or sale, our intention to complete, our ability to use or sell the asset, how the asset will generate future economic benefits, the availability of resources to complete the pipeline and the ability to measure reliably the expenditure during the development. We recognize development costs which do not meet these criteria as expenses when incurred. Our management will assess the progress of each of the research and development projects and determine the criteria met for capitalization. We recognized all development costs as expenses when incurred during the Track Record Period.

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DESCRIPTION OF CERTAIN KEY ITEMS OF THE CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

The following table sets forth summary of our consolidated statement of profit or loss and other comprehensive income items for the years indicated.

	<u>Year ended December 31,</u>		<u>Nine months ended</u>	
	<u>2021</u>	<u>2022</u>	<u>2022</u>	<u>September 30,</u>
			<i>(unaudited)</i>	
			<i>(Renminbi in thousands)</i>	
Other income	34,886	25,726	13,799	13,279
Other net (loss)/gain	(2,817)	14,402	17,194	(75)
Administrative expenses	(48,804)	(76,603)	(33,237)	(123,247)
Research and development expenses	(151,887)	(257,214)	(189,749)	(263,270)
Loss from operations	(168,622)	(293,689)	(191,993)	(373,313)
Finance costs	(17,842)	(18,692)	(13,987)	(12,246)
Changes in the carrying amount of financial instruments issued to investors	(240,080)	—	—	—
Loss before taxation	(426,544)	(312,381)	(205,980)	(385,559)
Income tax	73	73	55	55
Loss for the year/period	<u>(426,471)</u>	<u>(312,308)</u>	<u>(205,925)</u>	<u>(385,504)</u>
Attributable to:				
Equity shareholders of the Company	(411,039)	(298,191)	(196,649)	(373,978)
Non-controlling interests	(15,432)	(14,117)	(9,276)	(11,526)
	<u>(426,471)</u>	<u>(312,308)</u>	<u>(205,925)</u>	<u>(385,504)</u>

Revenue

We are a pre-revenue biotech company. We did not generate any revenue or incur any cost of revenue during the Track Record Period.

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Other Income

Other income primarily consists of (i) government grants received from various entities, including subsidies for encouragement of research and development activities, subsidy for the incurred interest expenses of bank loans, reimbursement for certain capital expenditure incurred for our manufacturing facilities and subsidies for talent recruitment, (ii) interest income from bank deposits, (iii) interest income from loans to a related party (see “—Material Transactions with Related Parties”), (iv) net realized and unrealized gains on financial assets measured at fair value through profit or loss (“FVTPL”), representing fair value changes incurred in our investment in certain wealth management products (see “—Description of Certain Consolidated Statement of Financial Position Items—Financial Assets at FVTPL”) and (v) net income from CDMO services we provided.

The following table summarizes a breakdown of our other income for the periods indicated.

	Year ended December 31,		Nine months ended September 30,	
	2021	2022	2022	2023
			<i>(unaudited)</i>	
			<i>(Renminbi in thousands)</i>	
Government grants (including amortization of deferred income)	19,978	9,194	1,847	4,340
Interest income from bank deposits	3,458	4,167	2,541	3,639
Interest income from loans to a related party	3,600	—	—	—
Net realized and unrealized gains on financial assets measured at FVTPL	6,479	11,897	9,203	4,605
Net income from CDMO services	732	172	222	614
Others ⁽¹⁾	639	296	(14)	81
Total	34,886	25,726	13,799	13,279

Note:

(1) Others mainly include income related to drugability research we provided to certain external parties.

We received a government subsidy for incurred interest expenses of bank loan of RMB12.0 million in 2021, accounting for 59.9% of our government grants in the same year. Our government grants decreased significantly from 2021 to 2022 primarily because such government subsidy received decreased to RMB5.0 million in 2022.

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Our government grants increased significantly from RMB1.8 million in the nine months ended September 30, 2022 to RMB4.3 million in the nine months ended September 30, 2023 primarily because an increase of RMB1.3 million in subsidies for encouragement of research and development activities and an increase of RMB1.1 million in subsidies for talent recruitment and retention.

Major Subsidies for Encouragement of R&D Activities

We received a non-recurring subsidy of RMB2.0 million pursuant to the 2020 Provincial Key R&D Project Subsidy (2020年省重點研發計劃獎金) of Jiangsu province. Such scheme subsidizes certain key biotech projects, especially innovative drug candidates that obtained an IND after 2017. Our QX002N was selected as a key R&D project and we received such subsidy in 2021.

We also received a non-recurring subsidy of RMB2.0 million pursuant to the 2022 Technology Innovation Company Research and Development Expenses Subsidy Fund (2022科技創新頭部企業研發費用獎勵資金) scheme. Such scheme subsidizes companies that have incurred qualified R&D expenses for a consecutive two years and recorded an increase of over RMB2.0 million in qualified R&D expenses compared to the previous year. The subsidy amount is determined based on the increase in R&D expenses and capped at RMB2.0 million for each company. Based on the increase in our R&D expenses from 2020 to 2021, we applied for an aggregate of RMB2.0 million of such subsidy, and received RMB1.0 million and RMB1.0 million in 2022 and the nine months ended September 30, 2023, respectively.

During the Track Record Period, while prioritizing our internal R&D, we provided CDMO services to enhance the utilization of our manufacturing capacity. Our CDMO orders and the utilization rate of our manufacturing capacity fluctuated during the Track Record Period. As a result, the allocated fixed manufacturing costs of our CDMO services fluctuated during the Track Record Period. Our net CDMO income for the nine months ended September 30, 2022 exceeded our net CDMO income for the year of 2022 because we incurred net losses for our CDMO services during the seven months ended December 31, 2022 due to the relatively high allocated fixed costs during such period. Our net CDMO income decreased from RMB0.7 million in 2021 to RMB0.2 million in 2022 primarily because we delivered less CDMO services and thus recognized less gross CDMO income in 2022 as compared to that in 2021. Our net CDMO income increased from RMB0.2 million in the nine months ended September 30, 2022 to RMB0.6 million in the nine months ended September 30, 2023 as we delivered more CDMO services in the nine months ended September 30, 2023 as compared to the nine months ended September 30, 2022.

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Other Net (Loss)/Gain

Other net (loss)/gain primarily includes net foreign exchange (loss)/gain resulting from the depreciation/appreciation of U.S. dollars against the Renminbi as part of our cash on hand was denominated in U.S. dollars. The following table summarizes a breakdown of our other net (loss)/gain for the periods indicated.

	Year ended December 31,		Nine months ended September 30,	
	2021	2022	2022	2023
			<i>(unaudited)</i>	
			<i>(Renminbi in thousands)</i>	
Net foreign exchange				
(loss)/gain	(2,722)	14,457	17,249	(66)
Others ⁽¹⁾	(95)	(55)	(55)	(9)
Total	(2,817)	14,402	17,194	(75)

Note:

(1) Others mainly include losses from disposals of long-term assets.

Our net foreign exchange loss in 2021 and the nine months ended September 30, 2023 and net foreign exchange gain in 2022 and the nine months ended September 30, 2022 primarily resulted from the depreciation and appreciation of U.S. dollars against the Renminbi in these periods, respectively, in connection with our cash on hand denominated in U.S. dollars.

Administrative Expenses

Our administrative expenses mainly consist of (i) staff costs, primarily including salaries, equity incentives and other welfare for our administrative staff, (ii) [REDACTED] expenses, (iii) depreciation and amortization, primarily representing the depreciation and amortization of our office buildings, located on the site of our manufacturing facility in Taizhou, and our office equipment, (iv) office and miscellaneous expenses, and (v) other professional service fees, which primarily include fees paid for legal, consulting and other administrative-related professional services.

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The following table summarizes a breakdown of our administrative expenses for the periods indicated.

	Year ended December 31,				Nine months ended September 30,			
	2021		2022		2022		2023	
	<i>(unaudited)</i>							
	<i>(Renminbi in thousands, except for percentages)</i>							
Staff costs	19,721	40.4%	48,345	63.1%	16,790	50.5%	95,960	77.9%
— Equity-settled share-based payment expenses	5,910	12.1%	30,356	39.6%	2,995	9.0%	75,449	61.2%
— Other staff costs	13,811	28.3%	17,989	23.5%	13,795	41.5%	20,511	16.6%
[REDACTED] expenses	[REDACTED]	[REDACTED]%	[REDACTED]	[REDACTED]%	[REDACTED]	[REDACTED]%	[REDACTED]	[REDACTED]%
Depreciation and amortization	5,098	10.5%	6,116	8.0%	4,472	13.5%	4,680	3.8%
Office and miscellaneous expense	4,365	8.9%	3,006	3.9%	2,087	6.3%	2,382	1.9%
Other professional service fees	2,746	5.6%	3,508	4.6%	2,342	7.0%	1,160	0.9%
Others ⁽¹⁾	5,889	12.1%	5,474	7.1%	3,645	11.0%	4,422	3.6%
Total	<u>[REDACTED]</u>	<u>[REDACTED]%</u>	<u>[REDACTED]</u>	<u>[REDACTED]%</u>	<u>[REDACTED]</u>	<u>[REDACTED]%</u>	<u>[REDACTED]</u>	<u>[REDACTED]%</u>

Note:

- (1) Others mainly include expenses for property tax and various government levies and business entertainment expenses.

Our staff costs increased significantly from RMB19.7 million in 2021 to RMB48.3 million in 2022 primarily attributable to an increase of RMB24.4 million in equity-settled share-based payment expenses, because we granted additional equity incentives in October 2022.

Our staff costs increased significantly from RMB16.8 million in the nine months ended September 30, 2022 to RMB96.0 million in the nine months ended September 30, 2023 primarily attributable to an increase of RMB72.5 million in equity-settled share-based payment expenses, as we amortized the additional equity incentives granted in October 2022 in the nine months ended September 30, 2023.

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Research and Development Expenses

Our research and development expenses mainly consist of (i) third-party contracting costs, primarily representing payments to CROs and trial sites in relation to our preclinical and clinical studies, (ii) staff costs, primarily including salaries, equity incentives and other welfare for our research and development personnel, (iii) cost of materials and consumables used for research and development of our biologic drug candidates, and (iv) depreciation and amortization, primarily representing the depreciation and amortization of our manufacturing facility and equipment used in our research and development activities.

The following table summarizes a breakdown of our research and development expenses for the periods indicated.

	Year ended December 31,		Year ended December 31,		Nine months ended September 30,		Nine months ended September 30,	
	2021	2022	2021	2022	2022	2023	2022	2023
	<i>(unaudited)</i>							
	<i>(Renminbi in thousands, except for percentages)</i>							
Third-party contracting costs	56,240	37.0%	114,822	44.6%	88,204	46.5%	140,365	53.3%
Staff costs	51,625	34.0%	68,664	26.7%	44,831	23.6%	70,612	26.8%
— Equity-settled share-based payment expenses	5,820	3.8%	11,200	4.4%	1,375	0.7%	24,039	9.1%
— Other staff costs	45,805	30.2%	57,464	22.3%	43,456	22.9%	46,573	17.7%
Cost of materials and consumables used	25,636	16.9%	30,800	12.0%	24,913	13.1%	17,840	6.8%
Depreciation and amortization	20,238	13.3%	24,365	9.5%	17,956	9.5%	17,259	6.6%
Others ⁽¹⁾	17,016	11.2%	18,563	7.2%	13,845	7.3%	17,194	6.5%
Less: Milestone payment from Zhongmei Huadong ⁽²⁾	(18,868)	(12.4%)	—	—	—	—	—	—
Total	151,887	100.0%	257,214	100.0%	189,749	100.0%	263,270	100.0%

Notes:

- (1) Others mainly include utility and office expenses.
- (2) On August 14, 2020, we entered into a collaboration agreement (the “QX001S Agreement”) with Zhongmei Huadong with respect to the joint development and exclusive commercialization of QX001S in China. Under the QX001S Agreement, Zhongmei Huadong made a milestone payment of RMB20 million (including value-added tax) to us to compensate us for the research and development costs we had incurred after we completed the sample production of QX001S for a Phase III clinical trial and have, upon a consultation with the CDE, obtained consent to proceed with such trial. Accordingly, we recognized the milestone payment (net of value-added tax) as a reimbursement of our research and development costs incurred for QX001S upon the achievement of such milestone in 2021.

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Our third-party contractors primarily consist of CROs and hospitals as trial sites. The following table summarizes a breakdown of our third-party contracting costs by type of contractors for the periods indicated.

	Year ended December 31,		Nine months ended September 30,	
	2021	2022	2022	2023
			<i>(unaudited)</i>	
			<i>(Renminbi in thousands)</i>	
CRO	41,438	77,551	61,034	84,063
Hospital	8,608	23,805	16,579	44,509
Others ⁽¹⁾	6,194	13,466	10,591	11,793
Total	56,240	114,822	88,204	140,365

Note:

- (1) Others mainly include third-party contracting costs for participant enrollment for clinical trials, consulting services, testing services and registration services.

We engaged CROs to assist in clinical trials, preclinical studies and early-stage studies and engaged hospitals as trial sites for clinical trials. The following table summarizes a breakdown of our third-party contracting costs by development stages for the periods indicated.

	Year ended December 31,		Nine months ended September 30,	
	2021	2022	2022	2023
			<i>(unaudited)</i>	
			<i>(Renminbi in thousands)</i>	
Clinical trials	21,929	64,217	48,497	116,582
Preclinical studies	26,299	39,018	31,451	13,720
Early-stage studies	3,591	6,662	4,656	9,404
Others ⁽¹⁾	4,421	4,924	3,600	659
Total	56,240	114,822	88,204	140,365

Note:

- (1) Others mainly include costs of third-party testing services, registration services and translation services for general R&D activities.

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Our third-party contracting costs increased significantly from RMB56.2 million in 2021 to RMB114.8 million in 2022 primarily attributable to an increase in contracting costs in relation to clinical trials and preclinical studies because we increased engagement of CROs and trial sites to support our development of QX002N, QX005N, QX006N and QX007N. See “Business—Research and Development—Collaboration with CROs” for details of our engagement of CROs.

Our staff costs increased significantly from RMB44.8 million in the nine months ended September 30, 2022 to RMB70.6 million in the nine months ended September 30, 2023, mainly attributable to an increase of RMB22.7 million in equity-settled share-based payment expenses, primarily as we amortized the additional equity incentives granted in October 2022 in the nine months ended September 30, 2023.

Finance Costs

Our finance costs primarily consist of (i) interest on interest-bearing borrowings and (ii) interest on lease liabilities. The following table summarizes a breakdown of our finance costs for the periods indicated.

	Year ended December 31,		Nine months ended September 30,	
	2021	2022	2022	2023
			<i>(unaudited)</i>	
			<i>(Renminbi in thousands)</i>	
Interest on interest-bearing borrowings	18,457	18,593	13,913	12,193
Interest on lease liabilities	76	99	74	53
Less: interest capitalized into properties under construction	(691)	—	—	—
Total	17,842	18,692	13,987	12,246

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Changes in the Carrying Amount of Financial Instruments Issued to Investors

During the Track Record Period, we conducted a series of equity financings. We recognized the financial instruments issued to certain [REDACTED] Investors as financial liabilities, as these financial instruments did not meet the definition of equity. We recorded changes in the carrying amount of financial instruments issued to investors of RMB240.1 million in 2021. In July 2021, we entered into supplementary agreements with our [REDACTED] Investors, pursuant to which the [REDACTED] Investors waived certain preferred rights. As a result, these financial instruments were reclassified from liabilities into equity, and we no longer recognized these financial instruments as financial liabilities or any changes in the carrying amount of such financial liabilities in our statement of profit or loss.

Income Tax

We had income tax credits of RMB73,000, RMB73,000, RMB55,000 and RMB55,000 in 2021, 2022 and the nine months ended September 30, 2022 and 2023, respectively. During the Track Record Period and up to the Latest Practicable Date, we had paid all relevant taxes in accordance with applicable tax laws and regulations and did not have any disputes or unresolved tax issues with the relevant tax authorities in all material respects.

Our principal applicable taxes and tax rates are set forth as follows:

Pursuant to the Enterprise Income Tax Law of the PRC, our Company and our subsidiaries in the PRC are subject to PRC income tax at 25% unless otherwise specified.

According to applicable PRC laws and regulations, our Company obtained the qualification as a high-technology enterprise on November 30, 2021 and is entitled to a preferential income tax rate of 15% from 2021 to 2023.

According to the tax incentive policies promulgated by the State Tax Bureau of the PRC, which were effective from January 1, 2018 to September 30, 2022, an additional 75% of qualified research and development expenses incurred would be allowed to be deducted from the taxable income. According to a new tax incentive policy promulgated by the State Tax Bureau of the PRC in September 2022, an additional 100% of qualified expenses incurred in the period from October 1, 2022 to December 31, 2023 were allowed to be deducted from taxable income.

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RESULTS OF OPERATIONS

Nine Months Ended September 30, 2023 Compared to Nine Months Ended September 30, 2022

Revenue

We did not have any revenue or cost of revenue in the nine months ended September 30, 2022 or 2023.

Other Income

Our other income decreased by 3.8% from RMB13.8 million in the nine months ended September 30, 2022 to RMB13.3 million in the nine months ended September 30, 2023. This decrease was primarily attributable to a decrease of RMB4.6 million in net realized and unrealized gains on financial assets measured at FVTPL as we reduced purchasing of wealth management products during the nine months ended September 30, 2023, partially offset by (i) an increase of RMB2.5 million in government grants, particularly subsidies for encouragement of research and development activities and subsidies for talent recruitment, and (ii) an increase of RMB1.1 million in interest income from bank deposits as our bank deposits increased during such period.

Other Net (Loss)/Gain

We recorded an other net gain of RMB17.2 million in the nine months ended September 30, 2022, primarily attributable to foreign exchange gain resulting from the appreciation of U.S. dollars against the Renminbi in such period in connection with our cash on hand denominated in U.S. dollars. We recorded an other net loss of RMB75,000 in the nine months ended September 30, 2023, primarily because we incurred loss by converting part of our cash on hand denominated in U.S. dollars in January 2023.

Administrative Expenses

Our administrative expenses increased significantly from RMB33.2 million in the nine months ended September 30, 2022 to RMB123.2 million in the nine months ended September 30, 2023, primarily attributable to an increase of RMB72.5 million in equity-settled share-based payment expenses, as we amortized the additional equity incentives granted in October 2022 in the nine months ended September 30, 2023.

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Research and Development Expenses

Our research and development expenses increased by 38.7% from RMB189.7 million in the nine months ended September 30, 2022 to RMB263.3 million in the nine months ended September 30, 2023, primarily attributable to (i) an increase of RMB52.2 million in third-party contracting costs as we increased engagement of CROs and trial sites to advance our drug development pipeline; and (ii) an increase of RMB22.7 million in equity-settled share-based payment expenses, mainly due to the amortization of the additional equity incentives granted in October 2022 in the nine months ended September 30, 2023.

Finance Costs

Our finance costs decreased by 12.4% from RMB14.0 million in the nine months ended September 30, 2022 to RMB12.2 million in the nine months ended September 30, 2023, primarily attributable to a decrease of RMB1.7 million in our interest on interest-bearing borrowings as we repaid part of our interest-bearing borrowings in December 2022 and June 2023.

Income Tax

Our income tax credits remained stable at RMB55,000 in the nine months ended September 30, 2022 and 2023.

Loss for the Year/Period

As a result of the above, we recorded a net loss of RMB205.9 million and RMB385.5 million in the nine months ended September 30, 2022 and 2023, respectively.

Year Ended December 31, 2022 Compared to Year Ended December 31, 2021

Revenue

We did not have any revenue or cost of revenue in 2021 or 2022.

Other Income

Our other income decreased by 26.3% from RMB34.9 million in 2021 to RMB25.7 million in 2022. This decrease was primarily attributable to a decrease of RMB10.8 million in government grants primarily because the reimbursement received for the incurred interest expenses of bank loans decreased significantly from 2021 to 2022.

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Other Net (Loss)/Gain

We recorded an other net loss of RMB2.8 million in 2021 and an other net gain of RMB14.4 million in 2022, primarily attributable to foreign exchange loss/gain resulting from the depreciation and appreciation of U.S. dollars against the Renminbi in these years, respectively, in connection with our cash on hand denominated in U.S. dollars.

Administrative Expenses

Our administrative expenses increased by 57.0% from RMB48.8 million in 2021 to RMB76.6 million in 2022, primarily attributable to an increase of RMB24.4 million in equity-settled share-based payment expenses as we granted additional equity incentives in October 2022.

Research and Development Expenses

Our research and development expenses increased by 69.3% from RMB151.9 million in 2021 to RMB257.2 million in 2022, primarily attributable to (i) an increase of RMB58.6 million in third-party contracting costs primarily because we increased engagement of CROs and trial sites as we advanced the development of our drug candidates, and (ii) an increase of RMB17.0 million in our staff costs as we increased our R&D headcount and generally increased the salaries for our R&D team.

Finance Costs

Our finance costs increased slightly from RMB17.8 million in 2021 to RMB18.7 million in 2022.

Changes in the Carrying Amount of Financial Instruments Issued to Investors

We incurred changes in the carrying amount of financial instruments issued to investors of RMB240.1 million in 2021, primarily attributable to the changes in the carrying amount of financial liabilities associated with certain preferred rights granted to certain [REDACTED] Investors. As such preferred rights were terminated by our Company and our [REDACTED] Investors in July 2021, the respective financial instruments were reclassified from liabilities into equity, and we did not recognize any changes in the carrying amount of such financial liabilities in our statement of profit or loss in 2022.

Income Tax

Our income tax credits remained stable at RMB73,000 in 2021 and 2022.

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Loss for the Year/Period

As a result of the above, we recorded a net loss of RMB426.5 million and RMB312.3 million in 2021 and 2022, respectively.

DESCRIPTION OF CERTAIN CONSOLIDATED STATEMENT OF FINANCIAL POSITION ITEMS

The following table sets forth a summary of our consolidated statement of financial position as of the dates indicated.

	As of December 31,		As of September 30,
	2021	2022	2023
	<i>(Renminbi in thousands)</i>		
Non-current assets			
Property, plant and equipment	378,335	363,125	346,154
Right-of-use assets	22,497	23,039	21,417
Intangible assets	376	3,052	2,522
Other non-current assets	18,024	9,936	11,924
	419,232	399,152	382,017
Current assets			
Inventories and other contract costs	—	—	7,216
Prepayments and other receivables	19,526	18,384	36,055
Other current assets	8,298	3,377	7,877
Financial assets at FVTPL	402,382	401,097	150,397
Cash and cash equivalents	218,055	213,090	257,635
	648,261	635,948	459,180

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	As of December 31,		As of
	2021	2022	September 30, 2023
	<i>(Renminbi in thousands)</i>		
Current liabilities			
Trade and other payables	53,848	59,930	91,692
Contract liabilities	—	—	3,810
Interest-bearing borrowings	14,869	60,508	82,323
Lease liabilities	956	1,752	917
Total current liabilities	69,673	122,190	178,742
Net current assets	578,588	513,758	280,438
Total assets less current liabilities	997,820	912,910	662,455
Non-current liabilities			
Non-current interest-bearing borrowings	274,045	232,521	239,591
Deferred income	18,659	18,018	17,536
Lease liabilities	391	472	—
Deferred tax liabilities	559	486	431
Total non-current liabilities	293,654	251,497	257,558
Net assets	704,166	661,413	404,897

Inventories and Other Contract Costs

We recorded inventories and other contract costs of RMB7.2 million as of September 30, 2023, mainly representing contract costs incurred to fulfill our CDMO services contracts. We entered into CDMO services contracts with Zhongmei Huadong and third parties in the nine months ended September 30, 2023, pursuant to which we will provide a series of process development and manufacturing services. See “Business—Manufacturing—Manufacturing Facility” for details of our CDMO services.

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Prepayments and Other Receivables

Our prepayment and other receivables primarily consist of (i) prepayments for R&D materials and clinical expenses, (ii) [REDACTED] expenses, (iii) deposits, mainly related to our leased properties, (iv) receivables from other debtors, mainly related to non-interest bearing borrowings we granted to certain employees as a benefit and (v) interest receivables, for our time deposits. The following table sets forth a breakdown of our prepayment and other receivables as of the dates indicated.

	As of December 31,		As of September 30,
	2021	2022	2023
	<i>(Renminbi in thousands)</i>		
Prepaid expenses	18,450	16,232	32,852
[REDACTED] expenses	[REDACTED]	[REDACTED]	[REDACTED]
Deposits	285	546	571
Receivables from other debtors	354	418	571
Interest receivables	—	244	96
Total	[REDACTED]	[REDACTED]	[REDACTED]

Our prepayments and other receivables increased significantly from RMB18.4 million as of December 31, 2022 to RMB36.1 million as of September 30, 2023, primarily attributable to an increase of RMB16.6 million in prepaid expenses due to our engagement of CROs and trial sites as we advanced the development of our drug candidates.

As of January 31, 2024, RMB15.8 million, or 48.0%, of our prepaid expenses as of September 30, 2023 had been subsequently utilized.

To maintain a stable talent team and as part of our comprehensive employee benefit system, we granted non-interest bearing loans to our outstanding employees to help them secure their first self-occupied homes in Taizhou during the Track Record Period. Pursuant to our employee benefit policies, qualified employees can apply for non-interest bearing borrowings of up to RMB0.2 million for a term of three years for this purpose. For loans approved by our general manager, we then enter into written agreements with the relevant employees, pursuant to which repayment in equal installments will be deducted from the employees’ monthly salaries. As of September 30, 2023, we had three outstanding loans granted to our employees, with an aggregate principal amount of RMB0.1 million. As confirmed by our PRC Legal Advisors, our loan agreements with employees are binding and valid and the provisions therein do not violate the Provisions of the Supreme People’s Court on Several Issues Concerning the Application of Law in the Trial of Private Lending Cases (最高人民法院關於審理民間借貸案件適用法律若干問題的規定).

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Financial Assets at FVTPL

Our financial assets at FVTPL represented certain wealth management products we purchased. These wealth management products are primarily principal-protected floating-return wealth management products managed by local branches of national commercial banks or regional commercial banks in Jiangsu province. These wealth management products have expected return rates ranging from 2.55% to 3.64% per annum with a term ranging from 30 days to 185 days. Our financial assets at FVTPL decreased significantly from RMB401.1 million as of December 31, 2022 to RMB150.4 million as of September 30, 2023 as we reduced purchasing of wealth management products in the nine months ended September 30, 2023.

We purchased wealth management products to improve the utilization of our cash on hand on a short-term basis. During the Track Record Period, we generally limited our purchase to short-term financial products described as having low level risks offered by reputable commercial banks. We believe that investment in low-risk financial products, such as wealth management products, helps us make better use of our cash while ensuring sufficient cash flow for business operations or capital expenditures. Considering that these wealth management products are short-term and principal-protected, we believe our credit risk exposure is limited. In the future, we will continue to purchase low-risk financial products with short maturity periods while prioritizing our operational needs.

We have implemented a series of treasury policies and internal control policies and rules setting forth overall principles, focusing on the appreciation of capital and supporting our liquidity needs in a manner that is consistent with our overall financial goals and risk considerations. Prior to making an investment, we ensure that there remains sufficient working capital for our business needs, operating activities, research and development and capital expenditures after purchasing such wealth management products. We adopt a prudent approach in selecting financial products. Our investment decisions are made on a case-by-case basis and after due and careful consideration of a number of factors, such as duration of the investment and the expected returns. We generally limit our investments to wealth management products described as having low level risks and offered by major and reputable commercial banks, and we do not permit investment in stock for trading or speculative purposes. In addition, all investments in wealth management products should comply with applicable laws and regulations. Under our investment policy, our finance department personnel should prepare wealth management products purchase plan, based on anticipated expenditures, operational expenses, our cash and bank balances and information of the relevant wealth management products, for the head of finance department and general manager to review. Our finance department is lead by Mr. Lin Weidong (林偉棟). Mr. Lin has accumulated extensive experience in corporate financial management by serving as the senior management at various enterprises. Mr. Lin received a master’s degree in business administration from Shanghai Jiao Tong University (上海交通大學) in June 2016 and was qualified as a Certified Public Accountant non-practicing member (中國註冊會計師協會非執業會員) by The Chinese Institute of Certified Public Accountants (中國註冊會計師協會) in February 2013. See “Directors, Supervisors and Senior Management—Board of Directors—Executive Directors”

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for more details. With authorization of the Board, all wealth management products purchase contracts are subject to approval by our general manager. Upon the [REDACTED], our investment in wealth management products is subject to the compliance with Chapter 14 of the Listing Rules.

Fair Value Measurement

The following table presents the fair value of our financial instruments measured at the end of each period on a recurring basis, categorised into the three-level fair value hierarchy as defined in IFRS. We determine the level of a fair value measurement with reference to the observability and significance of the inputs used in the valuation technique as follows:

- Level 1 valuations: Fair value measured using only Level 1 inputs, such as unadjusted quoted prices in active markets for identical assets or liabilities at the measurement date.
- Level 2 valuations: Fair value measured using Level 2 inputs, such as observable inputs which fail to meet Level 1, and not using significant unobservable inputs. Unobservable inputs are inputs for which market data are not available.
- Level 3 valuations: Fair value measured using significant unobservable inputs.

During the Track Record Period, we purchased wealth management products, which are classified as financial assets measured at fair value through profit or loss ("FVTPL"). Our Directors and responsible officers review the fair value measurements of our financial assets categorized into level 3 of the fair value hierarchy of which no quoted prices in an active market exist, taking into account the valuation techniques and assumptions of unobservable inputs and determine if the fair value measurements of level 3 instruments is in compliance with the applicable IFRS. In determining the fair value of the wealth management products classified as level 3 financial assets at FVTPL, our Directors have (i) reviewed the terms of agreements relating to the instruments; (ii) reviewed the valuation working papers and results prepared by our finance team; (iii) carefully considered all information especially those non-market related information input, such as the assets under management and the discount rate, which required management assessment and estimates; and (iv) analyzed and discussed with the designated team regarding the contents of the valuation analysis including but not limited to, the basis of computation, assumptions and valuation methodologies on which the valuation is based, the basis of the discount rates. Based on the above procedures and the professional advice received, our Directors are of the view that the valuation analysis performed on level 3 financial assets at FVTPL is fair and reasonable and the financial statements of our Group are properly prepared. Should any of the estimates and assumptions changed, it may lead to a change in the fair value of the level 3 financial assets at FVTPL.

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The Sole Sponsor has conducted relevant due diligence work, including (i) understanding from the Company the nature and details of the financial assets and liabilities and obtaining and reviewing the list of the financial assets and liabilities during the Track Record Period; (ii) obtaining and reviewing the terms of the relevant agreements and documents regarding the financial assets and liabilities; (iii) reviewing relevant notes in the Accountant’s Report as contained in Appendix I to this document; (iv) understanding from the Company the key bases and assumptions for the valuation of the financial assets and liabilities; and (v) discussing with the reporting accountants to understand the work it has performed in relation to the valuation of the level 3 financial assets for the purpose of reporting on the historical financial information, as a whole, of our Group. Having considered the work done by the management and the reporting accountants, and the relevant due diligence done as stated above, nothing material has come to the Sole Sponsor’s attention that indicates that the Company’s management have not undertaken independent and sufficient investigation and due diligence on such level 3 financial assets and liabilities.

For details of the fair value measurement of our level 3 financial instruments, including the fair value hierarchy, the valuation techniques and key inputs, see note 26(e) in the Accountants’ Report set out in Appendix I of this document. Our reporting accountants performed its work in accordance with Hong Kong Standard on Investment Circular Reporting Engagement 200 “Accountants’ Report on Historical Financial Information in Investment Circulars” issued by the Hong Kong Institute of Certified Public Accountants for the purpose of expressing an opinion on our historical information for the Track Record Period as a whole, and its opinion on the Group for the Track Record Period as a whole is set out in the Accountants’ Report in Appendix I of this document.

Cash and Cash Equivalents

Our cash and cash equivalents primarily consist of cash at bank. A large portion of our cash and cash equivalents during the Track Record Period, specifically part of the [REDACTED] we received from Series B++ Financing and Series C Financing, were denominated in U.S. dollars. We had cash and cash equivalents of RMB218.1 million, RMB213.1 million and RMB257.6 million as of December 31, 2021 and 2022 and September 30, 2023, respectively. See “—Liquidity and Capital Resources—Cash Flows.”

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Trade and Other Payables

Our trade and other payables primarily consist of (i) trade payables, (ii) payroll payables, (iii) accrued [REDACTED] expenses, (iv) payables for purchases of property, plant and equipment, (v) other payables and accruals, and (vi) interest payables. The following table sets forth the details of our other payables and accruals as of the dates indicated.

	As of December 31,		As of
	2021	2022	September 30, 2023
	<i>(Renminbi in thousands)</i>		
Trade payables	12,597	19,137	45,156
Payroll payable	18,569	24,185	28,620
Accrued [REDACTED] expenses	[REDACTED]	[REDACTED]	[REDACTED]
Payables for purchases of property, plant and equipment	14,466	7,823	5,669
Other payables and accruals	4,044	3,831	3,331
Interest payables	466	454	428
Total	[REDACTED]	[REDACTED]	[REDACTED]

Our trade and other payables increased by 11.3% from RMB53.8 million as of December 31, 2021 to RMB59.9 million as of December 31, 2022, primarily attributable to (i) an increase of RMB6.5 million in trade payables related to our engagement of CROs as we advanced the development of our drug candidates and (ii) an increase of RMB5.6 million in payroll payables as we generally increased our headcount and our employment compensations, partially offset by a decrease of RMB6.6 million in payables for purchases of property, plant and equipment as we settled part of our payables related to the construction of our manufacturing facility in Taizhou. Our trade and other payables further increased by 53.0% to RMB91.7 million as of September 30, 2023, primarily attributable to an increase of RMB26.0 million in trade payables mainly related to our engagement of CROs and trial sites as we advanced the development of our drug candidates.

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During the Track Record Period, with respect to our suppliers of CRO services, we typically settle in accordance with milestones in the relevant contracts; with respect to our procurement of raw materials, we were typically granted credit terms up to one month. All of our trade payables were within applicable credit period. The following table sets forth an aging analysis of our trade payables based on the invoice date as of the dates indicated.

	As of December 31,		As of September 30,
	2021	2022	2023
	<i>(Renminbi in thousands)</i>		
Within 6 months	12,597	19,137	45,156
Total	12,597	19,137	45,156

As of January 31, 2024, RMB18.5 million, or 41.0%, of our trade payables as of September 30, 2023 had been subsequently settled.

Contract Liabilities

We had contract liabilities of RMB3.8 million as of September 30, 2023, related to the prepayment received under our CDMO service contracts with Zhongmei Huadong and third parties. See “Business—Manufacturing—Manufacturing Facility” for details of our service contract with Zhongmei Huadong. The prepayment was recorded as contract liabilities and is expected to be recognized as income upon achievement of certain milestones under the respective contract.

LIQUIDITY AND CAPITAL RESOURCES

Overview

Our primary uses of cash during the Track Record Period were funding the research and development of our biologic drug candidates, purchase of raw materials, settlement of construction fees of our manufacturing facility in Taizhou, as well as other working capital needs. Historically, we have financed our operations primarily through equity financing and other capital requirements primarily through bank loans and bank balances. We expect to fund our future working capital and other cash requirements with bank balances, the [REDACTED] from this [REDACTED], bank and other borrowings and cash generated from our operations. As of January 31, 2024, we had cash and cash equivalents of RMB141.9 million and financial assets at FVTPL, comprising of short-maturity financial products we purchased, of RMB210.8 million. As of the same date, we also had total approved unutilized bank facilities of RMB473.0 million, including a bank facility of RMB262.5 million to replace our secured bank loan. See “—Indebtedness” for details of such bank facility.

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Net Current Assets

The following table sets forth our current assets and current liabilities as of the dates indicated.

	<u>As of December 31,</u>		<u>As of</u>	<u>As of</u>
	<u>2021</u>	<u>2022</u>	<u>September 30,</u>	<u>January 31,</u>
	<i>(Renminbi in thousands)</i>		<u>2023</u>	<u>2024</u>
			<i>(unaudited)</i>	
Current assets				
Inventories and other contract costs	—	—	7,216	6,062
Prepayments and other receivables	19,526	18,384	36,055	39,441
Other current assets	8,298	3,377	7,877	10,347
Financial assets at FVTPL	402,382	401,097	150,397	210,845
Cash and cash equivalents	218,055	213,090	257,635	141,863
Total current assets	648,261	635,948	459,180	408,558
Current liabilities				
Trade and other payables	53,848	59,930	91,692	144,587
Contract liabilities	—	—	3,810	1,950
Interest-bearing borrowings	14,869	60,508	82,323	129,660
Lease liabilities	956	1,752	917	1,294
Total current liabilities	69,673	122,190	178,742	277,492
Net current assets	578,588	513,758	280,438	131,066

The decrease in our net current assets from RMB578.6 million as of December 31, 2021 to RMB513.8 million as of December 31, 2022 was primarily due to an increase of RMB45.6 million in interest-bearing borrowings, primarily attributable to (i) a reclassification of RMB29.7 million from the non-current portion to the current portion of our secured bank loan of RMB300.0 million obtained in 2020 and (ii) short-term bank loans of RMB15.9 million obtained by one of our subsidiaries to fund working capital needs.

The decrease in our net current assets from RMB513.8 million as of December 31, 2022 to RMB280.4 million as of September 30, 2023 was primarily attributable to a decrease of RMB250.7 million in our financial assets at fair value through profit or loss as we reduced purchasing of wealth management products in the nine months ended September 30, 2023, which outpaced the increase in cash and cash equivalents of only RMB44.5 million, as we spent cash to support our daily operations in the nine months ended September 30, 2023.

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The decrease in our net current assets from RMB280.4 million as of September 30, 2023 to RMB131.1 million as of January 31, 2024 was attributable to (i) an increase of RMB98.8 million in current liabilities primarily due to (a) an increase of RMB52.9 million in trade and other payables primarily attributable to our increased engagement of CROs and trial sites as we advanced the development of our drug candidates and (b) an increase of RMB47.3 million in interest-bearing borrowings as we drew down credit facilities during such period to supplement our working capital; and (ii) a decrease of RMB51.3 million in current assets primarily due to a decrease of RMB115.8 million in our cash and cash equivalents, which outpaced the increase in financial assets at fair value through profit or loss of RMB60.4 million, as we spent cash to support our daily operations during such period.

Cash Operating Costs

The following table provides information regarding our cash operating costs for the periods indicated.

	Year ended December 31,		Nine months ended September 30,	
	2021	2022	2022	2023
			<i>(unaudited)</i>	
			<i>(Renminbi in thousands)</i>	
<i>Research and development expenses for our</i>				
<i>Core Products</i>				
Clinical expenses	22,472	55,122	36,041	90,409
Staff cost	8,997	18,247	12,580	16,609
Raw materials and consumables	7,553	17,360	10,969	9,797
Others	5,670	9,310	6,827	8,407
<i>Subtotal</i>	<u>44,692</u>	<u>100,039</u>	<u>66,417</u>	<u>125,221</u>
<i>Research and development expenses for other products and product candidates</i>				
<i>Preclinical and clinical expenses</i>				
Staff cost	37,407	52,705	38,104	39,009
Raw materials and consumables	31,508	35,067	28,997	30,064
Others	17,168	11,435	5,444	11,014
Others	11,331	9,510	7,047	6,995
<i>Subtotal</i>	<u>97,414</u>	<u>108,717</u>	<u>79,592</u>	<u>87,082</u>
Total research and development expenses	<u><u>142,106</u></u>	<u><u>208,756</u></u>	<u><u>146,009</u></u>	<u><u>212,303</u></u>

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	Year ended December 31,		Nine months ended September 30,	
	2021	2022	2022	2023
			<i>(unaudited)</i>	
			<i>(Renminbi in thousands)</i>	
Workforce employment⁽¹⁾	12,588	16,640	11,889	15,905
Non-income taxes, royalties and other government charges	2,493	2,439	1,849	1,879
Total cash operating cost	<u>157,187</u>	<u>227,835</u>	<u>159,747</u>	<u>230,087</u>

Note:

- (1) Workforce employment costs represented non-R&D staff costs, mainly including salaries and social insurance contributions.

Cash Flows

The following table provides information regarding our cash flows for the periods indicated.

	Year ended December 31,		Nine months ended September 30,	
	2021	2022	2022	2023
			<i>(unaudited)</i>	
			<i>(Renminbi in thousands)</i>	
Net cash outflow from operating activities before movements in working capital	(142,138)	(252,076)	(193,984)	(257,909)
Changes in working capital	19,562	26,864	35,954	5,752
Interest paid and/or tax paid	—	—	—	—
Net cash used in operating activities	(122,576)	(225,212)	(158,030)	(252,157)
Net cash (used in)/ generated from investing activities	(247,416)	(5,704)	(103,929)	252,705
Net cash generated from financing activities	281,482	211,494	222,970	44,063
Net (decrease)/increase in cash and cash equivalents	(88,510)	(19,422)	(38,989)	44,611
Cash and cash equivalents at beginning of the year/period	309,287	218,055	218,055	213,090

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	Year ended December 31,		Nine months ended September 30,	
	2021	2022	2022	2023
			<i>(unaudited)</i>	
			<i>(Renminbi in thousands)</i>	
Effect of foreign exchange rate changes	(2,722)	14,457	17,249	(66)
Cash and cash equivalents at ending of the year/period	218,055	213,090	196,315	257,635

Net Cash Used in Operating Activities

In the nine months ended September 30, 2023, our net cash used in operating activities was RMB252.2 million, primarily representing our loss before taxation of RMB385.5 million, as positively adjusted by (i) equity-settled share-based payment expenses of RMB99.5 million, (ii) increase in trade and other payables of RMB33.7 million, and (iii) depreciation of property, plant and equipment of RMB21.9 million and negatively adjusted by an increase in prepayments and other receivables of RMB16.8 million.

In 2022, our net cash used in operating activities was RMB225.2 million, primarily representing our loss before taxation of RMB312.4 million, as positively adjusted by (i) equity-settled share-based payment expenses of RMB41.6 million, (ii) depreciation of property, plant and equipment of RMB28.3 million, and (iii) finance costs of RMB18.7 million and negatively adjusted by net foreign exchange gain of RMB14.5 million.

In 2021, our net cash used in operating activities was RMB122.6 million, primarily representing our loss before taxation of RMB426.5 million, as positively adjusted by (i) changes in the carrying amount of financial instruments issued to investors of RMB240.1 million, (ii) depreciation of property, plant and equipment of RMB23.6 million, and (iii) finance costs of RMB17.8 million.

As a clinical-stage biotech company, we plan to improve our net cash outflow position from our operations by generating more net cash from our operating activities, launching our products and improving our cost control and operating efficiencies.

- We plan to advance the clinical development and commercialization of QX001S. We completed the Phase III clinical trial in June 2023 and Zhongmei Huadong, a subsidiary of Huadong Medicine and our commercialization partner for QX001S, submitted a BLA in China in July 2023, which was accepted by the NMPA in August 2023. We understand that Zhongmei Huadong plans to begin commercializing QX001S in the fourth quarter of 2024. In collaboration with Huadong Medicine, we aim to make QX001S more accessible to patients in China. See “Business—Our Drug Candidates—Our Other Key Product Candidates—QX001S.” Therefore, we expect that we will be able to improve our net operating cash outflow position through sales of QX001S in China.

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- We plan to advance the clinical development and commercialization of our Core Products, QX002N and QX005N. We are conducting a Phase III clinical trial of QX002N for the treatment of AS, which is expected to be completed in the second half of 2025. Our QX005N is also in the Phase II clinical stage for both AD in adults and PN and we had applied to consult with the NMPA for the commencement of Phase III clinical trials for AD in adults and PN as of the Latest Practicable Date. We believe we will be able to generate operating cash inflow if we can complete Phase III clinical trials and receive BLA approvals for QX002N and QX005N.
- We will also continue to develop external CDMO services to diversify our source of revenue. We entered into a service contract with Zhongmei Huadong in February 2023 as part of our strategic cooperation with it regarding CDMO services. See “Business—Manufacturing—Manufacturing Facility” for details.
- We plan to adopt comprehensive measures to effectively control our cost and operating expenses. We aim to optimize liquidity to gain a better return for our Shareholders while maintaining adequate risk control. After our product candidates are commercialized, we plan to closely monitor and manage the settlement of our trade receivables to avoid credit losses. We will also closely monitor the settlement of our trade payables to achieve better cash flow position.

Net Cash Used in Investing Activities

In the nine months ended September 30, 2023, our net cash generated from investing activities was RMB252.7 million, primarily attributable to proceeds from sale of financial assets measured at FVTPL of RMB885.3 million as part of the wealth management products we had acquired matured in the nine months ended September 30, 2023, partially offset by payment for purchase of financial assets measured at FVTPL of RMB630.0 million.

In 2022, our net cash used in investing activities was RMB5.7 million, primarily attributable to (i) payment for purchase of financial assets measured at FVTPL of RMB2,100 million, and (ii) payment for the purchase of property, plant and equipment of RMB20.1 million, partially offset by proceeds from sale of financial assets measured at FVTPL of RMB2,113.2 million.

In 2021, our net cash used in investing activities was RMB247.4 million, primarily attributable to (i) payment for purchase of financial assets measured at FVTPL of RMB800.0 million, and (ii) payment for the purchase of property, plant and equipment of RMB58.0 million, partially offset by proceeds from sale of financial assets measured at FVTPL of RMB604.5 million.

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Net Cash Generated from Financing Activities

In the nine months ended September 30, 2023, our net cash generated from financing activities was RMB44.1 million, which was primarily attributable to (i) proceeds from interest-bearing borrowings of RMB69.7 million, and (ii) proceeds from shares issued under the Original Share Option Scheme and the Employee Share Incentive Scheme of RMB29.5 million, partially offset by repayment of interest-bearing borrowings of RMB42.4 million.

In 2022, our net cash generated from financing activities was RMB211.5 million, which was primarily attributable to proceeds received from the Series C Financing of RMB227.5 million, partially offset by interest paid for interest-bearing borrowings of RMB15.4 million.

In 2021, our net cash generated from financing activities was RMB281.5 million, which was primarily attributable to proceeds from the Series B++ Financing of RMB300.1 million, partially offset by interest paid for interest-bearing borrowings of RMB15.3 million.

WORKING CAPITAL CONFIRMATION

We believe our liquidity requirements will be mainly satisfied by using funds from a combination of our bank balances, [REDACTED] from the [REDACTED], bank and other borrowings and cash generated from our operations. As of January 31, 2024, the latest practicable date for determining our indebtedness, we had cash and cash equivalents of RMB141.9 million and financial assets at FVTPL, comprising of short-maturity financial products we purchased, of RMB210.8 million. As of the same date, we also had unutilized bank facilities of RMB473.0 million. Taking into account of the above, together with the estimated [REDACTED] from this [REDACTED], the Directors are of the opinion that we have sufficient working capital to cover at least 125% of our costs, including general, administrative and operating costs and research and development 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, which includes research and development expenses, and (ii) capital expenditures. Taking into account our cash and cash equivalents and short-maturity financial products we purchased, and assuming average monthly net cash used in operating activities and capital expenditures going forward of 1.5 times the average level in 2021 and 2022, we estimate we will be able to maintain our financial viability for 12.9 months from the date of this document without considering [REDACTED] from the [REDACTED]; or, if we also take into account the [REDACTED] from [REDACTED], assuming an [REDACTED] of HK\$[REDACTED] per [REDACTED] (being the low-end of the indicative [REDACTED] range), 19.9 months from the date of this document. Our Directors and our management team will continue to monitor our working capital, cash flows and our business development status.

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INDEBTEDNESS

As of December 31, 2021 and 2022, September 30, 2023 and January 31, 2024, except as disclosed below, we did not have any outstanding mortgages, charges, debentures, other issued debt capital, bank overdrafts, borrowings, liabilities under acceptance or other similar indebtedness, acceptance credits, hire purchase commitments, any guarantees or other material contingent liabilities. Since January 31, 2024, the latest practicable date for the purpose of the indebtedness statement, and up to the date of this document, there has been no material adverse change to our indebtedness.

The following table provides information regarding our indebtedness as of the dates indicated.

	As of December 31,		As of September 30,	As of January 31,
	2021	2022	2023	2024
				<i>(unaudited)</i>
				<i>(Renminbi in thousands)</i>
Current				
Interest-bearing borrowings	14,869	60,508	82,323	129,660
Lease liabilities	956	1,752	917	1,294
Non-current				
Non-current interest-bearing borrowings	274,045	232,521	239,591	225,333
Lease liabilities	391	472	—	636
Total	290,261	295,253	322,831	356,923

Interest-bearing Borrowings

The following table provides information regarding our interest-bearing borrowings as of the dates indicated.

	As of December 31,		As of September 30,	As of January 31,
	2021	2022	2023	2024
				<i>(unaudited)</i>
				<i>(Renminbi in thousands)</i>
Current portion	14,869	60,508	82,323	129,660
Non-current portion	274,045	232,521	239,591	225,333
Total	288,914	293,029	321,914	354,993

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Cellularforce, a subsidiary of our Company, obtained a secured bank loan of RMB300.0 million in 2020 from a bank consortium to support the construction of our manufacturing facility. The loan is secured by our land use rights in Taizhou and guaranteed by Taizhou Huacheng Medical Investment Co., Ltd. (泰州華誠醫學投資集團有限公司) (“Taizhou Huacheng”), a related party of our Group. The loan is additionally secured by our manufacturing facilities in Taizhou after we obtained the relevant real estate title certificate in August 2023. Saifu Juli, our subsidiary holding our interest in Cellularforce, also pledged its equity interest in Cellularforce to Taizhou Huacheng as counter-security. Mr. Qiu also provided a personal guarantee to one of the banks. The guarantees provided by Taizhou Huacheng and Mr. Qiu were replaced by a guarantee provided by our Company in December 2023. Taizhou Huacheng also subsequently released the counter-security provided by Saifu Juli, whereas the security we provided remains unchanged.

The secured bank loan bears interest at floating rates ranging from 4.5% to 5.0% per annum during the Track Record Period, which was determined based on the Loan Prime Rate announced by the People’s Bank of China. In addition, we paid initial fees of RMB17.6 million to compensate the banks for arranging the loan facility. The initial fees were deferred and treated as an adjustment to the loan’s effective interest rate and recognized as an expense over the period of the loan facility.

As of December 31, 2021 and 2022 and September 30, 2023, the carrying amount of this secured bank loan was RMB288.9 million, RMB277.1 million and RMB256.2 million, respectively, which is represented by the net present value of all of our future cash repayments discounted at effective interest rate from 6.02% to 6.77% per annum.

We are subject to certain customary restrictive covenants under our secured bank loan. For example, we are prohibited from merger, spin-off, pledge, mortgage or transfer of material assets or reduction of registered capital without the prior consent of majority of the banks, or declaration of dividends. Our Directors confirm that we had not defaulted in the repayment of our bank loans and other borrowings during the Track Record Period and up to the Latest Practicable Date. Our Directors have confirmed that, as of the Latest Practicable Date, there was no breach of any covenants during the Track Record Period and up to the Latest Practicable Date.

In November 2023, Cellularforce was approved a credit facility of RMB262.5 million from a commercial bank. We plan to draw down this credit facility in its entirety in the first half of 2024 to repay the secured bank loan. Such credit facility will be secured by our land use rights and manufacturing facilities in Taizhou and guaranteed by our Company. Cellularforce is also subject to certain customary restrictive covenants under such credit facility. For example, Cellularforce is prohibited from declaration of dividends, incurring additional outbound investments and provision of additional guarantee without prior consent of the bank.

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CAPITAL EXPENDITURES

Our capital expenditures primarily consist of payments for machinery and equipment, construction in progress, other equipment, furniture and fixtures and intangible assets. We funded our capital expenditure requirements during the Track Record Period mainly from bank loans and the [REDACTED] Investments. The following table sets forth our capital expenditures for the periods indicated.

	Year ended December 31,		Nine months ended September 30,	
	2021	2022	2022	2023
			<i>(unaudited)</i>	
			<i>(Renminbi in thousands)</i>	
Machinery and equipment	9,527	12,700	5,571	2,262
Construction in progress	44,451	6,643	8,935	3,694
Other equipment, furniture and fixtures	3,997	771	672	431
Intangible assets	964	2,653	688	–
Total	58,939	22,767	15,866	6,387

As we completed construction of our manufacturing facility in Taizhou, we expect our capital expenditures to decrease from 2022 to 2023, which will primarily consist of expenses for procurement of additional equipment, machinery, furniture and other fixtures. We plan to finance such expenditures using our available cash. We may reallocate the funds to be utilized on capital expenditure based on our ongoing business needs.

CONTRACTUAL COMMITMENTS

As of December 31, 2021 and 2022 and September 30, 2023, we had capital commitments contracted for but not yet provided of RMB6.7 million, RMB3.3 million and RMB1.8 million, respectively, primarily in connection with contracts entered into with suppliers in relation to the purchase of equipment for and construction of our manufacturing facility in Taizhou.

CONTINGENT LIABILITIES

As of September 30, 2023, we did not have any contingent liabilities. Our Directors confirm that there had been no material change in our contingent liabilities since September 30, 2023 and up to the Latest Practicable Date.

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OFF-BALANCE SHEET COMMITMENTS AND ARRANGEMENTS

Aside from our capital commitments as disclosed above, we had not entered into any off-balance sheet transactions as of the Latest Practicable Date.

QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

We are exposed to a variety of market risks and other financial risks, including cash flow and fair value interest rate risk, credit risk, liquidity risk and currency risk, as set out below. Our overall risk management program focuses on the unpredictability of financial markets and seeks to minimize potential adverse effects on our financial performance. For further details, including relevant sensitivity analysis, see note 26 in the Accountants’ Report set out in Appendix I of this document.

Credit Risk

Credit risk refers to the risk that a counterparty will default on its contractual obligations resulting in a financial loss to our Group. Our credit risk is primarily attributable to other receivables. Our exposure to credit risk arising from cash and cash equivalents and wealth management products is limited because the counterparties are reputable banks or financial institution, for which we consider to have low credit risks.

Our management has assessed that, during the Track Record Period, other receivables had not had a significant increase in credit risk since initial recognition. Thus, our management adopts a 12-month expected credit loss approach that results from possible default event within 12 months of each reporting date. Our management expects the occurrence of losses from non-performance by the counterparties of other receivables was remote and loss allowance provision for other receivables was immaterial. The expected credit loss rate is insignificant and close to zero.

Liquidity Risk

Individual operating entities with our Group are responsible for their own cash management, including the short-term investment of cash surpluses and the raising of loans to cover expected cash demands, subject to approval by our Shareholders when the borrowings exceed certain predetermined levels of authority. Our policy is to regularly monitor our liquidity requirements and our compliance with lending covenants, to ensure that we maintain sufficient reserves of cash and readily realizable securities and adequate committed lines of funding from major financial institutions to meet our liquidity requirements in the short and longer term.

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Interest Rate Risk

Interest rate risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in market interest rates. Our interest rate risk arises primarily from long-term borrowings. Borrowings issued at variable rates and fixed rates expose our Group to cash flow interest rate risk and fair value interest rate risk respectively. We regularly review our strategy on interest rate risk management in the light of the prevailing market condition.

Currency Risk

We are exposed to currency risk primarily through deposits with bank which give rises to cash balances that are denominated in a foreign currency, *i.e.*, a currency other than the functional currency of the operations to which the transactions relate. The currency primarily relevant to this risk is the U.S. dollars.

KEY FINANCIAL RATIO

	As of December 31,		As of
	2021	2022	September 30,
			2023
Current ratio ⁽¹⁾	9.3	5.2	2.6

Note:

(1) Current ratio is calculated using current assets divided by current liabilities as of the same date.

Our current ratio decreased from 9.3 as of December 31, 2021 to 5.2 as of December 31, 2022, mainly attributable to an increase of RMB45.6 million in interest-bearing borrowings primarily attributable to (i) a reclassification of RMB29.7 million from the non-current portion to the current portion of our secured bank loan of RMB300.0 million obtained in January 2020 and (ii) short-term bank loans of RMB15.9 million obtained in March and May 2022 to fund our working capital needs.

Our current ratio decreased from 5.2 as of December 31, 2022 to 2.6 as of September 30, 2023, mainly attributable to a decrease of RMB250.7 million in our financial assets at fair value through profit or loss as we reduced purchasing of wealth management products in the nine months ended September 30, 2023, which outpaced the increase in cash and cash equivalents of only RMB44.5 million, as we spent cash to support our daily operations in the nine months ended September 30, 2023.

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MATERIAL TRANSACTIONS WITH RELATED PARTIES

We had the following material transactions during the Track Record Period with related parties.

	Year ended December 31,		Nine months ended September 30,	
	2021	2022	2022	2023
			<i>(unaudited)</i>	
			<i>(Renminbi in thousands)</i>	
Trade related:				
Reimbursement received from collaboration agreements	18,868	—	—	—
Rendering of services	—	283	151	2,084
Procurement of services	—	598	—	1,350
Non-trade related:				
Loans repaid by a related party	100,000	—	—	—
Loans to a related party	100,000	—	—	—
Interest income from loans to a related party	3,600	—	—	—
Payment on behalf of the Group	69	51	51	—

Reimbursement Received From Collaboration Agreements

In August 2020, we entered into a strategic cooperation agreement (the “QX001S Agreement”) with Zhongmei Huadong, a subsidiary of Huadong Medicine, with regard to the joint development and exclusive commercialization of QX001S in mainland China. Under the QX001S Agreement, we received a milestone payment of RMB20.0 million in July 2021 after we completed the sample production of QX001S for a Phase III clinical trial and have, upon a consultation with the CDE, obtained consent to proceed with such trial, which was deducted from our research and development expenses upon achieving the development milestone. For details of the collaboration agreement, see “Business—Collaboration with Zhongmei Huadong.”

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Loans to a Related Party

In January 2021, we provided a short-term loan of RMB100.0 million to Taizhou Huawei Investment Ltd. (泰州華威投資有限公司) (“Taizhou Huawei”), a subsidiary of Taizhou Huacheng Medical Investment Group Co., Ltd. (泰州華誠醫學投資集團有限公司), with an expected yield at 7.0% per annum. Taizhou Huawei is principally engaged in the business of investment management, asset management and infrastructure development. Taizhou Huawei is ultimately controlled by the Management Committee of Taizhou Medical New and High-tech Industrial Development Zone (泰州醫藥高新技術產業開發區管理委員會), a PRC governmental body. Given that this is a short-term secured loan with reasonable interest rate, we provided such loan to better utilize our cash on hand. The loan was fully settled in July 2021.

According to the General Lending Provisions (貸款通則) promulgated by the PBOC, only financial institutions may legally engage in the business of extending loans, and loans between non-financial institutions are prohibited. The PBOC may impose a fine of one to five times of the income, or the interests, from the loan advancing activities between companies. However, according to the Provisions of the Supreme People’s Court on Several Issues concerning the Application of Law in the Trial of Private Lending Cases (最高人民法院關於審理民間借貸案件適用法律若干問題的規定) (the “Private Lending Interpretations”), the Supreme People’s Court recognizes the validity and legality of financing arrangements and lending transactions between non-financial institutions so long as certain requirements, such as the interest rates, are satisfied and there is no violation of relevant provisions of laws and regulations. Our PRC Legal Advisors are of the view that the terms of our loan to Taizhou Huawei are compliant with relevant PRC legal requirements and are not in violation with the relevant provisions of laws and regulations. As of the Latest Practicable Date, the loan had been fully settled and no administrative action, fine or penalty had been imposed by the PBOC regarding such loan. Therefore, our PRC Legal Advisors are of the view that the risk that we would be subject to any penalty with respect to such interest-bearing loan pursuant to the General Lending Provisions by the relevant regulatory authorities is remote. Hence, we have not made any provision in respect of potential penalties. In addition, we have revised our treasury policy and do not plan to provide similar interest-bearing loans to related parties nor third parties going forward.

All of our non-trade balances had been settled as of September 30, 2023. Our Directors are of the view that the transactions with related parties were conducted on an arm’s-length basis.

DIVIDENDS

No dividend was paid or declared by our Company during the Track Record Period. The determination of whether to pay a dividend and in which amount are based on factors the Board may deem relevant. Any dividend distribution will also be subject to the approval of the Shareholders in a shareholders’ meeting. Under PRC law and the Articles of Association, the statutory common reserve requires annual appropriations of 10% of after-tax profits at each year-end until the balance reaches 50% of the relevant PRC entity’s registered capital. In view of our accumulated losses, as advised by our PRC Legal Advisors, we shall not declare or pay dividend until the accumulated losses are covered by our after-tax profits and sufficient statutory common reserve are drawn in accordance with the relevant laws and regulations.

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DISTRIBUTABLE RESERVES

As of September 30, 2023, we did not have any distributable reserves.

PROPERTY INTERESTS AND PROPERTY VALUATION

Asia-Pacific Consulting and Appraisal Limited, an independent property valuer, has valued our property interests as of November 30, 2023 and is of the opinion that the aggregate market value of the property in which we had an interest as of such date was RMB286.4 million, and the value attributable to our Group was RMB189.0 million. The full text of the letter, summary of valuation and valuation certificates with regard to our property interests are set out in “Appendix IV—Valuation Report” to this document.

The statement below shows the reconciliation of aggregate amounts of certain properties reflected in the audited consolidated financial information as of September 30, 2023 as set out in “Appendix I—Accountants’ Report” to this document with the valuation of these properties as of November 30, 2023 as set out in “Appendix IV—Valuation Report” to this document.

	<i>(RMB’000)</i>
Net book value of the following properties as of September 30, 2023	
Buildings.....	217,783
Land use right.....	20,185
Net valuation surplus.....	48,461
Valuation of properties of the Group as of November 30, 2023 as set out in the Property Valuation Report in Appendix IV to this document	286,429

[REDACTED] EXPENSES

Our [REDACTED] expenses include [REDACTED], professional fees and other fees incurred in connection to the [REDACTED] and the [REDACTED]. [REDACTED] expenses to be borne by us are estimated to be approximately RMB[REDACTED] (HK\$[REDACTED]), constituting approximately [REDACTED]% of the gross [REDACTED] from the [REDACTED]. The [REDACTED] expenses include fees and expenses of the Sole Sponsor and [REDACTED] (assuming an [REDACTED] of HK\$[REDACTED] per [REDACTED], being the mid-point of the indicative [REDACTED] of HK\$[REDACTED] to HK\$[REDACTED] per [REDACTED]) of approximately RMB[REDACTED], fees and expenses of legal advisors and accountants of approximately RMB[REDACTED] and other fees and expenses of approximately RMB[REDACTED], primarily including fees and expenses of internal control consultant, financial printer, industry consultant and background search agent. During the Track Record Period, we incurred a total of RMB[REDACTED] (HK\$[REDACTED]) in [REDACTED] expenses, among which RMB[REDACTED] (HK\$[REDACTED]) was recognized in our consolidated statement of profit or loss, and RMB[REDACTED] (HK\$[REDACTED]) was directly attributable to the issue of our Shares to the public and will be deducted from equity upon the [REDACTED]. We estimate that we will incur additional [REDACTED] expenses of approximately RMB[REDACTED] (HK\$[REDACTED]), of which approximately RMB[REDACTED] (HK\$[REDACTED]) is expected to be charged to our consolidated statements of profit or loss,

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and approximately RMB[REDACTED] (HK\$[REDACTED]) is directly attributable to the issue of our shares to the public and will be deducted from equity upon the [REDACTED]. The [REDACTED] expenses above are the latest practicable estimate for reference only, and the actual amount may differ from this estimate.

UNAUDITED PRO FORMA ADJUSTED CONSOLIDATED NET TANGIBLE ASSETS

The following unaudited *pro forma* statement of adjusted consolidated net tangible assets has been prepared in accordance with Rule 4.29 of the Listing Rules and with reference to Accounting Guideline 7 “Preparation of Pro Forma Financial Information for Inclusion in Investment Circulars” issued by the Hong Kong Institute of Certified Public Accountants to illustrate the effect of the [REDACTED] on the consolidated net tangible liabilities of our Group attributable to equity shareholders of the Company as of September 30, 2023 as if the [REDACTED] had taken place on that date.

The unaudited *pro forma* statement of adjusted consolidated net tangible assets of our Group has been prepared for illustrative purposes only and because of its hypothetical nature, it may not provide a true picture of the consolidated net tangible assets attributable to owners of our Company had the [REDACTED] been completed as of September 30, 2023 or at any future date.

Consolidated net tangible assets attributable to equity shareholders of the Company as of September 30, 2023 ⁽¹⁾	Estimated [REDACTED] from the [REDACTED] ⁽²⁾⁽⁴⁾	Unaudited pro forma adjusted net tangible assets attributable to equity shareholders of the Company	Unaudited pro forma adjusted net tangible assets attributable to equity shareholders of the Company per Share	
RMB'000	RMB'000	RMB'000	RMB ⁽³⁾	HK\$ ⁽⁴⁾
Based on an [REDACTED] of HK\$[REDACTED] per [REDACTED]	394,203	[REDACTED]	[REDACTED]	[REDACTED]
Based on an [REDACTED] of HK\$[REDACTED] per [REDACTED]	394,203	[REDACTED]	[REDACTED]	[REDACTED]

Notes:

- (1) The consolidated net tangible assets attributable to equity shareholders of the Company as of September 30, 2023 is calculated based on the consolidated total equity attributable to equity shareholders of the Company RMB396,725,000 as of September 30, 2023 after deduction of intangible assets of RMB2,522,000, as extracted from the Accountants’ Report as set out in Appendix I in this document.

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- (2) The estimated [REDACTED] from the [REDACTED] are based on the issuance of [REDACTED] Shares at estimated [REDACTED] of HK\$[REDACTED] per [REDACTED] (being the minimum [REDACTED]) or HK\$[REDACTED] per [REDACTED] (being the maximum [REDACTED]), after deduction of the [REDACTED] and related [REDACTED] expenses payable by the Group (excluding [REDACTED] expenses that have been accounted for prior to September 30, 2023).
- (3) The unaudited *pro forma* adjusted consolidated net tangible assets attributable to equity shareholders of the Company per Share is arrived at after adjustments as described in note (2) on the basis that [REDACTED] Shares were in issue, assuming that the [REDACTED] had been completed on September 30, 2023.
- (4) The estimated [REDACTED] from the [REDACTED] and the unaudited *pro forma* adjusted consolidated net tangible assets attributable to the equity shareholders of the Company per Share are converted into or from Renminbi at a rate of HK\$1 to RMB0.9082, being the exchange rate set by PBOC prevailing on February 17, 2024. No representation is made that the Hong Kong Dollars amounts have been, could have been or may be converted into Renminbi, or *vice versa*, at that rate.
- (5) No adjustment has been made to the unaudited *pro forma* statement of adjusted net tangible assets to reflect any trading results or other transactions we entered into subsequent to September 30, 2023.
- (6) Our property interests as at November 30, 2023 have been valued by Asia-Pacific Consulting and Appraisal Limited, an independent valuer. The relevant property valuation report is set out in Appendix IV to this document. The above unaudited *pro forma* statement of adjusted net tangible assets does not take into account the surplus arising from the revaluation of the Group’s property interests. Revaluation surplus has not been recorded in our historical financial information and will not be recorded in our consolidated financial statements in the future periods as our property, plant and equipment are stated at cost less accumulated depreciation and impairment losses, if any. If the valuation surplus were recorded in our financial statements, additional annual depreciation and amortization of approximately RMB1,634,000 would be charged against the profit in the future periods.

NO MATERIAL ADVERSE CHANGE

Our Directors confirm that, since September 30, 2023 (being the date on which the latest audited consolidated financial information of our Group was prepared) and up to the date of this document, there has been no material adverse change in our financial or trading position and there is no event which would materially affect the information shown in our consolidated financial information included in the Accountants’ Report in Appendix I to this document.

DISCLOSURE UNDER RULES 13.13 TO 13.19 OF THE LISTING RULES

Our Directors have confirmed that, as of the Latest Practicable Date, they were not aware of any circumstance that would give rise to a disclosure requirement under Rules 13.13 to 13.19 of the Listing Rules.

FUTURE PLANS AND [REDACTED]

FUTURE PLANS

For details of our future plans, see “Business—Our Strategies.”

[REDACTED]

We estimate that we will receive [REDACTED] of approximately HK\$[REDACTED] after deducting the [REDACTED] and expenses payable by us in the [REDACTED] assuming an [REDACTED] of HK\$[REDACTED] per [REDACTED], being the mid-point of the indicative [REDACTED] range of HK\$[REDACTED] to HK\$[REDACTED] per [REDACTED] set out in this document. We intend to use the [REDACTED] from the [REDACTED] for the following purposes:

- (i) approximately [REDACTED]%, or HK\$[REDACTED], will be allocated for the development and registration of our Core Product, QX002N, of which:
 - (a) approximately [REDACTED]%, or HK\$[REDACTED], will be allocated to fund the Phase III clinical trials (including costs for trial sites, CROs and subject enrollment) of QX002N in China for the treatment of AS. We commenced a Phase III clinical trial in China in September 2023 to evaluate safety and efficacy of QX002N in adult patients with active AS. We expect to complete such trial in the second half of 2025;
 - (b) approximately [REDACTED]%, or HK\$[REDACTED], will be allocated for the CMC costs and the preparation of requisite registration filings of QX002N;
- (ii) approximately [REDACTED]%, or HK\$[REDACTED], will be allocated for the development and registration of our other Core Product, QX005N, of which:
 - (a) approximately [REDACTED]%, or HK\$[REDACTED], will be allocated to fund the clinical trials (including costs for trial sites, CROs and subject enrollment) of QX005N in China for the treatment of AD in adults. We commenced a Phase II clinical trial for AD in adults in China in September 2022 to evaluate the efficacy, safety, PK and PD profile of QX005N in adult patients with moderate-to-severe AD. We expect to complete such trial in the first quarter of 2024. As of the Latest Practicable Date, we had applied to consult with the NPMA for the commencement of the Phase III clinical trial;
 - (1) approximately [REDACTED]%, or HK\$[REDACTED], will be allocated to the Phase II clinical trial; and
 - (2) approximately [REDACTED]%, or HK\$[REDACTED], will be allocated to the Phase III clinical trial;

FUTURE PLANS AND [REDACTED]

- (b) approximately [REDACTED]%, or HK\$[REDACTED], will be allocated to fund the clinical trials (including costs for trial sites, CROs and subject enrollment) of QX005N in China for the treatment of PN. We commenced a Phase II clinical trial for PN in China in February 2023 to evaluate the efficacy, safety, PK and PD profile of QX005N in adult patients with PN. We expect to complete the Phase II clinical trial in the first quarter of 2024. As of the Latest Practicable Date, we had applied to consult with the NMPA for the commencement of the Phase III clinical trial;
- (1) approximately [REDACTED]%, or HK\$[REDACTED], will be allocated to the Phase II clinical trial; and
- (2) approximately [REDACTED]%, or HK\$[REDACTED], will be allocated to the Phase III clinical trial;
- (c) approximately [REDACTED]%, or HK\$[REDACTED], will be allocated for the Phase II clinical trials (including costs for trial sites, CROs and subject enrollment) of QX005N in China for the treatment of CRSwNP. We commenced a Phase II clinical trial of QX005N in China for the treatment of CRSwNP in April 2023 to evaluate the safety, efficacy, PK and PD of QX005N in adult patients with CRSwNP and plan to complete such trial in the fourth quarter of 2024; and
- (d) approximately [REDACTED]%, or HK\$[REDACTED], will be allocated for the CMC costs and the preparation of requisite registration filings of QX005N;
- (iii) approximately [REDACTED]%, or HK\$[REDACTED], will be allocated for the development and registration of QX004N, including costs for trial sites, CROs and subject enrollment for the Phase Ib and Phase II clinical trials of QX004N for the treatment of Ps and the Phase Ib and Phase II clinical trials of QX004N for the treatment of CD, and CMC costs of QX004N. We commenced a Phase Ib clinical trial in China in February 2023 to evaluate the safety, tolerability, efficacy and PK profile of QX004N in adult patients with moderate-to-severe plaque Ps. We expect to complete such trial in the second quarter of 2024. We also commenced a Phase II clinical trial in China in September 2023 to evaluate the efficacy, safety and PK and PD profile of QX004N in adult patients with moderate-to-severe plaque Ps. We expect to complete such trial in the first half of 2025. We also plan to initiate a Phase Ib clinical trial in China depending the data from the Phase Ia clinical trial for CD to evaluate the safety, efficacy, PK and tolerability of multiple intravenous injections of QX004N in adult patients with CD.
- (iv) approximately [REDACTED]%, or HK\$[REDACTED], will be allocated for clinical development of QX006N, including the clinical trials (including costs for trial sites, CROs and subject enrollment), preparation of registration filings and CMC costs of QX006N; and
- (v) approximately [REDACTED]%, or HK\$[REDACTED], will be allocated for the research and development of certain of our other assets, including QX007N, QX010N and QX013N, and drug discovery.

FUTURE PLANS AND [REDACTED]

The above allocation of the [REDACTED] will be adjusted on a *pro rata* basis in the event that the [REDACTED] is fixed at a higher or lower level compared to the mid-point of the indicative [REDACTED] range. If the [REDACTED] is set at HK\$[REDACTED] per Share, being the high end of the indicative [REDACTED] range, the [REDACTED] from the [REDACTED] will increase by approximately HK\$[REDACTED]. If the [REDACTED] is set at HK\$[REDACTED] per Share, being the low end of the indicative [REDACTED] range, the [REDACTED] from the [REDACTED] will decrease by approximately HK\$[REDACTED].

If the [REDACTED] are not immediately applied to the above purposes, we will only deposit those [REDACTED] into short-term interest-bearing accounts at licensed commercial banks and/or other authorized financial institutions (as defined under the Securities and Futures Ordinance, and the relevant applicable laws in the relevant jurisdiction for non-Hong Kong based deposits). We will make an appropriate announcement if there is any change to the above proposed [REDACTED].

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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[REDACTED]

[REDACTED]

[REDACTED]

STRUCTURE OF THE [REDACTED]

[REDACTED]

STRUCTURE OF THE [REDACTED]

[REDACTED]

STRUCTURE OF THE [REDACTED]

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STRUCTURE OF THE [REDACTED]

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STRUCTURE OF THE [REDACTED]

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STRUCTURE OF THE [REDACTED]

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STRUCTURE OF THE [REDACTED]

[REDACTED]

STRUCTURE OF THE [REDACTED]

[REDACTED]

STRUCTURE OF THE [REDACTED]

[REDACTED]

HOW TO APPLY FOR [REDACTED]

[REDACTED]

HOW TO APPLY FOR [REDACTED]

[REDACTED]

HOW TO APPLY FOR [REDACTED]

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HOW TO APPLY FOR [REDACTED]

[REDACTED]

HOW TO APPLY FOR [REDACTED]

[REDACTED]

The following is the text of a report set out on pages I-1 to I-[●], received from the Company’s reporting accountants, KPMG, Certified Public Accountants, Hong Kong, for the purpose of incorporation in this document.



ACCOUNTANTS’ REPORT ON HISTORICAL FINANCIAL INFORMATION TO THE DIRECTORS OF QYUNS THERAPEUTICS CO., LTD AND CHINA INTERNATIONAL CAPITAL CORPORATION HONG KONG SECURITIES LIMITED

Introduction

We report on the historical financial information of Qyuns Therapeutics Co., Ltd. (the “Company”) and its subsidiaries (together, the “Group”) set out on pages I-5 to I-[●], which comprises the consolidated statements of financial position of the Group and the statements of financial position of the Company as at 31 December 2021, 2022 and 30 September 2023 and the consolidated statements of profit or loss and other comprehensive income, the consolidated statements of changes in equity and the consolidated statements of cash flows, for each of the years ended 31 December 2021 and 2022 and the nine months ended 30 September 2023 (the “Relevant Periods”), and a summary of material accounting policy information and other explanatory information (together, the “Historical Financial Information”). The Historical Financial Information set out on pages I-4 to I-[●] forms an integral part of this report, which has been prepared for inclusion in the document of the Company dated [REDACTED] (the “Document”) in connection with the [REDACTED] of shares of the Company on the Main Board of The Stock Exchange of Hong Kong Limited.

Directors’ responsibility for Historical Financial Information

The directors of the Company are responsible for the preparation of Historical Financial Information that gives a true and fair view in accordance with the basis of preparation and presentation set out in Note 1 to the Historical Financial Information, and for such internal control as the directors of the Company determine is necessary to enable the preparation of the Historical Financial Information that is free from material misstatement, whether due to fraud or error.

Reporting accountants’ responsibility

Our responsibility is to express an opinion on the Historical Financial Information and to report our opinion to you. We conducted our work in accordance with Hong Kong Standard on Investment Circular Reporting Engagements 200 “Accountants’ Reports on Historical Financial Information in Investment Circulars” issued by the Hong Kong Institute of Certified Public Accountants (“HKICPA”). This standard requires that we comply with ethical standards and plan and perform our work to obtain reasonable assurance about whether the Historical Financial Information is free from material misstatement.

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Our work involved performing procedures to obtain evidence about the amounts and disclosures in the Historical Financial Information. The procedures selected depend on the reporting accountants’ judgement, including the assessment of risks of material misstatement of the Historical Financial Information, whether due to fraud or error. In making those risk assessments, the reporting accountants consider internal control relevant to the entity’s preparation of Historical Financial Information that gives a true and fair view in accordance with the basis of preparation and presentation set out in Note 1 to the Historical Financial Information in order to design procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity’s internal control. Our work also included evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by the directors, as well as evaluating the overall presentation of the Historical Financial Information.

We believe that the evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Opinion

In our opinion, the Historical Financial Information gives, for the purpose of the accountants’ report, a true and fair view of the Company’s and the Group’s financial position as at 31 December 2021, 2022 and 30 September 2023 and of the Group’s financial performance and cash flows for the Relevant Periods in accordance with the basis of preparation and presentation set out in Note 1 to the Historical Financial Information.

Review of stub period corresponding financial information

We have reviewed the stub period corresponding financial information of the Group which comprises the consolidated statement of profit or loss and other comprehensive income, the consolidated statement of changes in equity and the consolidated statement of cash flows for the nine months ended 30 September 2022 and other explanatory information (the “Stub Period Corresponding Financial Information”). The directors of the Company are responsible for the preparation and presentation of the Stub Period Corresponding Financial Information in accordance with the basis of preparation and presentation set out in Note 1 to the Historical Financial Information. Our responsibility is to express a conclusion on the Stub Period Corresponding Financial Information based on our review. We conducted our review in accordance with Hong Kong Standard on Review Engagements 2410 “Review of Interim Financial Information Performed by the Independent Auditor of the Entity” issued by the HKICPA. A review consists of making enquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with Hong Kong Standards on Auditing and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion. Based on our review, nothing has come to our attention that causes

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us to believe that the Stub Period Corresponding Financial Information, for the purpose of the accountants' report, is not prepared, in all material respects, in accordance with the basis of preparation and presentation set out in Note 1 to the Historical Financial Information.

Report on matters under the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited and the Companies (Winding Up and Miscellaneous Provisions) Ordinance

Adjustments

In preparing the Historical Financial Information, no adjustments to the Underlying Financial Statements as defined on page I-4 have been made.

Dividends

We refer to Note 27(e) to the Historical Financial Information which states that no dividends have been paid by the Company in respect of the Relevant Periods.

KPMG

Certified Public Accountants

8th Floor, Prince's Building
10 Chater Road
Central, Hong Kong

[REDACTED]

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HISTORICAL FINANCIAL INFORMATION

Set out below is the Historical Financial Information which forms an integral part of this accountants’ report.

The consolidated financial statements of the Group for the Relevant Periods, on which the Historical Financial Information is based, were audited by KPMG Huazhen LLP Shanghai Branch (畢馬威華振會計師事務所(特殊普通合伙)上海分所) in accordance with Hong Kong Standards on Auditing issued by the HKICPA (the “Underlying Financial Statements”).

The Historical Financial Information is presented in Renminbi (“RMB”) and all values are rounded to the nearest thousand yuan (RMB’000) except when otherwise indicated.

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ACCOUNTANTS’ REPORT

CONSOLIDATED STATEMENTS OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

(Expressed in Renminbi)

	<i>Note</i>	Year ended 31 December 2021 <i>RMB’000</i>	Year ended 31 December 2022 <i>RMB’000</i>	Nine months ended 30 September 2022 <i>RMB’000</i> <i>(Unaudited)</i>	2023 <i>RMB’000</i>
Other income	5(a)	34,886	25,726	13,799	13,279
Other net (loss)/gain	5(b)	(2,817)	14,402	17,194	(75)
Administrative expenses		(48,804)	(76,603)	(33,237)	(123,247)
Research and development expenses		(151,887)	(257,214)	(189,749)	(263,270)
Loss from operations		(168,622)	(293,689)	(191,993)	(373,313)
Finance costs	6(a)	(17,842)	(18,692)	(13,987)	(12,246)
Changes in the carrying amount of financial instruments issued to investors	25	(240,080)	—	—	—
Loss before taxation	6	(426,544)	(312,381)	(205,980)	(385,559)
Income tax	7(a)	73	73	55	55
Loss for the year/period		<u>(426,471)</u>	<u>(312,308)</u>	<u>(205,925)</u>	<u>(385,504)</u>
Attributable to:					
Equity shareholders of the Company		(411,039)	(298,191)	(196,649)	(373,978)
Non-controlling interests		<u>(15,432)</u>	<u>(14,117)</u>	<u>(9,276)</u>	<u>(11,526)</u>
Loss for the year/period		(426,471)	(312,308)	(205,925)	(385,504)
Other comprehensive income for the year (after tax)		—	—	—	—
Total comprehensive income for the year/period		<u>(426,471)</u>	<u>(312,308)</u>	<u>(205,925)</u>	<u>(385,504)</u>
Attributable to:					
Equity shareholders of the Company		(411,039)	(298,191)	(196,649)	(373,978)
Non-controlling interests		<u>(15,432)</u>	<u>(14,117)</u>	<u>(9,276)</u>	<u>(11,526)</u>
Total comprehensive income for the year/period		<u>(426,471)</u>	<u>(312,308)</u>	<u>(205,925)</u>	<u>(385,504)</u>
Loss per share					
Basic and diluted (RMB)	10	<u>(2.57)</u>	<u>(1.68)</u>	<u>(1.11)</u>	<u>(1.83)</u>

The accompanying notes form part of the Historical Financial Information.

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ACCOUNTANTS’ REPORT

CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

(Expressed in Renminbi)

	<i>Note</i>	As at 31 December 2021 <i>RMB’000</i>	As at 31 December 2022 <i>RMB’000</i>	As at 30 September 2023 <i>RMB’000</i>
Non-current assets				
Property, plant and equipment	11	378,335	363,125	346,154
Right-of-use assets	12	22,497	23,039	21,417
Intangible assets		376	3,052	2,522
Other non-current assets	14	18,024	9,936	11,924
		<u>419,232</u>	<u>399,152</u>	<u>382,017</u>
Current assets				
Inventories and other contract costs	15	—	—	7,216
Prepayments and other receivables	16	19,526	18,384	36,055
Other current assets	17	8,298	3,377	7,877
Financial assets at fair value through profit or loss (“FVPL”)	18	402,382	401,097	150,397
Cash and cash equivalents	19	218,055	213,090	257,635
		<u>648,261</u>	<u>635,948</u>	<u>459,180</u>
Current liabilities				
Trade and other payables	20	53,848	59,930	91,692
Contract liabilities	21	—	—	3,810
Interest-bearing borrowings	22	14,869	60,508	82,323
Lease liabilities	24	956	1,752	917
		<u>69,673</u>	<u>122,190</u>	<u>178,742</u>
Net current assets		<u>578,588</u>	<u>513,758</u>	<u>280,438</u>
Total assets less current liabilities		<u>997,820</u>	<u>912,910</u>	<u>662,455</u>
Non-current liabilities				
Non-current interest-bearing borrowings	22	274,045	232,521	239,591
Deferred income	23	18,659	18,018	17,536
Lease liabilities	24	391	472	—
Deferred tax liabilities	7(c)	559	486	431
		<u>293,654</u>	<u>251,497</u>	<u>257,558</u>
NET ASSETS		<u>704,166</u>	<u>661,413</u>	<u>404,897</u>
CAPITAL AND RESERVES				
Share capital	27	166,480	180,525	210,025
Reserves		503,871	461,190	186,700
Total equity attributable to equity shareholders of the Company		<u>670,351</u>	<u>641,715</u>	<u>396,725</u>
Non-controlling interests		<u>33,815</u>	<u>19,698</u>	<u>8,172</u>
TOTAL EQUITY		<u>704,166</u>	<u>661,413</u>	<u>404,897</u>

The accompanying notes form part of the Historical Financial Information.

APPENDIX I

ACCOUNTANTS’ REPORT

STATEMENTS OF FINANCIAL POSITION OF THE COMPANY

(Expressed in Renminbi)

	<i>Note</i>	As at 31 December 2021 <i>RMB’000</i>	As at 31 December 2022 <i>RMB’000</i>	As at 30 September 2023 <i>RMB’000</i>
Non-current assets				
Property, plant and equipment		3,190	2,408	1,987
Right-of-use assets		1,535	2,521	1,232
Intangible assets		89	98	69
Interests in a subsidiary	13	90,000	116,470	116,470
Financial assets measured at amortised cost		–	–	26,000
Other non-current assets		7,782	7,148	10,520
		<u>102,596</u>	<u>128,645</u>	<u>156,278</u>
Current assets				
Prepayments and other receivables	16	46,674	45,461	57,396
Other current assets		3,995	3,377	7,627
Financial assets at fair value through profit or loss	18	402,382	401,097	150,397
Cash and cash equivalents	19	199,879	188,782	237,524
		<u>652,930</u>	<u>638,717</u>	<u>452,944</u>
Current liabilities				
Trade and other payables	20	23,757	31,960	63,646
Lease liabilities		956	1,752	917
Interest-bearing borrowings		–	–	450
		<u>24,713</u>	<u>33,712</u>	<u>65,013</u>
Net current assets		<u>628,217</u>	<u>605,005</u>	<u>387,931</u>
Total assets less current liabilities		<u>730,813</u>	<u>733,650</u>	<u>544,209</u>
Non-current liabilities				
Non-current interest-bearing borrowings		–	–	35,550
Lease liabilities		391	472	–
		<u>391</u>	<u>472</u>	<u>35,550</u>
NET ASSETS		<u>730,422</u>	<u>733,178</u>	<u>508,659</u>
CAPITAL AND RESERVES				
Share capital	27	166,480	180,525	210,025
Reserves		563,942	552,653	298,634
TOTAL EQUITY		<u>730,422</u>	<u>733,178</u>	<u>508,659</u>

The accompanying notes form part of the Historical Financial Information.

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ACCOUNTANTS’ REPORT

CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY
(Expressed in Renminbi)

		Attributable to equity shareholders of the Company									
		Paid-in capital	Share capital	Capital reserve	Share premium	Share-based payment reserve	Other reserve	Accumulated losses	Total	Non-controlling interests	Total (deficit)/equity
		RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
	<i>Note</i>										
		144,650	—	629,350	—	25,829	(600,000)	(337,160)	(137,331)	49,247	(88,084)
		—	—	—	—	—	—	(411,039)	(411,039)	(15,432)	(426,471)
	27(b)	21,830	—	278,244	—	—	—	—	300,074	—	300,074
		—	—	—	—	—	(300,074)	—	(300,074)	—	(300,074)
		—	—	—	—	—	1,206,991	—	1,206,991	—	1,206,991
		(166,480)	166,480	(907,594)	616,229	(34,499)	(306,917)	632,781	—	—	—
	26	—	—	—	—	11,730	—	—	11,730	—	11,730
		—	166,480	—	616,229	3,060	—	(115,418)	670,351	33,815	704,166

Balance at 1 January 2021

Changes in equity for 2021:

Total comprehensive income

Capital contributions by investors

Recognition of financial instruments issued with preferred rights

Termination of financial instruments with preferred rights

Conversion into a joint stock company

Equity-settled share-based transactions

Balance at 31 December 2021

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ACCOUNTANTS’ REPORT

CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY (CONTINUED)
(Expressed in Renminbi)

	Attributable to equity shareholders of the Company						
	Share capital	Share premium	Share-based payment reserve	Accumulated losses	Total	Non-controlling interests	Total equity
Note	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
Balance at 1 January 2022	166,480	616,229	3,060	(115,418)	670,351	33,815	704,166
Changes in equity for 2022:							
Total comprehensive income	—	—	—	(298,191)	(298,191)	(14,117)	(312,308)
Issuance of ordinary shares	13,545	213,954	—	—	227,499	—	227,499
Shares issued under share option scheme	500	—	—	—	500	—	500
Equity-settled share-based transactions	—	—	41,556	—	41,556	—	41,556
Balance at 31 December 2022	180,525	830,183	44,616	(413,609)	641,715	19,698	661,413

APPENDIX I

ACCOUNTANTS’ REPORT

CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY (CONTINUED)
(Expressed in Renminbi)

	Attributable to equity shareholders of the Company						
	Share capital	Share premium	Share-based payment reserve	Accumulated losses	Total	Non-controlling interests	Total equity
Note	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
(Unaudited) Balance at 1 January 2022	166,480	616,229	3,060	(115,418)	670,351	33,815	704,166
Changes in equity for the nine months ended 30 September 2022:							
Total comprehensive income	—	—	—	(196,649)	(196,649)	(9,276)	(205,925)
Issuance of ordinary shares	13,545	213,954	—	—	227,499	—	227,499
Equity-settled share-based transactions	—	—	4,370	—	4,370	—	4,370
Balance at 30 September 2022 (Unaudited)	<u>180,025</u>	<u>830,183</u>	<u>7,430</u>	<u>(312,067)</u>	<u>705,571</u>	<u>24,539</u>	<u>730,110</u>

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ACCOUNTANTS’ REPORT

CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY (CONTINUED)
(Expressed in Renminbi)

	Attributable to equity shareholders of the Company						
	Share capital	Share premium	Share-based payment reserve	Accumulated losses	Total	Non-controlling interests	Total equity
Note	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
Balance at 1 January 2023	180,525	830,183	44,616	(413,609)	641,715	19,698	661,413
Changes in equity for the nine months ended 30 September 2023:							
Total comprehensive income	—	—	—	(373,978)	(373,978)	(11,526)	(385,504)
Shares issued under share option scheme and restricted share scheme	29,500	—	—	—	29,500	—	29,500
Equity-settled share-based transactions	—	—	99,488	—	99,488	—	99,488
Balance at 30 September 2023	210,025	830,183	144,104	(787,587)	396,725	8,172	404,897

The accompanying notes form part of the Historical Financial Information.

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ACCOUNTANTS’ REPORT

CONSOLIDATED STATEMENTS OF CASH FLOWS

(Expressed in Renminbi)

	Year ended 31 December 2021	Year ended 31 December 2022	Nine months ended 30 September	
Note	2021	2022	2022	2023
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
			<i>(Unaudited)</i>	
Operating activities				
Cash used in operations	19(b)	(122,576)	(225,212)	(158,030)
Income tax paid		—	—	—
Net cash used in operating activities		<u>(122,576)</u>	<u>(225,212)</u>	<u>(158,030)</u>
Investing activities				
Payment for the purchase of property, plant and equipment		(57,975)	(20,114)	(15,178)
Payment for the termination of leases		—	(42)	(42)
Payment for the purchase of intangible assets		(964)	(2,653)	(688)
Payment for purchase of financial assets measured at FVPL		(800,000)	(2,100,000)	(1,700,000)
Proceeds from sale of financial assets measured at FVPL		604,465	2,113,182	1,609,597
Interest received from bank deposits		3,458	3,923	2,382
Interest received from loans to a related party		3,600	—	—
Loans lent to a related party		(100,000)	—	—
Loans prepaid by a related party		100,000	—	—
Net cash (used in)/ generated from investing activities		<u>(247,416)</u>	<u>(5,704)</u>	<u>(103,929)</u>
		<u>252,705</u>		

APPENDIX I

ACCOUNTANTS’ REPORT

CONSOLIDATED STATEMENTS OF CASH FLOWS (CONTINUED)

(Expressed in Renminbi)

		Year ended 31 December 2021	Year ended 31 December 2022	Nine months ended 30 September	
	<i>Note</i>	<u>RMB’000</u>	<u>RMB’000</u>	<u>2022</u>	<u>2023</u>
				<i>RMB’000</i>	<i>RMB’000</i>
				<i>(Unaudited)</i>	
Financing activities					
Proceeds from interest-bearing borrowings	<i>19(c)</i>	—	15,900	15,900	69,700
Repayment of interest-bearing borrowings	<i>19(c)</i>	—	(15,000)	(7,500)	(42,400)
Proceeds from the issuance of financial instruments to investors	<i>19(c)</i>	300,074	—	—	—
Capital injection received from shareholders	<i>27(c)</i>	—	227,499	227,499	—
Proceeds from shares issued under share option scheme and restricted share scheme	<i>27(c)</i>	—	500	—	29,500
Interest paid for interest-bearing borrowings	<i>19(c)</i>	(15,251)	(15,390)	(11,554)	(10,634)
Payment for capital element of lease liabilities	<i>19(c)</i>	(3,007)	(1,553)	(1,144)	(1,307)
Payment for interest element of lease liabilities	<i>19(c)</i>	(76)	(99)	(74)	(53)
[REDACTED] expenses paid		<u>[REDACTED]</u>	<u>[REDACTED]</u>	<u>[REDACTED]</u>	<u>[REDACTED]</u>
Net cash generated from financing activities		<u>[REDACTED]</u>	<u>[REDACTED]</u>	<u>[REDACTED]</u>	<u>[REDACTED]</u>

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ACCOUNTANTS’ REPORT

	Year ended 31 December 2021	Year ended 31 December 2022	Nine months ended 30 September 2022		2023
<i>Note</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	
			<i>(Unaudited)</i>		
Net (decrease)/ increase in cash and cash equivalents	(88,510)	(19,422)	(38,989)	44,611	
Cash and cash equivalents at the beginning of the year/period	309,287	218,055	218,055	213,090	
Effect of foreign exchange rate changes	(2,722)	14,457	17,249	(66)	
Cash and cash equivalents at the end of the year/period	<i>19(a)</i> 218,055	213,090	196,315	257,635	

The accompanying notes form part of the Historical Financial Information.

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NOTES TO THE HISTORICAL FINANCIAL STATEMENTS

1 BASIS OF PREPARATION AND PRESENTATION OF HISTORICAL FINANCIAL INFORMATION

Qyuns Therapeutics Co., Ltd. (the “Company”)* (江蘇荃信生物醫藥股份有限公司), formerly known as Qyuns Therapeutics Co., Ltd.* (江蘇荃信生物醫藥有限公司) was established in Taizhou, Jiangsu Province, People’s Republic of China (the “PRC”) on 16 June 2015 as a company with limited liability. Upon approval by the Company’s board meeting held on 2 September 2021, the Company was converted from a company with limited liability into a joint stock company with limited liability.

During the Relevant Periods, the Company and its subsidiaries (together, “the Group”) are principally engaged in research and development of biologic therapies for autoimmune and allergic diseases.

The financial statements of the Company and the subsidiaries of the Group for which there are statutory requirements were prepared in accordance with the relevant accounting rules and regulations applicable to entities in the countries in which they were incorporated and/or established. The statutory financial statements of the Company for the year ended 31 December 2021 and 2022 were prepared in accordance with the Accounting Regulations for Business Enterprises issued by the Ministry of Finance of the PRC and audited by Jiangsu Jingwei Certified Public Accountants Co., Ltd.* (江蘇經緯會計師事務所有限公司).

During the Relevant Periods, the Company has direct or indirect interests in the following principal subsidiaries, all of which are private companies with limited liabilities:

Company name	Place and date of incorporation/ establishment	Particulars of registered and paid-up capital	Proportion of ownership interest		Principal activities
			Directly held by the Company	Indirectly held by the Company	
Taizhou Saifu Juli Biomedical Co., Ltd. (“Saifu Juli”)* (“泰州市賽孚聚力生物醫藥有限公司”) (i)	6 July 2018 The PRC	RMB116,470,000/ RMB116,470,000	100%	—	Investment holding
Jiangsu Cellularforce Biotechnology Co., Ltd. (“Cellularforce”)* (“江蘇賽孚士生物技術有限公司”) (ii)	2 August 2018 The PRC	RMB176,470,000/ RMB176,470,000	—	66%	Research, development and production of pharmaceutical products, provision of technical consultation services

Notes:

- (i) The financial statements of Saifu Juli for the years ended 31 December 2021 and 2022 have not been prepared as of the date of this report.
 - (ii) The statutory financial statements of Cellularforce for the years ended 31 December 2021 and 2022 were audited by Jiangsu Jingwei Certified Public Accountants Co., Ltd.* (江蘇經緯會計師事務所有限公司).
- * The English translation of these entities is for reference only. The official names of the entities established in the PRC are in Chinese.

All companies comprising the Group have adopted 31 December as their financial year end date.

The Historical Financial Information has been prepared in accordance with all applicable International Financial Reporting Standards (“IFRSs”) which collective term includes all applicable individual International Financial Reporting Standards, International Accounting Standards and Interpretations issued by the International Accounting Standards Board (“IASB”). Further details of the material accounting policy information adopted are set out in Note 2.

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The IASB has issued a number of new and revised IFRSs. For the purpose of preparing this Historical Financial Information, the Group has adopted all applicable new and revised IFRSs to the Relevant Periods. The accounting policies set out in Note 2 have been applied consistently throughout the Relevant Periods and the Group has not adopted any new standards or interpretations that are effective for the accounting year beginning on or after 1 January 2024. The revised and new accounting standards and interpretations issued which effective for the accounting years beginning on or after 1 January 2024 and not yet adopted by the Group are set out in Note 31.

The Historical Financial Information also complies with the applicable disclosure provisions of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited (the “Stock Exchange”).

The accounting policies set out below have been applied consistently to all periods presented in the Historical Financial Information. The Stub Period Corresponding Financial Information has been prepared in accordance with the same basis of preparation and presentation adopted in respect of the Historical Financial Information.

2 MATERIAL ACCOUNTING POLICY INFORMATION

(a) Basis of measurement

As the Group’s operation are primarily located in the PRC and most of the Group’s transactions are conducted and denominated in Renminbi (“RMB”), which is the functional currency of the Group, the Historical Financial Information is presented in RMB, rounded to the nearest thousand, unless otherwise stated.

The measurement basis used in the preparation of the financial statements is the historical cost basis except that the assets are stated at their fair value as explained in the accounting policies as set out in Note 2(e).

(b) Use of estimates and judgements

The preparation of financial statements in conformity with IFRSs requires management to make judgements, estimates and assumptions that affect the application of policies and reported amounts of assets, liabilities, income and expenses. The estimates and associated assumptions are based on historical experience and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis of making the judgements about carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates.

The estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognised in the period in which the estimate is revised if the revision affects only that period, or in the period of the revision and future periods if the revision affects both current and future periods.

Judgements made by management in the application of IFRSs that have significant effect on the financial statements and major sources of estimation uncertainty are discussed in Note 3.

(c) Subsidiaries and non-controlling interests

Subsidiaries are entities controlled by the Group. The Group controls an entity when it is exposed, or has rights, to variable returns from its involvement with the entity and has the ability to affect those returns through its power over the entity. When assessing whether the Group has power, only substantive rights (held by the Group and other parties) are considered.

An investment in a subsidiary is consolidated into the consolidated financial statements from the date that control commences until the date that control ceases. Intra-group balances, transactions and cash flows and any unrealised profits arising from intra-group transactions are eliminated in full in preparing the consolidated financial statements. Unrealised losses resulting from intra-group transactions are eliminated in the same way as unrealised gains but only to the extent that there is no evidence of impairment.

Non-controlling interests represent the equity in a subsidiary not attributable directly or indirectly to the Company, and in respect of which the Group has not agreed any additional terms with the holders of those interests which would result in the Group as a whole having a contractual obligation in respect of those interests that meets the definition of a financial liability. For each business combination, the Group can elect to measure any non-controlling interests either at fair value or at the non-controlling interests’ proportionate share of the subsidiary’s net identifiable assets.

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Non-controlling interests are presented in the consolidated statement of financial position within equity, separately from equity attributable to the equity shareholders of the Company. Non-controlling interests in the results of the Group are presented on the face of the consolidated statement of profit or loss and the consolidated statement of profit or loss and other comprehensive income as an allocation of the total profit or loss and total comprehensive income for the year between non-controlling interests and the equity shareholders of the Company.

Changes in the Group’s interests in a subsidiary that do not result in a loss of control are accounted for as equity transactions, whereby adjustments are made to the amounts of controlling and non-controlling interests within consolidated equity to reflect the change in relative interests, but no adjustments are made to goodwill and no gain or loss is recognised.

When the Group loses control of a subsidiary, it is accounted for as a disposal of the entire interest in that subsidiary, with a resulting gain or loss being recognised in profit or loss. Any interest retained in that former subsidiary at the date when control is lost is recognised at fair value and this amount is regarded as the fair value on initial recognition of a financial asset (see Note 2(e)).

In the Company’s statement of financial position, an investment in a subsidiary is stated at cost less impairment losses (see Note 2(i) (ii)), unless the investment is classified as held for sale (or included in a disposal Group that is classified as held for sale).

(d) Joint Operations

A joint operation is a joint arrangement whereby the parties that have joint control of the arrangement have rights to the assets, and obligations for the liabilities, relating to the joint arrangement. Joint control is the contractually agreed sharing of control of an arrangement, which exists only when decisions about the relevant activities require unanimous consent of the parties sharing control.

When a group entity undertakes its activities under joint operations, the Group as a joint operator recognises in relation to its interest in a joint operation:

- its assets, including its share of any assets held jointly;
- its liabilities, including its share of any liabilities incurred jointly;
- its revenue from the sale of its share of the output arising from the joint operation;
- its share of the revenue from the sale of the output by the joint operation; and
- its expenses, including its share of any expenses incurred jointly.

The Group accounts for the assets, liabilities, revenues and expenses relating to its interest in a joint operation in accordance with the IFRSs applicable to the particular assets, liabilities, revenues and expenses.

When a group entity transacts with a joint operation in which a group entity is a joint operator (such as a sale or contribution of assets), the Group is considered to be conducting the transaction with the other parties to the joint operation, and gains and losses resulting from the transactions are recognised in the Group’s consolidated financial statements only to the extent of other parties’ interests in the joint operation. When a group entity transacts with a joint operation in which a group entity is a joint operator (such as a purchase of assets), the Group does not recognise its share of the gains and losses until it resells those assets to a third party.

(e) Other investments

The Group’s policies for other investments, other than investments in subsidiaries, are set out below.

Investments are recognised/derecognised on the date the Group commits to purchase/sell the investment. The investments are initially stated at fair value plus directly attributable transaction costs, except for those investments measured at fair value through profit or loss (“FVPL”) for which transaction costs are recognised directly in profit or loss. For an explanation of how the Group determines fair value of financial instruments, see Note 28(e). These investments are subsequently accounted for as follows, depending on their classification.

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ACCOUNTANTS’ REPORT

(i) *Investments other than equity investments*

Non-equity investments held by the Group are classified into one of the following measurement categories:

- amortised cost, if the investment is held for the collection of contractual cash flows which represent solely payments of principal and interest. Interest income from the investment is calculated using the effective interest method (see Note 2(s)(i)).
- fair value through other comprehensive income (“FVOCI”)—recycling, if the contractual cash flows of the investment comprise solely payments of principal and interest and the investment is held within a business model whose objective is achieved by both the collection of contractual cash flows and sale. Changes in fair value are recognised in other comprehensive income, except for the recognition in profit or loss of expected credit losses, interest income (calculated using the effective interest method) and foreign exchange gains and losses. When the investment is derecognised, the amount accumulated in other comprehensive income is recycled from equity to profit or loss.
- fair value through profit or loss (“FVPL”) if the investment does not meet the criteria for being measured at amortised cost or FVOCI (recycling). Changes in the fair value of the investment (including interest) are recognised in profit or loss.

(ii) *Equity investments*

An investment in equity securities is classified as FVPL unless the equity investment is not held for trading purposes and on initial recognition of the investment the Group makes an irrevocable election to designate the investment at FVOCI (non-recycling) such that subsequent changes in fair value are recognised in other comprehensive income. Such elections are made on an instrument-by-instrument basis, but may only be made if the investment meets the definition of equity from the issuer’s perspective. Where such an election is made, the amount accumulated in other comprehensive income remains in the fair value reserve (non-recycling) until the investment is disposed of. At the time of disposal, the amount accumulated in the fair value reserve (non-recycling) is transferred to retained earnings. It is not recycled through profit or loss. Dividends from an investment in equity securities, irrespective of whether classified as at FVPL or FVOCI, are recognised in profit or loss as other income.

(f) **Property, plant and equipment**

Property, plant and equipment, including right-of-use assets arising from leases over leasehold properties, plant and equipment (see Note 2(h)), are stated at cost less accumulated depreciation and impairment losses (see Note 2(i)(ii)).

The cost of self-constructed items of property, plant and equipment includes the direct costs of construction, capitalised borrowing costs (see Note 2(u)), and any other costs directly attributable to bringing the asset to working condition for its intended use. Subsequent expenditure relating to an item of property, plant and equipment that has already been recognised is added to the carrying amount of the asset when it is probable that the future economic benefits, in excess of the original assessed standard of performance of the existing asset, will flow to the Group or the Company. All other subsequent expenditure is recognised as an expense in profit or loss in the period in which it is incurred.

Items may be produced while bringing an item of property, plant and equipment to the location and condition necessary for it to be capable of operating in the manner intended by management. The proceeds from selling any such items and the related costs are recognised in profit or loss.

Gains or losses arising from the retirement or disposal of an item of property, plant and equipment are determined as the difference between the net disposal proceeds and the carrying amount of the item and are recognised in profit or loss on the date of retirement or disposal.

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Depreciation is calculated to write off the cost of items of property, plant and equipment, less their estimated residual value, if any, using the straight-line method over their estimated useful lives as follows:

Buildings	20-30 years
Equipment and Machinery	3-10 years
Other equipment, furniture and fixtures	3-5 years

Where parts of an item of property, plant and equipment have different useful lives, the cost is allocated on a reasonable basis between the parts and each part is depreciated separately. Both the useful life of an asset and its residual value, if any, are reviewed annually.

(g) Intangible assets

Expenditure on research activities is recognised as an expense in the period in which it is incurred. Expenditure on development activities is capitalised if the product or process is technically and commercially feasible and the Group has sufficient resources and the intention to complete development. The expenditure capitalised includes the costs of materials, direct labour, and an appropriate proportion of overheads and borrowing costs, where applicable. Capitalised development costs are stated at cost less accumulated amortisation and impairment losses (see Note 2(i)(ii)). Other development expenditure is recognised as an expense in the period in which it is incurred.

Other intangible assets that are acquired by the Group are stated at cost less accumulated amortisation (where the estimated useful life is finite) and impairment losses (see Note 2(i)(ii)). Expenditure on internally generated goodwill and brands is recognised as an expense in the period in which it is incurred.

Amortisation of intangible assets with finite useful lives is charged to profit or loss on a straight-line basis over the assets’ estimated useful lives. The following intangible assets with finite useful lives are amortised from the date they are available for use and their estimated useful lives are as follows:

—software	5 years
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Both the period and method of amortisation are reviewed annually.

(h) Leased assets

At inception of a contract, the Group assesses whether the contract is, or contains, a lease. A contract is, or contains, a lease if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration. Control is conveyed where the customer has both the right to direct the use of the identified asset and to obtain substantially all of the economic benefits from that use.

(i) As a lessee

Where the contract contains lease component(s) and non-lease component(s), the Group has elected not to separate non-lease components and accounts for each lease component and any associated non-lease components as a single lease component for all leases.

At the lease commencement date, the Group recognises a right-of-use asset and a lease liability, except for short-term leases that have a lease term of 12 months or less and leases of low-value assets. When the Group enters into a lease in respect of a low-value asset, the Group decides whether to capitalise the lease on a lease-by-lease basis. The lease payments associated with those leases which are not capitalised are recognised as an expense on a systematic basis over the lease term.

Where the lease is capitalised, the lease liability is initially recognised at the present value of the lease payments payable over the lease term, discounted using the interest rate implicit in the lease or, if that rate cannot be readily determined, using a relevant incremental borrowing rate. After initial recognition, the lease liability is measured at amortised cost and interest expense is calculated using the effective interest method. Variable lease payments that do not depend on an index or rate are not included in the measurement of the lease liability and hence are charged to profit or loss in the accounting period in which they are incurred.

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The right-of-use asset recognised when a lease is capitalised is initially measured at cost, which comprises the initial amount of the lease liability plus any lease payments made at or before the commencement date, and any initial direct costs incurred. Where applicable, the cost of the right-of-use assets also includes an estimate of costs to dismantle and remove the underlying asset or to restore the underlying asset or the site on which it is located, discounted to their present value, less any lease incentives received. The right-of-use asset is subsequently stated at cost less accumulated depreciation and impairment losses (see Notes 2(f) and 2(i)(ii)).

The lease liability is remeasured when there is a change in future lease payments arising from a change in an index or rate, or there is a change in the Group’s estimate of the amount expected to be payable under a residual value guarantee, or there is a change arising from the reassessment of whether the Group will be reasonably certain to exercise a purchase, extension or termination option. When the lease liability is remeasured in this way, a corresponding adjustment is made to the carrying amount of the right-of-use asset, or is recorded in profit or loss if the carrying amount of the right-of-use asset has been reduced to zero.

The lease liability is also remeasured when there is a change in the scope of a lease or the consideration for a lease that is not originally provided for in the lease contract (“lease modification”) that is not accounted for as a separate lease. In this case the lease liability is remeasured based on the revised lease payments and lease term using a revised discount rate at the effective date of the modification. The only exceptions are rent concessions that occurred as a direct consequence of the COVID-19 pandemic and met the conditions set out in paragraph 46B of IFRS 16 Leases. In such cases, the group has taken advantage of the practical expedient not to assess whether the rent concessions are lease modifications, and recognised the change in consideration as negative variable lease payments in profit or loss in the period in which the event or condition that triggers the rent concessions occurred.

In the consolidated statement of financial position, the current portion of long-term lease liabilities is determined as the present value of contractual payments that are due to be settled within twelve months after the reporting period.

(i) Credit losses and impairment of assets

(i) *Credit losses from financial instruments*

The Group recognises a loss allowance for expected credit losses (“ECLs”) on the financial assets measured at amortised cost (including cash and cash equivalents and other receivables).

Other financial assets measured at fair value, including equity and debt securities measured at FVPL, are not subject to the ECL assessment.

Measurement of ECLs

ECLs are a probability-weighted estimate of credit losses. Credit losses are measured as the present value of all expected cash shortfalls (i.e. the difference between the cash flows due to the Group in accordance with the contract and the cash flows that the Group expects to receive).

The expected cash shortfalls are discounted using the following discount rates where the effect of discounting is material:

- fixed-rate financial assets, trade and other receivables and contract assets: effective interest rate determined at initial recognition or an approximation thereof;
- variable-rate financial assets: current effective interest rate.

The maximum period considered when estimating ECLs is the maximum contractual period over which the Group is exposed to credit risk.

In measuring ECLs, the Group takes into account reasonable and supportable information that is available without undue cost or effort. This includes information about past events, current conditions and forecasts of future economic conditions.

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ECLs are measured on either of the following bases:

- 12-month ECLs: these are losses that are expected to result from possible default events within the 12 months after the reporting date; and
- lifetime ECLs: these are losses that are expected to result from all possible default events over the expected lives of the items to which the ECL model applies.

Loss allowances for other receivables are always measured at an amount equal to lifetime ECLs. ECLs on these financial assets are estimated using a provision matrix based on the Group’s historical credit loss experience, adjusted for factors that are specific to the debtors and an assessment of both the current and forecast general economic conditions at the reporting date.

For all other financial instruments (including loan commitments issued), the Group recognises a loss allowance equal to 12-month ECLs unless there has been a significant increase in credit risk of the financial instrument since initial recognition, in which case the loss allowance is measured at an amount equal to lifetime ECLs.

Significant increases in credit risk

In assessing whether the credit risk of a financial instrument (including a loan commitment) has increased significantly since initial recognition, the Group compares the risk of default occurring on the financial instrument assessed at the reporting date with that assessed at the date of initial recognition. In making this reassessment, the Group considers that a default event occurs when (i) the borrower is unlikely to pay its credit obligations to the Group in full, without recourse by the Group to actions such as realising security (if any is held); or (ii) the financial asset is 90 days past due. The Group considers both quantitative and qualitative information that is reasonable and supportable, including historical experience and forward-looking information that is available without undue cost or effort.

In particular, the following information is taken into account when assessing whether credit risk has increased significantly since initial recognition:

- failure to make payments of principal or interest on their contractually due dates;
- an actual or expected significant deterioration in a financial instrument’s external or internal credit rating (if available);
- an actual or expected significant deterioration in the operating results of the debtor; and
- existing or forecast changes in the technological, market, economic or legal environment that have a significant adverse effect on the debtor’s ability to meet its obligation to the Group.

Depending on the nature of the financial instruments, the assessment of a significant increase in credit risk is performed on either an individual basis or a collective basis. When the assessment is performed on a collective basis, the financial instruments are grouped based on shared credit risk characteristics, such as past due status and credit risk ratings.

ECLs are remeasured at each reporting date to reflect changes in the financial instrument’s credit risk since initial recognition. Any change in the ECL amount is recognised as an impairment gain or loss in profit or loss. The Group recognises an impairment gain or loss for all financial instruments with a corresponding adjustment to their carrying amount through a loss allowance account.

Basis of calculation of interest income

Interest income recognised in accordance with Note 2(s)(i) is calculated based on the gross carrying amount of the financial asset unless the financial asset is credit-impaired, in which case interest income is calculated based on the amortised cost (i.e. the gross carrying amount less loss allowance) of the financial asset.

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At each reporting date, the Group assesses whether a financial asset is credit-impaired. A financial asset is credit-impaired when one or more events that have a detrimental impact on the estimated future cash flows of the financial asset have occurred.

Evidence that a financial asset is credit-impaired includes the following observable events:

- significant financial difficulties of the debtor;
- a breach of contract, such as a default or past due event;
- it becoming probable that the borrower will enter into bankruptcy or other financial reorganisation;
- significant changes in the technological, market, economic or legal environment that have an adverse effect on the debtor; or
- the disappearance of an active market for a security because of financial difficulties of the issuer.

Write-off policy

The gross carrying amount of a financial asset is written off (either partially or in full) to the extent that there is no realistic prospect of recovery. This is generally the case when the Group or the Company determines that the debtor does not have assets or sources of income that could generate sufficient cash flows to repay the amounts subject to the write-off.

Subsequent recoveries of an asset that was previously written off are recognised as a reversal of impairment in profit or loss in the period in which the recovery occurs.

(ii) Impairment of other non-current assets

Internal and external sources of information are reviewed at the end of each reporting period to identify indications that the following assets may be impaired or, except in the case of goodwill, an impairment loss previously recognised no longer exists or may have decreased:

- property, plant and equipment, including right-of-use assets;
- intangible assets; and
- investments in subsidiaries in the Company’s statement of financial position.

If any such indication exists, the asset’s recoverable amount is estimated. In addition, for intangible assets that are not yet available for use and intangible assets that have indefinite useful lives, the recoverable amount is estimated annually whether or not there is any indication of impairment.

— Calculation of recoverable amount

The recoverable amount of an asset is the greater of its fair value less costs of disposal and value in use. In assessing value in use, the estimated future cash flows are discounted to their present value using a pre-tax discount rate that reflects current market assessments of the time value of money and the risks specific to the asset. Where an asset does not generate cash inflows largely independent of those from other assets, the recoverable amount is determined for the smallest Group of assets that generates cash inflows independently (i.e. a cash-generating unit). A portion of the carrying amount of a corporate asset (for example, head office building) is allocated to an individual cash-generating unit if the allocation can be done on a reasonable and consistent basis, or to the smallest group of cash-generating units if otherwise.

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— *Recognition of impairment losses*

An impairment loss is recognised in profit or loss if the carrying amount of an asset, or the cash-generating unit to which it belongs, exceeds its recoverable amount. Impairment losses recognised in respect of cash-generating units are allocated first to reduce the carrying amount of any goodwill allocated to the cash-generating unit (or group of units) and then, to reduce the carrying amount of the other assets in the unit (or group of units) on a pro rata basis, except that the carrying value of an asset will not be reduced below its individual fair value less costs of disposal (if measurable) or value in use (if determinable).

— *Reversals of impairment losses*

In respect of assets other than goodwill, an impairment loss is reversed if there has been a favourable change in the estimates used to determine the recoverable amount. An impairment loss in respect of goodwill is not reversed.

A reversal of an impairment loss is limited to the asset’s carrying amount that would have been determined had no impairment loss been recognised in prior years. Reversals of impairment losses are credited to profit or loss in the year in which the reversals are recognised.

(j) Inventories and other contract costs

(i) Inventories

Inventories are assets which are held for sale in the ordinary course of business, in the process of production for such sale or in the form of materials or supplies to be consumed in the production process or in the rendering of services.

Inventories are carried at the lower of cost and net realisable value.

Cost is calculated using the weighted average cost formula and comprises all costs of purchase, costs of conversion and other costs incurred in bringing the inventories to their present location and condition.

Net realisable value is the estimated selling price in the ordinary course of business less the estimated costs of completion and the estimated costs necessary to make the sale.

When inventories are sold, the carrying amount of those inventories is recognised as an expense in the period in which the related revenue is recognised.

The amount of any write-down of inventories to net realisable value and all losses of inventories are recognised as an expense in the period the write-down or loss occurs. The amount of any reversal of any write-down of inventories is recognised as a reduction in the amount of inventories recognised as an expense in the period in which the reversal occurs.

(ii) Other contract costs

Other contract costs are either the incremental costs of obtaining a contract with a customer or the costs to fulfil a contract with a customer which are not capitalised as inventory (see note 2(j)(i)), property, plant and equipment (see note 2(f)) or intangible assets (see note 2(g)).

Incremental costs of obtaining a contract are capitalised if the costs relate to income which will be recognised in a future reporting period and the costs are expected to be recovered. Other costs of obtaining a contract are expensed when incurred.

Costs to fulfil a contract are capitalised if the costs relate directly to an existing contract or to a specifically identifiable anticipated contract; generate or enhance resources that will be used to provide goods or services in the future; and are expected to be recovered. Otherwise, costs of fulfilling a contract, which are not capitalised as inventory, property, plant and equipment or intangible assets, are expensed as incurred.

Capitalised contract costs are stated at cost less accumulated amortisation and impairment losses.

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(k) Receivables

A receivable is recognised when the Group has an unconditional right to receive consideration. A right to receive consideration is unconditional if only the passage of time is required before payment of that consideration is due.

All receivables are subsequently stated at amortised cost, using the effective interest method and including an allowance for credit losses (see Note 2(i)(i)).

(l) Cash and cash equivalents

Cash and cash equivalents comprise cash at bank and on hand, demand deposits with banks and other financial institutions, and short-term, highly liquid investments that are readily convertible into known amounts of cash and which are subject to an insignificant risk of changes in value, having been within three months of maturity at acquisition. Bank overdrafts that are repayable on demand and form an integral part of the Group’s cash management are also included as a component of cash and cash equivalents for the purpose of the consolidated cash flow statement. Cash and cash equivalents are assessed for ECLs in accordance with the policy set out in Note 2(i)(i).

(m) Trade and other payables and contract liabilities

(i) Trade and other payables

Trade and other payables are initially recognised at fair value. Subsequent to initial recognition, trade and other payables are stated at amortised cost unless the effect of discounting would be immaterial, in which case they are stated at cost.

(ii) Contract liabilities

A contract liability is recognised when the customer pays non-refundable consideration before the Group recognises the related income. A contract liability would also be recognised if the Group has an unconditional right to receive non-refundable consideration before the Group recognises the related income. In such cases, a corresponding receivable would also be recognised (see Note 2(k)).

(n) Financial instruments issued to investors with preferred rights

A contract that contains an obligation to purchase the Company’s equity instruments for cash or another financial asset gives rise to a financial liability even if the Company’s obligation to purchase is conditional on the counterparty exercising a right to redeem. The financial instruments issued to investors with preferred rights are recognised as financial liabilities initially at the present value of the redemption amount, and are reclassified from equity. Subsequently, changes in the carrying amount of the financial liabilities are recognised in profit or loss.

The Group derecognises the financial liability when, and only when, the Group’s obligations are discharged, cancelled or have expired. Upon a termination of the redemption obligation, the carrying amount of the financial instruments derecognised was credited into the equity.

(o) Interest-bearing borrowings

Interest-bearing borrowings are measured initially at fair value less transaction costs. Subsequent to initial recognition, interest-bearing borrowings are stated at amortised cost using the effective interest method. Interest expense is recognised in accordance with the Group’s accounting policy for borrowing costs (see Note 2(u)).

Fees paid on the establishment of loan facilities are recognised as transaction costs of the loan to the extent that it is probable that some or all of the facility will be drawn down. In this case, the fee is deferred and treated as an adjustment to the loan’s effective interest rate and recognised as an expense over the period of the loan facility to which it relates.

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(p) Employee benefits

(i) *Short-term employee benefits and contributions to defined contribution retirement plans*

Salaries, annual bonuses, paid annual leave, contributions to defined contribution retirement plans and the cost of non-monetary benefits are accrued in the year in which the associated services are rendered by employees. Where payment or settlement is deferred and the effect would be material, these amounts are stated at their present values.

(ii) *Share-based payments*

The fair value of equity-settled share-based payments awards granted to employees is recognised as an employee cost with a corresponding increase in a capital reserve within equity. The fair value is measured at grant date using the valuation techniques, taking into account the terms and conditions upon which the equity-settled share-based payments awards were granted. Where the employees have to meet vesting conditions before becoming unconditionally entitled to the equity-settled share-based payments awards, the total estimated fair value of the equity-settled share-based payments awards is spread over the vesting period, taking into account the probability that the equity-settled share-based payments awards will vest.

During the vesting period, the number of equity-settled share-based payments awards that is expected to vest is reviewed. Any resulting adjustment to the cumulative fair value recognised in prior years is charged/credited to the profit or loss for the year of the review, unless the original employee expenses qualify for recognition as an asset, with a corresponding adjustment to the capital reserve. On vesting date, the amount recognised as an expense is adjusted to reflect the actual number of equity-settled share-based payments awards that vest (with a corresponding adjustment to the capital reserve) except where forfeiture is only due to not achieving vesting conditions that relate to the market price of the Company's shares. The equity amount is recognised in the capital reserve until either the equity-settled share-based payments award is exercised (when it is included in the amount recognised in share capital for the shares issued) or the equity-settled share-based payments award expires (when it is released directly to retained profits).

Modifications of an equity settled share-based payment arrangement are accounted for only if they are beneficial to the employee. If the Group modifies the terms and conditions of the equity instruments granted in a manner that reduces the fair value of the equity instruments granted, or is not otherwise beneficial to the employee, the Group continues to recognize the services received measured as the grant date fair value of the equity instruments granted, unless those equity instruments do not vest because of failure to satisfy a vesting condition (other than a market condition) that was specified at grant date.

(iii) *Termination benefits*

Termination benefits are recognised at the earlier of when the Group can no longer withdraw the offer of those benefits and when it recognises restructuring costs involving the payment of termination benefits.

(q) Income tax

Income tax for the year comprises current tax and movements in deferred tax assets and liabilities. Current tax and movements in deferred tax assets and liabilities are recognised in profit or loss except to the extent that they relate to items recognised in other comprehensive income or directly in equity, in which case the relevant amounts of tax are recognised in other comprehensive income or directly in equity, respectively.

Current tax is the expected tax payable on the taxable income for the year, using tax rates enacted or substantively enacted at the end of the reporting period, and any adjustment to tax payable in respect of previous years.

Deferred tax assets and liabilities arise from deductible and taxable temporary differences respectively, being the differences between the carrying amounts of assets and liabilities for financial reporting purposes and their tax bases. Deferred tax assets also arise from unused tax losses and unused tax credits.

Apart from certain limited exceptions, all deferred tax liabilities, and all deferred tax assets to the extent that it is probable that future taxable profits will be available against which the asset can be utilised, are recognised. Future taxable profits that may support the recognition of deferred tax assets arising from deductible temporary differences include those that will arise from the reversal of existing taxable temporary differences, provided those

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differences relate to the same taxation authority and the same taxable entity, and are expected to reverse either in the same period as the expected reversal of the deductible temporary difference or in periods into which a tax loss arising from the deferred tax asset can be carried back or forward. The same criteria are adopted when determining whether existing taxable temporary differences support the recognition of deferred tax assets arising from unused tax losses and credits, that is, those differences are taken into account if they relate to the same taxation authority and the same taxable entity, and are expected to reverse in a period, or periods, in which the tax loss or credit can be utilised.

The limited exceptions to recognition of deferred tax assets and liabilities are those temporary differences arising from goodwill not deductible for tax purposes, the initial recognition of assets or liabilities that affect neither accounting nor taxable profit (provided they are not part of a business combination), and temporary differences relating to investments in subsidiaries to the extent that, in the case of taxable differences, the Group controls the timing of the reversal and it is probable that the differences will not reverse in the foreseeable future, or in the case of deductible differences, unless it is probable that they will reverse in the future.

The amount of deferred tax recognised is measured based on the expected manner of realisation or settlement of the carrying amount of the assets and liabilities, using tax rates enacted or substantively enacted at the end of the reporting period. Deferred tax assets and liabilities are not discounted.

The carrying amount of a deferred tax asset is reviewed at the end of each reporting period and is reduced to the extent that it is no longer probable that sufficient taxable profits will be available to allow the related tax benefit to be utilised. Any such reduction is reversed to the extent that it becomes probable that sufficient taxable profits will be available.

Additional income taxes that arise from the distribution of dividends are recognised when the liability to pay the related dividends is recognised.

Current tax balances and deferred tax balances, and movements therein, are presented separately from each other and are not offset. Current tax assets are offset against current tax liabilities, and deferred tax assets against deferred tax liabilities, if the Company or the Group has the legally enforceable right to set off current tax assets against current tax liabilities and the following additional conditions are met:

- in the case of current tax assets and liabilities, the Company or the Group intends either to settle on a net basis, or to realise the asset and settle the liability simultaneously; or
- in the case of deferred tax assets and liabilities, if they relate to income taxes levied by the same taxation authority on either:
 - the same taxable entity; or
 - different taxable entities, which, in each future period in which significant amounts of deferred tax liabilities or assets are expected to be settled or recovered, intend to realise the current tax assets and settle the current tax liabilities on a net basis or realise and settle simultaneously.

(r) Provisions and contingent liabilities

Provisions are recognised when the Group has a legal or constructive obligation arising as a result of a past event, it is probable that an outflow of economic benefits will be required to settle the obligation and a reliable estimate can be made. Where the time value of money is material, provisions are stated at the present value of the expenditure expected to settle the obligation.

Where it is not probable that an outflow of economic benefits will be required, or the amount cannot be estimated reliably, the obligation is disclosed as a contingent liability, unless the probability of outflow of economic benefits is remote. Possible obligations, whose existence will only be confirmed by the occurrence or non-occurrence of one or more future events are also disclosed as contingent liabilities unless the probability of outflow of economic benefits is remote.

Where some or all of the expenditure required to settle a provision is expected to be reimbursed by another party, a separate asset is recognised for any expected reimbursement that would be virtually certain. The amount recognised for the reimbursement is limited to the carrying amount of the provision.

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(s) Other income

Further details of the Group’s other income recognition policy are as follows:

(i) Interest income

Interest income is recognised as it accrues under the effective interest method using the rate that exactly discounts estimated future cash receipts through the expected life of the financial asset to the gross carrying amount of the financial asset. For financial assets measured at amortised cost or FVOCI (recycling) that are not credit-impaired, the effective interest rate is applied to the gross carrying amount of the asset. For credit-impaired financial assets, the effective interest rate is applied to the amortised cost (i.e. gross carrying amount net of loss allowance) of the asset (see Note 2(i)(i)).

(ii) Government grants

Government grants are recognised in the statement of financial position initially when there is reasonable assurance that they will be received and that the Group will comply with the conditions attaching to them. Grants that compensate the Group for expenses incurred are recognised as income in profit or loss on a systematic basis in the same periods in which the expenses are incurred. Grants that compensate the Group for the cost of an asset are recognised as deferred income and subsequently recognised in profit or loss on a systematic basis over the useful life of the asset.

(t) Translation of foreign currencies

Foreign currency transactions during the year are translated at the foreign exchange rates ruling at the transaction dates. Monetary assets and liabilities denominated in foreign currencies are translated at the foreign exchange rates ruling at the end of the reporting period. Exchange gains and losses are recognised in profit or loss.

Non-monetary assets and liabilities that are measured in terms of historical cost in a foreign currency are translated using the foreign exchange rates ruling at the transaction dates. The transaction date is the date on which the Company initially recognises such non-monetary assets or liabilities. Non-monetary assets and liabilities denominated in foreign currencies that are stated at fair value are translated using the foreign exchange rates ruling at the dates the fair value was measured.

(u) Borrowing costs

Borrowing costs that are directly attributable to the acquisition, construction or production of an asset which necessarily takes a substantial period of time to get ready for its intended use or sale are capitalised as part of the cost of that asset. Other borrowing costs are expensed in the period in which they are incurred.

The capitalisation of borrowing costs as part of the cost of a qualifying asset commences when expenditure for the asset is being incurred, borrowing costs are being incurred and activities that are necessary to prepare the asset for its intended use or sale are in progress. Capitalisation of borrowing costs is suspended or ceases when substantially all the activities necessary to prepare the qualifying asset for its intended use or sale are interrupted or complete.

(v) Related parties

(a) A person, or a close member of that person’s family, is related to the Group if that person:

(i) has control or joint control over the Group;

(ii) has significant influence over the Group; or

(iii) is a member of the key management personnel of the Group or the Group’s parent.

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- (b) An entity is related to the Group if any of the following conditions applies:
- (i) The entity and the group are members of the same group (which means that each parent, subsidiary and fellow subsidiary is related to the others).
 - (ii) One entity is an associate or joint venture of the other entity (or an associate or joint venture of a member of a Group of which the other entity is a member).
 - (iii) Both entities are joint ventures of the same third party.
 - (iv) One entity is a joint venture of a third entity and the other entity is an associate of the third entity.
 - (v) The entity is a post-employment benefit plan for the benefit of employees of either the group or an entity related to the Group.
 - (vi) The entity is controlled or jointly controlled by a person identified in (a).
 - (vii) A person identified in (a)(i) has significant influence over the entity or is a member of the key management personnel of the entity (or of a parent of the entity).
 - (viii) The entity, or any member of a group of which it is a part, provides key management personnel services to the Group or to the Group's parent.

Close members of the family of a person are those family members who may be expected to influence, or be influenced by, that person in their dealings with the entity.

(w) Segment reporting

Operating segments, and the amounts of each segment item reported in the financial statements, are identified from the financial information provided regularly to the Group's most senior executive management for the purposes of allocating resources to, and assessing the performance of, the Group's various lines of business and geographical locations.

Individually material operating segments are not aggregated for financial reporting purposes unless the segments have similar economic characteristics and are similar in respect of the nature of products and services, the nature of production processes, the type or class of customers, the methods used to distribute the products or provide the services, and the nature of the regulatory environment. Operating segments which are not individually material may be aggregated if they share a majority of these criteria.

3 ACCOUNTING JUDGEMENT AND ESTIMATES

(a) Critical accounting judgements in applying the Group's accounting policies

In the process of applying the Group's accounting policies, management has made the following accounting judgement:

(i) *Research and development expenses*

Development expenses incurred on the Group's pipelines are capitalised and deferred only when the Group can demonstrate the technical feasibility of completing the intangible asset so that it will be available for use or sale, the Group's intention to complete and the Group's ability to use or sell the asset, how the asset will generate future economic benefits, the availability of resources to complete the pipeline and the ability to measure reliably the expenditure during the development. Development expenses which do not meet these criteria are expensed when incurred. Management will assess the progress of each of the research and development projects and determine the criteria met for capitalisation. All development expenses were expensed when incurred during the Relevant Periods.

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(b) Sources of estimation uncertainty

Notes 25 and 26 contains information about the assumptions and risk factors relating to fair value of financial instruments and equity settled share-based transactions. Other key sources of estimation uncertainty are as follows:

(i) *Depreciation*

Property, plant and equipment are depreciated on a straight-line basis over the estimated useful lives of the assets, after taking into account the estimated residual values. The Group reviews the estimated useful lives of the assets regularly in order to determine the amount of depreciation expenses to be recorded during the Relevant Periods. The useful lives are based on the Group’s historical experience with similar assets and taking into account anticipated technological changes. The depreciation expenses for future periods are adjusted if there are significant changes from previous estimates.

(ii) *Income tax*

Determining income tax provisions involves judgement on the future tax treatment of certain transactions. The management carefully evaluates tax implications of transactions and tax provisions are set up accordingly. The tax treatment of these transactions is reconsidered periodically to take into account changes in tax legislations. Deferred tax assets are recognised for deductible temporary differences and cumulative tax losses.

As those deferred tax assets can only be recognised to the extent that it is probable that future taxable profit will be available against which they can be utilised, management’s judgement is required to assess the probability of future taxable profits. Management’s assessment is constantly reviewed and additional deferred tax assets are recognised if it becomes probable that future taxable profits will allow the deferred tax asset to be recovered.

(iii) *Impairment of non-current assets*

If circumstances indicate that the carrying amount of a non-current asset may not be recoverable, the asset may be considered “impaired”, and an impairment loss would be recognised in accordance with accounting policy for impairment of non-current assets as described in Note 2(i)(ii). The carrying amounts of the Group’s non-current assets, including property, plant and equipment, right-of-use assets, and intangible assets are reviewed periodically to determine whether there is any indication of impairment. These assets are tested for impairment whenever events or changes in circumstances indicate that their recorded carrying amounts may not be recoverable. The recoverable amount of an asset or cash-generating unit is the greater of its value in use and the fair value less costs to sell. An impairment loss is recognised if the carrying amount of an asset or its cash-generating unit exceeds its estimated recoverable amount. It is difficult to precisely estimate selling price of the Group’s non-current assets because quoted market prices for such assets may not be readily available. In determining the value in use, expected future cash flows generated by the asset are discounted to their present value, which requires significant judgement relating to level of revenue, amount of operating costs and applicable discount rate. Management uses all readily available information in determining an amount that is a reasonable approximation of recoverable amount, including estimates based on reasonable and supportable assumptions and projections of revenue and amount of operating costs.

(iv) *Determining the lease term*

As explained in Note 2(h), the lease liability is initially recognised at the present value of the lease payments payable over the lease term. In determining the lease term at the commencement date for leases that include renewal options exercisable by the Group, the Group evaluates the likelihood of exercising the renewal options taking into account all relevant facts and circumstances that create an economic incentive for the Group to exercise the option, including favourable terms, leasehold improvements undertaken and the importance of that underlying asset to the Group’s operation. The lease term is reassessed when there is a significant event or significant change in circumstance that is within the Group’s control. Any increase or decrease in the lease term would affect the amount of lease liabilities and right-of-use assets recognised in future years.

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4 SEGMENT REPORTING

(a) Segment reporting

For the purpose of resource allocation and performance assessment, the Group’s chief executive officer, being the chief operating decision maker, reviews the consolidated results when making decisions about allocating resources and assessing performance of the Group as a whole and hence, the Group has only one reportable segment which is engaged in the research and development of biologic therapies for autoimmune and allergic diseases and no further analysis of this single segment is presented during the Relevant Periods.

(b) Geographic information

All of the non-current assets of the Group are physically located in the PRC. The geographical location of customers is based on the location at which the customers operate is all derived from operations in the PRC during the Relevant Periods.

5 OTHER INCOME AND OTHER NET (LOSS)/GAIN

(a) Other income

	Year ended 31 December 2021	Year ended 31 December 2022	Nine months ended 30 September	
	<u>RMB'000</u>	<u>RMB'000</u>	<u>2022</u>	<u>2023</u>
			<i>(Unaudited)</i>	
			<u>RMB'000</u>	<u>RMB'000</u>
Government grants (including amortisation of deferred income, see Note 23) (i)	19,978	9,194	1,847	4,340
Interest income from bank deposits	3,458	4,167	2,541	3,639
Interest income from loans to a related party	3,600	—	—	—
Net realised and unrealised gains on financial assets measured at FVPL	6,479	11,897	9,203	4,605
Others	1,371	468	208	695
	<u>34,886</u>	<u>25,726</u>	<u>13,799</u>	<u>13,279</u>

(i) Government grants mainly represent (i) government subsidies for encouragement of research and development activities and compensation on the incurred interest expenses of bank loans, which were recognised in profit or loss when received; (ii) government subsidies for compensation on certain capital expenditure incurred for the construction of manufacturing facilities, which were recognised in profit or loss when amortised over the estimated useful lives of the relevant assets (see Note 23).

(b) Other net (loss)/gain

	Year ended 31 December 2021	Year ended 31 December 2022	Nine months ended 30 September	
	<u>RMB'000</u>	<u>RMB'000</u>	<u>2022</u>	<u>2023</u>
			<i>(Unaudited)</i>	
			<u>RMB'000</u>	<u>RMB'000</u>
Net foreign exchange (loss)/gain	(2,722)	14,457	17,249	(66)
Others	(95)	(55)	(55)	(9)
	<u>(2,817)</u>	<u>14,402</u>	<u>17,194</u>	<u>(75)</u>

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6 LOSS BEFORE TAXATION

Loss before taxation is arrived at after charging/(crediting):

(a) Finance costs

	Year ended 31 December 2021	Year ended 31 December 2022	Nine months ended 30 September 2022		2023
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	
			<i>(Unaudited)</i>		
Interest on lease liabilities <i>(Note 19(c))</i>	76	99	74	53	
Interest on interest-bearing borrowings <i>(Note 19(c))</i>	18,457	18,593	13,913	12,193	
Total finance costs on financial liabilities not at FVPL	18,533	18,692	13,987	12,246	
Less: interest capitalised into properties under construction <i>(Note 19(c))</i>	(691)	—	—	—	
	<u>17,842</u>	<u>18,692</u>	<u>13,987</u>	<u>12,246</u>	

(b) Staff costs

	Year ended 31 December 2021	Year ended 31 December 2022	Nine months ended 30 September 2022		2023
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	
			<i>(Unaudited)</i>		
Salaries, wages and other benefits	55,279	69,164	53,919	65,258	
Contributions to defined contribution retirement schemes <i>(i)</i>	4,364	6,563	3,565	4,746	
Equity-settled share-based payment expenses <i>(Note 26(c))</i>	11,730	41,556	4,370	99,488	
	<u>71,373</u>	<u>117,283</u>	<u>61,854</u>	<u>169,492</u>	

- (i) Pursuant to the relevant labor rules and regulations in the PRC, the Company and its subsidiaries in the PRC to participate in defined contribution retirement benefit schemes (the “Schemes”) organised by the local government authorities whereby the Company and its subsidiaries in the PRC are required to make contributions to the Schemes based on certain percentages of the eligible employee’s salaries. The local government authorities are responsible for the entire pension obligations payable to the retired employees.

The Group has no other material obligation for the payment of retirement benefits associated with the scheme beyond the annual contributions described above.

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(c) Other items

	Year ended 31 December 2021 <i>RMB'000</i>	Year ended 31 December 2022 <i>RMB'000</i>	Nine months ended 30 September 2022 2023 <i>RMB'000</i> <i>(Unaudited)</i>	
Amortisation cost of intangible assets	78	338	166	530
Depreciation charge of property, plant and equipment (<i>Note 11</i>)	23,618	28,310	21,051	21,934
Depreciation charge of right-of-use assets (<i>Note 12</i>)	1,948	1,892	1,377	1,622
Total amortisation and depreciation	<u>25,644</u>	<u>30,540</u>	<u>22,594</u>	<u>24,086</u>
Auditors’ remuneration	1,925	2,001	1,304	1,757
[REDACTED] expenses (<i>i</i>)	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Research and development expenses (<i>ii</i>) (<i>iii</i>)	151,887	257,214	189,749	263,270

- (i) During the year ended 31 December 2021 and 2022 and the nine months ended 30 September 2022 and 2023, the Group recognised auditors’ remuneration in respect of [REDACTED] of RMB1,762,000, RMB1,931,000, RMB1,234,000 (unaudited) and RMB1,586,000 respectively, which is also included in the [REDACTED] expenses disclosed separately above.
- (ii) During the year ended 31 December 2021 and 2022 and the nine months ended 30 September 2022 and 2023, research and development expenses include staff costs and depreciation and amortisation expenses of RMB71,863,000, RMB93,029,000, RMB62,787,000 (unaudited) and RMB87,871,000 respectively, which are also included in the respective total amounts disclosed separately above.
- (iii) During the year ended 31 December 2021, research and development expenses has been reduced by RMB18,868,000, which was a reimbursement of research and development (“R&D”) expenses incurred for QX001S received from Hangzhou Zhongmei Huadong Pharmaceutical Co., Ltd. (杭州中美華東製藥有限公司) (“Zhongmei Huadong”), one of the shareholders of the Company.

In August 2020, the Group entered into a collaboration agreement (the “QX001S Agreement”) with Zhongmei Huadong with respect to the joint development and commercialization of QX001S in China. Pursuant to the QX001S Agreement, the Group granted Zhongmei Huadong joint clinical development, manufacturing and exclusive commercialization rights of QX001S in mainland China. During the term of the QX001S Agreement, Zhongmei Huadong shall be responsible for any expenses related to the clinical research and registrational matters of QX001S during R&D stage; the Group shall be responsible for expenses related to the sample production and manufacturing process optimisation of QX001S. During commercialisation stage, the Group shall be solely responsible for the commercial production and quality control of QX001S; and Zhongmei Huadong shall be the marketing authorization holder (MAH) of QX001S in mainland China to exclusively conduct marketing activities and commercialization of QX001S. The parties agree that the pre-tax profit generated from sales of QX001S in China (as calculated pursuant to the QX001S Agreement) shall be shared by the two parties on a 50%:50% basis. As such, the Group accounted for the QX001S Agreement as joint operation.

Pursuant to the QX001S Agreement, the Group has received a milestone payment of RMB20 million (including value-added tax) from Zhongmei Huadong in 2021 to compensate the Group for incurred R&D costs was received and recognised as a reduction of the Group’s research and development.

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7 INCOME TAX IN THE CONSOLIDATED STATEMENTS OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

(a) Taxation in the consolidated statements of profit or loss represents:

	Year ended 31 December 2021	Year ended 31 December 2022	Nine months ended 30 September 2023	
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
			<i>(Unaudited)</i>	
Current tax—PRC Tax	—	—	—	—
Deferred tax	(73)	(73)	(55)	(55)
	<u>(73)</u>	<u>(73)</u>	<u>(55)</u>	<u>(55)</u>

(b) Reconciliation between tax expense and accounting loss at applicable tax rates:

	Year ended 31 December 2021	Year ended 31 December 2022	Nine months ended 30 September 2023	
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
			<i>(Unaudited)</i>	
Loss before taxation	<u>(426,544)</u>	<u>(312,381)</u>	<u>(205,980)</u>	<u>(385,559)</u>
Notional tax on loss before taxation, calculated at the rates applicable to profits in the PRC <i>(i)</i>	(106,636)	(78,095)	(51,495)	(96,390)
Effect of preferential tax rate <i>(ii)</i>	37,993	25,816	17,308	33,897
Effect of additional deduction on research and development expenses <i>(iii)</i>	(11,717)	(24,146)	(16,512)	(28,704)
Tax effect of changes in the carrying amount of financial instruments issued to investors	36,012	—	—	—
Tax effect of other non-deductible expenses	445	493	96	495
Tax effect of deductible temporary differences not recognised	1,024	9,255	5,126	21,364
Tax effect of unused tax losses not recognised	<u>42,806</u>	<u>66,604</u>	<u>45,422</u>	<u>69,283</u>
Actual tax expense	<u>(73)</u>	<u>(73)</u>	<u>(55)</u>	<u>(55)</u>

(i) Pursuant to the Enterprise Income Tax (the “EIT”) Law of the PRC (the “EIT Law”), the Company and its PRC subsidiaries are liable to EIT at a rate of 25% unless otherwise specified.

(ii) According to the Administrative Measures for Determination of High-Tech Enterprises (Guokefahuo [2016] No. 32) issued by Ministry of Finance of the People’s Republic of China, Ministry of Science and Technology of the People’s Republic of China and National Taxation Bureau of the People’s Republic of China, the Company obtained the qualification as high-tech enterprise and was entitled to a preferential income tax rate of 15% for the years from 2021 to 2023.

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- (iii) According to the tax incentive policies promulgated by the State Tax Bureau of the PRC, which were effective from 1 January 2018 to 30 September 2022, an additional 75% of qualified research and development expenses incurred would be allowed to be deducted from the taxable income.

According to a new tax incentives policy promulgated by the State Tax Bureau of the PRC in September 2022, an additional 100% of qualified expenses incurred from 1 October 2022 to 31 December 2023 is allowed to be deducted from the taxable income.

(c) Movement of deferred tax liabilities

The components of deferred tax liabilities recognised in the consolidated statements of financial position and the movements during the years are as follows:

	Depreciation charge of property, plant and equipment
	<i>RMB'000</i>
Deferred tax arising from:	
At 1 January 2021	632
Credited to profit or loss	<u>(73)</u>
At 31 December 2021 and 1 January 2022	559
Credited to profit or loss	<u>(73)</u>
31 December 2022 and 1 January 2023	486
Credited to profit or loss	<u>(55)</u>
30 September 2023	<u><u>431</u></u>

(d) Deferred tax assets not recognised

As at 31 December 2021, 2022 and 30 September 2023, the Group has not recognised deferred tax assets in respect of their respective cumulative tax losses of RMB601,407,000 and RMB992,871,000 and RMB1,381,922,000 and temporary differences of RMB75,821,000, RMB122,657,000 and RMB264,968,000 respectively, in accordance with the accounting policy set out in Note 2(q), as it is not probable that future taxable profits against which the losses can be utilised will be available in the relevant tax jurisdiction and entity.

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8 DIRECTORS’ EMOLUMENTS

Details of the emoluments of the directors and supervisors of the Company during the Relevant Periods are as follows:

For the year ended 31 December 2021	Salaries, allowances and benefits in kind	Discretionary bonuses	Retirement scheme contributions	Sub-total	Share-based payments	Total
	RMB’000	RMB’000	RMB’000	RMB’000	RMB’000	RMB’000
Executive directors						
Mr. Qiu Jiwan (裘霽宛) (i)	1,874	720	30	2,624	3,610	6,234
Mr. Wu Yiliang (吳亦亮) (ii)	1,095	300	30	1,425	1,203	2,628
Mr. Lin Weidong (林偉棟) (xi)	464	143	25	632	—	632
Non-executive directors						
Dr. Yu Guoliang (余國良) (iii)	—	—	—	—	1,203	1,203
Mr. Yu Xi (余熹) (iv)	—	—	—	—	—	—
Mr. Zhang Chunfeng (張純峰) (v)	—	—	—	—	—	—
Dr. Xue Mingyu (薛明宇) (vi)	—	—	—	—	—	—
Mr. Wu Zhiqiang (吳志強) (vii)	—	—	—	—	—	—
Supervisors						
Ms. Wang Yujiao (王玉姣) (viii)	613	160	30	803	361	1,164
Ms. Zhang Jie (張潔) (ix)	—	—	—	—	—	—
Mr. Ye Xiang (葉翔) (x)	—	—	—	—	—	—
	4,046	1,323	115	5,484	6,377	11,861
For the year ended 31 December 2022						
	RMB’000	RMB’000	RMB’000	RMB’000	RMB’000	RMB’000
Executive directors						
Mr. Qiu Jiwan (裘霽宛) (i)	1,877	720	32	2,629	18,470	21,099
Mr. Wu Yiliang (吳亦亮) (ii)	1,102	300	32	1,434	1,916	3,350
Mr. Lin Weidong (林偉棟) (xi)	1,281	400	63	1,744	2,010	3,754
Non-executive directors						
Dr. Yu Guoliang (余國良) (iii)	—	—	—	—	2,216	2,216
Mr. Yu Xi (余熹) (iv)	—	—	—	—	—	—
Dr. Xue Mingyu (薛明宇) (vi)	—	—	—	—	—	—
Mr. Wu Zhiqiang (吳志強) (vii)	—	—	—	—	—	—
Supervisors						
Ms. Wang Yujiao (王玉姣) (viii)	621	160	32	813	1,426	2,239
Ms. Zhang Jie (張潔) (ix)	—	—	—	—	—	—
Mr. Ye Xiang (葉翔) (x)	—	—	—	—	—	—
Dr. Ding Chao (丁超) (xii)	—	—	—	—	—	—
	4,881	1,580	159	6,620	26,038	32,658

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For the nine months ended 30 September 2022 (Unaudited)	Salaries, allowances and benefits in kind	Discretionary bonuses	Retirement scheme contributions	Sub-total	Share-based payments	Total
	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
Executive directors						
Mr. Qiu Jiwan (裘霽宛) (i)	1,406	540	27	1,973	1,169	3,142
Mr. Wu Yiliang (吳亦亮) (ii)	825	225	27	1,077	390	1,467
Mr. Lin Weidong (林偉棟) (xi)	970	300	43	1,313	–	1,313
Non-executive directors						
Dr. Yu Guoliang (余國良) (iii)	–	–	–	–	1,451	1,451
Mr. Yu Xi (余熹) (iv)	–	–	–	–	–	–
Dr. Xue Mingyu (薛明宇) (vi)	–	–	–	–	–	–
Mr. Wu Zhiqiang (吳志強) (vii)	–	–	–	–	–	–
Supervisors						
Ms. Wang Yujiao (王玉姣) (viii)	464	122	26	612	117	729
Ms. Zhang Jie (張潔) (ix)	–	–	–	–	–	–
Mr. Ye Xiang (葉翔) (x)	–	–	–	–	–	–
	3,665	1,187	123	4,975	3,127	8,102

For the nine months ended 30 September 2023	Salaries, allowances and benefits in kind	Discretionary bonuses	Retirement scheme contributions	Sub-total	Share-based payments	Total
	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
Executive directors						
Mr. Qiu Jiwan (裘霽宛) (i)	1,400	540	34	1,974	43,592	45,566
Mr. Wu Yiliang (吳亦亮) (ii)	802	225	35	1,062	3,763	4,825
Mr. Lin Weidong (林偉棟) (xi)	950	300	50	1,300	5,448	6,748
Non-executive directors						
Mr. Yu Xi (余熹) (iv)	–	–	–	–	–	–
Dr. Xue Mingyu (薛明宇) (vi)	–	–	–	–	–	–
Mr. Wu Zhiqiang (吳志強) (vii)	–	–	–	–	–	–
Supervisors						
Ms. Wang Yujiao (王玉姣) (viii)	455	120	34	609	3,277	3,886
Mr. Ye Xiang (葉翔) (x)	–	–	–	–	–	–
Dr. Ding Chao (丁超) (xii)	–	–	–	–	–	–
	3,607	1,185	153	4,945	56,080	61,025

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Notes:

- (i) Mr. Qiu Jiwan (裘霽宛) was appointed as an executive director of the Company on 16 June 2015. He was key management personnel of the Group and his remuneration disclosed above included those for services rendered by him as key management personnel.
- (ii) Mr. Wu Yiliang (吳亦亮) was appointed as an executive director of the Company on 10 April 2019. He was key management personnel of the Group and his remuneration disclosed above included those for services rendered by him as key management personnel.
- (iii) Dr. Yu Guoliang (余國良) was appointed as a non-executive director of the Company on 16 June 2015 and resigned on 16 February 2022 due to his plan to devote to his personal business. He was appointed as a consultant of the Group after his resignation as a non-executive director.
- (iv) Mr. Yu Xi (余熹) was appointed as a non-executive director of the Company on 14 August 2020.
- (v) Mr. Zhang Chunfeng (張純峰) was appointed as a non-executive director of the Company on 10 April 2019 which was nominated by two of the shareholders of the Company and resigned on 17 September 2021 due to his departure from the relevant shareholders.
- (vi) Dr. Xue Mingyu (薛明宇) was appointed as a non-executive director of the Company on 29 March 2021.
- (vii) Mr. Wu Zhiqiang (吳志強) was appointed as a non-executive director of the Company on 17 September 2021.
- (viii) Ms. Wang Yujiao (王玉姣) was appointed as a supervisor of the Company on 17 September 2021. She was also an employee of the Group during the Relevant Periods and the Group paid emoluments to her in her capacity as the employee of the Group before her appointment as a supervisor of the Company.
- (ix) Ms. Zhang Jie (張潔) was appointed as a supervisor of the Company on 14 August 2020 which was nominated by one of the shareholders of the Company and resigned on 15 September 2022 due to her departure from the relevant shareholder.
- (x) Mr. Ye Xiang (葉翔) was appointed as a supervisor of the Company on 17 September 2021.
- (xi) Mr. Lin Weidong (林偉棟) was appointed as an executive director of the Company on 16 March 2022. He was key management personnel of the Group and his remuneration disclosed above included those for services rendered by him as key management personnel.
- (xii) Dr. Ding Chao (丁超) was appointed as a supervisor of the Company on 15 September 2022.
- (xiii) During the year ended 31 December 2021 and 2022 and the nine months ended 30 September 2022 (unaudited) and 2023, there were no amounts paid or payable by the Group to the directors or any of the highest paid individuals set out in Note 9 below as an inducement to join or upon joining the Group or as a compensation for loss of office.

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9 INDIVIDUALS WITH HIGHEST EMOLUMENTS

During the Relevant Periods, of the five individuals with the highest emoluments of the Group, two and three are directors for the year ended 31 December 2021 and 2022 and the nine months ended 30 September 2022 (unaudited) and 2023, respectively, whose emoluments are disclosed in Note 8. The aggregate of the emoluments in respect of the remaining individuals during the Relevant Periods are as follows:

	Year ended 31 December 2021	Year ended 31 December 2022	Nine months ended 30 September	
	<u>2021</u>	<u>2022</u>	<u>2022</u>	<u>2023</u>
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
			<i>(Unaudited)</i>	
Salaries, allowances and benefits in kind	3,268	2,612	1,958	1,080
Discretionary bonuses	1,076	900	675	432
Retirement scheme contributions	92	58	42	—
Equity-settled share-based payments	1,310	4,630	428	7,887
	<u>5,746</u>	<u>8,200</u>	<u>3,103</u>	<u>9,399</u>

The emoluments of the individuals who are not director or supervisor and with the highest emoluments are within the following bands:

	Year ended 31 December		Nine months ended 30 September	
	<u>2021</u>	<u>2022</u>	<u>2022</u>	<u>2023</u>
	<i>Number of individuals</i>	<i>Number of individuals</i>	<i>Number of individuals</i>	<i>Number of individuals</i>
			<i>(Unaudited)</i>	
Hong Kong Dollar (“HK\$”)				
1,500,001 – HK\$2,000,000	1	—	2	—
HK\$2,000,001 – HK\$2,500,000	1	—	—	—
HK\$2,500,001 – HK\$3,000,000	1	—	—	—
HK\$3,500,001 – HK\$4,000,000	—	1	—	—
HK\$5,500,001 – HK\$6,000,000	—	1	—	—
HK\$10,000,001 – HK\$15,000,000	—	—	—	1

10 LOSS PER SHARE

Basic loss per share is calculated by dividing the loss attributable to ordinary equity shareholders of the Company by the weighted average number of ordinary shares in issue during the Relevant Periods:

	Year ended 31 December 2021	Year ended 31 December 2022	Nine months ended 30 September	
	<u>2021</u>	<u>2022</u>	<u>2022</u>	<u>2023</u>
			<i>(Unaudited)</i>	
Loss for the year attributable to ordinary equity shareholders of the Company (in RMB'000) (a)	(298,273)	(298,191)	(196,649)	(373,978)
Weighted average number of ordinary shares in issue (in thousands) (b)	<u>116,250</u>	<u>177,804</u>	<u>177,048</u>	<u>204,200</u>
Basic loss per share (in RMB)	<u>(2.57)</u>	<u>(1.68)</u>	<u>(1.11)</u>	<u>(1.83)</u>

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(a) Loss for the year attributable to ordinary equity shareholders of the Company

	Year ended 31 December 2021	Year ended 31 December 2022	Nine months ended 30 September	
	<u>RMB'000</u>	<u>RMB'000</u>	<u>2022</u>	<u>2023</u>
			<i>(Unaudited)</i>	
			<u>RMB'000</u>	<u>RMB'000</u>
Loss for the year attributable to ordinary equity shareholders of the Company	(411,039)	(298,191)	(196,649)	(373,978)
Allocation of loss for the year attributable to financial instruments with preferred rights <i>(Note 25)</i>	<u>112,766</u>	<u>—</u>	<u>—</u>	<u>—</u>
Loss for the year attributable to ordinary equity shareholders of the Company	<u>(298,273)</u>	<u>(298,191)</u>	<u>(196,649)</u>	<u>(373,978)</u>

(b) Weighted average number of ordinary shares in issue

	Year ended 31 December 2021	Year ended 31 December 2022	Nine months ended 30 September	
	<u>'000</u>	<u>'000</u>	<u>2022</u>	<u>2023</u>
			<i>(Unaudited)</i>	
			<u>'000</u>	<u>'000</u>
Ordinary shares at 1 January in issue or deemed to be in issue (i)	144,650	166,480	166,480	180,525
Effect of ordinary shares in issue or deemed to be in issue	15,550	11,324	10,568	23,675
Effect of financial instruments with preferred rights <i>(Note 25)</i>	<u>(43,950)</u>	<u>—</u>	<u>—</u>	<u>—</u>
Weighted average number of ordinary shares at the end of the year	<u>116,250</u>	<u>177,804</u>	<u>177,048</u>	<u>204,200</u>

(i) As set out in Note 27(c), the Company was converted into a joint stock company with limited liability in September 2021. For the purpose of calculating basic loss per share, the weighted average number of ordinary shares deemed to be in issue before the Company’s conversion into a joint stock company was determined assuming the conversion into joint stock company had occurred since 1 January 2021, at the exchange ratio established in the conversion in September 2021.

(c) Ordinary shares with redemption rights issued to investors (Note 25) and share options granted by the Company were not included in the calculation of diluted loss per share because their effect would have been anti-dilutive. Accordingly, diluted loss per share for the year ended 31 December 2021 and 2022 and the nine months ended 30 September 2022 (unaudited) and 2023 were the same as basic loss per share of the respective years/periods.

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11 PROPERTY, PLANT AND EQUIPMENT

	<u>Buildings</u>	<u>Equipment and Machinery</u>	<u>Other equipment, furniture and fixtures</u>	<u>Construction in progress</u>	<u>Total</u>
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Cost:					
At 1 January 2021	1,649	122,925	3,225	252,520	380,319
Additions	—	9,920	3,537	15,290	28,747
Transfers in/(out) from construction in progress	237,082	23,678	5,040	(265,800)	—
Disposals	—	(94)	(146)	—	(240)
At 31 December 2021 and 1 January 2022	238,731	156,429	11,656	2,010	408,826
Additions	—	7,462	682	4,956	13,100
Transfers in/(out) from construction in progress	—	2,010	—	(2,010)	—
At 31 December 2022 and 1 January 2023	238,731	165,901	12,338	4,956	421,926
Additions	—	3,226	382	1,363	4,971
Transfers in/(out) from construction in progress	—	4,956	—	(4,956)	—
Disposals	—	—	(155)	—	(155)
At 30 September 2023	238,731	174,083	12,565	1,363	426,742
Accumulated depreciation:					
At 1 January 2021	(351)	(5,294)	(1,455)	—	(7,100)
Charge for the year	(7,033)	(14,920)	(1,665)	—	(23,618)
Written back on disposals	—	89	138	—	227
At 31 December 2021 and 1 January 2022	(7,384)	(20,125)	(2,982)	—	(30,491)
Charge for the year	(7,751)	(18,063)	(2,496)	—	(28,310)
At 31 December 2022 and 1 January 2023	(15,135)	(38,188)	(5,478)	—	(58,801)
Charge for the period	(5,813)	(14,266)	(1,855)	—	(21,934)
Written back on disposals	—	—	147	—	147
At 30 September 2023	(20,948)	(52,454)	(7,186)	—	(80,588)
Net book value:					
At 31 December 2021	<u>231,347</u>	<u>136,304</u>	<u>8,674</u>	<u>2,010</u>	<u>378,335</u>
At 31 December 2022	<u>223,596</u>	<u>127,713</u>	<u>6,860</u>	<u>4,956</u>	<u>363,125</u>
At 30 September 2023	<u>217,783</u>	<u>121,629</u>	<u>5,379</u>	<u>1,363</u>	<u>346,154</u>

The Group obtained real estate title certificate for the manufacturing facility on 17 January 2023, which was pledged as collateral in August 2023 under the Group’s borrowing arrangements.

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12 RIGHT-OF-USE ASSETS

The analysis of the net book value of right-of-use assets by class of underlying asset is presented below:

	Land use rights	Other properties	Total
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
	<i>(i)</i>	<i>(ii)</i>	
At 1 January 2021	21,406	3,319	24,725
Additions	—	2,158	2,158
Effects of termination of leases	—	(2,438)	(2,438)
Charge for the year	(444)	(1,504)	(1,948)
At 31 December 2021 and 1 January 2022	20,962	1,535	22,497
Additions	—	1,651	1,651
Effects of termination of leases	—	(198)	(198)
Lease modification	—	981	981
Charge for the year	(444)	(1,448)	(1,892)
At 31 December 2022 and 1 January 2023	20,518	2,521	23,039
Charge for the period	(333)	(1,289)	(1,622)
At 30 September 2023	<u>20,185</u>	<u>1,232</u>	<u>21,417</u>

(i) The Group has obtained land use rights in the PRC where the manufacturing facility are located. The land use rights are granted for 50 years, on the expiry of which the land reverts to the government. The payment for leasing the land is made in full at the start of the land use rights period. The land use rights of the Group have been pledged as collateral under the Group’s borrowing arrangements with the carrying amount of RMB20,962,000 and RMB20,518,000 and RMB20,185,000 at 31 December 2021, 2022 and 30 September 2023.

(ii) The Group has leased other properties as its manufacturing facilities and office buildings through tenancy agreements. The leases typically run for an initial period of two years. None of the leases includes variable lease payments.

The analysis of expense items in relation to leases recognised in profit or loss is as follows:

	Year ended 31 December 2021	Year ended 31 December 2022	Nine months ended 30 September 2022	
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
			<i>(Unaudited)</i>	
Depreciation charge of right-of-use assets by class of underlying asset:				
Land use rights	444	444	333	333
Properties leased for own use	1,504	1,448	1,044	1,289
	<u>1,948</u>	<u>1,892</u>	<u>1,377</u>	<u>1,622</u>
Interest on lease liabilities (<i>Note 6(a)</i>)	76	99	74	53
Expense relating to short-term leases	287	386	285	373

Details of total cash outflow for leases and the maturity analysis of lease liabilities and the future cash outflows arising from leases that are not yet commenced are set out in Notes 19(d) and 24, respectively.

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13 INVESTMENTS IN A SUBSIDIARY

(a) The carrying amount of interest in a subsidiary is listed below:

	As at 31 December 2021	As at 31 December 2022	As at 30 September 2023
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Unlisted, at cost			
Taizhou Saifu Juli Biomedical Co., Ltd.	90,000	116,470	116,470

On 27 October 2022, the registered capital of Saifu Juli was increased to RMB116,470,000, which was fully subscribed by the Company and paid up in cash. As at 30 September 2023, Saifu Juli was an investment holding company and a wholly owned subsidiary of the Group.

Details of the information of the subsidiary is set forth in Note 1.

(b) **Material non-controlling interest (the “NCI”)**

The following table lists out the information relating to Cellularforce, the only subsidiary of the Group which has a non-controlling interest (“NCI”). The summarised financial information of Cellularforce presented below represents the amounts before any inter-company elimination.

	Year ended 31 December 2021	Year ended 31 December 2022	Nine months ended 30 September	
	<i>RMB’000</i>	<i>RMB’000</i>	2022	2023
			<i>(Unaudited)</i>	
			<i>RMB’000</i>	<i>RMB’000</i>
NCI percentage	34%	34%	34%	34%
Current assets	32,975	39,028	30,253	40,763
Non-current assets	406,637	386,977	391,198	368,209
Current liabilities	(73,365)	(117,045)	(103,026)	(136,927)
Non-current liabilities	(293,263)	(251,025)	(272,722)	(248,008)
Net assets	72,984	57,935	45,703	24,037
Carrying amount of NCI	33,815	19,698	24,539	8,172
Revenue	54,478	84,956	73,837	58,424
Loss for the year	(45,392)	(41,519)	(27,280)	(33,899)
Total comprehensive income	(45,392)	(41,519)	(27,280)	(33,899)
Loss allocated to NCI	(15,432)	(14,117)	(9,276)	(11,526)
Cash flows generated from/(used in)				
operating activities	65,904	16,572	16,938	(4,383)
Cash flows used in investing				
activities	(59,018)	(22,417)	(15,469)	(6,261)
Cash flows (used in)/generated from				
financing activities	(15,321)	11,980	(3,154)	6,448

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14 OTHER NON-CURRENT ASSETS

	As at 31 December 2021	As at 31 December 2022	As at 30 September 2023
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Value-added tax (“VAT”) recoverable (i)	10,202	6,790	9,623
Deposits	2,150	—	—
Prepayments for property, plant and equipment	5,091	2,787	1,404
Prepayments for an R&D Contract	—	—	688
Others	581	359	209
	<u>18,024</u>	<u>9,936</u>	<u>11,924</u>

- (i) As at 31 December 2021 and 2022 and 30 September 2023, VAT recoverable was classified as other non-current assets to the extent that they are not expected to be recovered or deducted from future value-added tax payables arising on the Group’s revenue within the next 12 months from the end of each of the reporting period.

15 INVENTORIES AND OTHER CONTRACT COSTS

Inventories and other contract costs in the consolidated statement of financial position comprise:

	As at 31 December 2021	As at 31 December 2022	As at 30 September 2023
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Costs to fulfil contracts	<u>—</u>	<u>—</u>	<u>7,216</u>

16 PREPAYMENTS AND OTHER RECEIVABLES

The Group	As at 31 December 2021	As at 31 December 2022	As at 30 September 2023
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Prepaid expenses	18,450	16,232	32,852
[REDACTED] expenses	[REDACTED]	[REDACTED]	[REDACTED]
Deposits	285	546	571
Interest receivables	—	244	96
Other debtors	354	418	571
	<u>[REDACTED]</u>	<u>[REDACTED]</u>	<u>[REDACTED]</u>

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The Company	As at 31 December 2021	As at 31 December 2022	As at 30 September 2023
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Prepaid expenses	45,423	43,532	54,621
[REDACTED] expenses	[REDACTED]	[REDACTED]	[REDACTED]
Deposits	264	532	557
Interest receivables	—	244	96
Other debtors	550	209	157
	<u>[REDACTED]</u>	<u>[REDACTED]</u>	<u>[REDACTED]</u>

All of the prepayments and other receivables are expected to be recovered or recognised as expense within one year.

17 OTHER CURRENT ASSETS

	As at 31 December 2021	As at 31 December 2022	As at 30 September 2023
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
VAT recoverable	8,298	3,377	7,877

18 FINANCIAL ASSETS AT FVPL

The Group and the Company	As at 31 December 2021	As at 31 December 2022	As at 30 September 2023
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Wealth management products	402,382	401,097	150,397

Financial assets measured at FVPL comprise the investments in wealth management products purchased from banks in the PRC during the Relevant Periods.

19 CASH AND CASH EQUIVALENTS AND OTHER CASH FLOW INFORMATION

(a) Cash and cash equivalents comprise:

The Group	As at 31 December 2021	As at 31 December 2022	As at 30 September 2023
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Cash at bank	218,055	171,302	257,635
Time deposits with banks	—	41,788	—
Cash and cash equivalents	218,055	213,090	257,635

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<u>The Company</u>	<u>As at 31 December 2021</u>	<u>As at 31 December 2022</u>	<u>As at 30 September 2023</u>
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Cash at bank	199,879	146,994	237,524
Time deposits with banks	—	41,788	—
Cash and cash equivalents	<u>199,879</u>	<u>188,782</u>	<u>237,524</u>

(b) Reconciliation of loss before taxation to cash used in operations:

<i>Note</i>	<u>Year ended 31 December 2021</u>	<u>Year ended 31 December 2022</u>	<u>Nine months ended 30 September 2022</u>	
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
			<i>(Unaudited)</i>	
Loss before taxation	(426,544)	(312,381)	(205,980)	(385,559)
Adjustments for:				
Depreciation of property, plant and equipment	<i>6(c)</i> 23,618	28,310	21,051	21,934
Depreciation of right-of-use assets	<i>6(c)</i> 1,948	1,892	1,377	1,622
Amortisation of intangible assets	<i>6(c)</i> 78	338	166	530
Net (gain)/loss on termination of leases	(88)	38	38	—
Net loss on disposal of property, plant and equipment	13	—	—	8
Changes in the carrying amount of financial instruments issued to investors	<i>25</i> 240,080	—	—	—
Finance costs	<i>6(a)</i> 17,842	18,692	13,987	12,246
Interest income	<i>5(a)</i> (7,058)	(4,167)	(2,541)	(3,639)
Net foreign exchange loss/(gain)	<i>5(b)</i> 2,722	(14,457)	(17,249)	66
Net realised and unrealised gains on financial assets measured at FVPL	<i>5(a)</i> (6,479)	(11,897)	(9,203)	(4,605)
Equity-settled share-based payment expenses	<i>6(b)</i> 11,730	41,556	4,370	99,488
Changes in working capital:				
(Increase)/decrease in prepayments and other receivables	(10,907)	1,893	4,112	(16,799)
Increase in trade and other payables	17,377	12,811	26,398	33,665
Increase in contract liabilities	—	—	—	3,810
Decrease in deferred income	(588)	(641)	(482)	(482)
Increase in other current assets and other non-current assets	13,680	12,801	5,926	(7,226)
Increase in inventories and other contract cost	—	—	—	(7,216)
Cash used in operations	<u>(122,576)</u>	<u>(225,212)</u>	<u>(158,030)</u>	<u>(252,157)</u>

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(c) Reconciliation of liabilities arising from financing activities

The table below details changes in the Group’s liabilities from financing activities, including both cash and non-cash changes. Liabilities arising from financing activities are liabilities for which cash flows were, or future cash flows will be, classified in the Group’s consolidated cash flow statement as cash flows from financing activities.

	Interest-bearing borrowings and interest payables	Leases liabilities	Financial instruments issued to investors	Total
	<i>RMB’000</i> <i>(Note 20/22)</i>	<i>RMB’000</i> <i>(Note 24)</i>	<i>RMB’000</i> <i>(Note 25)</i>	<i>RMB’000</i>
At 1 January 2021	286,174	4,722	666,837	957,733
Changes from financing cash flows:				
Proceeds from the issuance of financial instruments to investors	—	—	300,074	300,074
Capital element of lease liabilities	—	(3,007)	—	(3,007)
Interest element of lease liabilities	—	(76)	—	(76)
Interest paid for interest-bearing borrowings	(15,251)	—	—	(15,251)
Total changes from financing cash flows	(15,251)	(3,083)	300,074	281,740
Other changes:				
Interest expenses	17,766	76	—	17,842
Capitalised borrowing costs	691	—	—	691
Changes in the carrying amount of financial instruments issued to investors	—	—	240,080	240,080
Reclassification of financial instruments issued to investors as equity	—	—	(1,206,991)	(1,206,991)
Termination of leases	—	(2,526)	—	(2,526)
Increase in lease liabilities from entering into new leases during the year	—	2,158	—	2,158
Total other changes	18,457	(292)	(966,911)	(948,746)
At 31 December 2021 and 1 January 2022	289,380	1,347	—	290,727
Changes from financing cash flows:				
Repayment of interest-bearing borrowings	(15,000)	—	—	(15,000)
Proceeds from interest-bearing borrowings	15,900	—	—	15,900
Capital element of lease liabilities	—	(1,553)	—	(1,553)
Interest element of lease liabilities	—	(99)	—	(99)
Interest paid for interest-bearing borrowings	(15,390)	—	—	(15,390)
Total changes from financing cash flows	(14,490)	(1,652)	—	(16,142)

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	Interest-bearing borrowings and interest payables	Leases liabilities	Financial instruments issued to investors	Total
	<i>RMB’000</i> <i>(Note 20/22)</i>	<i>RMB’000</i> <i>(Note 24)</i>	<i>RMB’000</i> <i>(Note 25)</i>	<i>RMB’000</i>
Other changes:				
Interest expense	18,593	99	—	18,692
Termination of leases	—	(202)	—	(202)
Lease modification	—	981	—	981
Increase in lease liabilities from entering into new leases during the year	—	1,651	—	1,651
Total other changes	<u>18,593</u>	<u>2,529</u>	<u>—</u>	<u>21,122</u>
At 31 December 2022 and 1 January 2023	<u>293,483</u>	<u>2,224</u>	<u>—</u>	<u>295,707</u>
Changes from financing cash flows:				
Repayment of interest-bearing borrowings	(42,400)	—	—	(42,400)
Proceeds from interest-bearing borrowings	69,700	—	—	69,700
Capital element of lease liabilities	—	(1,307)	—	(1,307)
Interest element of lease liabilities	—	(53)	—	(53)
Interest paid for interest-bearing borrowings	(10,634)	—	—	(10,634)
Total changes from financing cash flows	<u>16,666</u>	<u>(1,360)</u>	<u>—</u>	<u>15,306</u>
Other changes:				
Interest expense	12,193	53	—	12,246
Total other changes	<u>12,193</u>	<u>53</u>	<u>—</u>	<u>12,246</u>
At 30 September 2023	<u>322,342</u>	<u>917</u>	<u>—</u>	<u>323,259</u>

(d) Total cash outflow for leases

Amounts included in the cash flow statement for leases comprise the following:

	As at 31 December 2021	As at 31 December 2022	As at 30 September 2022	As at 30 September 2023
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i> <i>(Unaudited)</i>	<i>RMB’000</i>
Within operating cash flows	233	420	401	375
Within financing cash flows	3,083	1,652	1,218	1,360
	<u>3,316</u>	<u>2,072</u>	<u>1,619</u>	<u>1,735</u>

All these amounts related to the rental payments.

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20 TRADE AND OTHER PAYABLES

The Group	As at 31 December 2021	As at 31 December 2022	As at 30 September 2023
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Trade payables (i)	12,597	19,137	45,156
Payroll payables	18,569	24,185	28,620
Interest payables	466	454	428
Payables for purchases of property, plant and equipment	14,466	7,823	5,669
Accrued [REDACTED] expenses	[REDACTED]	[REDACTED]	[REDACTED]
Other payables and accruals	4,044	3,831	3,331
	<u>[REDACTED]</u>	<u>[REDACTED]</u>	<u>[REDACTED]</u>
The Company	As at 31 December 2021	As at 31 December 2022	As at 30 September 2023
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Trade payables (i)	10,535	15,426	40,313
Payroll payables	7,849	11,163	13,870
Accrued [REDACTED] expenses	[REDACTED]	[REDACTED]	[REDACTED]
Other payables and accruals	1,667	871	975
	<u>[REDACTED]</u>	<u>[REDACTED]</u>	<u>[REDACTED]</u>

(i) As of the end of the reporting period, the ageing analysis of trade payables based on the invoice date is as follows:

The Group	As at 31 December 2021	As at 31 December 2022	As at 30 September 2023
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Within 6 months	<u>12,597</u>	<u>19,137</u>	<u>45,156</u>
The Company	As at 31 December 2021	As at 31 December 2022	As at 30 September 2023
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Within 6 months	<u>10,535</u>	<u>15,426</u>	<u>40,313</u>

All of the above balances classified as current liabilities are expected to be settled within one year.

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21 CONTRACT LIABILITIES

	As at 31 December 2021	As at 31 December 2022	As at 30 September 2023
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
At the beginning of the year/period	—	—	—
Decrease in contract liabilities as a result of recognizing revenue during the year/period that was included in the contract liabilities at the beginning of the year/period	—	—	—
Increase in contract liabilities as a result of receiving advance payments during the period	—	—	3,810
Balance at the end of the year/period	<u>—</u>	<u>—</u>	<u>3,810</u>

All the contract liabilities are expected to be recognised as income within one year.

22 INTEREST-BEARING BORROWINGS

(a) The analysis of the carrying amount of interest-bearing borrowings is as follows:

	As at 31 December 2021	As at 31 December 2022	As at 30 September 2023
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Unsecured short-term bank loans (i)	—	15,900	29,700
Current proportion of unsecured long-term bank loans (i)	—	—	450
Current proportion of secured long-term bank loans (ii)	14,869	44,608	52,173
Within 1 year or on demand	<u>14,869</u>	<u>60,508</u>	<u>82,323</u>
Unsecured long-term bank loans (i)	—	—	35,550
Secured long-term bank loans (ii)	274,045	232,521	204,041
Non-current	<u>274,045</u>	<u>232,521</u>	<u>239,591</u>
	<u>288,914</u>	<u>293,029</u>	<u>321,914</u>

(i) In 2022 and 2023, the Group was granted with banking facilities amounting to RMB20,000,000 and RMB110,000,000. As at 31 December 2022 and 30 September 2023, the unsecured short-term bank loans represent the utilised banking facilities amounting to RMB15,900,000 and RMB65,700,000 respectively, which carry interest rate from 3.30% to 4.30%. Such interest rate is determined based on the Loan Prime Rate (“LPR”) announced by the People’s Bank of China (“PBOC”).

(ii) As at 31 December 2021 and 2022 and 30 September 2023, the secured long-term bank loans obtained from a bank consortium were secured by the Group’s land use right with the carrying amount of RMB20,962,000 and RMB20,518,000 and RMB20,185,000, and guaranteed by Taizhou Huacheng Medical Investment Group Co., Ltd. (“Taizhou Huacheng”). The loan is additionally secured by the Cellularforce’s manufacturing facilities in Taizhou in August 2023 after the Cellularforce obtained the relevant real estate title certificate. Saifu Juli also pledged its equity interest in Cellularforce to Taizhou Huangcheng as a counter-security. Mr. Qiu Jiwan (裘霽宛) also provided a personal guarantee to one of the bank in the amount of RMB30,000,000. During the relevant periods, the secured long-term bank loan born interest rates from 4.5% to 5.0% per annum. The guarantee provided by the Group’s related parties—Taizhou Huacheng and Mr. Qiu Jiwan—was replaced by a guarantee provided by the Company in December 2023. Taizhou Huacheng also subsequently released the counter-security provided by Saifu Juli in December 2023.

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(b) As at 31 December 2021 and 2022 and 30 September 2023, the analysis of the repayment schedule of bank loans is as follows:

	As at 31 December 2021	As at 31 December 2022	As at 30 September 2023
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Within 1 year or on demand	15,000	60,900	82,650
After 1 year but within 2 years	45,000	60,000	72,450
After 2 years but within 5 years	240,000	180,000	173,100
	<u>285,000</u>	<u>240,000</u>	<u>245,550</u>
	<u>300,000</u>	<u>300,900</u>	<u>328,200</u>

An initial facility fee totalling RMB17,634,000 was paid to compensate the banks for the arrangement of the secured long-term loans, which were deferred and adjusted to the loans’ effective interest rate and recognised as an expense over the period of the loan facility. As at 31 December 2021 and 2022 and 30 September 2023, the carrying amount of the secured bank loans was RMB288,914,000 and RMB277,129,000 and RMB256,214,000 respectively, which represented the net present value of all future cash repayments discounted at effective interest rates from 6.02% to 6.77% per annum.

23 DEFERRED INCOME

	Government grants
	<i>RMB’000</i>
At 1 January 2021	19,247
Released to other income	<u>(588)</u>
At 31 December 2021 and 1 January 2022	18,659
Released to other income	<u>(641)</u>
At 31 December 2022 and 1 January 2023	18,018
Released to other income	<u>(482)</u>
At 30 September 2023	<u>17,536</u>

As at 31 December 2021, 2022 and 30 September 2023, deferred income of the Group represented unamortised government subsidies for compensation on the Group’s capital expenditure incurred for the construction of manufacturing facilities, which were amortised over the estimated useful lives of the relevant assets.

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24 LEASE LIABILITIES

The following table shows the remaining contractual maturities of the Group’s lease liabilities at the end of each of the reporting period.

	31 December 2021		31 December 2022		30 September 2023	
	Present value of the minimum lease payments	Total minimum lease payments	Present value of the minimum lease payments	Total minimum lease payments	Present value of the minimum lease payments	Total minimum lease payments
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Within 1 year	956	996	1,752	1,813	917	930
After 1 year but within 2 years	391	396	472	477	—	—
	<u>391</u>	<u>396</u>	<u>472</u>	<u>477</u>	<u>—</u>	<u>—</u>
	<u>1,347</u>	<u>1,392</u>	<u>2,224</u>	<u>2,290</u>	<u>917</u>	<u>930</u>
Less: total future interest expenses		(45)		(66)		(13)
Present value of lease liabilities		<u>1,347</u>		<u>2,224</u>		<u>917</u>

25 FINANCIAL INSTRUMENTS ISSUED TO INVESTORS

In 2015, the Company entered into agreements with several investors (the “Series Pre-A Investors”), pursuant to which the Series Pre-A Investors agreed to inject a total of RMB140,000,000 into the Company as a consideration for the subscription of the Company’s newly issued paid-in capital of RMB10,000,000.

In 2016, the Company entered into agreements with several investors (the “Series A Investors”), pursuant to which the Series A Investors agreed to inject a total of RMB120,000,000 into the Company as a consideration for the subscription of the Company’s newly issued paid-in capital of RMB30,000,000.

In April 2019, November 2019 and April 2020, the Company entered into agreements with several investors (the “Series B Investors”), pursuant to which the Series B Investors agreed to inject a total of RMB230,000,000 into the Company as a consideration for the subscription of the Company’s newly issued paid-in capital of RMB28,750,000.

In August 2020, the Company entered into agreements with an investor (the “Series B+ Investor”), pursuant to which the Series B+ Investor agreed to inject RMB370,000,000 into the Company as a consideration for the subscription of the Company’s newly issued paid-in capital of RMB35,900,000.

In April 2021, the Company entered into agreements with investors (the “Series B++ Investors”), pursuant to which the Series B++ Investors agreed to inject a total of RMB300,074,000 into the Company as a consideration for the subscription of the Company’s newly issued paid-in capital of RMB21,830,000.

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In accordance with the respective agreements, the Series B Investors, the Series B+ Investor and the Series B++ Investors (collectively, the “Investors with Preferred Rights”) were granted certain preferred rights, including the redemption rights upon specified contingent events and the anti-dilution right. The key terms of these preferred rights that impacted the financial statements of the Group and the Company are outlined below:

Investors’ redemption rights upon occurrence of contingent events

The Investors with Preferred Rights had the right to require the Company to redeem their paid-in capital for cash upon certain events, including (i) a non-completion of a qualified [REDACTED] (“[REDACTED]”) of the Company by 1 March 2024; or (ii) a change of control of the Company resulting from the exercise of pledges of the Company’s equity interests; or (iii) a change in the Company’s controlling shareholder such that it has an adverse impact on the progress of a qualified [REDACTED] or mergers and acquisitions of the Company; or (iv) the Company receives the redemption requests from any other investors with Preferred Rights.

The redemption amount was the higher of: (i) the original investment amount plus an annual simple rate of 6.5% for the period commencing from the investment amount payment date to the redemption settlement date and any declared but unpaid dividends if any; and (ii) a pro-rata share of the value of the audited net assets of the Company on the redemption date.

Anti-dilution right

If the Company increases its paid-in capital at a price lower than the price paid by the Investors with Preferred Rights on a per paid-in capital basis, the Investors with Preferred Rights have a right to require the Company to issue additional paid-in capital for nil (or nominal) consideration to the investors, so that the total amount paid by the investors divided by the total amount of paid-in capital obtained is equal to the price per paid-in capital in the new issuance.

Presentation and classification

The Company did not have an unconditional right to avoid redeeming its paid-in capital for cash, since not all specified contingent events were within its control. The Company recognised financial liabilities that were initially measured at the highest present value of those redemption amounts in accordance with the accounting policies set out in Note 2(n). These financial liabilities were subsequently measured at an amount expected to be paid to the investors upon redemption that could be payable upon occurrence of these events at the end of each reporting period with changes in the carrying amount of the liabilities recognised in “changes in the carrying amount of financial instruments issued to investors”.

The movements of the Financial Instruments Issued to Investors are set out below:

The Group and the Company	As at 31 December 2021
	<i>RMB’000</i>
At the beginning of the year	666,837
Recognition of financial instruments issued to investors	300,074
Changes in the carrying amount	240,080
Termination of preferred rights (i)	(1,206,991)
At the end of the year	<u>—</u>

- (i) In July 2021, pursuant to the supplementary agreement signed by the Company and the investors, the Company’s redemption obligations were terminated. Accordingly, the directors of the Company considered that the financial liabilities recognised for the redemption obligations shall be reclassified from financial liabilities to equity thereafter.

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The Financial Instruments Issued to Investors were measured by the directors of the Company with reference to valuation reports prepared by an independent qualified professional valuer. The Group applied the discounted cash flow method to determine the underlying equity value of the Company and allocate corresponding value to each share on a pro-rata basis to determine the carrying amount of the Financial Instruments Issued to Investors as of the dates of issuance and at the end of each reporting period.

Key valuation assumptions used to determine the carrying amount of the Financial Instruments Issued to Investors are as follows:

	As at 31 July 2021
	<i>RMB’000</i>
Discount rate	21%
Risk-free interest rate	3.29%
Implied lack of marketability discount	11%
Volatility	30.00%
Dividend yield	0.00%

26 EQUITY SETTLED SHARE-BASED TRANSACTIONS

(a) Share option scheme

A share option scheme was granted on 31 May 2019 (the “Share Option Scheme”) to reward the contributions of eligible employees, directors and individual consultants (“Participants”) who render services to the Company or its subsidiaries. Pursuant to the Share Option Scheme, the Participants have right to acquire certain equity interest in certain employee shareholding platforms, which enables the Participants have indirect equity interest in the Company. The Share Option Scheme is subject to certain performance and service conditions that the respective portions of options shall be vested upon the achievement of relevant conditions.

On 15 September 2022, a resolution was passed to amend the Share Option Scheme. Under which, the options previously granted and had not been cancelled or forfeited were replaced by a restricted share (“RS”) scheme (the “Replacement Scheme”), where, non-beneficial modifications of relevant performance and service conditions were made. The Group accounts for these modifications in accordance with the accounting policy set out in Note 2(p)(ii). Accordingly, there was no financial impact as a result of the Replacement Scheme.

(i) The movement and weighted average exercise prices of the share options and the RSs of the Replacement Scheme (together refer to as “equity instruments”) is as follows:

	31 December 2021		31 December 2022		30 September 2023	
	Weighted average exercise price	Number of equity instruments	Weighted average exercise price	Number of equity instruments	Weighted average exercise price	Number of equity instruments
	<i>RMB</i>	<i>’000</i>	<i>RMB</i>	<i>’000</i>	<i>RMB</i>	<i>’000</i>
Outstanding at the beginning of the year/period	1.00	6,955	1.00	5,530	1.00	5,000
Exercised during the year/period	1.00	(1,425)	1.00	(530)	1.00	(5,000)
Forfeited during the year/period	—	—	—	—	—	—
Outstanding at the end of the year/period	1.00	<u>5,530</u>	1.00	<u>5,000</u>	—	<u>—</u>
Exercisable at the end of the year/period	1.00	<u>5,530</u>				

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As at 31 December 2021 and 31 December 2022 and 30 September 2023, the weighted average remaining contractual life for the equity instruments granted was 0.13 years and 1.84 years and nil respectively.

(ii) Fair value of share options and assumptions

The fair value of services received in return for share options is measured by reference to the fair value of share options granted. The grant-date fair values of each share options granted are between RMB5.60 to RMB5.66. Back-solve method was used to determine the equity fair value of the ordinary shares of the Company and the estimated fair value of the share options granted is measured based on a binomial tree model. Key assumptions adopted in determining the fair value are as follows (before the Capitalisation Issue):

Key Assumptions

Fair value at measurement dates	RMB5.60 – RMB5.66
Share price	RMB6.60
Expected exercise price	RMB1.00
Risk-free interest rate	2.70% – 2.92%
Expected volatility	32.03% – 32.88%
Expected dividend yield	0.00%
Option life	2.59 – 3.00 years

The expected volatility is based on the historic volatility, adjusted for any expected changes to future volatility based on publicly available information. Expected dividend yield is based on historical dividend. Changes in the subjective input assumptions could materially affect the fair value estimate.

(b) Restricted share scheme

On 15 September 2022, a restricted share scheme (the “2022 RS Scheme”) was authorised to reward the contributions of eligible directors, employees and consultant of the Company or its subsidiaries. The Participants of the 2022 RS Scheme have rights to invest in the Company by way of (i) subscribing for newly issued share capital of the Company; or (ii) acquiring share capital of the Company through certain employee incentive platforms.

(i) The terms and conditions of RSs granted are as follows:

	<u>Number of RS</u>	<u>Granted prices</u>	<u>Vesting condition</u>
	’000		
RSs granted to directors:			
— on 15 October 2022	1,100	RMB1.00	Service period of 3 years and non-market performance conditions
— on 15 October 2022	1,000	RMB1.00	Service period of less than 3 years and non-market performance conditions
— on 15 October 2022	7,570	RMB1.00	Non-market performance conditions

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	<u>Number of RS</u>	<u>Granted prices</u>	<u>Vesting condition</u>
	’000		
RSs granted to employees:			
— on 15 October 2022	4,230	RMB1.00	Service period of 3 years and non-market performance conditions
— on 15 October 2022	2,060	RMB1.00	Service period of less than 3 years and non-market performance conditions
— on 15 October 2022	3,100	RMB1.00	Non-market performance conditions
— on 13 February 2023	1,000	RMB1.00	Service period of 3 years and non-market performance conditions
— on 1 March 2023	540	RMB1.00	Service period of 3 years and non-market performance conditions
RSs granted to a consultant:			
— on 15 October 2022	500	RMB1.00	Non-market performance conditions
	<hr/>		
Total RSs granted	<u>21,100</u>		

(ii) Fair value of RSs and assumptions

The fair value of services received in return for restricted shares granted is measured by reference to the fair value of restricted shares granted. Discounted cash flow method was used to determine the underlying equity fair value of the Company, based on which, the fair value of per underlying share was calculated considering total number of shares.

Key assumptions adopted in determining the fair value are as follows (before the Capitalisation Issue):

Key Assumptions

Fair value at measurement dates	RMB13.13 – RMB13.95
Share price	RMB17.14
Risk-free interest rate	2.97%
Expected volatility	25.00%
Expected dividend yield	0.00%
Implied lack of marketability discount	6%

The expected volatility is based on the historic volatility, adjusted for any expected changes to future volatility based on publicly available information. Expected dividend yield is based on historical dividends. Changes in the subjective input assumptions could materially affect the fair value estimate.

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(c) Equity-settled share-based payment expenses recognised in the consolidated statements of profit or loss and other comprehensive income during the Relevant Periods

For the year ended 31 December 2021 and 2022 and the nine months ended 30 September 2023, expenses arising from share-based payment transactions are as follows:

	Year ended 31 December 2021	Year ended 31 December 2022	Nine months ended 30 September 2022		2023
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
			<i>(Unaudited)</i>		
Research and development expenses	5,820	11,200	1,375		24,039
Administrative expenses	5,910	30,356	2,995		75,449
	<u>11,730</u>	<u>41,556</u>	<u>4,370</u>		<u>99,488</u>

27 CAPITAL, RESERVES AND DIVIDENDS

(a) Movements in components of equity

The reconciliation between the opening and closing balances of each component of the Group’s consolidated equity is set out in the consolidated statement of changes in equity. Details of the changes in the Company’s individual components of equity between the beginning and the end of the year are set out below:

The Company	<i>Note</i>	Paid-in capital	Share capital	Capital reserve	Share premium	Share- based payment reserve	Other reserve	Accumulated losses	Total
		<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Balance at 1 January 2021		144,650	—	629,350	—	25,829	(600,000)	(308,199)	(108,370)
Changes in equity for 2021:									
Total comprehensive income for the year		—	—	—	—	—	—	(379,929)	(379,929)
Capital contributions by investors		21,830	—	278,244	—	—	—	—	300,074
Recognition of financial instruments issued with preferred rights		—	—	—	—	—	(300,074)	—	(300,074)
Termination of financial instruments with preferred rights		—	—	—	—	—	1,206,991	—	1,206,991
Conversion into a joint stock company		(166,480)	166,480	(907,594)	616,229	(34,499)	(306,917)	632,781	—
Equity settled share-based transactions	<i>26(c)</i>	—	—	—	—	11,730	—	—	11,730
Balance at 31 December 2021		<u>—</u>	<u>166,480</u>	<u>—</u>	<u>616,229</u>	<u>3,060</u>	<u>—</u>	<u>(55,347)</u>	<u>730,422</u>

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The Company	Note	Share-based				Total
		Share capital	Share premium	payment reserve	Accumulated losses	
		RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
Balance at 1 January 2022		166,480	616,229	3,060	(55,347)	730,422
Changes in equity for 2022:						
Total comprehensive income for the year		—	—	—	(266,799)	(266,799)
Capital contributions by investors		13,545	213,954	—	—	227,499
Shares issued under share option scheme		500	—	—	—	500
Equity settled share-based transactions	26(c)	—	—	41,556	—	41,556
Balance at 31 December 2022		180,525	830,183	44,616	(322,146)	733,178

The Company	Note	Share-based				Total
		Share capital	Share premium	payment reserve	Accumulated losses	
		RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
Balance at 1 January 2023		180,525	830,183	44,616	(322,146)	733,178
Changes in equity for the nine months ended 30 September 2023:						
Total comprehensive income for the year		—	—	—	(353,507)	(353,507)
Shares issued under share option scheme and restricted share scheme		29,500	—	—	—	29,500
Equity settled share-based transactions	26(c)	—	—	99,488	—	99,488
Balance at 30 September 2023		210,025	830,183	144,104	(675,653)	508,659

(b) Paid-in capital

	Total
	RMB'000
At 1 January 2021	144,650
Capital contribution by investors (i)	21,830
Conversion into a joint stock company (Note 27(c))	(166,480)
At 31 December 2021 and 31 December 2022 and 30 September 2023	—

- (i) For the year ended 31 December 2021, the Series B++ Investors completed the injections totaling RMB300,074,000 in the Company for the subscription of the Company’s newly issued paid-in capital of RMB21,830,000 (see Note 25).

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(c) **Share capital and share premium**

	Numbers of shares	<i>RMB’000</i>
Authorised shares:		
At 1 January 2021	—	—
Issue of ordinary shares upon conversion into a joint stock company (i)	166,480,000	166,480
At 31 December 2021 and 1 January 2022	166,480,000	166,480
Issue of ordinary shares (ii)	13,545,200	13,545
Share issued under share option scheme and restricted share scheme (iii)	30,000,000	30,000
At 31 December 2022, 1 January 2023 and 30 September 2023	<u>210,025,200</u>	<u>210,025</u>

	Numbers of ordinary shares	Share capital	Share premium	Total
		<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Issued and fully paid				
At 1 January 2021	—	—	—	—
Issue of ordinary shares upon conversion into a joint stock company (i)	166,480,000	166,480	616,229	782,709
At 31 December 2021 and 1 January 2022	166,480,000	166,480	616,229	782,709
Issue of ordinary shares (ii)	13,545,200	13,545	213,954	227,499
Share issued under share option scheme (iii)	500,000	500	—	500
At 31 December 2022 and 1 January 2023	180,525,200	180,525	830,183	1,010,708
Share issued under share option scheme and restricted share scheme (iii)	29,500,000	29,500	—	29,500
At 30 September 2023	<u>210,025,200</u>	<u>210,025</u>	<u>830,183</u>	<u>1,040,208</u>

(i) The Company was converted into a joint stock limited company under the Company Law of the PRC in September 2021. The net assets of the Company under the PRC GAAP as of the conversion base date were converted into 166,480,000 share capital at RMB1.00 each (the “Share”). The excess of the net assets of the Company converted over the nominal value of the shares was credited to the Company’s share premium account.

(ii) In January 2022, the Company entered into investment agreements with certain investors (the “Crossover Investors”). In February 2022, the Crossover Investors made an injection totaling RMB227,499,000 into the Company for the subscription of the Company’s newly issued share capital of RMB13,545,200.

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(iii) Pursuant to a written resolution passed on 15 September 2022, the number of authorised shares increased from 180,025,200 to 210,025,200. The increased shares were subscribed under the Share Option Scheme and 2022 RS Scheme. As at 31 December 2022 and 30 September 2023, the Company received cash consideration of RMB500,000 and RMB29,500,000 respectively under the Share Option Scheme and 2022 RS Scheme from eligible persons who were rewarded for their contribution to the Group, all of which were credited to share capital.

(d) Other reserves

The other reserve primarily comprises the recognition of financial instruments issued to investors as stipulated in Note 25.

(e) Dividends

No dividends were paid or declared by the Company or any of its subsidiaries during the Relevant Periods.

(f) Capital reserves

The capital reserve primarily represents the excess of the net contributions from the shareholders of the Company over the total paid-in capital/share capital issued.

(g) Capital management

The Group’s objectives in the aspect of managing capital are to safeguard the Group’s ability to continue as a going concern in order to provide returns for shareholders and benefits for other stakeholders and to maintain an optimal capital structure to reduce the cost of capital.

The Group manages its capital structure and makes adjustments to it in light of changes in economic conditions and the risk characteristics of the underlying assets. To maintain or adjust the capital structure, the Group may return capital to shareholders or issue new shares. The Group is not subject to any externally imposed capital requirements. No changes were made in the objectives, policies or processes for managing capital as at the end of each of the Relevant Periods.

28 FINANCIAL RISK MANAGEMENT AND FAIR VALUES OF FINANCIAL INSTRUMENTS

Exposure to credit, liquidity, interest rate and currency risks arises in the normal course of the Group’s business. The Group is also exposed to equity price risk arising from its equity investments in other entities and movements in its own equity share price.

The Group’s exposure to these risks and the financial risk management policies and practices used by the Group to manage these risks are described below.

(a) Credit risk

Credit risk refers to the risk that a counterparty will default on its contractual obligations resulting in a financial loss to the Group. The Group’s credit risk is primarily attributable to other receivables. The Group’s exposure to credit risk arising from cash and cash equivalents and wealth management products is limited because the counterparties are reputable banks or financial institution, for which the Group considers to have low credit risks.

Management has assessed that during the Relevant Periods, other receivables have not had a significant increase in credit risk since initial recognition. Thus, a 12-month expected credit loss approach that results from possible default event within 12 months of each reporting date is adopted by management. Management of the Company expect the occurrence of losses from non-performance by the counterparties of other receivables was remote and loss allowance provision for other receivables was immaterial. The expected credit loss rate is insignificant and close to zero.

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(b) Liquidity risk

Individual operating entities within the Group are responsible for their own cash management, including the short-term investment of cash surpluses and the raising of loans to cover expected cash demands, subject to approval by the Company’s shareholders when the borrowings exceed certain predetermined levels of authority. The Group’s policy is to regularly monitor its liquidity requirements and its compliance with lending covenants, to ensure that it maintains sufficient reserves of cash and readily realisable marketable securities and adequate committed lines of funding from major financial institutions to meet its liquidity requirements in the short and longer term.

The following tables show the remaining contractual maturities as of the end of the reporting periods of the Group’s non-derivative financial liabilities, which are based on contractual undiscounted cash flows (including interest payments computed using contractual rates or, if floating, based on rates current as at the end of each of the reporting period) and the earliest date the Group can be required to pay:

As at 31 December 2021 contractual undiscounted cash outflow						
	Within 1 year or on demand	More than 1 year but less than 2 years	More than 2 years but less than 5 years	More than 5 years	Total	Carrying amount
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Lease liabilities	996	396	—	—	1,392	1,347
Trade and other payables	53,848	—	—	—	53,848	53,848
Interest-bearing borrowings	30,002	58,861	263,088	—	351,951	288,914
	<u>84,846</u>	<u>59,257</u>	<u>263,088</u>	<u>—</u>	<u>407,191</u>	<u>344,109</u>

As at 31 December 2022 contractual undiscounted cash outflow						
	Within 1 year or on demand	More than 1 year but less than 2 years	More than 2 years but less than 5 years	More than 5 years	Total	Carrying amount
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Lease liabilities	1,813	477	—	—	2,290	2,224
Trade and other payables	59,930	—	—	—	59,930	59,930
Interest-bearing borrowings	74,638	71,320	191,562	—	337,520	293,029
	<u>136,381</u>	<u>71,797</u>	<u>191,562</u>	<u>—</u>	<u>399,740</u>	<u>355,183</u>

As at 30 September 2023 contractual undiscounted cash outflow						
	Within 1 year or on demand	More than 1 year but less than 2 years	More than 2 years but less than 5 years	More than 5 years	Total	Carrying amount
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Lease liabilities	930	—	—	—	930	917
Trade and other payables	91,692	—	—	—	91,692	91,692
Interest-bearing borrowings	95,157	82,013	179,021	—	356,191	321,914
	<u>187,779</u>	<u>82,013</u>	<u>179,021</u>	<u>—</u>	<u>448,813</u>	<u>414,523</u>

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(c) Interest rate risk

Interest rate risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in market interest rates. The Group’s interest rate risk arises primarily from long-term borrowings. Borrowings issued at variable rates and fixed rates expose the Group to cash flow interest rate risk and fair value interest rate risk respectively. The Group regularly reviews its strategy on interest rate risk management in the light of the prevailing market condition. The Group’s interest rate profile as monitored by management is set out in (i) below.

(i) Interest rate risk profile

The following table, as reported to the management of the Group, details the interest rate risk profile of the Group’s borrowings at the end of the reporting period:

	Effective interest rate	As at 31 December 2021	Effective interest rate	As at 31 December 2022	Effective interest rate	As at 30 September 2023
	%	RMB’000	%	RMB’000	%	RMB’000
Fixed rate instruments:						
Lease liabilities	4.35%	(1,347)	4.07%-4.35%	(2,224)	4.07%-4.35%	(917)
		<u>(1,347)</u>		<u>(2,224)</u>		<u>(917)</u>
Variable rate instruments:						
Cash at bank	0.30%-0.35%	218,055	0.25%-0.35%	171,302	0.05%-0.25%	257,635
Time deposits with banks	—	—	4.46%-4.59%	41,788	5.12%	—
Financial assets at FVPL	3.15%-3.20%	402,382	2.85%-3.64%	401,097	2.55%-3.24%	150,397
Interest-bearing borrowings	6.18%-6.77%	(288,914)	4.30%-6.75%	(293,029)	3.30%-6.75%	(321,914)
		<u>331,523</u>		<u>321,158</u>		<u>86,118</u>
Net exposure		<u>331,523</u>		<u>321,158</u>		<u>86,118</u>

(iii) Sensitivity analysis

The following table details the effect on the Group’s loss after tax for each year of the Relevant Periods and accumulated losses as at the end of each reporting period that an increase/decrease of 100 basis points in interest rates would have.

	As at 31 December 2021			As at 31 December 2022			As at 30 September 2023		
	Increase/ (decrease) of basis point	Effect on loss after tax	Effect on accumulated losses	Increase/ (decrease) of basis point	Effect on loss after tax	Effect on accumulated losses	Increase/ (decrease) of basis point	Effect on loss after tax	Effect on accumulated losses
		RMB’000	RMB’000		RMB’000	RMB’000		RMB’000	RMB’000
Interest rates	100	(4,629)	(4,629)	100	(4,104)	(4,104)	100	(1,756)	(1,756)
	(100)	4,629	4,629	(100)	4,104	4,104	(100)	1,756	1,756

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The sensitivity analysis above indicates the instantaneous change in the Group’s loss after tax and accumulated losses that would arise assuming that the change in interest rates had occurred at the end of the reporting periods and had been applied to re-measure those financial instruments held by the Group which expose the Group to fair value interest rate risk at the end of the reporting periods. In respect of the exposure to cash flow interest rate risk arising from floating rate non-derivative instruments held by the Group at the end of the reporting periods, the impact on the Group’s loss after tax and accumulated losses is estimated as an annualised impact on interest expense or income of such a change in interest rates.

(d) Currency risk

The Group is exposed to currency risk primarily through deposit with bank which give rises to cash balances that are denominated in a foreign currency, i.e. a currency other than the functional currency of the operations to which the transactions relate. The currencies giving rise to this risk are primarily United States dollars (“US\$”).

(i) Exposure to currency risk

The following table details the Group’s exposure as at the end of each of the Relevant Periods to currency risk arising from recognised assets denominated in a currency other than the functional currency of the entity to which they relate. For presentation purposes, the amounts of the exposure are shown in RMB, translated using the spot rate at the year end date.

	As at 31 December 2021	As at 31 December 2022	As at 30 September 2023
	<i>US\$ RMB’000</i>	<i>US\$ RMB’000</i>	<i>US\$ RMB’000</i>
Cash and cash equivalents	133,532	142,026	26,475
Prepayments and other receivables	—	49	—
	133,532	142,075	26,475

(ii) Sensitivity analysis

The following table indicates the instantaneous change in the Group’s loss after tax (and accumulated losses) that would arise if foreign exchange rates to which the Group has significant exposure at the end of the reporting period had changed at that date, assuming all other risk variables remained constant.

	As at 31 December 2021		As at 31 December 2022		As at 30 September 2023	
	Increase/ (decrease) in foreign exchange rates	Effect on loss after tax and accumulated losses	Increase/ (decrease) in foreign exchange rates	Effect on loss after tax and accumulated losses	Increase/ (decrease) in foreign exchange rates	Effect on loss after tax and accumulated losses
US\$	10%	(13,353)	10%	(14,208)	10%	(2,648)
	(10%)	13,353	(10%)	14,208	(10%)	2,648

Results of the analysis as presented in the above table represent an aggregation of the instantaneous effects on each of the Group entities’ loss after tax and equity measured in the respective functional currencies, translated into RMB at the exchange rate ruling at the end of the reporting period for presentation purposes.

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(e) **Fair value measurement**

(i) *Financial assets and liabilities measured at fair value*

Fair value hierarchy

The following table presents the fair value of the Group’s financial instruments measured at the end of the reporting period on a recurring basis, categorised into the three-level fair value hierarchy as defined in IFRS 13, *Fair value measurement*. The level into which a fair value measurement is classified is determined with reference to the observability and significance of the inputs used in the valuation technique as follows:

- Level 1 valuations: Fair value measured using only Level 1 inputs i.e., unadjusted quoted prices in active markets for identical assets or liabilities at the measurement date
- Level 2 valuations: Fair value measured using Level 2 inputs i.e., observable inputs which fail to meet Level 1, and not using significant unobservable inputs. Unobservable inputs are inputs for which market data are not available
- Level 3 valuations: Fair value measured using significant unobservable inputs

The Group has a team headed by the finance manager performing valuation for wealth management products which are categorized into Level 3 of the fair value hierarchy. The team reports directly to the head of finance department. A valuation analysis of changes in fair value measurement is prepared by the team periodically, and is reviewed and approved by the head of finance department.

	Fair value at 31 December 2021	Fair value at 31 December 2022	Fair value at 30 September 2023
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Level 3—Wealth management products	402,382	401,097	150,397

The fair values of wealth management products have been estimated using a discounted cash flow valuation model based on assumptions that are not supported by observable market prices or rates. The valuation requires the directors to make estimates about the expected future cash flows including expected future interest return on maturity of the wealth management products. The directors believe that the estimated fair values resulting from the valuation technique are reasonable, and that they were the most appropriate values at the end of reporting periods.

Below is a summary of significant unobservable inputs to the valuation of these wealth management products together with a quantitative sensitivity analysis at the end of reporting periods:

31 December 2021

	Valuation techniques	Significant unobservable inputs	Range	Sensitivity of fair value to the input
Wealth management products, at fair value	Discounted cash flow method	Interest return rate	3.15% to 3.20%	0.50% increase/(decrease) in interest return rate would result in increase/(decrease) in fair value by RMB372,000.

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31 December 2022

	Valuation techniques	Significant unobservable inputs	Range	Sensitivity of fair value to the input
Wealth management products, at fair value	Discounted cash flow method	Interest return rate	2.85% to 3.64%	0.50% increase/ (decrease) in interest return rate would result in increase/(decrease) in fair value by RMB189,000.

30 September 2023

	Valuation techniques	Significant unobservable inputs	Range	Sensitivity of fair value to the input
Wealth management products, at fair value	Discounted cash flow method	Interest return rate	2.55% to 3.24%	0.50% increase/ (decrease) in interest return rate would result in increase/(decrease) in fair value by RMB64,000.

The movements during the period in the balance of these Level 3 fair value measurements are as follows:

	As at 31 December 2021	As at 31 December 2022	As at 30 September 2023
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Wealth management products			
At the beginning of the year/period	200,368	402,382	401,097
Payment for purchases	800,000	2,100,000	630,000
Changes in fair value recognised in profit or loss during the year/period	6,479	11,897	4,605
Redemption of investment	(604,465)	(2,113,182)	(885,305)
At the end of the year/period	<u>402,382</u>	<u>401,097</u>	<u>150,397</u>

During the year ended 31 December 2021 and 2022 and the nine months ended 30 September 2023, there were no transfers between Level 1 and Level 2, or transfers into or out of Level 3.

(ii) Fair values of financial assets and liabilities carried at other than fair value

The carrying amounts of the Group’s financial instruments carried at cost or amortised cost were not materially different from their fair values as at 31 December 2021 and 2022 and 30 September 2023.

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29 COMMITMENTS

Capital commitments outstanding at 31 December 2021 and 2022 and 30 September 2023 not provided for in the financial statements were as follows:

	As at 31 December 2021	As at 31 December 2022	As at 30 September 2023
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Contracted for	6,694	3,325	1,771

30 MATERIAL RELATED PARTY TRANSACTIONS

(a) Key management personnel remuneration

Remuneration for key management personnel of the Group, including amounts paid to the Company’s directors as disclosed in Note 8 and certain of the highest paid employees as disclosed in Note 9, is as follows:

	Year ended 31 December 2021	Year ended 31 December 2022	Nine months ended 30 September	
	<i>RMB’000</i>	<i>RMB’000</i>	2022	2023
			<i>RMB’000</i>	<i>RMB’000</i>
			<i>(Unaudited)</i>	
Salaries and other benefits	6,039	7,055	6,276	7,244
Discretionary bonuses	2,059	2,368	1,996	2,081
Retirement scheme contributions	139	200	196	266
Share-based payments	6,590	28,607	3,117	70,661
	14,827	38,230	11,585	80,253

(b) Related party transactions

During the Relevant Periods, the directors are of the view that the following parties are related parties:

Name of party	Relationship
Mr. Qiu Jiwan (裘霽宛)	Chief executive officer and director of the Company
Mr. Yu Guo’an (余國安)	Joint control of the Company
Dr. Yu Guoliang (余國良) (ii)	Close member of Mr. Yu Guo’an
Hangzhou Zhongmei Huadong Pharmaceutical Co., Ltd. (“Zhongmei Huadong”) 杭州中美華東製藥有限公司 (i)	Shareholder of the Company
Taizhou Huacheng Medical Investment Group Co., Ltd. (“Taizhou Huacheng”) 泰州華誠醫學投資集團有限公司 (i)	Non-controlling shareholder of Cellularforce
Taizhou Huawei Investment Co., Ltd. (“Huawei Investment”) 泰州華威投資有限公司 (i)	Subsidiary of Taizhou Huacheng
Hangzhou Quanyi Investment Management Partnership (General Partnership) (“Hangzhou Quanyi”) 杭州荃毅投資管理合夥企業 (普通合夥) (i)	Shareholder of the Company
Apollomics Inc. (“Apollomics”) 浙江冠科美博生物科技有限公司 (i)	Associate of Dr. Yu Guoliang

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- (i) The English translation of these entities is for reference only. The official names of the entities established in the PRC are in Chinese.
- (ii) Dr. Yu Guoliang was appointed as a non-executive director of the Company on 16 June 2015 and resigned on 16 February 2022 due to his plan to devote to his personal business.

During the Relevant Periods, the Group entered into the following material related party transactions:

	Year ended 31 December 2021	Year ended 31 December 2022	Nine months ended 30 September	
	<u>2021</u>	<u>2022</u>	<u>2022</u>	<u>2023</u>
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
			<i>(Unaudited)</i>	
Reimbursement received from collaborative agreements	18,868	—	—	—
Loans repaid by a related party	100,000	—	—	—
Loans to a related party	100,000	—	—	—
Interest income from loans to a related party	3,600	—	—	—
Payment on behalf of the Group	69	51	51	—
Rendering of services	—	283	151	2,084
Procurement of services	—	598	—	1,350

During the Relevant Periods, Taizhou Huacheng had provided the Group with banking facilities guarantees and Mr. Qiu Jiwan (裘霁苑) had provided a personal guarantee to one of the banks for loan amount of RMB30,000,000, which were replaced by a guarantee provided by the Company in December 2023 as detailed in Note 22.

(c) Related party balances

The outstanding balances arising from the above transactions are as follows:

	Year ended 31 December 2021	Year ended 31 December 2022	Nine months ended 30 September 2023
	<u>2021</u>	<u>2022</u>	<u>2023</u>
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Amounts due from related parties			
<i>Trade related:</i>			
<i>Prepayments and other receivables:</i>			
Zhongmei Huadong	—	180	—
Amounts due to related parties			
<i>Trade related:</i>			
<i>Contract liabilities:</i>			
Zhongmei Huadong	—	—	(3,324)

APPENDIX I

ACCOUNTANTS’ REPORT

31 POSSIBLE IMPACT OF AMENDMENTS, NEW STANDARDS AND INTERPRETATIONS ISSUED BUT NOT YET EFFECTIVE FOR THE RELEVANT PERIODS

Up to the date of issue of this report, the IASB has issued a number of amendments, and a new standards and interpretations which are effective for the accounting year beginning from January 1, 2024 and which have not been adopted in the Historical Financial Information as follows:

	<u>Effective for accounting periods beginning on or after</u>
Amendments to IAS 7 and IFRS 7, <i>Supplier Finance Arrangements</i>	1 January 2024
Amendments to IAS 1, <i>Non-current Liabilities with Covenants</i>	1 January 2024
Amendments to IAS 1, <i>Classification of Liabilities as Current or Non-current</i>	1 January 2024
Amendments to IFRS 16, <i>Lease Liability in a Sale and Leaseback</i>	1 January 2024
Amendments to IAS 21, <i>Lack of Exchangeability</i>	1 January 2025
Amendments to IFRS 10 and IAS 28, <i>Sale or contribution of assets between an investor and its associate or joint venture</i>	To be determined

The Group is in the process of making an assessment of what the impact of these amendments, new standards and interpretations is expected to be in the period of initial application. So far the Group has concluded that the adoption of them is unlikely to have a significant impact on the Group’s results of operations and financial position.

32 SUBSEQUENT EVENTS

[In January 2024, the Group entered into a technology transfer agreement with a third party pharmaceutical company to grant the third party an exclusive license to develop, manufacture and commercialise QX008N, one of the Group’s developing products, in mainland China, Hong Kong and Macau. The Group retains the exclusive rights to develop, manufacture and commercialise QX008N outside the licensed territory.]

Subsequent Financial Statements

No audited financial statements have been prepared by the Company or any of its subsidiaries in respect of any period subsequent to 30 September 2023.

APPENDIX II UNAUDITED PRO FORMA FINANCIAL INFORMATION

The following information does not form part of the Accountants’ Report from KPMG, Certified Public Accountants, Hong Kong, the Company’s reporting accountants, as set out in Appendix I to this document, and is included for illustrative purposes only. The unaudited pro forma financial information should be read in conjunction with the “Financial Information” section in this document and the Accountants’ Report set out in Appendix I to this document.

[REDACTED]

APPENDIX II UNAUDITED PRO FORMA FINANCIAL INFORMATION

[REDACTED]

APPENDIX II UNAUDITED PRO FORMA FINANCIAL INFORMATION

[REDACTED]

APPENDIX II UNAUDITED PRO FORMA FINANCIAL INFORMATION

[REDACTED]

APPENDIX II UNAUDITED PRO FORMA FINANCIAL INFORMATION

[REDACTED]

**APPENDIX III UNAUDITED PRELIMINARY FINANCIAL INFORMATION
FOR THE YEAR ENDED DECEMBER 31, 2023**

The following is the preliminary financial information of our Group as of and for the year ended December 31, 2023 (the “2023 Preliminary Financial Information”), together with comparative figures as of and for the year ended December 31, 2022 and a discussion and analysis of our Group’s financial condition and results of operations. The 2023 Preliminary Financial Information has not been audited. [REDACTED] should bear in mind that the 2023 Preliminary Financial Information in this Appendix III may be subject to adjustments.

2023 PRELIMINARY FINANCIAL INFORMATION

CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

	<i>Note</i>	<u>2022</u>	<u>2023</u>
		<i>RMB’000</i>	<i>RMB’000</i> <i>(unaudited)</i>
Other income	2	25,726	24,921
Other net gain/(loss)	2	14,402	(435)
Administrative expenses		(76,603)	(164,594)
Research and development expenses		(257,214)	(364,404)
Loss from operations		(293,689)	(504,512)
Finance costs	3	(18,692)	(16,821)
Loss before taxation	3	(312,381)	(521,333)
Income tax	4	73	73
Loss for the year		<u>(312,308)</u>	<u>(521,260)</u>
Attributable to:			
Equity shareholders of the Company		(298,191)	(507,748)
Non-controlling interests		(14,117)	(13,512)
Loss for the year		(312,308)	(521,260)
Other comprehensive income for the year (after tax)		—	—
Total comprehensive income for the year		<u>(312,308)</u>	<u>(521,260)</u>
Attributable to:			
Equity shareholders of the Company		(298,191)	(507,748)
Non-controlling interests		(14,117)	(13,512)
Total comprehensive income for the year		<u>(312,308)</u>	<u>(521,260)</u>
Loss per share			
Basic and diluted (RMB)	5	<u>(1.68)</u>	<u>(2.47)</u>

**APPENDIX III UNAUDITED PRELIMINARY FINANCIAL INFORMATION
FOR THE YEAR ENDED DECEMBER 31, 2023**

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

	<i>Note</i>	31 December 2022	31 December 2023
		<i>RMB'000</i>	<i>RMB'000 (unaudited)</i>
Non-current assets			
Property, plant and equipment		363,125	339,106
Right-of-use assets		23,039	22,329
Intangible assets		3,052	2,347
Other non-current assets		9,936	13,472
		<u>399,152</u>	<u>377,254</u>
Current assets			
Inventories and other contract costs		—	4,937
Prepayments and other receivables	6	18,384	26,468
Other current assets		3,377	10,210
Financial assets at fair value through profit or loss		401,097	160,414
Cash and cash equivalents		213,090	216,300
		<u>635,948</u>	<u>418,329</u>
Current liabilities			
Trade and other payables	7	59,930	129,914
Contract liabilities		—	870
Interest-bearing borrowings	8	60,508	119,702
Lease liabilities		1,752	1,290
		<u>122,190</u>	<u>251,776</u>
Net current assets		<u>513,758</u>	<u>166,553</u>
Total assets less current liabilities		<u>912,910</u>	<u>543,807</u>
Non-current liabilities			
Non-current interest-bearing borrowings	8	232,521	224,433
Deferred income		18,018	17,377
Lease liabilities		472	634
Deferred tax liabilities		486	413
		<u>251,497</u>	<u>242,857</u>
NET ASSETS		<u>661,413</u>	<u>300,950</u>
CAPITAL AND RESERVES			
Share capital		180,525	210,025
Reserves		461,190	84,739
Total equity attributable to equity shareholders of the Company		<u>641,715</u>	<u>294,764</u>
Non-controlling interests		<u>19,698</u>	<u>6,186</u>
TOTAL EQUITY		<u>661,413</u>	<u>300,950</u>

**APPENDIX III UNAUDITED PRELIMINARY FINANCIAL INFORMATION
FOR THE YEAR ENDED DECEMBER 31, 2023**

NOTES TO THE 2023 PRELIMINARY FINANCIAL INFORMATION

1 MATERIAL ACCOUNTING POLICY

The 2023 Preliminary Financial Information does not constitute the consolidated financial statements of the Company and its subsidiaries (collectively referred to as the “Group”) for the year ended 31 December 2023 but is extracted from those financial statements.

(a) Statement of compliance

The Group’s consolidated financial statements have been prepared in accordance with all applicable International Financial Reporting Standards (“IFRSs”), which collective term includes all applicable individual International Financial Reporting Standards, International Accounting Standards (“IASs”) and Interpretations issued by the International Accounting Standards Board (“IASB”) and the requirements of the Hong Kong Companies Ordinance. These financial statements also comply with the applicable disclosure provisions of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited (the “Stock Exchange”). Significant accounting policies adopted by the Group are disclosed in Note 2 in “Appendix I—Accountants’ Report”. There has been no change in the significant accounting policies used in preparing the consolidated financial statements for the years ended 31 December 2022 and 2023.

The IASB has issued a number of new and revised IFRSs. For the purpose of preparing these consolidated financial statements, the Group has adopted all applicable new and revised IFRSs for the accounting period beginning on 1 January 2023. The Group has not early adopted any other new standards or interpretations that are not yet effective for the accounting period beginning on 1 January 2023. The revised and new accounting standards and interpretations issued but not yet effective for the accounting period beginning on 1 January 2023 are set out in note 10.

(b) Basis of preparation of the financial statements

The consolidated financial statements for the year ended 31 December 2023 comprise the Company and its subsidiaries.

As the Group’s operation are primarily located in the PRC and most of the Group’s transactions are conducted and denominated in Renminbi (“RMB”), which is the functional currency of the Group, the consolidated financial statements are presented in RMB, rounded to the nearest thousand, unless otherwise stated.

The measurement basis used in the preparation of the financial statements is the historical cost basis except that the financial assets measured at fair value through profit or loss (“FVPL”) is stated at their fair value.

The preparation of financial statements in conformity with IFRSs requires management to make judgements, estimates and assumptions that affect the application of policies and reported amounts of assets, liabilities, income and expenses. The estimates and associated assumptions are based on historical experience and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis of making the judgements about carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates.

The estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognised in the period in which the estimate is revised if the revision affects only that period, or in the period of the revision and future periods if the revision affects both current and future periods.

**APPENDIX III UNAUDITED PRELIMINARY FINANCIAL INFORMATION
FOR THE YEAR ENDED DECEMBER 31, 2023**

2 OTHER INCOME AND OTHER NET GAIN/(LOSS)

(a) Other income

	<u>2022</u>	<u>2023</u>
	<i>RMB'000</i>	<i>RMB'000</i> <i>(unaudited)</i>
Government grants (including amortisation of deferred income) (i)	9,194	13,596
Interest income from bank deposits	4,167	4,466
Net realised and unrealised gains on financial assets measured at FVPL	11,897	5,704
Others	468	1,155
	<u>25,726</u>	<u>24,921</u>

- (i) Government grants mainly represent (i) government subsidies for encouragement of research and development activities and compensation on the incurred interest expenses of bank loans, which were recognised in profit or loss when received; (ii) government subsidies for compensation on certain capital expenditure incurred for the construction of manufacturing facilities, which were amortised in profit or loss over the estimated useful lives of the relevant assets.

(b) Other net gain/(loss)

	<u>2022</u>	<u>2023</u>
	<i>RMB'000</i>	<i>RMB'000</i> <i>(unaudited)</i>
Net foreign exchange gain/(loss)	14,457	(426)
Others	(55)	(9)
	<u>14,402</u>	<u>(435)</u>

3 LOSS BEFORE TAXATION

Loss before taxation is arrived at after charging/(crediting):

(a) Finance costs

	<u>2022</u>	<u>2023</u>
	<i>RMB'000</i>	<i>RMB'000</i> <i>(unaudited)</i>
Interest on lease liabilities	99	65
Interest on interest-bearing borrowings	18,593	16,756
Total finance costs on financial liabilities not at FVPL	<u>18,692</u>	<u>16,821</u>

**APPENDIX III UNAUDITED PRELIMINARY FINANCIAL INFORMATION
FOR THE YEAR ENDED DECEMBER 31, 2023**

(b) Staff costs

	<u>2022</u>	<u>2023</u>
	<i>RMB'000</i>	<i>RMB'000</i> <i>(unaudited)</i>
Salaries, wages and other benefits	69,164	84,078
Contributions to defined contribution retirement schemes	6,563	7,026
Equity-settled share-based payment expenses	41,556	131,297
	<u>117,283</u>	<u>222,401</u>

(c) Other items

	<u>2022</u>	<u>2023</u>
	<i>RMB'000</i>	<i>RMB'000</i> <i>(unaudited)</i>
Amortisation cost of intangible assets	338	705
Depreciation charge of property, plant and equipment	28,310	29,422
Depreciation charge of right-of-use assets	1,892	2,158
	<u>30,540</u>	<u>32,285</u>
Auditors' remuneration	2,001	2,457
[REDACTED] expenses	[REDACTED]	[REDACTED]
Research and development expenses	257,214	364,404

4 INCOME TAX IN THE CONSOLIDATED STATEMENTS OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

(a) Taxation in the consolidated statements of profit or loss represents:

	<u>2022</u>	<u>2023</u>
	<i>RMB'000</i>	<i>RMB'000</i> <i>(unaudited)</i>
Current tax—PRC Tax	—	—
Deferred tax	(73)	(73)
	<u>(73)</u>	<u>(73)</u>

**APPENDIX III UNAUDITED PRELIMINARY FINANCIAL INFORMATION
FOR THE YEAR ENDED DECEMBER 31, 2023**

(b) Reconciliation between tax expense and accounting loss at applicable tax rates:

	<u>2022</u>	<u>2023</u>
	<i>RMB'000</i>	<i>RMB'000</i> <i>(unaudited)</i>
Loss before taxation	<u>(312,381)</u>	<u>(521,333)</u>
Notional tax on loss before taxation, calculated at the rates applicable to profits in the PRC (i)	(78,095)	(130,334)
Effect of preferential tax rate (ii)	25,816	45,941
Effect of additional deduction on research and development expenses (iii)	(24,146)	(40,002)
Tax effect of other non-deductible expenses	493	839
Tax effect of deductible temporary differences not recognised	9,255	27,754
Tax effect of unused tax losses not recognised	<u>66,604</u>	<u>95,729</u>
Actual tax expense	<u>(73)</u>	<u>(73)</u>

- (i) Pursuant to the Enterprise Income Tax (the “EIT”) Law of the PRC (the “EIT Law”), the Company and its PRC subsidiaries are liable to EIT at a rate of 25% unless otherwise specified.
- (ii) According to the Administrative Measures for Determination of High-Tech Enterprises (Guokefahuo [2016] No. 32) issued by Ministry of Finance of the People’s Republic of China, Ministry of Science and Technology of the People’s Republic of China and National Taxation Bureau of the People’s Republic of China, the Company obtained the qualification as high-tech enterprise and was entitled to a preferential income tax rate of 15% for the years from 2021 to 2023.
- (iii) According to the tax incentive policies promulgated by the State Tax Bureau of the PRC, which were effective from 1 January 2018 to 30 September 2022, an additional 75% of qualified research and development expenses incurred would be allowed to be deducted from the taxable income.

According to a new tax incentives policy promulgated by the State Tax Bureau of the PRC in September 2022, an additional 100% of qualified expenses incurred from 1 October 2022 to 31 December 2023 is allowed to be deducted from the taxable income.

5 LOSS PER SHARE

The calculation of basic loss per share for the year ended 31 December 2023 is based on the loss attributable to ordinary equity shareholders of the Company of RMB507,748,000 (2022: RMB298,191,000) and the weighted average of 205,668,000 ordinary shares (2022: 177,804,000) in issue during the year, calculated as follows:

Weighted average number of ordinary shares

	<u>2022</u>	<u>2023</u>
	<i>RMB'000</i>	<i>RMB'000</i> <i>(unaudited)</i>
Ordinary shares at 1 January in issue or deemed to be in issue	166,480	180,525
Effect of ordinary shares in issue or deemed to be in issue	<u>11,324</u>	<u>25,143</u>
Weighted average number of ordinary shares at the end of the year	<u>177,804</u>	<u>205,668</u>

**APPENDIX III UNAUDITED PRELIMINARY FINANCIAL INFORMATION
FOR THE YEAR ENDED DECEMBER 31, 2023**

Share options granted by the Company were not included in the calculation of diluted loss per share because their effect would have been anti-dilutive. Accordingly, diluted loss per share for the year ended 31 December 2023 and 2022 were the same as basic loss per share of the respective years.

6 PREPAYMENTS AND OTHER RECEIVABLES

	<u>2022</u>	<u>2023</u>
	<i>RMB'000</i>	<i>RMB'000</i> <i>(unaudited)</i>
Prepaid expenses	16,232	23,029
[REDACTED] expenses	[REDACTED]	[REDACTED]
Deposits	546	541
Interest receivables	244	40
Other debtors	418	324
	<u>[REDACTED]</u>	<u>[REDACTED]</u>

All of the prepayments and other receivables are expected to be recovered or recognised as expense within one year.

7 TRADE AND OTHER PAYABLES

	<u>2022</u>	<u>2023</u>
	<i>RMB'000</i>	<i>RMB'000</i> <i>(unaudited)</i>
Trade payables (i)	19,137	72,958
Payroll payables	24,185	31,007
Interest payables	454	445
Payables for purchases of property, plant and equipment	7,823	5,016
Accrued [REDACTED] expenses	[REDACTED]	[REDACTED]
Other payables and accruals	3,831	5,155
	<u>[REDACTED]</u>	<u>[REDACTED]</u>

(i) As of the end of the reporting period, the ageing analysis of trade payables based on the invoice date is as follows:

	<u>2022</u>	<u>2023</u>
	<i>RMB'000</i>	<i>RMB'000</i> <i>(unaudited)</i>
Within 6 months	<u>19,137</u>	<u>72,958</u>

**APPENDIX III UNAUDITED PRELIMINARY FINANCIAL INFORMATION
FOR THE YEAR ENDED DECEMBER 31, 2023**

8 INTEREST-BEARING BORROWINGS

(a) The analysis of the carrying amount of interest-bearing borrowings is as follows:

	<u>2022</u>	<u>2023</u>
	<i>RMB'000</i>	<i>RMB'000</i> <i>(unaudited)</i>
Unsecured short-term bank loans	15,900	59,600
Current proportion of unsecured long-term bank loans	—	625
Current proportion of secured long-term bank loans	<u>44,608</u>	<u>59,477</u>
Within 1 year or on demand	<u>60,508</u>	<u>119,702</u>
Unsecured long-term bank loans	—	49,375
Secured long-term bank loans	<u>232,521</u>	<u>175,058</u>
Non-current	<u>232,521</u>	<u>224,433</u>
	<u>293,029</u>	<u>344,135</u>

As at 31 December 2023, the secured long-term bank loans were obtained by Cellularforce, a subsidiary of the Company, from a bank consortium to support the construction of its manufacturing facilities. The loans were secured by the Cellularforce’s land use right and manufacturing facilities in Taizhou and guaranteed by the Company.

(b) The analysis of the repayment schedule of bank loans is as follows:

	<u>2022</u>	<u>2023</u>
	<i>RMB'000</i>	<i>RMB'000</i> <i>(unaudited)</i>
Within 1 year or on demand	<u>60,900</u>	<u>120,225</u>
After 1 year but within 2 years	60,000	84,625
After 2 years but within 5 years	<u>180,000</u>	<u>144,750</u>
	<u>240,000</u>	<u>229,375</u>
	<u>300,900</u>	<u>349,600</u>

9 DIVIDENDS

No dividends were paid or declared by the Company or any of its subsidiaries for the years ended 31 December 2023 and 2022.

**APPENDIX III UNAUDITED PRELIMINARY FINANCIAL INFORMATION
FOR THE YEAR ENDED DECEMBER 31, 2023**

**10 POSSIBLE IMPACT OF AMENDMENTS, NEW STANDARDS AND INTERPRETATIONS ISSUED
BUT NOT YET EFFECTIVE FOR THE YEAR ENDED 31 DECEMBER 2023**

Up to the date of issue of these financial statements, the HKICPA has issued a number of new or amended standards, which are not yet effective for the year ended 31 December 2023 and which have not been adopted in these financial statements. These developments include the following which may be relevant to the Group.

	<u>Effective for accounting periods beginning on or after</u>
Amendments to IAS 7 and IFRS 7, <i>Supplier Finance Arrangements</i>	1 January 2024
Amendments to IAS 1, <i>Non-current Liabilities with Covenants</i>	1 January 2024
Amendments to IAS 1, <i>Classification of Liabilities as Current or Non-current</i>	1 January 2024
Amendments to IFRS 16, <i>Lease Liability in a Sale and Leaseback</i>	1 January 2024
Amendments to IAS 21, <i>Lack of Exchangeability</i>	1 January 2025
Amendments to IFRS 10 and IAS 28, <i>Sale or Contribution of Assets between an investor and its Associate or Joint Venture</i>	To be determined

The Group is in the process of making an assessment of what the impact of these amendments, new standards and interpretations is expected to be in the period of initial application. So far the Group has concluded that the adoption of them is unlikely to have a significant impact on the Group’s results of operations and financial position.

**MANAGEMENT’S DISCUSSION AND ANALYSIS OF RESULTS OF OPERATIONS
AND FINANCIAL CONDITION**

Business Review

We are a clinical-stage biotech company exclusively focused on biologic therapies for autoimmune and allergic diseases, with a self-developed drug pipeline and an established commercial-scale in-house manufacturing capability. To address significant unmet medical needs in the autoimmune and allergic disease drug market in China, we have built a broad pipeline that covers the four major disease areas in the field, including skin, rheumatic, respiratory and digestive diseases. Our mission is to pursue scientific innovation and deliver affordable and quality therapeutics.

As a pre-revenue biotech company, we were not profitable and incurred operating losses in 2022 and 2023. In 2023, we had net loss of RMB521.3 million in 2023, compared to a net loss of RMB312.3 million in 2022. Our operating losses were primarily attributable to research and development expenses and administrative expenses.

**APPENDIX III UNAUDITED PRELIMINARY FINANCIAL INFORMATION
FOR THE YEAR ENDED DECEMBER 31, 2023**

Future Plans and Prospects

We plan to pursue the following strategies:

- Build leadership in dermatology, advance other drug candidates and strategically expand our pipeline;
- Continue to optimize CMC quality management system and improve production efficiency and enhance manufacturing capacity utilization;
- Cooperate with established pharmaceutical companies in commercialization;
- Explore international expansion opportunities; and
- Continue to recruit and develop talent.

Our Directors confirm that there has been no material adverse change in the financial or trading position or prospects of our Group since December 31, 2023 and up to the Latest Practicable Date.

Discussion of Certain Key Items of the Consolidated Statement of Profit or Loss and Other Comprehensive Income

The following table sets forth summary of our consolidated statement of profit or loss and other comprehensive income items for the years indicated.

	Year ended December 31,	
	2022	2023
	<i>(RMB'000)</i>	
	<i>(unaudited)</i>	
Other income	25,726	24,921
Other net gain/(loss)	14,402	(435)
Administrative expenses	(76,603)	(164,594)
Research and development expenses	(257,214)	(364,404)
Loss from operations	(293,689)	(504,512)
Finance costs	(18,692)	(16,821)
Loss before taxation	(312,381)	(521,333)
Income tax	73	73
Loss for the year	(312,308)	(521,260)

**APPENDIX III UNAUDITED PRELIMINARY FINANCIAL INFORMATION
FOR THE YEAR ENDED DECEMBER 31, 2023**

Year to Year Comparison

Revenue

We did not have any revenue or cost of revenue in 2022 or 2023.

Other Income

Our other income decreased by 3.1% from RMB25.7 million in 2022 to RMB24.9 million in 2023. This decrease was primarily attributable to a decrease of RMB6.2 million in net realized and unrealized gains on financial assets measured at FVTPL as we reduced purchasing of wealth management products in 2023, partially offset by an increase of RMB4.4 million in government grants, particularly subsidies for encouragement of research and development activities.

Other Net Gain/(Loss)

We recorded an other net gain of RMB14.4 million in 2022, primarily attributable to foreign exchange gain resulting from the appreciation of U.S. dollars against the Renminbi in 2022, in connection with our cash on hand denominated in U.S. dollars. [We recorded an other net loss of RMB0.4 million in 2023, primarily because we incurred loss by converting part of our cash on hand denominated in U.S. dollars in January 2023, which outweighs our foreign exchange gain resulting from the appreciation of U.S. dollars against the Renminbi in 2023, in connection with our cash on hand denominated in U.S. dollars.

Administrative Expenses

Our administrative expenses increased significantly from RMB76.6 million in 2022 to RMB164.6 million in 2023, primarily attributable to (i) an increase of RMB67.4 million in equity-settled share-based payment expenses, as we amortized the additional equity incentives granted in October 2022 throughout 2023; and (ii) an increase of RMB12.1 million in [REDACTED] expenses.

Research and Development Expenses

Our research and development expenses increased by 41.7% from RMB257.2 million in 2022 to RMB364.4 million in 2023, primarily attributable to (i) an increase of RMB85.6 million in third-party contracting costs as we increased engagement of CROs and trial sites to advance our drug development pipeline; and (ii) an increase of RMB22.3 million in equity-settled share-based payment expenses, mainly due to the amortization of the additional equity incentives granted in October 2022 throughout 2023.

**APPENDIX III UNAUDITED PRELIMINARY FINANCIAL INFORMATION
FOR THE YEAR ENDED DECEMBER 31, 2023**

Finance Costs

Our finance costs decreased by 10.0% from RMB18.7 million in 2022 to RMB16.8 million in 2023, primarily attributable to a decrease of RMB1.8 million in our interest on interest-bearing borrowings as we repaid part of our interest-bearing borrowings in June and December 2023.

Income Tax

Our income tax credits remained stable at RMB73,000 in 2022 and 2023.

Loss for the Year/Period

As a result of the above, we recorded a net loss of RMB312.3 million and RMB521.3 million in 2022 and 2023, respectively.

Discussion of Certain Consolidated Statement of Financial Position Items

Net Current Assets

	As of December 31,	
	2022	2023
	<i>(RMB'000)</i>	
	<i>(unaudited)</i>	
Current assets		
Inventories and other contract costs	–	4,937
Prepayments and other receivables	18,384	26,468
Other current assets	3,377	10,210
Financial assets at FVTPL	401,097	160,414
Cash and cash equivalents	213,090	216,300
	<u>635,948</u>	<u>418,329</u>
Total current assets	635,948	418,329
Current liabilities		
Trade and other payables	59,930	129,914
Contract liabilities	–	870
Interest-bearing bank borrowings	60,508	119,702
Lease liabilities	1,752	1,290
	<u>122,190</u>	<u>251,776</u>
Total current liabilities	122,190	251,776
Net current assets	513,758	166,553

**APPENDIX III UNAUDITED PRELIMINARY FINANCIAL INFORMATION
FOR THE YEAR ENDED DECEMBER 31, 2023**

The decrease in our net current assets from RMB513.8 million as of December 31, 2022 to RMB166.6 million as of December 31, 2023 was primarily attributable to (i) a decrease of RMB240.7 million in our financial assets at fair value through profit or loss as we reduced purchasing of wealth management products in 2023, which outpaced the increase in cash and cash equivalents of only RMB3.2 million, as we spent cash to support our daily operations in 2023; and (ii) an increase of RMB70.0 million in trade and other payables primarily attributable to our increased engagement of CROs and trial sites as we advanced the development of our drug candidates.

Inventories and Other Contract Costs

We recorded inventories and other contract costs of RMB4.9 million as of December 31, 2023, mainly representing our inventories of QX001S for the purpose of regulatory filings.

Prepayments and Other Receivables

The following table sets forth a breakdown of our prepayment and other receivables as of the dates indicated.

	As of December 31,	
	2022	2023
	<i>(RMB'000)</i>	
	<i>(unaudited)</i>	
Prepaid expenses	16,232	23,029
[REDACTED] expenses	[REDACTED]	[REDACTED]
Deposits	546	541
Receivables from other debtors	418	324
Interest receivables	244	40
Total	<u>[REDACTED]</u>	<u>[REDACTED]</u>

Our prepayments and other receivables increased by 44.0% from RMB18.4 million as of December 31, 2022 to RMB26.5 million as of December 31, 2023, primarily attributable to an increase of RMB6.8 million in prepaid expenses primarily due to our increased engagement of CROs and trial sites as we advanced the development of our drug candidates.

**APPENDIX III UNAUDITED PRELIMINARY FINANCIAL INFORMATION
FOR THE YEAR ENDED DECEMBER 31, 2023**

Trade and Other Payables

The following table sets forth the details of our other payables and accruals as of the dates indicated.

	As of December 31,	
	2022	2023
	<i>(RMB'000)</i>	
	<i>(unaudited)</i>	
Trade payables	19,137	72,958
Payroll payable	24,185	31,007
Accrued [REDACTED] expenses	[REDACTED]	[REDACTED]
Payables for purchases of property, plant and equipment	7,823	5,016
Other payables and accruals	3,831	5,155
Interest payables	454	445
Total	<u>[REDACTED]</u>	<u>[REDACTED]</u>

Our trade and other payables increased significantly from RMB59.9 million as of December 31, 2022 to RMB129.9 million as of December 31, 2023, primarily attributable to an increase of RMB53.8 million in trade payables mainly related to our increased engagement of CROs and trial sites as we advanced the development of our drug candidates.

Contract Liabilities

We had contract liabilities of RMB0.9 million as of December 31, 2023, related to the prepayment received under our CDMO service contracts with Zhongmei Huadong and third parties. The prepayment was recorded as contract liabilities and is expected to be recognized as income upon achievement of certain milestones under the respective contract.

**APPENDIX III UNAUDITED PRELIMINARY FINANCIAL INFORMATION
FOR THE YEAR ENDED DECEMBER 31, 2023**

Indebtedness

The following table provides information regarding our indebtedness as of the dates indicated.

	As of December 31,	
	2022	2023
	<i>(RMB'000)</i>	
	<i>(unaudited)</i>	
Current		
Interest-bearing borrowings	60,508	119,702
Lease liabilities	1,752	1,290
Non-current		
Non-current interest-bearing borrowings	232,521	224,433
Lease liabilities	472	634
Total	295,253	346,059

We had interest-bearing borrowings of RMB293.0 million and RMB344.1 million as of December 31, 2022 and 2023, respectively, which primarily consist of a secured bank loan used to support the construction of our manufacturing facility and unsecured bank loans to support our operation.

Key Financial Ratios

	As of December 31,	
	2022	2023
	<i>(unaudited)</i>	
Current ratio ⁽¹⁾	5.2	1.7

Note:

(1) Current ratio is calculated using current assets divided by current liabilities as of the same date.

Our current ratio decreased from 5.2 as of December 31, 2022 to 1.7 as of December 31, 2023, mainly attributable (i) a decrease of RMB240.7 million in our financial assets at fair value through profit or loss as we reduced purchasing of wealth management products in 2023, which outpaced the increase in cash and cash equivalents of only RMB3.2 million, as we spent cash to support our daily operations in 2023; and (ii) an increase of RMB70.0 million in trade and other payables primarily attributable to our increased engagement of CROs and trial sites as we advanced the development of our drug candidates.

**APPENDIX III UNAUDITED PRELIMINARY FINANCIAL INFORMATION
FOR THE YEAR ENDED DECEMBER 31, 2023**

DISCLOSURE ABOUT MARKET RISK

See “Financial Information—Quantitative and Qualitative Disclosure About Market Risk.”

CODE ON CORPORATE GOVERNANCE PRACTICES

Since we were not yet [REDACTED] on the Stock Exchange during the year ended December 31, 2023, the Corporate Governance Code as set out in Appendix C1 to the Listing Rules was not applicable to us during such period. After the [REDACTED], save for the deviation as disclosed in “Directors, Supervisors and Senior Management—Corporate Governance”, we will comply with all the code provisions set forth in the Corporate Governance Code.

REVIEW OF OUR PRELIMINARY FINANCIAL INFORMATION

The unaudited financial information in respect of our consolidated statement of financial position, consolidated statement of profit or loss and other comprehensive income and the related notes thereto for the year ended December 31, 2023 as set out in the section headed “2023 Preliminary Financial Information” in this Appendix III of this document have been agreed by the reporting accountants of our Company to the amounts set out in our draft consolidated financial statements for the year ended December 31, 2023, following their work under Practice Note 730 (Revised) “Guidance for Auditors Regarding Preliminary Announcement of Annual Results” issued by the Hong Kong Institute of Certified Public Accountants. The work performed by the reporting accountants of our Company in this respect did not constitute an assurance engagement and consequently no opinion or assurance conclusion has been expressed by the reporting accountants of our Company on the 2023 Preliminary Financial Information.

PURCHASE, SALE OR REDEMPTION OF OUR COMPANY’S SHARES

Since we were not yet [REDACTED] on the Stock Exchange during the year ended December 31, 2023, this disclosure requirement is not applicable to us.

APPENDIX IV

VALUATION REPORT

The following is the text of a letter, summary of values and valuation certificate prepared for the purpose of incorporation in this document received from Asia-Pacific Consulting and Appraisal Limited, an independent property valuer, in connection with its valuation as at 30 November 2023 of the selected property interests held by the Group.



CONSULTING & APPRAISAL
亞太評估

Asia-Pacific Consulting and Appraisal Limited

Flat/Rm A, 12/F
Kiu Fu Commercial Building
300 Lockhart Road
Wan Chai
Hong Kong

[REDACTED]

The Board of Directors
Qyuns Therapeutics Co., Ltd.
Room 1310, Building 1
No. 907 Yaocheng Avenue
Taizhou City
Jiangsu Province,
The PRC

Dear Sirs,

INSTRUCTIONS, PURPOSE AND DATE OF VALUATION

In accordance with your instructions to value the selected property interests held by Qyuns Therapeutics Co., Ltd. (the “**Company**”) and its subsidiaries (hereinafter together referred to as the “**Group**”) in the People’s Republic of China (the “**PRC**”). We confirm that we have carried out inspections, made relevant enquiries and searches and obtained such further information as we consider necessary for the purpose of providing you with our opinion on the market values of the selected property interests as at 30 November 2023 (the “**Valuation Date**”).

The selected property interests form part of the Group’s non-property activities that has a carrying amount of 15% or more of the Group’s total assets and therefore the valuation report of this property interests is required to be included in this document.

APPENDIX IV

VALUATION REPORT

BASIS OF VALUATION

Our valuation was carried out on a market value basis. Market value is defined as “the estimated amount for which an asset or liability should exchange on the Valuation Date between a willing buyer and a willing seller in an arm’s-length transaction after proper marketing and where the parties had each acted knowledgeably, prudently, and without compulsion”.

METHODS OF VALUATION

Due to the nature of the buildings and structures of the property in Group I and the particular location in which they are situated, there are unlikely to be relevant market comparable sales readily available, the buildings and structures of the property have been valued by the cost approach with reference to their depreciated replacement costs.

Depreciated replacement cost is defined as “the current cost of replacing an asset with its modern equivalent asset less deductions for physical deterioration and all relevant forms of obsolescence and optimization.” It is based on an estimate of the market value for the existing use of the land, plus the current cost of replacement of the improvements, less deduction for physical deterioration and all relevant forms of obsolescence and optimization. In arriving at the value of the land portion, reference has been made to the sales evidence as available in the locality. The depreciated replacement cost of the property interest is subject to adequate potential profitability of the concerned business. In our valuation, it applies to the whole of the complex or development as a unique interest, and no piecemeal transaction of the complex or development is assumed.

We have valued the portions of the property in Group II by the comparison approach assuming sale of the land property interests in their existing states with the benefit of immediate vacant possession and by making reference to comparable land sales transactions as available in the market. This approach rests on the wide acceptance of the market transactions as the best indicator and pre-supposes that evidence of relevant transactions in the market place can be extrapolated to similar land properties, subject to allowances for variable factors.

VALUATION ASSUMPTIONS

Our valuation has been made on the assumption that the seller sells the selected property interests in the market without the benefit of a deferred term contract, leaseback, joint venture, management agreement or any similar arrangement, which could serve to affect the values of the selected property interests.

No allowance has been made in our report for any charge, mortgage or amount owing on any of the selected property interests valued nor for any expense or taxation which may be incurred in effecting a sale. Unless otherwise stated, it is assumed that the property is free from encumbrances, restrictions and outgoings of an onerous nature, which could affect their values.

APPENDIX IV

VALUATION REPORT

VALUATION STANDARDS

In valuing the selected property interests, we have complied with all requirements contained in Chapter 5 and Practice Note 12 of the Rules Governing the Listing of Securities issued by The Stock Exchange of Hong Kong Limited; the RICS Valuation – Global Standards published by the Royal Institution of Chartered Surveyors; the HKIS Valuation Standards published by the Hong Kong Institute of Surveyors, and the International Valuation Standards issued by the International Valuation Standards Council.

SOURCE OF INFORMATION

We have relied to a very considerable extent on the information given by the Group and have accepted advice given to us on such matters as tenure, planning approvals, statutory notices, easements, particulars of occupancy, lettings, and all other relevant matters.

We have had no reason to doubt the truth and accuracy of the information provided to us by the Group. We have also sought confirmation from the Group that no material factors have been omitted from the information supplied. We consider that we have been provided with sufficient information to arrive an informed view, and we have no reason to suspect that any material information has been withheld.

DOCUMENT AND TITLE INVESTIGATION

We have been shown copies of various title documents including Real Estate Title Certificate and other official permits relating to the selected property interests and have made relevant enquiries. Where possible, we have examined the original documents to verify the existing title to the selected property interests in the PRC and any material encumbrance that might be attached to the selected property interests or any tenancy amendment. We have relied considerably on the advice given by the Company's PRC legal advisor – JunHe LLP, concerning the validity of the selected property interests in the PRC.

AREA MEASUREMENT AND INSPECTION

We have not carried out detailed measurements to verify the correctness of the areas in respect of the property but have assumed that the areas shown on the title documents and official site plans handed to us are correct. All documents and contracts have been used as reference only and all dimensions, measurements and areas are approximations. No on-site measurement has been taken.

We have inspected the exterior and, where possible, the interior of the property. However, we have not carried out investigation to determine the suitability of the ground conditions and services for any development thereon. Our valuation has been prepared on the assumption that these aspects are satisfactory and that no unexpected cost and delay will be incurred during construction. Moreover, no structural survey has been made, but in the course of our inspection, we did not note any serious defect. We are not, however, able to report whether the property is free of rot, infestation or any other structural defect. No tests were carried out on any of the services.

APPENDIX IV

VALUATION REPORT

The site inspection was carried out in 25 September 2023 by Kay Liu who is a Certified Public Valuer in PRC and has over 9 years' experience in property valuation in the PRC.

CURRENCY

All monetary figures stated in this report are in Renminbi (RMB).

Our summary of values and valuation certificates are attached below for your attention.

Yours faithfully,
for and on behalf of
Asia-Pacific Consulting and Appraisal Limited

David G. D. Cheng
MRICS
Executive Director

Note: David G. D. Cheng is a Chartered Surveyor who has 22 years' experience in the valuation of assets in the Greater China Region, the Asia-Pacific region, the United States and Canada.

APPENDIX IV

VALUATION REPORT

SUMMARY OF VALUES

Group I – Property interest held and occupied by the Group in the PRC

Group II – Property interest held to be developed by the Group in the PRC

Property	Market value in existing state as at the Valuation Date	Market value in existing state as at the Valuation Date	Interest attributable to the Group	The Total Market value attributable to the Group as at the Valuation Date
	<i>RMB</i>	<i>RMB</i>		<i>RMB</i>
	<i>Group I:</i>	<i>Group II:</i>		
A parcel of land, 6 buildings and various structures located at southern side of Yaocheng Avenue and western side of Huatuo Road, Yiyao Hi-tech Zone, Taizhou City, Jiangsu Province, The PRC	278,429,000	8,000,000	66%	189,043,000
Total:	<u>278,429,000</u>	<u>8,000,000</u>	<u>–</u>	<u>189,043,000</u>

APPENDIX IV

VALUATION REPORT

VALUATION CERTIFICATE

Property	Description and tenure	Particulars of occupancy	Market value in existing state as at the Valuation Date
			<i>RMB</i>
<p>A parcel of land, 6 buildings and various structures located at southern side of Yaocheng Avenue and western side of Huatuo Road, Yiyao Hi-tech Zone, Taizhou City, Jiangsu Province, The PRC</p>	<p>The property comprises a parcel of land with a site area of approximately 57,977.00 sq.m., among which the phase I of the property occupies portions of the land with a site area of approximately 40,770.06 sq.m. and 6 buildings and various structures erected thereon which were completed in 2021 (categorized as Group I). The phase II of the property is bare land as at the valuation date with a site area of approximately 17,206.94 sq.m. (categorized as Group II).</p> <p>The buildings and structures have a total gross floor area of approximately 43,571.43 sq.m., mainly include office buildings, warehouses and plants, gates, corridors and wastewater treatment facilities.</p> <p>The land use rights of the property have been granted to the Group for a term expiring on 13 March 2069 for industry use.</p>	<p>The phase I of the property is occupied by the Group for production and ancillary purposes, and the phase II of the property is bare land as at the valuation date.</p>	<p>286,429,000</p> <p>(66% interest attributable to the Group: 189,043,000)</p>

Notes:

1. Pursuant to a Real Estate Title Certificate – Su (2019) Taizhou Bu Dong Chan Quan Di No. 0003129, the land use rights of a parcel of land with a site area of approximately 57,977.00 sq.m. have been granted to Jiangsu Cellularforce Biotechnology Co., Ltd. (江蘇賽孚士生物技術有限公司, or abbreviated as “Cellularforce”, which is an indirect non-wholly owned subsidiary of the Company) for a term expiring on 13 March 2069 for industry use.

APPENDIX IV

VALUATION REPORT

2. Pursuant to a Real Estate Title Certificate – Su (2023) Taizhou Bu Dong Chan Quan Di No. 0004234, 9 buildings and structures and 4 corridors with a total gross floor area of approximately 43,571.43 sq.m. are owned by Cellularforce. The details are set out as follows:

<u>No.</u>	<u>Usage</u>	<u>Gross Floor Area</u> <i>(sq.m.)</i>
1	Research and development complex building	11,701.43
2	Quality control and pilot building	8,498.13
3	Stoste and preparation complex	13,002.48
4	Main warehouse	3,801.49
5	Central power station	5,765.10
6	Gate#1	26.02
7	Gate#2	26.02
8	Chemical warehouse	108.00
9	Wastewater treatment facilities	342.00
10	Corridor#1	81.69
11	Corridor#2	54.31
12	Corridor#3	73.57
13	Corridor#4	91.19
Total		43,571.43

3. We have been provided with a legal opinion regarding the property interest by the Company’s PRC legal advisors, which contains, inter alia, the following:

- a. The Group legally own the land use rights of the property mentioned in Note 1 for the production and operation use.
- b. The Group legally own the property interests of the buildings and structures mentioned in Note 2 for the production and operation use.
- c. The land and buildings of the property was mortgaged. The mortgagee is Taizhou Branch of Shanghai Pudong Development Bank Co., Ltd.

4. For the purpose of this report, the property is classified into the following groups according to the purpose for which it is held, we are of the opinion that the market value of each group as at the Valuation Date in its existing state is set out as below:

<u>Group</u>	<u>Market value</u> <u>in existing state</u> <u>as at the</u> <u>Valuation Date</u> <i>(RMB)</i>
Group I – Property interest held and occupied by the Group in the PRC	278,429,000
Group II – Property interest held to be developed by the Group in the PRC	8,000,000
Grand-total:	286,429,000

APPENDIX V

TAXATION AND FOREIGN EXCHANGE

TAXATION FOR HOLDERS OF SECURITIES

Income tax and capital gains tax of holders of the H Shares is subject to the laws and practices of the PRC and of jurisdictions in which holders of H Shares are residents or otherwise subject to tax. The following summary of certain relevant taxation provisions is based on current laws and practices, and has not taken in to account the expected change or amendment to the relevant laws and policies and does not constitute any opinion or advice. The discussion does not deal with all possible tax consequences relating to an investment in the H shares, nor does it take into account the specific circumstances of any particular investor, some of which may be subject to special regulation. Accordingly, you should consult your own tax advisor regarding the tax consequences of an investment in the H shares. The discussion is based upon laws and relevant interpretations in effect as of the Latest Practicable Date, all of which are subject to change and may have retrospective effect.

No issues on PRC or Hong Kong taxation other than income tax, capital gain tax and profits tax, business tax/VAT, stamp duty and estate duty were referred in the discussion. Prospective investors are urged to consult their financial advisors regarding the PRC, Hong Kong and other tax consequences of owning and disposing of the H Shares.

THE PRC TAXATION

Taxation on Dividends

Individual Investor

Pursuant to the Individual Income Tax Law of the PRC (《中華人民共和國個人所得稅法》), which was most recently amended on August 31, 2018 and the Implementation Provisions of the Individual Income Tax Law of the PRC (《中華人民共和國個人所得稅法實施條例》), which was most recently amended on December 18, 2018 (hereinafter collectively referred to as the “**IIT Law**”), dividends distributed by PRC enterprises are subject to individual income tax levied at a flat rate of 20%. For a foreign individual who is not a resident of the PRC, the receipt of dividends from an enterprise in the PRC is normally subject to individual income tax of 20% unless specifically exempted by the tax authority of the State Council or reduced by relevant tax treaty.

Pursuant to the Arrangement between the Mainland of China and the Hong Kong Special Administrative Region for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with respect to Taxes on Income (《內地和香港特別行政區關於對所得避免雙重徵稅和防止偷漏稅的安排》) (hereinafter referred to as the “**Arrangement for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with respect to Taxes on Income** (《對所得避免雙重徵稅和防止偷漏稅的安排》)”) signed by the Mainland of China and the Hong Kong Special Administrative Region on August 21, 2006, the PRC government may impose tax on dividends paid by a PRC company to a Hong Kong resident (including natural person and legal entity), but such tax shall not exceed 10% of the total amount of dividends payable. If a Hong Kong resident directly holds 25% or more of equity interest in a PRC

APPENDIX V

TAXATION AND FOREIGN EXCHANGE

company and the Hong Kong resident is the beneficial owner of the dividends and meets other conditions, such tax shall not exceed 5% of the total amount of dividends payable by the PRC company. The Fifth Protocol to the Arrangement between the Mainland of China and the Hong Kong Special Administrative Region for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with Respect to Taxes on Income (《國家稅務總局關於〈內地和香港特別行政區關於對所得避免雙重徵稅和防止偷漏稅的安排〉第五議定書》) (the “**Fifth Protocol** (《第五協議書》)”) issued by the SAT and became effective on December 6, 2019 provides that such provisions shall not apply to arrangements or transactions made for one of the primary purposes of obtaining such tax benefits.

Enterprise Investors

In accordance with the Enterprise Income Tax Law of the PRC (《中華人民共和國企業所得稅法》) issued by NPC on March 16, 2007 and latest amended on December 29, 2018 and the Implementation Provisions of the Enterprise Income Tax Law of the PRC (《中華人民共和國企業所得稅法實施條例》) issued by the State Council on December 6, 2007, came into effect on January 1, 2008 and amended on April 23, 2019 (hereinafter collectively referred to as the “**EIT Law**”), a non-resident enterprise is generally subject to a 10% enterprise income tax on PRC-sourced income (including dividends received from a PRC resident enterprise), if it does not have an establishment or premise in the PRC or has an establishment or premise in the PRC but its PRC-sourced income has no real connection with such establishment or premise. The aforesaid income tax payable for non-resident enterprises are deducted at source, where the payer of the income is required to withhold the income tax from the amount to be paid to the non-resident enterprise. Such withholding tax may be reduced or exempted pursuant to an applicable treaty for the avoidance of double taxation.

The Circular of the State Administration of Tax on Issues Relating to the Withholding and Remitting of Enterprise Income Tax by PRC Resident Enterprises on Dividends Distributed to Overseas Non-Resident Enterprise Shareholders of H Shares (《國家稅務總局關於中國居民企業向境外H股非居民企業股東派發股息代扣代繳企業所得稅有關問題的通知》), which was issued and implemented by the SAT on November 6, 2008, further clarified that a PRC-resident enterprise must withhold corporate income tax at a rate of 10% on the dividends paid to non-PRC resident enterprise holders of H Shares which are derived out of profit generated since 2008. Non-PRC resident enterprise shareholders who need to enjoy tax treaty benefits, the relevant provisions of such tax treaty shall apply.

Pursuant to the Arrangement for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with respect to Taxes on Income (《對所得避免雙重徵稅和防止偷漏稅的安排》), the PRC government may impose tax on dividends paid by a PRC company to a Hong Kong resident (including natural person and legal entity), but such tax shall not exceed 10% of the total amount of dividends payable. If a Hong Kong resident directly holds 25% or more of equity interest in a PRC company and the Hong Kong resident is the beneficial owner of the dividends and meets other conditions, such tax shall not exceed 5% of the total amount of dividends payable by the PRC company. The Fifth Protocol (《第五協議書》) provides that such provisions shall not apply to arrangements or transactions made for one of the primary purposes of obtaining such tax benefits.

APPENDIX V

TAXATION AND FOREIGN EXCHANGE

Although there may be other provisions under the Arrangement for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with respect to Taxes on Income (《對所得避免雙重徵稅和防止偷漏稅的安排》), the treaty benefits under the criteria shall not be granted in the circumstance where relevant gains, after taking into account all relevant facts and conditions, are reasonably deemed to be one of the main purposes for the arrangement or transactions which will bring any direct or indirect benefits under this Arrangement, except when the grant of benefits under such circumstance is consistent with relevant objective and goal under the Arrangement. The application of the dividend clause of tax agreements is subject to the requirements of PRC tax law and regulation, such as the Notice of the State Administration of Taxation on the Issues Concerning the Application of the Dividend Clauses of Tax Agreements (《國家稅務總局關於執行稅收協定股息條款有關問題的通知》).

Tax Treaties

Non-resident investors residing in jurisdictions which have entered into treaties or adjustments for the avoidance of double taxation with the PRC might be entitled to a reduction of the Chinese corporate income tax imposed on the dividends received from PRC companies. The PRC currently has entered into Avoidance of Double Taxation Treaties or Arrangements with a number of countries and regions including Hong Kong Special Administrative Region, Macau Special Administrative Region, Australia, Canada, France, Germany, Japan, Malaysia, the Netherlands, Singapore, the United Kingdom and the United States. Non-PRC resident enterprises entitled to preferential tax rates in accordance with the relevant taxation treaties or arrangements are required to apply to the Chinese tax authorities for a refund of the corporate income tax in excess of the agreed tax rate, and the refund application is subject to approval by the Chinese tax authorities.

Taxation on Share Transfer

VAT and Local Additional Tax

Pursuant to the Notice of Ministry of Finance and State Administration of Taxation on Fully Implementing the Pilot Reform for the Transition from Business Tax to Value-added Tax (《財政部、國家稅務總局關於全面推開營業稅改徵增值稅試點的通知》) (the “**Circular 36**”), which was implemented on May 1, 2016 and partially repealed on July 1, 2017, January 1, 2018 and April 1, 2019, entities and individuals engaged in the services sale in the PRC are subject to VAT and “engaged in the services sale in the PRC” means that the seller or buyer of the taxable services is located in the PRC. Circular 36 also provides that transfer of financial products, including transfer of the ownership of marketable securities, shall be subject to VAT at 6% on the taxable revenue (which is the balance of sales price upon deduction of purchase price), for a general or a foreign VAT taxpayer. However, individuals who transfer financial products are exempt from VAT, which is also provided in the Notice of Ministry of Finance and State Administration of Taxation on Several Tax Exemption Policies for Business Tax on Sale and Purchase of Financial Commodities by Individuals (《財政部、國家稅務總局關於個人金融商品買賣等營業稅若干免稅政策的通知》) effective on January 1, 2009. According to these regulations, if the holder is a non-resident individual, the PRC VAT is exempted from the sale or disposal of H shares; if the holder is a non-resident enterprise and the H-share buyer is an individual or entity located outside the PRC, the holder is not necessarily required to pay the PRC VAT, but if the H-share buyer is an individual or entity located in China, the holder may be required to pay the PRC VAT.

APPENDIX V

TAXATION AND FOREIGN EXCHANGE

However, in view of no clear regulations, it is still uncertain whether the non-Chinese resident enterprises are required to pay the PRC VAT for the disposal of H shares in practice.

At the same time, VAT payers are also required to pay urban maintenance and construction tax, education surtax and local education surcharge, which shall be usually subject to 12% of the VAT payable (if any).

Income Tax

Individual Investors

According to the IIT Law, gains on the transfer of equity interests in the PRC resident enterprises are subject to individual income tax at a rate of 20%.

Pursuant to the Circular on Declaring that Individual Income Tax Continues to be Exempted over Income of Individuals from the Transfer of Shares (《關於個人轉讓股票所得繼續暫免徵收個人所得稅的通知》) issued by the Ministry of Finance and the SAT on March 30, 1998, from January 1, 1997, income of individuals from transfer of the shares of listed enterprises continues to be exempted from individual income tax. The Ministry of Finance and the SAT have not expressly stated whether they will continue to exempt tax on income of individuals from transfer of the shares of listed enterprises in the latest amended IIT Law.

However, on December 31, 2009, the Ministry of Finance, SAT and CSRC jointly issued the Circular on Related Issues on Levying Individual Income Tax over the Income Received by Individuals from the Transfer of Listed Shares Subject to Sales Limitation (《關於個人轉讓上市公司限售股所得徵收個人所得稅有關問題的通知》), which came into effect on January 1, 2010, which states that individuals' income from the transfer of listed shares obtained from the public offering of listed companies and transfer market on the Shanghai Stock Exchange and the Shenzhen Stock Exchange shall continue to be exempted from individual income tax, except for the relevant shares which are subject to sales restriction (as defined in the Supplementary Notice on Issues Concerning the Levy of Individual Income Tax on Individuals' Income from the Transfer of Restricted Stocks of Listed Companies (《關於個人轉讓上市公司限售股所得徵收個人所得稅有關問題的補充通知》) jointly issued and implemented by such departments on November 10, 2010). As of the Latest Practicable Date, no aforesaid provisions have expressly provided that individual income tax shall be levied from non-Chinese resident individuals on the transfer of shares in PRC resident enterprises listed on overseas stock exchanges.

Enterprise Investors

In accordance with the EIT Law, a non-resident enterprise is generally subject to corporate income tax at the rate of a 10% on PRC-sourced income, including gains derived from the disposal of equity interests in a PRC resident enterprise, if it does not have an establishment or premise in the PRC or has an establishment or premise in the PRC but its PRC-sourced income has no real connection with such establishment or premise. Such income

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tax payable for non-resident enterprises are deducted at source, where the payer of the income is required to withhold the income tax from the amount to be paid to the non-resident enterprise. Such tax may be reduced or exempted pursuant to relevant tax treaties or agreements on avoidance of double taxation.

Stamp Duty

According to the Stamp Duty Law of the PRC (《中華人民共和國印花稅法》), which was promulgated on June 10, 2021 and came into effect on July 1, 2022, PRC stamp duty only applies to specific taxable document executed or received within the PRC, having legally binding force in the PRC and protected under the PRC laws, thus the requirements of the stamp duty imposed on the transfer of shares of PRC listed companies shall not apply to the acquisition and disposal of H Shares by non-PRC investors outside of the PRC.

Estate Duty

As of the date of this document, no estate duty has been levied in the PRC under the PRC laws.

EIT

According to the EIT Law, enterprises and other income-generating organizations (hereinafter collectively referred to as "an enterprise" or "enterprises") within the territory of the PRC are the taxpayers of enterprise income tax and shall pay enterprise income tax in accordance with the provisions of the EIT Law. The Enterprise Income Tax rate is 25%.

According to the Administrative Measures for Determination of High and New Tech Enterprises (《高新技術企業認定管理辦法》), which was promulgated by the Ministry of Science and Technology, the Ministry of Finance and the State Administration of Taxation on April 14, 2008, amended on January 29, 2016 and became effective on January 1, 2016, an enterprise recognized as a high and new technology enterprise may apply for a preferential enterprise income tax rate of 15% pursuant to the relevant requirements of the EIT Law.

VAT

Pursuant to the Interim Regulations on Value-added Tax of the PRC (《中華人民共和國增值稅暫行條例》) issued on December 13, 1993 by the State Council, came into effect on January 1, 1994, and revised on November 10, 2008, February 6, 2016 and November 19, 2017, as well as the Implementation Rules for the Interim Regulations on Value-Added Tax of the PRC (《中華人民共和國增值稅暫行條例實施細則》) issued on December 25, 1993 by the MOF, came into effect on the same day and revised on December 15, 2008 and October 28, 2011, any entities and individuals engaged in the sale of goods, supply of processing, repair and replacement services, and import of goods within the territory of the PRC are taxpayers of VAT and shall pay the VAT in accordance with the law and regulation. The rate of VAT for sale of goods is 17% unless otherwise specified, such as the rate of VAT for sale of transportation

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is 11%. With the VAT reforms in the PRC, the rate of VAT has been changed several times. The MOF and the SAT issued the Notice of on Adjusting VAT Rates (《財政部、國家稅務總局關於調整增值稅稅率的通知》) on April 4, 2018 to adjust the tax rates of 17% and 11% applicable to any taxpayer's VAT taxable sale or import of goods to 16% and 10%, respectively, this adjustment became effect on May 1, 2018. Subsequently, the MOF, the SAT and the General Administration of Customs jointly issued the Announcement on Relevant Policies for Deepening the VAT Reform (《財政部、國家稅務總局關於深化增值稅改革有關政策的公告》) on March 20, 2019 to make a further adjustment, which came into effect on April 1, 2019. The tax rate of 16% applicable to the VAT taxable sale or import of goods shall be adjusted to 13%, and the tax rate of 10% applicable thereto shall be adjusted to 9%.

TAXATION IN HONG KONG

Tax on Dividends

Under the current practice of the Inland Revenue Department of Hong Kong, no tax is payable in Hong Kong in respect of dividends paid by us.

Capital Gains Tax and Profit Tax

No tax is imposed in Hong Kong in respect of capital gains from the [REDACTED] of H Shares. However, [REDACTED] gains from the [REDACTED] of the H Shares by persons carrying on a trade, profession or business in Hong Kong, where such gains are derived from or arise in Hong Kong from such trade, profession or business will be subject to Hong Kong profits tax, which is currently imposed at the maximum rate of 16.5% on corporations and at the maximum rate of 15% on unincorporated businesses. Certain categories of taxpayers (for example, financial institutions, insurance companies and securities dealers) are likely to be regarded as deriving [REDACTED] gains rather than capital gains unless these taxpayers can prove that the investment securities are held for long-term investment purposes. [REDACTED] gains from sales of H Shares effected on the Stock Exchange will be considered to be derived from or arise in Hong Kong. Liability for Hong Kong profits tax would thus arise in respect of [REDACTED] gains from [REDACTED] of H Shares effected on the Stock Exchange realized by persons carrying on a business of [REDACTED] or [REDACTED] in securities in Hong Kong.

Stamp Duty

Hong Kong stamp duty, currently charged at the ad valorem rate of 0.1% on the higher of the consideration for or the [REDACTED] of the H Shares, will be payable by the purchaser on every purchase and by the seller on every [REDACTED] of Hong Kong securities, including H Shares (in other words, a total of 0.2% is currently payable on a typical sale and purchase transaction involving H Shares). In addition, a fixed duty of HK\$5.00 is currently payable on any instrument of transfer of H Shares. Where one of the parties is a resident outside Hong Kong and does not pay the ad valorem duty due by it, the duty not paid will be assessed on the instrument of transfer (if any) and will be payable by the transferee. If no stamp duty is paid on or before the due date, a penalty of up to ten times the duty payable may be imposed.

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Estate Duty

The Revenue (Abolition of Estate Duty) Ordinance 2005 came into effect on February 11, 2006 in Hong Kong, pursuant to which no Hong Kong estate duty is payable and no estate duty clearance papers are needed for an application of a grant of representation in respect of holders of H Shares whose deaths occur on or after February 11, 2006.

FOREIGN EXCHANGE ADMINISTRATION IN THE PRC

The lawful currency of the PRC is Renminbi, which is currently subject to foreign exchange control and cannot be freely converted into foreign currency. The SAFE, with the authorization of the People's Bank of China (the "PBOC"), is empowered with the functions of administering all matters relating to foreign exchange, including the enforcement of foreign exchange control regulations.

The Administrative Regulations on Foreign Exchange of the PRC (《中華人民共和國外匯管理條例》) which was issued by the State Council on January 29, 1996, implemented on April 1, 1996 and latest amended on 5 August, 2008, classifies all international payments and transfers into current items and capital items. Current items are subject to the reasonable examination of the veracity of transaction documents and the consistency of the transaction documents and the foreign exchange receipts and payments by financial institutions engaging in conversion and sale of foreign currencies and supervision and inspection by the foreign exchange control authorities. For capital items, overseas organizations and overseas individuals making direct investments in the PRC shall, upon approval by the relevant authorities in charge, process registration formalities with the foreign exchange control authorities. Foreign exchange income received overseas can be repatriated or deposited overseas, and foreign exchange and foreign exchange settlement funds under the capital account are required to be used only for purposes as approved by the competent authorities and foreign exchange administrative authorities. In the event that international revenues and expenditure occur or may occur a material imbalance, or the national economy encounters or may encounter a severe crisis, the State may adopt necessary safeguard and control measures on international revenues and expenditure.

The Regulations for the Administration of Settlement, Sale and Payment of Foreign Exchange (《結匯、售匯及付匯管理規定》), which was promulgated by the PBOC on June 20, 1996 and implemented on July 1, 1996, removes other restrictions on convertibility of foreign exchange under current items, while imposing existing restrictions on foreign exchange transactions under capital account items.

According to the Announcement on Improving the Reform of the Renminbi Exchange Rate Formation Mechanism (《關於完善人民幣匯率形成機制改革的公告》), which was issued by the PBOC and implemented on July 21, 2005, the PRC has started to implement a managed floating exchange rate system in which the exchange rate would be determined based on market supply and demand and adjusted with reference to a basket of currencies since July

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21, 2005. Therefore, the Renminbi exchange rate was no longer pegged to the U.S. dollar. PBOC would publish the closing price of the exchange rate of the Renminbi against trading currencies such as the U.S. dollar in the interbank foreign exchange market after the closing of the market on each working day, as the central parity of the currency against Renminbi transactions on the following working day.

According to the relevant laws and regulations in the PRC, PRC enterprises (including foreign investment enterprises) which need foreign exchange for current item transactions may, without the approval of the foreign exchange administrative authorities, effect payment through foreign exchange accounts opened at the designated foreign exchange bank, on the strength of valid transaction receipts and proof. Foreign investment enterprises which need foreign exchange for the distribution of profits to their shareholders and PRC enterprises which, in accordance with regulations, are required to pay dividends to their shareholders in foreign exchange (such as our Company) may, on the strength of resolutions of the board of directors or the shareholders' meeting on the distribution of profits, effect payment from foreign exchange accounts at the designated foreign exchange bank, or effect exchange and payment at the designated foreign exchange bank.

According to the Decisions on Matters including Canceling and Adjusting a Batch of Administrative Approval Items (《國務院關於取消和調整一批行政審批項目等事項的決定》) which was promulgated by the State Council on October 23, 2014, it decided to cancel the approval requirement of the SAFE and its branches for the remittance and settlement of the proceeds raised from the overseas listing of the foreign shares into RMB domestic accounts.

According to the Notice of the State Administration of Foreign Exchange on Issues Concerning the Foreign Exchange Administration of Overseas Listing (《國家外匯管理局關於境外上市外匯管理有關問題的通知》) issued by the SAFE and implemented on December 26, 2014, a domestic company shall, within 15 business days from the date of the end of its overseas listing issuance, register the overseas listing with the local branch office of state administration of foreign exchange at the place of its establishment; the proceeds from an overseas listing of a domestic company may be remitted to the domestic account or deposited in an overseas account, but the use of the proceeds shall be consistent with the content of the document and other disclosure documents.

According to the Notice of the State Administration of Foreign Exchange of the PRC on Revolutionizing and Regulating Capital Account Settlement Management Policies (《國家外匯管理局關於改革和規範資本項目結匯管理政策的通知》) which was promulgated by the SAFE and implemented on June 9, 2016, foreign currency earnings in capital account that relevant policies of willingness exchange settlement have been clearly implemented on (including the recalling of raised capital by overseas listing) may undertake foreign exchange settlement in the banks according to actual business needs of the domestic institutions.

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The tentative percentage of foreign exchange settlement for foreign currency earnings in capital account of domestic institutions is 100%, subject to adjustments of the SAFE in due time in accordance with international revenue and expenditure situations. The Circular on Issues Concerning the Administration of Foreign Exchange in Offshore Investments and Financing and Return Investments by Domestic Residents through Special Purpose Vehicles (《國家外匯管理局關於境內居民通過特殊目的公司境外投融資及返程投資外匯管理有關問題的通知》) (the “**Circular 37**”) was promulgated and implemented by the SAFE on July 4, 2014. According to Circular 37, domestic residents, individuals and entities shall apply to the SAFE for registration of foreign exchange for offshore investment before making contributions to special purpose vehicles with domestic and overseas legal assets or equities. In addition, any domestic resident who is a shareholder of an overseas special purpose vehicle shall complete the registration formality of foreign exchange alteration for offshore investment with the SAFE in a timely manner in the event of any change of significant matters of such overseas special purpose vehicle such as capital increase/decrease, equity transfer or swap, merge and spin-off.

The subsequent foreign exchange business (including remittance of profits and dividend) of a domestic resident who fails to comply with the registration requirements as set out in Circular 37 may be restricted. Domestic residents that have made contributions to special purpose vehicles with domestic and overseas legal assets or equities without the required registration of foreign exchange for offshore investment prior to the implementation of Circular 37 shall issue a letter of explanation to the SAFE containing specific reasons. The SAFE shall make a post-registration following the principles of legality and rationality and impose administrative penalties in case of suspected violation of the Regulations on Foreign Exchange Control of the PRC. According to the Circular on Further Simplifying and Improving Foreign Exchange Administration Policies in Respect of Direct Investment (《關於進一步簡化和改進直接投資外匯管理政策的通知》), which was issued by the SAFE on February 13, 2015, came into effect on June 1, 2015 and partially repealed on 30 December, 2019, the confirmation of foreign exchange registration under domestic direct investment and the confirmation of foreign exchange registration under overseas direct investment shall be directly examined and handled by banks and the foreign exchange authorities shall indirectly regulate the foreign exchange registration of direct investment through banks. The banks that have obtained financial institution identification codes from foreign exchange authorities and have connected to the Capital Account Information System with the local foreign exchange authorities may directly handle the registration under Circular 37.

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SUMMARY OF PRINCIPAL LEGAL AND REGULATORY PROVISIONS

PRC LEGAL SYSTEM

The PRC legal system is based on the Constitution of the PRC (《中華人民共和國憲法》) (the “Constitution”) and is made up of written laws, administrative regulations, local regulations, separate regulations, autonomous regulations, rules and regulations of departments, rules and regulations of local governments, international treaties of which the PRC government is a signatory, and other regulatory documents. Court verdicts do not constitute binding precedents. However, they may be used as judicial reference and guidance.

According to the Constitution and the Legislation Law of the PRC (2023 revision) (《中華人民共和國立法法(2023年修訂)》) (the “Legislation Law”), the NPC and the SCNPC are empowered to exercise the legislative power of the State. The NPC has the power to formulate and amend basic laws governing civil and criminal matters, state organs and other matters. The SCNPC is empowered to formulate and amend laws other than those required to be enacted by the NPC and to supplement and amend any parts of laws enacted by the NPC during the adjournment of the NPC, provided that such supplements and amendments are not in conflict with the basic principles of such laws.

The State Council is the highest organ of the PRC administration and has the power to formulate administrative regulations based on the Constitution and laws.

The people’s congresses of provinces, autonomous regions and municipalities and their respective standing committees may formulate local regulations based on the specific circumstances and actual requirements of their own respective administrative areas, provided that such local regulations do not contravene any provision of the Constitution, laws or administrative regulations.

The ministries and commissions of the State Council, PBOC, National Audit Office of the PRC as well as the other organs endowed with administrative functions directly under the State Council may, in accordance with the laws as well as the administrative regulations, decisions and orders of the State Council and within the limits of their power, formulate rules.

The people’s congresses of cities divided into districts and their respective standing committees may formulate local regulations in terms of urban and rural development and management, environmental protection, and historical and cultural protection based on the specific circumstances and actual requirements of such cities, which will become enforceable after being reported to and approved by the standing committees of the people’s congresses of the relevant provinces or autonomous regions but such local regulations shall conform with the Constitution, laws, administrative regulations, and the relevant local regulations of the relevant provinces or autonomous regions. People’s congresses of national autonomous areas have the power to enact autonomous regulations and separate regulations in light of the political, economic and cultural characteristics of the nationality (nationalities) in the areas concerned.

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The people’s governments of the provinces, autonomous regions, and municipalities directly under the central government and the cities divided into districts or autonomous prefectures may enact rules, in accordance with laws, administrative regulations and the local regulations of their respective provinces, autonomous regions or municipalities. The Constitution has supreme legal authority and no laws, administrative regulations, local regulations, autonomous regulations or separate regulations may contravene the Constitution. The authority of laws is greater than that of administrative regulations, local regulations and rules. The authority of administrative regulations is greater than that of local regulations and rules. The authority of local regulations is greater than that of the rules of the local governments at or below the corresponding level. The authority of the rules enacted by the people’s governments of the provinces or autonomous regions is greater than that of the rules enacted by the people’s governments of the city divided into districts or autonomous prefecture within the administrative areas of the provinces and the autonomous regions.

The NPC has the power to alter or annul any inappropriate laws enacted by the SCNPC, and to annul any autonomous regulations or separate regulations which have been approved by the SCNPC but which contravene the Constitution or the Legislation Law. The SCNPC has the power to annul any administrative regulations that contravene the Constitution and laws, to annul any local regulations that contravene the Constitution, laws or administrative regulations, and to annul any autonomous regulations or local regulations which have been approved by the standing committees of the people’s congresses of the relevant provinces, autonomous regions or municipalities directly under the central government, but which contravene the Constitution and the Legislation Law. The State Council has the power to alter or annul any inappropriate ministerial rules and rules of local governments. The people’s congresses of provinces, autonomous regions or municipalities directly under the central government have the power to alter or annul any inappropriate local regulations enacted or approved by their respective standing committees. The people’s governments of provinces and autonomous regions have the power to alter or annul any inappropriate rules enacted by the people’s governments at a lower level.

According to the Constitution and the Legislation Law, the power to interpret laws is vested in the SCNPC. According to the Decision of the Standing Committee of the NPC Regarding the Strengthening of Interpretation of Laws (《全國人民代表大會常務委員會關於加強法律解釋工作的決議》) passed on June 10, 1981, the Supreme People’s Court of the PRC (the “Supreme People’s Court”) has the power to give general interpretation on questions involving the specific application of laws and decrees in court trials. The State Council and its ministries and commissions are also vested with the power to give interpretation of the administrative regulations and department rules which they have promulgated. At the regional level, the power to give interpretations of the local laws and regulations as well as administrative rules is vested in the regional legislative and administrative organs which promulgate such laws, regulations and rules.

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PRC JUDICIAL SYSTEM

Under the Constitution and the PRC Law on the Organization of the People’s Courts (2018 revision) (《中華人民共和國人民法院組織法(2018年修訂)》), the PRC judicial system is made up of the Supreme People’s Court, the local people’s courts and special people’s courts.

The local people’s courts are comprised of the primary people’s courts, the intermediate people’s courts and the higher people’s courts. The higher level people’s courts supervise the primary and intermediate people’s courts. The people’s procuratorates also have the right to exercise legal supervision over the civil proceedings of people’s courts of the same level and lower levels. The Supreme People’s Court is the highest judicial body in the PRC. It supervises the judicial administration of the people’s courts at all levels.

The PRC Civil Procedure Law (2021 revision) (《中華人民共和國民事訴訟法(2021年修訂)》) (the “Civil Procedure Law”), which was adopted in 1991 and amended in 2007, 2012, 2017 and 2021 and was last amended by SCNPC on September 1, 2023 and will come into effect on January 1, 2024, sets forth the criteria for instituting a civil action, the jurisdiction of the people’s courts, the procedures to be followed for conducting a civil action and the procedures for enforcement of a civil judgment or order. All parties to a civil action conducted within the PRC must comply with the Civil Procedure Law. Generally, a civil case is initially heard by a local court of the municipality or province in which the defendant resides. The parties to a contract may, by express agreement, select a judicial court where civil actions may be brought, provided that the judicial court is either the plaintiff’s or the defendant’s domicile, the place of execution or implementation of the contract or the place of the object of the action, provided that such choice shall not violate the requirements of the level of jurisdiction and exclusive jurisdiction.

A foreign national or enterprise generally has the same litigation rights and obligations as a citizen or legal person of the PRC. If a foreign country’s judicial system limits the litigation rights of PRC citizens and enterprises, the PRC courts may apply the same limitations to the citizens and enterprises of that foreign country within the PRC.

If any party to a civil action refuses to comply with a judgment or ruling made by a people’s court or an award made by an arbitration panel in the PRC, the other party may apply to the people’s court for the enforcement of the same. There are time limits of two years imposed on the right to apply for such enforcement. If a person fails to satisfy a judgment made by the court within the stipulated time, the court will, upon application by either party, enforce the judgment in accordance with the law.

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A party seeking to enforce a judgment or ruling of a people’s court against a party who is not personally or whose property is not within the PRC may apply to a foreign court with jurisdiction over the case for recognition and enforcement of the judgment or ruling. A foreign judgment or ruling may also be recognized and enforced by the people’s court according to PRC enforcement procedures if the PRC has entered into or acceded to an international treaty with the relevant foreign country, which provides for such recognition and enforcement, or if the judgment or ruling satisfies the court’s examination according to the principle of reciprocity, unless the people’s court finds that the recognition or enforcement of such judgment or ruling will result in a violation of the basic legal principles of the PRC, its sovereignty or security or against social and public interest.

According to the Arrangement on Mutual Recognition and Enforcement of Judgments in Civil and Commercial Matters by the Courts of the Mainland China and of the Hong Kong Special Administrative Region Pursuant to Agreed Jurisdiction by Parties Concerned (《最高人民法院關於內地與香港特別行政區法院相互認可和執行當事人協議管轄的民商事案件判決的安排》) promulgated by the Supreme People’s Court on July 3, 2008 and implemented on August 1, 2008, in the case of final judgment, defined with payment amount and enforcement power, made between the court of China and the court of the Hong Kong Special Administrative Region in a civil and commercial case with written jurisdiction agreement, any party concerned may apply to the People’s Court of China or the court of the Hong Kong Special Administrative Region for recognition and enforcement based on this arrangement. “Choice of court agreement in written” refers to a written agreement defining the exclusive jurisdiction of either the People’s Court of China or the court of the Hong Kong Special Administrative Region in order to resolve dispute with particular legal relation occurred or likely to occur by the party concerned. Therefore, the party concerned may apply to the Court of China or the court of the Hong Kong Special Administrative Region to recognize and enforce the final judgment made in China or Hong Kong that meet certain conditions of the aforementioned regulations.

THE COMPANY LAW, THE OVERSEAS LISTING TRIAL MEASURES AND THE GUIDELINES

A joint stock limited company which was incorporated in the PRC and seeking a listing on the HKSE is mainly subject to the following three laws and regulations in the PRC:

The Company Law of the PRC (《中華人民共和國公司法》) (the “Company Law”) which was promulgated by the Standing Committee of the NPC on December 29, 1993, came into effect on July 1, 1994, revised on December 25, 1999, August 28, 2004, October 27, 2005, December 28, 2013 and October 26, 2018 respectively, and was latest revised on December 29, 2023 and will come into effect on July 1, 2024.

The Overseas Listing Trial Measures which were promulgated by the CSRC on February 17, 2023 and came into effect on March 31, 2023, and were applicable to the overseas offering and listing of PRC domestic companies’ securities.

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The Guidelines for Articles of Association of Listed Companies(《上市公司章程指引》) (the “Guidelines”) which were issued by the CSRC on December 16, 1997, latest revised on December 15, 2023 and came into effect on the same date, providing the guidelines for the Articles of Association. As such, the contents provided in the Guidelines are set out in the Articles of Association of the Company, the summary of which is set out in the section entitled “Appendix VII—Summary of Articles of Association” in this document.

Set out below is a summary of the major provisions of the Company Law, the Overseas Listing Trial Measures and the Guidelines applicable to the Company.

General

A joint stock limited company refers to an enterprise legal person incorporated in accordance with the Company Law with its registered capital divided into shares of equal par value. The liability of its shareholders is limited to the amount of shares held by them and the company is liable to its creditors for an amount equal to the total value of its assets.

A joint stock limited company shall conduct its business in accordance with laws and administrative regulations. It may invest in other limited liability companies and joint stock limited companies and its liabilities with respect to such invested companies are limited to the amount invested. Unless otherwise provided by laws, the joint stock limited company may not be a contributor that undertakes joint and several liabilities for the debts of the invested companies.

Incorporation

A joint stock limited company may be incorporated by promotion or public subscription.

A joint stock limited company may be incorporated by a minimum of two but not more than 200 promoters, and at least half of the promoters must have residence within the PRC.

The promoters must convene an inaugural meeting within 30 days after the issued shares have been fully paid up, and must give notice to all subscribers or make an announcement of the date of the inaugural meeting 15 days before the meeting. The inaugural meeting may be convened only with the presence of promoters or subscribers representing at least half of the shares in the company. At the inaugural meeting, matters including the adoption of articles of association and the election of members of the board of directors and members of the board of supervisors of the company will be dealt with. All resolutions of the meeting require the approval of subscribers with more than half of the voting rights present at the meeting.

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Within 30 days after the conclusion of the inaugural meeting, the board of directors must apply to the registration authority for registration of the establishment of the joint stock limited company. A company is formally established, and has the status of a legal person, after the business license has been issued by the relevant registration authority. Joint stock limited companies established by the subscription method shall file the approval on the offering of shares issued by the securities administration department of the State Council with the company registration authority for record.

A joint stock limited company's promoters shall be liable for: (i) the payment of all expenses and debts incurred in the incorporation process jointly and severally if the company cannot be incorporated; (ii) the refund of subscription monies to the subscribers, together with interest, at bank rates for a deposit of the same term jointly and severally if the company cannot be incorporated; and (iii) damages suffered by the company as a result of the default of the promoters in the course of incorporation of the company. According to the Interim Provisional Regulations on the Administration of Share Issuance and Trading (《股票發行與交易管理暫行條例》) promulgated by the State Council on April 22, 1993 (which is only applicable to the issuance and trading of shares in the PRC and their related activities), if a company is established by means of public subscription, the promoters of such company are required to sign on the document to ensure that the document does not contain any misrepresentation, serious misleading statements or material omissions, and assume joint and several responsibility for it.

Registered Capital

The promoters may make a capital contribution in currencies, or non-monetary assets such as in kind or intellectual property rights or land use rights which can be appraised with monetary value and transferred lawfully, except for assets which are prohibited from being contributed as capital by the laws or administrative regulations. If a capital contribution is made in non-monetary assets, a valuation of the assets contributed must be carried out pursuant to the provisions of the laws or administrative regulations on valuation without any over-valuation or under-valuation.

A company may issue registered or bearer share. However, shares issued to promoter(s) or legal person(s) shall be in the form of registered share and shall be registered under the name(s) of such promoter(s) or legal person(s) and shall not be registered under a different name or the name of a representative.

The transfer of shares by shareholders should be conducted via the legally established stock exchange or in accordance with other methods as stipulated by the State Council. Transfer of registered shares by a shareholder must be made by means of an endorsement or by other means stipulated by laws or administrative regulations. Bearer shares are transferred by delivery of the share certificates to the transferee.

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Shares held by a promoter of a company shall not be transferred within one year after the date of the company's incorporation. Shares issued by a company prior to the public offer of its shares shall not be transferred within one year from the date of listing of the shares of the company on a stock exchange. Directors, supervisors and senior management of a company shall not transfer over 25% of the shares held by each of them in the company each year during their term of office and shall not transfer any share of the company held by each of them within one year after the listing date. There is no restriction under the Company Law as to the percentage of shareholding a single shareholder may hold in a company.

Increase of Registered Capital and Issue of Shares

According to the Company Law, in the event a company proposes to issue new shares, resolutions shall be passed at general meeting in accordance with the articles of association to determine the class, amount and issue price of the new shares. All issue of shares of a joint stock limited company shall be based on the principles of equality and fairness. The same class of shares must carry equal rights. Shares issued at the same time and within the same class must be issued on the same conditions and at the same price. It may issue shares at par value or at a premium, but it may not issue shares below the par value.

After the new share issuance has been paid up, the change shall be registered with the company registration authorities and an announcement shall be made.

According to the Company Law, when the company issues shares in registered form, it shall maintain a register of shareholders, stating the following matters:

- the name and domicile of each shareholder;
- the number of shares held by each shareholder;
- the serial numbers of shares held by each shareholder; and
- the date on which each shareholder acquired the shares.

Reduction of Registered Capital

A company may reduce its registered capital in accordance with the following procedures prescribed by the Company Law:

- the company shall prepare a balance sheet and an inventory of the assets;
- the reduction of registered capital shall be approved by a general meeting;

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- the company shall inform its creditors of the reduction in registered capital within 10 days and publish an announcement of the reduction in the newspaper within 30 days after the resolution approving the reduction has been passed;
- creditors shall within 30 days after receiving the notice, or within 45 days of the public announcement if no notice has been received, require the company to pay its debts or provide corresponding guarantees covering the debts;
- the company shall apply to the relevant administration of registration for the registration of the reduction in registered capital.

Repurchase of Shares

According to the Company Law, a joint stock limited company may not purchase its shares other than for one of the following purposes: (i) to reduce its registered capital; (ii) to merge with another company that holds its shares; (iii) to grant its shares for carrying out an employee stock ownership plan or equity incentive plan; (iv) to purchase its shares from shareholders who vote against the resolution regarding the merger or division with other companies at a general meeting; (v) to apply shares for conversion of convertible corporate bonds issued by a listed company; and (vi) to maintain the company value and protect the shareholders' interests of a listed company as necessary.

Repurchase of its own shares on the grounds set out in (i) and (ii) above shall be subject to resolution passed by the general meeting; repurchase of its own shares on the grounds set out in (iii), (v) or (vi) above shall be subject to a resolution of the company's board of directors shall be made by a two-third majority of directors attending the meeting in accordance with the provisions of the company's articles of association or as authorized by the general meeting.

Following the repurchase of its own shares in accordance with (i) above, such shares shall be canceled within 10 days from the date of repurchase; the shares shall be transferred or canceled within six months if the repurchase of its own shares is in accordance with either (ii) or (iv) above; and the shares repurchased in accordance with (iii), (v) or (vi) above shall not exceed 10% of the company's total issued shares, and shall be transferred or canceled within three years.

A listed company shall perform its obligation of information disclosure according to the provisions of the Securities Law when repurchasing its own shares. In the event the repurchase of its own shares is in accordance with (iii), (v) or (vi) above, centralized public trading shall be adopted.

A company shall not accept its own shares as the subject matter of a mortgage.

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Transfer of Shares

Shares held by shareholders may be transferred in accordance with the relevant laws and regulations. Pursuant to the Company Law, transfer of shares by shareholders shall be carried out at a legally established securities exchange or in other ways stipulated by the State Council. No modifications of registration in the share register caused by transfer of registered shares shall be carried out within 20 days prior to the convening of a general meeting or 5 days prior to the base date for determination of dividend distributions. However, where there are separate provisions by law on alternation of registration in the share register of listed companies, those provisions shall prevail.

According to the Company law, shares issued prior to the public issuance of shares shall not be transferred within one year from the date of the joint stock limited company's listing on a stock exchange. Directors, supervisors and the senior management shall declare to the company their shareholdings in the company and any changes of such shareholdings; they shall not transfer more than 25% of all the shares they hold in the company annually during their tenure; and they shall not transfer the shares they hold within one year from the date on which the company's shares are listed and commenced trading on a stock exchange, nor within six months after their resignation from their positions with the company.

Shareholders

According to the Company Law and the Guidelines, the rights of holders of ordinary shares of a joint stock limited company include:

- the right to attend or appoint a proxy to attend general meetings and to vote thereat;
- the right to transfer shares in accordance with laws, administrative regulations and provisions of the articles of association;
- the right to inspect the company's articles of association, share register, counterfoil of company debentures, minutes of general meetings, resolutions of meetings of the board of directors, resolutions of meetings of the board of supervisors and financial and accounting reports and to make proposals or enquiries on the company's operations;
- the right to bring an action in the people's court to rescind resolutions passed by general meetings and board of directors where the articles of association is violated by the above resolutions;
- the right to receive dividends and other types of interest distributed in proportion to the number of shares held;

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- in the event of the termination or liquidation of the company, the right to participate in the distribution of residual properties of the company in proportion to the number of shares held; and
- other rights granted by laws, administrative regulations, other regulatory documents and the company's articles of association.

The obligations of a shareholder include the obligation to abide by the Company's articles of association, to pay the subscription moneys in respect of the shares subscribed for and in accordance with the form of making capital contributions, to be liable for the company's debts and liabilities to the extent of the amount of his or her subscribed shares and any other shareholders' obligation specified in the company's articles of association.

General Meetings

The general meeting is the organ of authority of the company, which exercises its powers in accordance with the Company Law. According to the Company Law, the general meeting exercises the following principal powers:

- to decide on the company's operational policies and investment plans;
- to elect or remove the directors and supervisors (other than the representative of the employees of the company) and to decide on matters relating to the remuneration of directors and supervisors;
- to examine and approve reports of the board of directors;
- to examine and approve reports of the board of supervisors;
- to examine and approve the company's proposed annual financial budget and final accounts;
- to examine and approve the company's proposals for profit distribution plans and loss recovery plans;
- to decide on any increase or reduction of the company's registered capital;
- to decide on the issue of bonds by the company;
- to decide on issues such as merger, division, dissolution and liquidation of the company and other matters;
- to amend the company's articles of association; and
- other powers as provided for in the articles of association.

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Annual general meeting is required to be held once every year. Extraordinary general meeting is required to be held within two months after the occurrence of any of the following:

- the number of directors is less than the number stipulated by the law or less than two thirds of the number specified in the articles of association;
- the aggregate losses of the company which are not recovered reach one-third of the company's total paid-in registered capital;
- when shareholders individually or in aggregate holding 10% or more of the company's shares request the convening of an extraordinary general meeting;
- whenever the board of directors deems necessary;
- when the board of supervisors so requests; or
- other circumstances as provided for in the articles of associations.

According to the Company Law, general meetings shall be convened by the board of directors, and presided over by the chairman of the board of directors. In the event that the chairman is incapable of performing or does not perform his duties, the meeting shall be presided over by the vice chairman. In the event that the vice chairman is incapable of performing or not performing his duties, a director nominated by more than half of directors shall preside over the meeting.

Where the board of directors is incapable of performing or not performing its duties of convening the general meeting, the board of supervisors shall convene and preside over such meeting in a timely manner. In case the board of supervisors fails to convene and preside over such meeting, shareholders alone or in aggregate holding more than 10% of the company's shares for 90 days consecutively may unilaterally convene and preside over such meeting.

According the Company Law, notice of annual general meeting shall state the time and venue of and matters to be considered at the meeting and shall be given to all shareholders 20 days before the meeting. Notice of extraordinary general meetings shall be given to all shareholders 15 days prior to the meeting.

There is no specific provision in the Company Law regarding the number of shareholders constituting a quorum in a general meeting.

According to the Company Law, shareholders present at general meeting have one vote for each share they hold, save that shares held by the company are not entitled to any voting rights.

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Pursuant to the provisions of the articles of association or a resolution of the general meeting, the accumulative voting system may be adopted for the election of directors and supervisors at the general meeting. Under the accumulative voting system, each share shall be entitled to vote equivalent to the number of directors or supervisors to be elected at the general meeting and shareholders may consolidate their voting rights when casting a vote.

Pursuant to the Company Law, resolutions of the general meeting shall be adopted by more than half of the voting rights held by the shareholders present at the meeting. However, resolutions of the general meeting regarding the following matters shall be adopted by more than two-thirds of the voting rights held by the shareholders present at the meeting: (i) amendments to the articles of association; (ii) the increase or decrease of registered capital; (iii) the issue of any types of shares, warrants or other similar securities; (iv) the issue of debentures; (v) the merger, division, dissolution, liquidation or change in the form of the company; (vi) other matters considered by the general meeting, by way of an ordinary resolution, to be of a nature which may have a material impact on the company and should be adopted by a special resolution.

According to the Company Law, meeting minutes shall be prepared in respect of decisions on matters discussed at the general meeting. The chairman of the meeting and directors attending the meeting shall sign to endorse such minutes. The minutes shall be kept together with the shareholders' attendance register and the proxy forms.

Board

According to the Company Law, a joint stock limited company shall have a board of directors, which shall consist of 5 to 19 members. Members of the board of directors may include representatives of the employees of the company, who shall be democratically elected by the company's staff at the staff representative assembly, general staff meeting or otherwise. The term of a director shall be stipulated in the articles of association, but no term of office shall last for more than three years. Directors may serve consecutive terms if re-elected. A director shall continue to perform his duties in accordance with the laws, administrative regulations and articles of association until a duly re-elected director takes office, if re-election is not conducted in a timely manner upon the expiry of his term of office, or if the resignation of directors results in the number of directors being less than the quorum.

According to the Company Law, the board of directors mainly exercises the following powers:

- to convene the general meetings and report on its work to the general meetings;
- to implement the resolutions passed in general meetings;

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- to decide on the company's business plans and investment proposals;
- to formulate the company's proposed annual financial budget and final accounts;
- to formulate the company's profit distribution proposals and loss recovery proposals;
- to formulate proposals for the increase or reduction of the company's registered capital and the issuance of corporate bonds;
- to prepare plans for the merger, division, dissolution and change in the form of the company;
- to formulate the company's basic management system; and
- to exercise any other power under the articles of association.

Board Meetings

According to the Company Law, meetings of the board of directors of a joint stock limited company shall be convened at least twice a year. Notice of meeting shall be given to all directors and supervisors 10 days before the meeting. Interim board meetings may be proposed to be convened by shareholders representing more than 10% of voting rights, more than one-third of the directors or the board of supervisors. The chairman shall convene and preside over such meeting within 10 days after receiving such proposal. Meetings of the board of directors shall be held only if half or more of the directors are present. Resolutions of the board of directors shall be passed by more than half of all directors. Each director shall have one vote for resolutions to be approved by the board of directors. Directors shall attend board meetings in person. If a director is unable to attend a board meeting, he may appoint another director by a written power of attorney specifying the scope of the authorization to attend the meeting on his behalf.

If a resolution of the board of directors violates the laws, administrative regulations or the articles of association, and as a result of which the company sustains serious losses, the directors participating in the resolution are liable to compensate the company. However, if it can be proved that a director expressly objected to the resolution when the resolution was voted on, and that such objection was recorded in the minutes of the meeting, such director may be released from that liability.

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Chairman of the Board

According to the Company Law, the board of directors shall appoint a chairman and may appoint a vice chairman. The chairman and the vice chairman are elected with approval of more than half of all the directors. The chairman shall convene and preside over board meetings and examine the implementation of board resolutions. The vice chairman shall assist the work of the chairman. In the event that the chairman is incapable of performing or not performing his duties, the duties shall be performed by the vice chairman. In the event that the vice chairman is incapable of performing or not performing his duties, a director nominated by more than half of the directors shall perform his duties.

Qualification of Directors

The Company Law provides that the following persons may not serve as a director:

- a person who is unable or has limited ability to undertake any civil liabilities;
- a person who has been convicted of an offense of bribery, corruption, embezzlement or misappropriation of property, or the destruction of socialist market economy order; or who has been deprived of his political rights due to his crimes, in each case where less than five years have elapsed since the date of completion of the sentence;
- a person who has been a former director, factory manager or manager of a company or an enterprise that has entered into insolvent liquidation and who was personally liable for the insolvency of such company or enterprise, where less than three years have elapsed since the date of the completion of the bankruptcy and liquidation of the company or enterprise;
- a person who has been a legal representative of a company or an enterprise that has had its business license revoked due to violations of the law and has been ordered to close down by law and the person was personally responsible, where less than three years have elapsed since the date of such revocation; or
- a person who is liable for a relatively large amount of debts that are overdue.

Board of Supervisors

A joint stock limited company shall have a board of supervisors composed of not less than three members. The board of supervisors is made up of representatives of the shareholders and an appropriate proportion of representatives of the employees of the company. The actual proportion shall be stipulated in the articles of association, provided that the proportion of representatives of the employees shall not be less than one third of the supervisors. Representatives of the employees of the company in the board of supervisors shall be democratically elected by the employees at the employees' representative assembly, employees' general meeting or otherwise.

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The directors and senior management may not act concurrently as supervisors.

The board of supervisors shall appoint a chairman and may appoint a vice chairman. The chairman and the vice chairman of the board of supervisors are elected with approval of more than half of all the supervisors. The chairman of the board of supervisors shall convene and preside over the meetings of the board of supervisors. In the event that the chairman of the board of supervisors is incapable of performing or not performing his duties, the vice chairman of the board of supervisors shall convene and preside over the meetings of the board of supervisors. In the event that the vice chairman of the board of supervisors is incapable of performing or not performing his duties, a supervisor nominated by more than half of the supervisors shall convene and preside over the meetings of the board of supervisors.

Each term of office of a supervisor is three years and he or she may serve consecutive terms if re-elected. A supervisor shall continue to perform his duties in accordance with the laws, administrative regulations and articles of association until a duly re-elected supervisor takes office, if re-election is not conducted in a timely manner upon the expiry of his term of office, or if the resignation of supervisors results in the number of supervisors being less than the quorum.

The board of supervisors of a company shall hold at least one meeting every six months. According to the Company Law, a resolution of the board of supervisors shall be passed by more than half of all the supervisors, while according to the Opinions on Supplementary Amendment to Articles of Associations by Companies to be listed in Hong Kong (《關於到香港上市公司對公司章程作補充修改的意見的函》), a resolution of the board of supervisors shall be passed by more than two-thirds of all the supervisors.

The board of supervisors exercises the following powers:

- to review the company's financial position;
- to supervise the directors and senior management in their performance of their duties and to propose the removal of directors and senior management who have violated laws, regulations, the articles of association or the resolutions of the general meeting;
- when the acts of directors and senior management are harmful to the company's interests, to require correction of those acts;
- to propose the convening of extraordinary general meetings and to convene and preside over general meetings when the board of directors fails to perform the duty of convening and presiding over general meeting under this law;
- to initiate proposals for resolutions to general meeting;

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- to initiate proceedings against directors and senior management;
- other powers specified in the articles of association; and
- Supervisors may attend board meetings and make enquiries or proposals in respect of board resolutions. The board of supervisors may initiate investigations into any irregularities identified in the operation of the company and, where necessary, may engage an accounting firm to assist their work at the company's expense.

Manager and Senior Management

According to the Company Law, a company shall have a manager who shall be appointed or removed by the board of directors. The manager shall report to the board of directors and may exercise the following powers:

- to supervise the business and administration of the company and arrange for the implementation of resolutions of the board of directors;
- to arrange for the implementation of the company's annual business plans and investment proposals;
- to formulate the general administration system of the company;
- to formulate the company's detailed rules;
- to recommend the appointment and dismissal of deputy managers and person in charge of finance;
- to appoint or dismiss other administration officers (other than those required to be appointed or dismissed by the board of directors); and
- to other powers conferred by the board of directors or the articles of association.

The manager shall comply with other provisions of the articles of association concerning his/her powers. The manager shall attend board meetings.

According to the Company Law, senior management shall mean the manager, deputy manager(s), person-in-charge of finance, board secretary (in case of a listed company) of a company and other personnel as stipulated in the articles of association.

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Duties of Directors, Supervisors and Senior Management

Directors, supervisors and senior management of the company are required in accordance with the Company Law to comply with the relevant laws, regulations and the articles of association, and have fiduciary and diligent duties to the company. Directors, supervisors and senior management are prohibited from abusing their powers to accept bribes or other unlawful income and from misappropriating of the company's properties. Directors and senior management are prohibited from:

- misappropriation of the company's funds;
- depositing the company's funds into accounts under his own name or the name of other individuals;
- loaning company funds to others or providing guarantees in favor of others supported by the company's assets in violation of the articles of association or without prior approval of the general meeting or board of directors;
- entering into contracts or deals with the company in violation of the articles of association or without prior approval of the general meeting;
- using their position and powers to procure business opportunities for themselves or others that should have otherwise been available to the company or operating for their own benefits or managing on behalf of others businesses similar to that of the company without prior approval of the general meeting;
- accept and possess commissions paid by a third party for transactions conducted with the company;
- unauthorized divulgence of confidential business information of the company; or
- other acts in violation of their duty of loyalty to the company.

A director, supervisor or senior management who contravenes any law, regulation or the company's articles of association in the performance of his duties resulting in any loss to the company shall be personally liable to the company.

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Finance and Accounting

According to the Company Law, a company shall establish financial and accounting systems in accordance with laws, administrative regulations and the regulations of the financial department of the State Council and shall at the end of each financial year prepare a financial and accounting report which shall be audited by an accounting firm as required by law. The company's financial and accounting report shall be prepared in accordance with provisions of the laws, administrative regulations and the regulations of the financial department of the State Council.

Pursuant to the Company Law, the company shall deliver its financial and accounting reports to all shareholders within the time limit stipulated in the articles of association and make its financial and accounting reports available at the company for inspection by the shareholders at least 20 days before the convening of an annual general meeting of shareholders. A company that makes public stock offerings shall publish its financial and accounting reports.

When distributing each year's after-tax profits, it shall set aside 10% of its after-tax profits into a statutory common reserve fund (except where the fund has reached 50% of its registered capital).

If its statutory common reserve fund is not sufficient to make up losses of the previous year, profits of the current year shall be applied to make up losses before allocation is made to the statutory common reserve fund pursuant to the above provisions.

After allocation of the statutory common reserve fund from after-tax profits, it may, upon a resolution passed at the general meeting, allocate discretionary common reserve fund from after-tax profits.

The remaining after-tax profits after making up losses and allocation of common reserve fund shall be distributed in proportion to the number of shares held by the shareholders, unless otherwise stipulated in the articles of association.

Shares held by the Company shall not be entitled to any distribution of profit.

The premium received through issuance of shares at prices above par value and other incomes required by the financial department of the State Council to be allocated to the capital reserve fund shall be allocated to the company's capital reserve fund.

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The Company's reserve fund shall be applied to make up losses of the company, expand its business operations or be converted to increase the registered capital of the company. However, the capital reserve fund may not be applied to make up the company's losses. Upon the conversion of statutory common reserve fund into capital, the balance of the statutory common reserve fund shall not be less than 25% of the registered capital of the company before such conversion.

The Company shall have no other accounting books except the statutory accounting books. Its assets shall not be deposited in any accounts opened in the name of any individual.

Appointment and Retirement of Accounting Firms

Pursuant to the Company Law, the appointment or dismissal of accounting firms responsible for the auditing of the company shall be determined by general meeting or board of directors in accordance with provisions of articles of association. The accounting firm should be allowed to make representations when the general meeting or board of directors conducts a vote on the dismissal of the accounting firm. The company should provide true and complete accounting evidences, books, financial and accounting reports and other accounting data to the accounting firm it employs without any refusal, withholding and misrepresentation.

Distribution of Profits

According to the Company Law, a company shall not distribute profits before losses are covered and the statutory common reserve is drawn.

Amendments to Articles of Association

Any amendments to the company's articles of association must be made in accordance with the procedures set out in the company's articles of association. In relation to matters involving the company's registration, the amendment to articles of association shall be registered with the relevant authority in accordance with the applicable laws.

Dissolution and Liquidation

According to the Company Law, a company shall be dissolved by reason of the following: (i) the term of its operations set down in the articles of association has expired or other events of dissolution specified in the articles of association have occurred; (ii) the general meeting resolve to dissolve the company; (iii) the company is dissolved by reason of merger or division; (iv) the business license is revoked; the company is ordered to close down or be dissolved; or (v) the company is dissolved by the people's court in response to the request of shareholders holding shares that represent more than 10% of the voting rights of all its shareholders, on the grounds that the company suffers significant hardship in its operation and management that cannot be resolved through other means, and the ongoing existence of the company would bring significant losses for shareholders.

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In the event of (i) above, a company may carry on its existence by amending its articles of association. The amendment of the articles of association in accordance with provisions set out above shall require approval of more than two thirds of voting rights of shareholders attending a general meeting.

Where the company is dissolved in the circumstances described in subparagraphs (i), (ii), (iv), or (v) above, a liquidation group shall be established and the liquidation process shall commence within 15 days after the occurrence of an event of dissolution.

The members of the company's liquidation group shall be composed of its directors or the personnel appointed by the general meeting. If a liquidation group is not established within the stipulated period, creditors may apply to the people's court and request the court to appoint relevant personnel to form the liquidation group. The people's court should accept such application and form a liquidation group to conduct liquidation in a timely manner.

The liquidation group shall exercise the following powers during the liquidation period:

- to handle the company's assets and to prepare a balance sheet and an inventory of the assets;
- to notify creditors through notice or public announcement;
- to deal with the company's outstanding businesses related to liquidation;
- to pay any tax overdue as well as tax amounts arising from the process of liquidation;
- to claim credits and pay off debts;
- to handle the company's remaining assets after its debts have been paid off; and
- to represent the company in civil lawsuits.

The liquidation group shall notify the company's creditors within 10 days after its establishment and issue public notices in newspapers within 60 days. A creditor shall lodge his claim with the liquidation group within 30 days after receiving notification, or within 45 days of the public notice if he did not receive any notification. A creditor shall state all matters relevant to his creditor rights in making his claim and furnish evidence. The liquidation group shall register such creditor rights. The liquidation group shall not make any debt settlement to creditors during the period of claim.

Upon liquidation of properties and the preparation of the balance sheet and inventory of assets, the liquidation group shall draw up a liquidation plan to be submitted to the general meeting or people's court for confirmation.

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The company's remaining assets after payment of liquidation expenses, wages, social insurance expenses and statutory compensation, outstanding taxes and debts shall be distributed to shareholders according to their shareholding proportion. It shall continue to exist during the liquidation period, although it can only engage in any operating activities that are related to the liquidation. The company's properties shall not be distributed to the shareholders before repayments are made in accordance to the foregoing provisions.

Upon liquidation of the company's properties and the preparation of the balance sheet and inventory of assets, if the liquidation group becomes aware that the company does not have sufficient assets to meet its liabilities, it must apply to the people's court for a declaration for bankruptcy.

Following such declaration, the liquidation group shall hand over all matters relating to the liquidation to the people's court.

Upon completion of the liquidation, the liquidation group shall submit a liquidation report to the general meeting or the people's court for verification. Thereafter, the report shall be submitted to the registration authority of the company in order to cancel the company's registration, and a public notice of its termination shall be issued. Members of the liquidation group are required to discharge their duties honestly and in compliance with the relevant laws. Members of the liquidation group shall be prohibited from abusing their powers to accept bribes or other unlawful income and from misappropriating the company's properties.

A member of the liquidation group is liable to indemnify the company and its creditors in respect of any loss arising from his intentional or gross negligence.

Overseas Listing

According to the Overseas Listing Trial Measures, a Chinese domestic company that seeks overseas listing shall file the application with the CSRC according to the administrative filing procedures necessary for the Overseas Listing Trial Measures.

Merger and Demerger

Companies may merge through merger by absorption or through the establishment of a newly merged entity. If it merges by absorption, the company which is absorbed shall be dissolved. If it merges by forming a new corporation, both companies will be dissolved.

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SECURITIES LAW AND REGULATIONS

The PRC has promulgated a number of regulations that relate to the issue and trading of shares and disclosure of information. In October 1992, the State Council established the Securities Committee and the CSRC. The Securities Committee is responsible for coordinating the drafting of securities regulations, formulating securities-related policies, planning the development of securities markets, directing, coordinating and supervising all securities related institutions in the PRC and administering the CSRC. The CSRC is the regulatory arm of the Securities Committee and is responsible for the drafting of regulatory provisions of securities markets, supervising securities companies, regulating public offers of securities by PRC companies in the PRC or overseas, regulating the trading of securities, compiling securities related statistics and undertaking relevant research and analysis. In April 1998, the State Council consolidated the two departments and reformed the CSRC.

The Interim Provisional Regulations on the Administration of Share Issuance and Trading (《股票發行與交易管理暫行條例》) deals with the application and approval procedures for public offerings of equity securities, trading in equity securities, the acquisition of listed companies, deposit, clearing and transfer of listed equity securities, the disclosure of information with respect to a listed company, investigation, penalties and dispute settlement.

On December 25, 1995, the State Council promulgated and implemented the Regulations of the State Council Concerning Domestic Listed Foreign Shares of Joint Stock Limited Companies (《國務院關於股份有限公司境內上市外資股的規定》). These regulations deal mainly with the issue, subscription, trading and declaration of dividends and other distributions of domestic listed and foreign invested shares and disclosure of information of joint stock limited companies having domestic listed and foreign invested shares.

The Securities Law of the People’s Republic of China (《中華人民共和國證券法》) (the “Securities Law”) took effect on July 1, 1999 and was revised on August 28, 2004, October 27, 2005, June 29, 2013, August 31, 2014 and December 28, 2019, respectively. The latest revised Securities Law came into effect on March 1, 2020. This is the first national securities law in the PRC, which is divided into 14 chapters and 226 articles regulating, among other things, the issuance and trading of securities, takeovers by listed companies, securities exchanges, securities companies and the duties and responsibilities of the State Council’s securities regulatory authorities. The Securities Law comprehensively regulates activities in the PRC securities market. Article 224 of the Securities Law provides that domestic enterprises shall comply with the relevant provisions of the State Council to list its shares outside the PRC. Currently, the issuance and trading of foreign issued shares (including H shares) are mainly governed by the rules and regulations promulgated by the State Council and the CSRC.

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**SUMMARY OF PRINCIPAL LEGAL
AND REGULATORY PROVISIONS**

On November 14, 2019, CSRC promulgated the Guidance for the Application for the “Full Circulation” of the Domestic Unlisted Shares of H-share Companies (《H股公司境內未上市股份申請“全流通”業務指引》), which came into effect on the same day and was partly revised on August 10, 2023 according to the Decision on Revising and Abolishing Part of Securities and Futures Policy Documents by CSRC (《中國證券監督管理委員會關於修改、廢止部分證券期貨制度檔的決定》). This guideline is to regulate the listing and circulation (hereinafter referred to as “Full Circulation”) of unlisted domestic shares of domestic joint-stock limited companies (hereinafter referred to as H-share Companies) listed on the Stock Exchange (including unlisted domestic shares held by domestic shareholders before overseas listing, unlisted domestic shares issued in China after overseas listing and unlisted shares held by foreign shareholders).

H-share Companies applying for “Full Circulation” shall submit the application to the CSRC for filing procedures. H-share companies may submit the application for “Full Circulation” separately or simultaneously when applying for overseas refinancing. Unlisted domestic joint stock limited companies may submit the application for “Full Circulation” simultaneously when applying for overseas initial public offering and listing.

APPENDIX VII SUMMARY OF ARTICLES OF ASSOCIATION

1. DIRECTORS AND BOARD OF DIRECTORS

(1) Power to allocate and issue shares

The Articles of Association provide that the shareholders may authorize the board of directors through a general mandate at a general meeting to allocate or issue shares of no more than 20% of the total issued share capital. The board of directors shall prepare suggestions for share allotment or issue, which are subject to approval by the shareholders at the general meeting in the form of a special resolution. Any such allotment or issue shall be in accordance with the procedures stipulated in appropriate laws, administrative regulations and supervision rules of shares listed region.

(2) Power to dispose assets of our Company or any subsidiary

The sale of substantial assets that exceeds 30% of total assets of the latest audited financial statement are subject to approval by the shareholders at the general meeting in the form of a special resolution. The boards of directors may decide on the disposal of assets of our Company as authorized by the shareholders in a general meeting except the sale of substantial assets that exceeds 30% of total assets of the latest audited financial statement, which is subject to the approval by the shareholders at the general meeting.

(3) Compensation or payments for loss of office

Not applicable.

(4) Loans to directors

Not applicable.

(5) Giving of financial assistance to purchase our Company or any subsidiary's shares

Our Company or its subsidiaries (including its subsidiaries) shall not provide any financial assistance to those who purchase or intend to purchase Company's Shares in the form of gifts, advances, guarantees, compensations, or loans.

(6) Disclosure of interests in contracts with our Company or any subsidiary

Directors shall not conclude any contract or engage in any transaction with our Company either in violation of the Articles of Association or without the approval of the general meeting.

(7) Remuneration

The emoluments or compensation for directors and supervisors that are not representative of employees of our Company are subject to approval by the shareholders at the general meeting in the form of a ordinary resolution.

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(8) Retirement, appointment, removal

The board of directors consists of nine directors, three of which are independent non-executive directors. The board of directors has one chairman. Directors are elected at the general meeting.

The chairman of the Board shall be elected and dismissed by a vote of more than one half of the directors. Provided that it is in compliance with relevant laws, regulations and rules as well as the regulatory rules of which our Company's shares are listed, the general meeting may remove any director whose term has not expired by an ordinary resolution without affecting any claim for damages that may be made pursuant to any contract.

The chairman of the Board and other directors all serve three-year terms. Upon expiration of the term, the director may be re-elected. Director can be the general manager or other senior management personnel at the same time. There is no provision in the Articles of Association that imposes any age limit for directors beyond which retirement of a director is mandatory.

None of the following persons shall serve as our director, supervisor or senior management:

- i. A person who has no civil capacity or has limited civil capacity;
- ii. A person who has been imposed penalty for the offense of corruption, bribery, embezzlement, larceny, or disrupting the socialist economic order and is within five years of the expiry date of punishment or has been deprived of political rights because of this conviction and is within five years of the expiry date of the sentence;
- iii. A person who is a former director, factory manager or general manager of a company or enterprise that is bankrupt and liquidated because of poor operation, was personally liable for the bankruptcy of such company or enterprise, and is within three years of the date of completion of bankruptcy and liquidation of such company or enterprise;
- iv. A person who has served as the legal representative of a company or enterprise whose business license was revoked or was ordered to close due to violation of laws, was personally liable, and is within three years of the date on which the business license of such company or enterprise was revoked;
- v. A person who has a relatively large sum of debt, which was not paid at maturity;
- vi. a person who is prohibited by China Securities Regulation Commission's from entering into the securities market and is still in such prohibition period; or
- vii. Any other person who is otherwise not eligible under laws, administrative regulations, regulations of the authorities, regulatory documents and other conditions set out by the relevant regulatory bodies.

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The election, appointment or employment of the directors, supervisors or other senior management shall be invalid if such election, appointment or employment is against the Articles of Association. If the directors, supervisors or senior management falls into the situations provided in the above-mentioned situations during their term of office, they would be dismissed by our Company.

(9) Borrowing powers

The Articles of Association do not contain any specific provisions regarding directors' exercise of lending powers.

(10) Duties

Directors shall comply with laws, administrative regulations, and the Articles of Association, with the following duties of loyalty to our Company:

- i. Directors shall not abuse their authority by receiving any bribe or other illegal income, and shall not embezzle any of the property of our Company;
- ii. Directors shall not misappropriate our Company's funds;
- iii. Directors shall not deposit company assets into accounts held in their own names or in the name of any other individual;
- iv. Directors shall not, in violation of the Articles of Association, lend Company funds to other people or provide guarantee for other people with Company assets without the consent of the shareholders' general meeting or the board of directors;
- v. Directors shall not enter into contracts or trade with our Company either in violation of the Articles of Association or without the consent of the shareholders' general meeting;
- vi. Without the consent of the shareholders' general meeting, any director shall not take advantage of his/her position to seek business opportunities that should belong to our Company for himself/herself or for any other person, or operate business of the same kind for himself/herself or for any other person;
- vii. Directors shall not accept commissions for transactions with our Company as their own;
- viii. Directors shall not disclose Company secrets without authorization;
- ix. Directors shall not make use of their related-party relationship to damage our Company's interests; and
- x. Directors shall have other duties of loyalty specified by laws, administrative regulations, departmental rules and the Articles of Association.

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Any income obtained by a director in violation of this article shall belong to our Company; if losses are caused to our Company, the director shall be liable for compensation.

Directors shall comply with laws, administrative regulations, and the Articles of Association, with the following duties of diligence to our Company:

- i. Directors shall be prudent, scrupulous and diligent in exercising the authority conferred by our Company to ensure that the business activities of our Company comply with the laws, administrative regulations and various economic policy requirements, and that the business activities do not go beyond the scope of business activities specified in our Company's business license;
- ii. Directors shall treat all shareholders equally;
- iii. Directors shall keep abreast of our Company's business management status;
- iv. Directors shall sign written statements confirming periodic reports of our Company, and ensure that the information disclosed by our Company is true, accurate, and complete;
- v. Directors shall provide accurate information and materials to the board of supervisors, and shall not interfere with the performance of duties by the board of supervisors or individual supervisors; and
- vi. Directors shall have other diligence duties prescribed by laws, administrative regulations, departmental rules and the Articles of Association.

2. ALTERNATIONS TO CONSTITUTIONAL DOCUMENTS

Our Company may amend the Articles of Association based on the provisions of the laws, administrative regulations and Articles of Association.

In the event that the amendments to the Articles of Association passed by the general meetings need the examination and approval of the competent authorities, these amendments shall be submitted hereto for approval. Where the amendment of the Articles of Association involves registration, it shall be necessary to carry out the lawfully prescribed procedures for registration change.

3. VARIATION OF RIGHTS OF EXISTING SHARES OR CLASSES OF SHARE

Not applicable.

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4. SPECIAL RESOLUTIONS – MAJORITY REQUIRED

The resolutions of the general meeting shall be divided into ordinary resolutions and special resolutions.

An ordinary resolution may be adopted by a simple majority of the votes held by the shareholders (including proxies of shareholders) attending the general meeting.

A special resolution can be adopted by a two-thirds majority of the votes held by the shareholders (including proxies of shareholders) attending the general meeting. The following matters shall be passed by a special resolution of the Shareholders' Meeting:

- (i) increase or decrease in registered capital of our Company;
- (ii) amendment to this Articles of Association;
- (iii) the division, division, merger, dissolution, and liquidation of our Company;
- (iv) purchases or sells significant assets or enters into guarantees with an amount exceeding 30% of the total assets in the latest audited consolidated financial statements within one year;
- (v) equity incentive plan;
- (vi) other matters required by laws, administrative regulations, the Listing Rules or the Articles of Association, as well as those determined by ordinary resolutions of the Shareholders' Meeting to have a significant impact on our Company, and which require special resolutions to be passed.

5. VOTING RIGHTS (GENERALLY AND ON A POLL)

The ordinary shareholders have the right to attend or appoint a proxy to attend and vote at the general meeting. When voting at the general meeting, the shareholder (including proxy) may exercise his or her voting rights in accordance with the number of shares with voting power held with each share representing one vote.

Any shareholder who is required by the applicable laws, regulations, normative documents, and the Listing Rules to abstain from voting on a matter or is limited to an affirmative or negative vote shall abstain from voting or be required to so vote; any vote cast by or on behalf of relevant shareholder which is cast in violation of such requirement or restriction shall not be counted in the voting result.

The shares held by our Company itself shall have no voting right and shall not be counted in the total number of voting shares at the general meeting.

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6. REQUIREMENTS FOR ANNUAL GENERAL MEETINGS

The general meetings are divided into annual general meetings and extraordinary general meetings. The annual general meeting shall be convened once a year and be held within six months of the end of the previous fiscal year.

7. ACCOUNTING AND AUDITS

(1) Financial and accounting policies

Our Company shall develop our financial accounting policies pursuant to laws, administrative regulations and rules developed by the competent department.

The interim results or financial information published or disclosed by our Company shall at the same time be prepared in accordance with the PRC accounting standards, rules and regulations as well as international accounting standards or the accounting standards of the overseas area in which the shares are listed.

Our Company shall publish the financial reports twice in each accounting year. Interim financial reports shall be published within three months of the end of the first six months of a fiscal year, while the annual financial report shall be published within four months of the end of each accounting year.

(2) Appointment and Dismissal of Accountants

Our Company shall appoint a reputable accounting firm that meets appropriate requirements of the relevant regulations of the PRC to be responsible for auditing its annual financial report and reviewing its other financial reports.

The term of the appointment of the accounting firm shall be one year.

If the position of an appointed accounting firm is vacant, the board of directors may appoint an accounting firm before the start of general meeting. However, if during the vacant period, our Company has other incumbent accounting firm, such accounting firm may take the vacant.

Except the circumstances as above said, our Company shall appoint an accounting firm by the decision of the general meeting. The shareholders may replace the accounting firm through an ordinary resolution at the general meeting.

8. NOTICE AND AGENDA OF GENERAL SHAREHOLDERS' MEETINGS

The general meeting is the authorized organ of our Company that performs duties and exercises powers in accordance with the law.

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Under any of the following circumstances, the board of directors shall convene an extraordinary general meeting within two months:

- i. The number of directors is less than the number specified in the PRC Company Law or less than two thirds of the number required in the Articles of Association;
- ii. The uncovered losses of our Company reach one-third of its total paid-in registered capital;
- iii. The shareholders with 10% or more shares of our Company separately or jointly request to convene an extraordinary general meeting in writing (the number of shares shall be calculated by the day of the request);
- iv. The board of directors considers it necessary;
- v. Two or more independent non-executive directors make such proposal;
- vi. The board of supervisors makes such proposal;
- vii. Any other circumstances stipulated in laws, regulations, the Listing Rules, the Articles of Association.

In the event that the general meeting is convened, the board of directors, the board of supervisors and shareholders who separately or jointly hold more than 3% of the shares of our Company may submit a proposal with time limit set by the Listing Rules.

When convening a general meeting, our Company shall send a written notice 21 days before it is convened. When convening an extraordinary general meeting, our Company shall send a written notice 15 days before it is convened.

The extraordinary general meeting shall not decide on issues which are not listed in the notice.

The notice of the general meeting shall be made in writing, including the following contents:

- i. The place, the date and the hour of the meeting;
- ii. The matters and proposals to be discussed at the meeting;
- iii. Conspicuous statement that all shareholders are entitled to attend the meeting and appoint proxy to attend and vote and that proxy need not be a shareholder;
- iv. The date of record for the shareholders who are entitled to attend the meeting;

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- v. The name and telephone number of the contact person for the meeting;
- vi. The time and procedure of voting online or by any other means;
- vii. other requirements stipulated by laws, administrative regulations, department rules, Listing Rules or these Articles of Association.

The resolution of the general meeting includes ordinary resolution and special resolution. The following matters shall be approved by the general meeting through ordinary resolutions:

- i. Work report of the board of directors and the board of supervisors;
- ii. Plans of earnings distribution and loss make-up schemes drafted by the board of directors;
- iii. Appointment or dismissal of the members of the board of directors and the board of supervisors, and their enumeration and payment methods;
- iv. Annual budget and closing account report, balance sheet, income statement and other financial statements;
- v. Annual reports of our Company;
- vi. Other matters other than those approved by special resolution stipulated in the laws, administrative regulations, Listing Rules or the Articles of Association.

The following matters shall be approved by special resolution at the general meeting:

- i. The increase or decrease of the registered capital;
- ii. Division, merger, dissolution and liquidation of our Company;
- iii. Amendment of the Articles of Association;
- iv. The purchase or sale by our Company within one year of material assets exceeding 30% of the audited total assets of our Company at latest audited financial statement;
- v. Share incentive scheme;
- vi. Other matters recognized by ordinary resolution of the general meeting that could materially affect our Company and need to be approved by special resolution or as required by the laws, administrative regulations, Listing Rules or the Articles of Association;

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In the event that any resolution of the general meeting or resolution of the board of directors violates laws or administrative regulations, any shareholder is entitled to request the court to deem it as invalid.

In the event that the convening procedure or voting formula of the shareholders meeting or meeting of the board of directors violates any of laws, administrative regulations or the Articles of Association, or resolution of which violates the Articles of Association, any shareholder is entitled to ask the court to overturn within 60 days after the resolution was adopted.

9. SHARES TRANSFERS

The shares of our Company holding by the funders thereof shall not be transferred within one year of the date of establishment of our Company. The shares issued before the public issuance of shares by our Company shall not be transferred within one year of the date on which the stocks of our Company are [REDACTED] and [REDACTED] on a securities exchange.

The directors, supervisors, and senior management of our Company shall declare, to our Company, information on their holdings of the shares of our Company and the changes thereto. The shares transferable by them during each year of their term of office shall not exceed 25 percent of their total holdings of the shares of our Company. The shares that they held in our Company shall not be transferred within one year of the date on which the stocks of our Company are [REDACTED] and [REDACTED]. The aforesaid persons shall not transfer their shares of our Company within six months from the date of their resignation.

With regard to the H Shares that capital of which has been full-paid could be transferred without limitation in accordance with the Articles of Association. However, unless meeting the following conditions, the board of directors may refuse to recognize any transfer document without giving any reason:

- i. The transfer documents only involve H Shares;
- ii. The stamp duty chargeable on the transfer documents has been paid;
- iii. The relevant share certificate, and upon the reasonable request of the board of directors, any evidence in relation to the right of the transferor to transfer the shares has been submitted;
- iv. Our Company does not have any lien on the relevant shares; and
- v. The shares shall not be transferred to minors or the person who is insane or is found to be of unsound mind.

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10. RIGHTS OF OUR COMPANY TO PURCHASE OUR OUTSTANDING ISSUED SHARES

Under any of the following circumstances, our Company may submit to relevant competent authorities for approval to buy back our outstanding issued shares according to legal procedures with the approval of procedures stipulated in the Articles of Association:

- i. Reduce our Company's registered capital;
- ii. Merger with other companies which hold our shares;
- iii. Granting shares to the staff of our Company as incentives;
- iv. Requesting our Company to buy back its shares from shareholders who vote against any resolutions adopted at the general meeting concerning the merger and division of our Company;
- v. To convert shares into bond issued by our Company which is convertible to stock of our Company;
- vi. Necessary for our Company to maintain our Company's value and shareholders' equity; or
- vii. Other circumstances as permitted by the laws, administrative regulations, regulations of the authorities and Listing Rules.

11. POWER FOR ANY SUBSIDIARY OF OUR COMPANY TO OWN SHARES IN ITS PARENT

Not applicable.

12. DIVIDEND AND OTHER METHODS OF DISTRIBUTION

Our Company may distribute dividends in the following manner of cash or stock. Profit distribution shall be carried out through resolutions of shareholders' the general meeting after the corresponding statutory reserve fund is withdrawn.

13. PROXIES

Shareholders may attend the shareholders' general meeting in person or authorize proxies to attend and vote on their behalf. A legal person shareholder should attend the meeting by its legal representatives or persons authorized by its board of directors or other decision-making authorities.

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Any blank power of attorney form sent by the directors to the shareholder for appointing a shareholder proxy shall allow the shareholder, according to his or her free will, to instruct the proxy to vote and provide instructions separately for matters to be put to vote on each item on the meeting agenda.

14. CALLS ON SHARES AND FORFEITURE OF SHARES

Not applicable.

15. INSPECTION OF REGISTER OF MEMBERS

Our Company shall make a register of shareholders in accordance with evidentiary documents provided by the securities registration authorities.

Pursuant to the understanding and agreement entered into between the competent agency in charge of securities of the PRC and the overseas securities regulatory authorities, our Company may keep the original register of the shareholders of the H shares and entrust an overseas entity to manage it. The original register of the shareholders of the H shares shall be kept in Hong Kong.

Our Company shall keep a copy of the register of the holders of the H shares at our residential address. The overseas entrusted agency shall at all times maintain consistency between the original and copy of the register of the holders of the H shares.

In case of inconsistency between the original and copy of the register of the holders of the H shares, the original shall prevail.

When our Company convenes the general meeting, pays dividends, goes into liquidation or is involved in other actions that require the confirmation of identities, the board of directors shall fix a date as the equity registration date, upon expiration of which the shareholders whose names registered on the register of shareholders shall be the shareholders entitled to relevant equity.

16. QUORUM FOR MEETINGS AND SEPARATE CLASS MEETINGS

There is no quorum requirement for the general meeting of shareholders.

A meeting of board of directors shall require the presence of at least half of the board members.

17. RESTRICTIONS ON RIGHTS OF CONTROLLING SHAREHOLDER

The controlling shareholder and de facto controller of our Company shall not take advantage of their associated relationship to damage our Company's interests. Any loss caused to our Company as a result of such violation shall be compensated.

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The controlling shareholder and de facto controller of our Company are obliged to act in good faith to our Company and the general public company shareholders. The controlling shareholder shall exercise their rights as capital contributors in strict accordance with the law and shall not impair the lawful rights and interests of our Company or of the general public company shareholders by means of the distribution of profits, reorganization of assets, external investment, misappropriation of assets, loan, or guaranty, nor shall he make use of his controlling position to impair the interests of our Company or of the general public company shareholders.

18. RIGHTS OF THE MINORITIES IN RELATION TO FRAUD OR OPPRESSION THEREOF

If directors and senior management personnel violate laws, administrative regulations, or the provisions of the Articles of Association while performing their duties, causing losses to our Company, shareholders who individually or jointly hold more than 1% of our Company's shares for more than 180 consecutive days have the right to request in writing that the board of supervisors file a lawsuit with the people's court; If the board of directors violates laws, administrative regulations, or the provisions of these articles of association while performing its duties, causing losses to our Company, the aforementioned shareholders may request in writing that the board of directors file a lawsuit with the people's court.

If the board of supervisors or the board of directors refuses to file a lawsuit after receiving a written request from the shareholders specified in the preceding paragraph, or fails to file a lawsuit within 30 days from the date of receiving the request, or if the situation is urgent and the failure to file a lawsuit immediately will cause irreparable damage to our Company's interests, the shareholders specified in the preceding paragraph have the right to directly file a lawsuit in their own name to the people's court for the benefit of our Company.

If another person infringes on the legitimate rights and interests of our Company and causes losses to our Company, shareholders who individually or jointly hold more than 1% of our Company's shares for more than 180 consecutive days may file a lawsuit with the people's court in accordance with the provisions of the preceding two paragraphs.

If Directors and senior management personnel violate laws, administrative regulations, or the provisions of the Articles of Association and harm the interests of shareholders, shareholders may file a lawsuit with the people's court.

If the shareholders of our Company abuse their shareholder rights and cause losses to our Company or other shareholders, they shall bear compensation liability in accordance with the law. If a Company's shareholder abuses the independent status of our Company's legal person and the limited liability of shareholders, evade debts, and seriously harm the interests of our Company's creditors, they shall bear joint and several liability for our Company's debts.

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The controlling shareholder and de facto controller of our Company shall not use their affiliated relationships to harm the interests of our Company. Those who violate regulations and cause losses to our Company shall be liable for compensation. The controlling shareholder and actual controllers of our Company have a fiduciary obligation towards our Company and all shareholders of our Company. The controlling shareholder shall strictly exercise the rights of the funders in accordance with the law. The controlling shareholder, de facto controller, and their affiliated parties shall not use profit distribution, asset restructuring, external investment, fund occupation, loan guarantee, etc. to harm the legitimate rights and interests of our Company and all shareholders, and shall not use their controlling position to harm the interests of our Company and all shareholders.

19. PROCEDURES FOR LIQUIDATION

Under any of the following circumstances, our Company shall be lawfully dissolved and liquidated:

- i. The term of business of our Company has expired or other events of dissolution occur under the Article of Association;
- ii. The general meeting adopts a resolution to dissolve our Company;
- iii. Our Company needs to be dissolved for the purpose of merger or division;
- iv. The business license is revoked, or our Company is ordered to close or be eliminated according to applicable law; or
- v. Where our Company encounters significant difficulties in business and management, continuous survival may be significantly detrimental to the interests of the shareholders, and the difficulties may not be overcome through other means, shareholders who hold more than 10% of all voting rights of our Company's shareholders may request the People's Court to dissolve our Company.

Where our Company is dissolved due to the provisions set forth in i, ii, iv and v above, the liquidation team shall be established within 15 days from the date of the event leading to liquidation to commence dissolution and the personnel of the liquidation team shall consist of the persons determined by the directors or the general meeting. In the event the liquidation team is not established to conduct liquidation during such period, the creditors can request the people's court to appoint relevant personnel to establish the liquidation team for liquidation.

Within 10 days of the establishment of the liquidation team, the creditors shall be notified and an announcement shall be published within 60 days. The creditors shall declare their claims to the liquidation team within 30 days of the date on which the notice is received or 45 days of the date of announcement if the notice is not received.

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Creditors who declare claims shall state relevant issues related to the claims and provide proofs. The liquidation team shall carry out registration of the claims.

During the period for declaration of claims, the liquidation group shall not make any repayment to the creditors.

During the liquidation, our Company shall continue to exist, but shall not carry out business activities irrelevant to the liquidation. The property of our Company shall not be distributed to any shareholder before full payments have been made out of the property according to the aforesaid provision.

In the event the liquidation team finds that, after taking stock of our Company's property and preparing the balance sheet and list of property, that the assets are insufficient to pay the debts, it shall immediately apply to the people's court to declare bankruptcy.

After our Company is declared bankrupt by ruling of the people's court, the liquidation team shall turn over matters regarding the liquidation to the people's court.

Upon closure of liquidation of our Company, the liquidation team shall prepare a liquidation report, and shall be submitted to our general meeting or the people's court for recognition. The liquidation team shall submit the above-mentioned documents to our Company registration authority and apply for cancelation of our registration and publish an announcement on our termination.

20. OTHER IMPORTANT PROVISIONS FOR OUR COMPANY OR SHAREHOLDERS

(1) General Provisions

Our Company is a permanently existing joint stock limited company.

According to the Articles of Association, any shareholder may bring a lawsuit against another shareholder, a director, a supervisor, or the senior management, any shareholder may bring a lawsuit against our Company, and our Company may bring a lawsuit against any shareholder, director, supervisor or the senior management.

(2) Share and Transfer

Our Company may increase stock capital by the following means:

- i. Issuing shares in a public offering;
- ii. Issuing shares via a private placement;

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- iii. Giving bonus shares to existing shareholders;
- iv. Converting reserve funds into shares; and
- v. Other means approved by the laws, administrative regulations and relevant regulatory authorities.

Our Company may decrease our registered capital and shall comply with the procedures stipulated in Company Law of the PRC, other related regulations and the Articles of Association.

(3) Shareholders

The rights of our ordinary shareholders are as follows:

- i. To receive distribution of dividends and other forms of benefits according to the number of shares held;
- ii. To participate in or appoint a shareholder proxy to participate in and exercise corresponding voting rights at the general meeting;
- iii. To supervise and manage business and operational activities of our Company, provide suggestions or submit queries;
- iv. To transfer, grant and pledge our Company's shares held according to the provisions of the laws, administrative regulations and the Articles of Association;
- v. To obtain relevant information according to the provisions of the Articles of Association, including:
 - (i) Obtaining the Articles of Association after the cost is paid;
 - (ii) Right to inspect and copy information as follows after the reasonable fee is paid:
 - (1) All parts of the register of shareholders;
 - (2) Personal information of the director, supervisor, or senior management, including:
 - (a) Current and former name and alias;
 - (b) Principle address (domicile);

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- (c) Nationality;
 - (d) Full-time and other part-time occupation/position;
 - (e) Identity documents and ID number;
 - (3) Share capital status of our Company;
 - (4) A report of the total book value, the number, the highest buying price and the lowest buying price for shares repurchased by our Company since the last financial year, and of all expenses incurred thereon;
 - (5) Meeting minutes of the general meeting;
 - (6) Latest audited financial statement of our Company and the reports of the board of directors, the board of supervisors, and auditors;
 - (7) Copy of annual report as filed with market regulation administration and other authorities;
 - (8) Receipt of corporate bond, decisions of meeting of board of directors and decisions of meeting of board of supervisors; and
 - (9) Minutes of shareholder's general meeting.
- vi. To participate in the distribution of the remaining assets of our Company according to the proportion of shares held upon our termination or liquidation;
 - vii. To request our Company to buy back their shares as dissenting shareholders in decision of merger or division of our Company;
 - viii. Other rights conferred by laws, administrative regulations, regulations of the authorities, regulatory rules where our Company's shares are listed, or the Articles of Association.

(4) The board of directors

The board of directors is responsible to the general meeting and exercises the following powers:

- i. To convene the general meeting and report on work to the general meeting;
- ii. Implement the resolutions of the general meeting;
- iii. Determine the business and investment plans of our Company;

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- iv. Devise the annual financial budget and closing account plans of our Company;
- v. Devise the earnings distribution and loss offset plans of our Company;
- vi. Formulate the plans for increasing or decreasing our Company's registered capital, the issuance of corporate bonds;
- vii. Formulate plans for major acquisition, share buy-back, corporate merger, separation and dissolution of our Company;
- viii. Determine, within the scope authorized by the general meeting, such matters as our Company's external investments, the purchase and sale of assets, asset mortgages, external guarantees, entrusted management of finance, related-party transactions and external donations;
- ix. Decide on the setup of our Company's internal management organization;
- x. Appoint or dismiss the general manager, secretary of the board, and other senior managers of our Company; based on the nomination of the general manager, appoint or dismiss senior management of our Company such as deputy general manager, Chief financial officer (CFO) and other senior managers and determine their remuneration;
- xi. Set the basic management systems of our Company;
- xii. Make the modification plan to the Articles of Association;
- xiii. Manage disclosure matters of our Company;
- xiv. Make proposals to the shareholders' general meeting on the appointment or replacement of the accounting firm that provides auditing services to our Company;
- xv. Hear work report of senior managers and to inspect the manager's work;
- xvi. Formulate and implement share incentive plans of our Company; and
- xvii. Other powers and duties authorized by the laws, administrative regulations, regulations of the authorities, listing rules of the place where the shares of our Company are listed and the Articles of Association.

Meetings of the board of directors shall be attended by more than one-half of the directors (including proxies) before the board of directors meeting can be convened.

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(5) Independent Non-executive director

The board of directors of our Company has three independent non-executive directors. At least one independent non-executive director shall have applicable professional qualification or are equipped with applicable accounting or relevant financial management expertise.

(6) Secretary of the Board of Directors

Our Company shall have one secretary of the board of directors.

(7) Board of Supervisors

Our Company shall set up a board of supervisors.

The board of supervisors consists of three supervisors and includes one chairman. The chairman of the board of supervisors shall be elected and dismissed by a simple majority vote of the members of the board of supervisors.

The board of supervisors shall consist of shareholder’s representatives and employee’s representatives. The supervisors assumed by the employee representatives shall be elected and dismissed democratically by the employees and shall account for no less than one-third of the board of supervisors of our Company.

Resolutions of the board of supervisors shall require approval from majority of all the supervisors. The supervisors serve three-year terms.

The supervisors may, after the expiration of the term of office, be re-elected and re-appointed.

The directors and senior management shall not also serve as supervisors.

The board of supervisors is responsible to the general meeting and lawfully exercises the following powers:

- i. Examine the financial standing of our Company;
- ii. Supervise our Company’s duties performing of directors and senior management, and put forward suggestions for dismissing any directors or senior management who are in breach of the laws, administrative regulations, the Articles of Association or resolutions of the general meetings;
- iii. Require the directors and senior management to take corrective measures when their actions are detrimental to our Company’s interests;

APPENDIX VII SUMMARY OF ARTICLES OF ASSOCIATION

- iv. Review regular reports prepared by the board of directors and provide review opinions in writing;
- v. Propose to convene an extraordinary general meeting and to convene and preside over the shareholders' general meeting when the board of directors fails to perform its duty to convene and preside over a general meeting prescribed in the Company Law;
- vi. Submit proposals to the general meetings;
- vii. Bring a lawsuit against any director or senior manager in accordance with the Company Law;
- viii. Conduct investigation if any abnormality in the operation of our Company is found, and, where necessary, engage an accounting firm, law firm or any other specialized agency to assist in its work at the expense of our Company;
- ix. Other powers and duties stipulated in laws stipulated in laws, regulations, regulatory documents and the Articles of Association.

The supervisors may attend the meetings of the board of directors, query or provide suggestions on the resolution matters of the Board meeting.

(8) General manager

Our Company has one general manager, appointed or dismissed by the board of directors. The general manager of our Company is responsible to the board of directors and exercises the following powers:

- i. Be in charge of the producing and operational management of our Company, organize the enforcement of resolutions of the board of directors and report to the board of directors on work;
- ii. Organize the implementation of the annual operation plans and investment schemes decided by the board of directors;
- iii. Formulate the structure scheme of the internal management department of our Company;
- iv. Formulate the fundamental management policies of our Company;
- v. Formulate the specific management rules of our Company;

APPENDIX VII

SUMMARY OF ARTICLES OF ASSOCIATION

- vi. Propose the appointment or dismissal of our Company's deputy general manager (executive president), Chief financial officer and other senior management;
- vii. Appoint or dismiss other management personnel except those who shall be appointed or dismissed by the board of directors;
- viii. Other responsibilities authorized by the Articles of Association and the board of directors.

(9) Reserves

When the annual after-tax earnings of our Company are distributed, our Company must allocate 10% of the earnings to the statutory reserve of our Company.

When the total amount of the statutory reserve exceeds 50% of our Company's registered capital, no more allocations need to be drawn.

If our Company's statutory reserve is insufficient to offset our losses during the previous year, the earnings generated during the current year must be used to make up the losses before allocating the statutory reserve in accordance with the requirements set forth above.

After allocation to the statutory reserve from the after-tax earnings of our Company, we may also allocate to the reserves at will from after-tax earnings in line with the resolution(s) adopted at the general meeting.

After our Company has made up for its losses and made allocations to its statutory reserve fund, the remaining profits are distributed in proportion to the number of shares held by the shareholders, unless otherwise specified by the Articles of Association.

If the general meeting or directors violates the above provisions and profits are distributed to the shareholders before our Company makes up for losses or makes allocations to the statutory reserve fund, the profits distributed in violation of the provisions must be returned by such shareholders to our Company.

The shares held by our Company itself shall not be subject to profit distribution.

Our Company's reserves may be used only for offsetting losses of our Company, expanding the scale of business and operations or for conversion into capital to increase our capital, but the capital reserve shall not be used to offset losses of our Company.

Where the statutory reserve converses into capital, the remaining statutory reserve shall not be less than 25% of the registered capital of our Company before such conversion.

APPENDIX VIII

STATUTORY AND GENERAL INFORMATION

A. FURTHER INFORMATION ABOUT OUR GROUP

1. Establishment of our Company

Our Company was established in the PRC on June 16, 2015 and was converted to a joint stock company with limited liability under the Company Law with effect from September 30, 2021. Our Company has established a principal place of business in Hong Kong at 5/F, Manulife Place, 348 Kwun Tong Road, Kowloon, Hong Kong and was registered with the Registrar of Companies in Hong Kong as a non-Hong Kong company in Hong Kong under Part 16 of the Companies Ordinance on May 5, 2023. Ms. Tang King Yin (鄧景賢), one of our joint company secretaries, has been appointed as the authorized representative of our Company for the acceptance of service of process and notices on behalf of our Company in Hong Kong.

As our Company was established in the PRC, our corporate structure and Articles of Association are subject to the relevant laws and regulations of the PRC. A summary of the relevant provisions of our Articles of Association is set out in “Appendix VII—Summary of Articles of Association” to this document.

2. Changes in the share capital of our Company

As of the date of the establishment of our Company, our registered capital was RMB50,000,000. The following sets out the changes in the share capital of our Company within the two years immediately preceding the date of this document:

On September 30, 2021, our Company was converted into a joint stock company with limited liability under the PRC Company Law. Upon completion of such conversion, the registered capital of our Company was RMB166,480,000 divided into 166,480,000 Shares with a nominal value of RMB1.00 each.

On March 1, 2022, our registered capital was increased from RMB166,480,000 to RMB180,025,200.

On December 7, 2022, our registered capital was further increased from RMB180,025,200 to RMB210,025,200.

Immediately following the completion of the [REDACTED] and conversion of [REDACTED] Shares into H Shares, the registered share capital of our Company will be increased to RMB225,035,200 divided into 17,322,400 [REDACTED] Shares and 207,712,800 H Shares fully paid up or credited as fully paid up. Save as aforesaid and as mentioned in “—4. Resolutions of our Shareholders passed on March 23, 2023” below, there has been no alteration in our share capital within the two years immediately preceding the date of this document.

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3. Restriction of share repurchase

For details of the restrictions on the share repurchase by our Company, see “Appendix VII—Summary of Articles of Association” to this document.

4. Resolutions of our Shareholders passed on March 23, 2023

At the extraordinary general meeting of our Company held on March 23, 2023, among other things, the following resolutions were passed by our Shareholders:

- (a) the issue of H Shares with a nominal value of RMB1.00 each and such H Shares to be [REDACTED] on the Stock Exchange was approved;
- (b) the number of H Shares to be issued shall be no more than [REDACTED]% of the total issued share capital of our Company upon completion of the [REDACTED];
- (c) subject to the completion of the filing procedure with the CSRC, upon completion of the [REDACTED], the conversion of [REDACTED] Shares in aggregate into H Shares on a one-for-one basis was approved;
- (d) subject to the completion of the [REDACTED], the Articles of Association were approved and adopted, which shall become effective on the [REDACTED], and our Board has been authorized to amend the Articles of Association in accordance with any comments from the Stock Exchange and the relevant PRC regulatory authorities; and
- (e) our Board has been authorized to handle all relevant matters relating to, among other things, the [REDACTED], the issue of H Shares and the [REDACTED].

5. Particulars of our subsidiaries

Particulars of our Subsidiaries are set forth in note 1 of the Accountants’ Report.

Set out below is certain information of our subsidiaries as of the Latest Practicable Date:

No.	Name of subsidiaries	Name of shareholder(s)	Percentage of the equity interests held
1.	Saifu Juli	Our Company	100%
2.	Cellularforce	Saifu Juli	66%
		Taizhou Huacheng	34%

6. Change in the registered capital of our subsidiaries

Our Company’s subsidiaries are set out in the Accountants’ Report, the text of which is set out in Appendix I to this document. Save as disclosed in “History and Corporate Structure” in this document, there has been no other alteration in the registered capital of any of our subsidiaries within the two years immediately preceding the date of this document.

APPENDIX VIII

STATUTORY AND GENERAL INFORMATION

B. FURTHER INFORMATION ABOUT OUR BUSINESS

1. Summary of material contracts

We have entered into the following contracts (not being contracts entered into in the ordinary course of business) within the two years preceding the date of this document that are or may be material:

- (a) a capital increase agreement dated January 31, 2022 entered into among (i) Qyuns Therapeutics Co., Ltd. (江蘇荃信生物醫藥股份有限公司); (ii) Taizhou Saifu Juli Biomedical Co., Ltd. (泰州市賽孚聚力生物醫藥有限公司); (iii) Mr. Qiu Jiwan (裘霽宛) and Mr. Yu Guo’an (余國安); (iv) Hangzhou Quanyi Investment Management Partnership (General Partnership) (杭州荃毅投資管理合夥企業(普通合夥)), Shenzhen Qianhai Efung Taihe Equity Investment Fund Enterprise (Limited Partnership) (深圳市前海倚鋒太和股權投資基金企業(有限合夥)), Taizhou China Medical City Rongjianda Venture Capital Co., Ltd. (泰州中國醫藥城融健達創業投資有限公司), Taizhou Jianxin Venture Capital Co., Ltd. (泰州健鑫創業投資有限公司), Nanjing Tongren Boda Equity Investment Center (limited Partnership) (南京同人博達股權投資中心(有限合夥)), Shanghai Quanyou Fanyue Investment Management Partnership (Limited Partnership) (上海荃友凡悅投資管理合夥企業(有限合夥)), Shanghai Shuo Chen Investment Management Co., Ltd. (上海碩臣投資管理有限公司), Nanjing Huayuxiang Asset Management Center (General Partnership) (南京華裕祥資產管理中心(普通合夥)) (currently known as Nanjing Yuzhijia Pharmaceutical Technology Partnership (Limited Partnership) (南京裕之華醫藥科技合夥企業(有限合夥))), Taizhou Hongtai Health Investment Management Center (Limited Partnership) (泰州洪泰健康投資管理中心(有限合夥)), Suzhou Hefu Ruitai Equity Investment Center (Limited Partnership) (蘇州合富瑞泰股權投資中心(有限合夥)), Shenzhen Triwise Rozman Phase II Investment Partnership (Limited Partnership) (深圳勤智羅茲曼二期投資合夥企業(有限合夥)), Shenzhen Triwise Kangxin Venture Capital Partnership (Limited Partnership) (深圳勤智康信創業投資合夥企業(有限合夥)), Shenzhen Lucky-source III Venture Capital Center (Limited Partnership) (深圳瑞享源三號創業投資中心(有限合夥)), Gongqingcheng Jiayin Lucky-source Equity Investment Partnership (Limited Partnership) (共青城佳銀瑞享源股權投資合夥企業(有限合夥)), Shenzhen Lucky-source IV Venture Capital Center (Limited Partnership) (深圳瑞享源肆號創業投資中心(有限合夥)), Hangzhou Zhongmei Huadong Pharmaceutical Co., Ltd. (杭州中美華東製藥有限公司), Matrix Partners China VI Hong Kong Limited, Suzhou Guan hong Venture Capital Center (Limited Partnership) (蘇州冠鴻創業投資中心(有限合夥)), Shenzhen Yuanzhi Fuhai New Industry II Investment Co., Ltd. (深圳遠致富海新興產業二期投資企業(有限合夥)), Xinyu Tongchuang Guosheng Science and Innovation Industry Investment Partnership (Limited Partnership) (新余市同創國盛科創產業投資合夥企業(有限合夥)), Everest No. 37 (Shenzhen) Venture Capital Center (Limited Partnership) (朗瑪三十七號(深圳)創業投資中心(有限合夥)) and Shenzhen Triwise Detai New Technology Venture Capital Enterprise (Limited Partnership) (深圳勤智德泰新科技創業投資企業(有限合夥)); and (v) Gongqingcheng Triwise Huisheng

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Venture Capital Partnership (Limited Partnership) (共青城勤智慧升創業投資合夥企業(有限合夥)), Gongqingcheng Triwise Kangxin Venture Capital Partnership (Limited Partnership) (共青城勤智康鑫創業投資合夥企業(有限合夥)), TWVC Panglin Qyuns Investment Limited, Jiaxing Jiquan Equity Investment Partnership (Limited Partnership) (嘉興集荃股權投資合夥企業(有限合夥)) and Shenzhen Kaitian Yunqi Venture Capital Center (Limited Partnership) (深圳開天雲起創業投資中心(有限合夥)), pursuant to which, among others, (i) Gongqingcheng Triwise Huisheng Venture Capital Partnership (Limited Partnership) (共青城勤智慧升創業投資合夥企業(有限合夥)) agreed to subscribe for 595,400 Shares at a consideration of RMB10,000,000; (ii) Gongqingcheng Triwise Kangxin Venture Capital Partnership (Limited Partnership) (共青城勤智康鑫創業投資合夥企業(有限合夥)) agreed to subscribe for 3,899,800 Shares at a consideration of RMB65,500,000; (iii) TWVC Panglin Qyuns Investment Limited agreed to subscribe for 2,500,600 Shares at a consideration of US\$ equivalent to RMB42,000,000; (iv) Jiaxing Jiquan Equity Investment Partnership (Limited Partnership) (嘉興集荃股權投資合夥企業(有限合夥)) agreed to subscribe for 3,572,400 Shares at a consideration of RMB60,000,000; and (v) Shenzhen Kaitian Yunqi Venture Capital Center (Limited Partnership) (深圳開天雲起創業投資中心(有限合夥)) agreed to subscribe for 2,977,000 Shares at a consideration of RMB50,000,000;

- (b) an equity transfer agreement dated September 15, 2022 entered into between Taizhou Saifu Juli Biomedical Co., Ltd. (泰州市賽孚聚力生物醫藥有限公司) and Taizhou Saifu Meibo Enterprise Management Partnership (Limited Partnership) (泰州市賽孚美博企業管理合夥企業(有限合夥)), pursuant to which Taizhou Saifu Meibo Enterprise Management Partnership (Limited Partnership) (泰州市賽孚美博企業管理合夥企業(有限合夥)) agreed to transfer its 15% equity interest in Jiangsu Cellularforce Biotechnology Co., Ltd. (江蘇賽孚士生物技術有限公司) to Taizhou Saifu Juli Biomedical Co., Ltd. (泰州市賽孚聚力生物醫藥有限公司) at nil consideration;
- (c) a capital increase agreement dated October 15, 2022 entered into among Qyuns Therapeutics Co., Ltd. (江蘇荃信生物醫藥股份有限公司), Taizhou Xinfu Tongxin Enterprise Management Partnership (Limited Partnership) (泰州信孚同心企業管理合夥企業(有限合夥)), Mr. Qiu Jiwan (裘霽宛), Dr. Yu Guoliang (余國良), Dr. Li Jianwei (李建偉), Dr. Qiu Zhihua (裘之華) and Mr. Guo Xinjun (郭新軍), pursuant to which Taizhou Xinfu Tongxin Enterprise Management Partnership (Limited Partnership) (泰州信孚同心企業管理合夥企業(有限合夥)) agreed to subscribe for 15,550,000 Shares at a consideration of RMB15,550,000; Mr. Qiu Jiwan (裘霽宛) agreed to subscribe for 10,000,000 Shares at a consideration of RMB10,000,000; Dr. Yu Guoliang (余國良) agreed to subscribe for 1,500,000 Shares at a consideration of RMB1,500,000 (including equivalent US\$); Dr. Li Jianwei (李建偉) agreed to subscribe for 1,450,000 Shares at a consideration of RMB 1,450,000 (including equivalent US\$); Dr. Qiu Zhihua (裘之華) agreed to subscribe for 1,000,000 Shares at a consideration of RMB1,000,000 (including equivalent US\$) and Mr. Guo Xinjun (郭新軍) agreed to subscribe for 500,000 Shares at a consideration of RMB500,000;

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- (d) a shareholders’ agreement dated November 30, 2022 entered into among (i) Qyuns Therapeutics Co., Ltd. (江蘇荃信生物醫藥股份有限公司); (ii) Taizhou Saifu Juli Biomedical Co., Ltd. (泰州市賽孚聚力生物醫藥有限公司); (iii) Mr. Qiu Jiwan (裘霽宛) and Mr. Yu Guo’an (余國安); and (iv) Hangzhou Quanyi Investment Management Partnership (General Partnership) (杭州荃毅投資管理合夥企業(普通合夥)), Shenzhen Qianhai Efung Taihe Equity Investment Fund Enterprise (Limited Partnership) (深圳市前海倚鋒太和股權投資基金企業(有限合夥)), Taizhou China Medical City Rongjianda Venture Capital Co., Ltd. (泰州中國醫藥城融健達創業投資有限公司), Taizhou Jianxin Venture Capital Co., Ltd. (泰州健鑫創業投資有限公司), Nanjing Tongren Boda Equity Investment Center (limited Partnership) (南京同人博達股權投資中心(有限合夥)), Nanjing Talent Innovation Venture Capital Fund Partnership (Limited Partnership) (南京市人才創新創業投資基金合夥企業(有限合夥)), Shanghai Quanyou Fanyue Investment Management Partnership (Limited Partnership) (上海荃友凡悅投資管理合夥企業(有限合夥)), Shanghai Shuochen Investment Management Co., Ltd. (上海碩臣投資管理有限公司), Nanjing Yuzhuhua Pharmaceutical Technology Partnership (Limited Partnership) (南京裕之華醫藥科技合夥企業(有限合夥)), Taizhou Hongtai Health Investment Management Center (Limited Partnership) (泰州洪泰健康投資管理中心(有限合夥)), Suzhou Hefu Ruitai Equity Investment Center (Limited Partnership) (蘇州合富瑞泰股權投資中心(有限合夥)), Shenzhen Triwise Rozman Phase II Investment Partnership (Limited Partnership) (深圳勤智羅茲曼二期投資合夥企業(有限合夥)), Shenzhen Triwise Kangxin Venture Capital Partnership (Limited Partnership) (深圳勤智康信創業投資合夥企業(有限合夥)), Shenzhen Lucky-source III Venture Capital Center (Limited Partnership) (深圳瑞享源三號創業投資中心(有限合夥)), Gongqingcheng Jiayin Lucky-source Equity Investment Partnership (Limited Partnership) (共青城佳銀瑞享源股權投資合夥企業(有限合夥)), Shenzhen Lucky-source IV Venture Capital Center (Limited Partnership) (深圳瑞享源肆號創業投資中心(有限合夥)), Hangzhou Zhongmei Huadong Pharmaceutical Co., Ltd. (杭州中美華東製藥有限公司), Matrix Partners China VI, L.P., Matrix Partners China VI-A, L.P., Suzhou Guan hong Venture Capital Center (Limited Partnership) (蘇州冠鴻創業投資中心(有限合夥)), Shenzhen Yuanzhi Fuhai New Industry II Investment Co., Ltd. (深圳遠致富海新興產業二期投資企業(有限合夥)), Xinyu Tongchuang Guosheng Science and Innovation Industry Investment Partnership (Limited Partnership) (新余市同創國盛科創產業投資合夥企業(有限合夥)), Everest No. 37 (Shenzhen) Venture Capital Center (Limited Partnership) (朗瑪三十七號(深圳)創業投資中心(有限合夥)), Shenzhen Triwise Detai New Technology Venture Capital Enterprise (Limited Partnership) (深圳勤智德泰新科技創業投資企業(有限合夥)), Gongqingcheng Triwise Huisheng Venture Capital Partnership (Limited Partnership) (共青城勤智慧升創業投資合夥企業(有限合夥)), Gongqingcheng Triwise Kangxin Venture Capital Partnership (Limited Partnership) (共青城勤智康鑫創業投資合夥企業(有限合夥)), TWVC Panglin Qyuns Investment Limited, Jiaxing Jiquan Equity Investment Partnership with (Limited Partnership) (嘉興集荃股權投資合夥企業(有限合夥)) and Shenzhen Kaitian Yunqi Venture Capital Center (Limited Partnership) (深圳開天雲起創業投資中心(有限合夥)), pursuant to which the shareholders’ rights were agreed among the parties;

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- (e) a supplementary agreement to shareholders' agreement dated March 10, 2023 entered into among (i) Qyuns Therapeutics Co., Ltd. (江蘇荃信生物醫藥股份有限公司); (ii) Taizhou Saifu Juli Biomedical Co., Ltd. (泰州市賽孚聚力生物醫藥有限公司); (iii) Mr. Qiu Jiwan (裘霽宛) and Mr. Yu Guo'an (余國安) and (iv) Hangzhou Quanyi Investment Management Partnership (General Partnership) (杭州荃毅投資管理合夥企業(普通合夥)), Shenzhen Qianhai Efung Taihe Equity Investment Fund Enterprise (Limited Partnership) (深圳市前海倚鋒太和股權投資基金企業(有限合夥)), Taizhou China Medical City Rongjianda Venture Capital Co., Ltd. (泰州中國醫藥城融健達創業投資有限公司), Taizhou Jianxin Venture Capital Co., Ltd. (泰州健鑫創業投資有限公司), Nanjing Tongren Boda Equity Investment Center (limited Partnership) (南京同人博達股權投資中心(有限合夥)), Nanjing Talent Innovation Venture Capital Fund Partnership (Limited Partnership) (南京市人才創新創業投資基金合夥企業(有限合夥)), Shanghai Quanyou Fanyue Investment Management Partnership (Limited Partnership) (上海荃友凡悅投資管理合夥企業(有限合夥)), Shanghai Shuochen Investment Management Co., Ltd. (上海碩臣投資管理有限公司), Nanjing Yuzhijia Pharmaceutical Technology Partnership (Limited Partnership) (南京裕之華醫藥科技合夥企業(有限合夥)), Taizhou Hongtai Health Investment Management Center (Limited Partnership) (泰州洪泰健康投資管理中心(有限合夥)), Suzhou Hefu Ruitai Equity Investment Center (Limited Partnership) (蘇州合富瑞泰股權投資中心(有限合夥)), Shenzhen Triwise Rozman Phase II Investment Partnership (Limited Partnership) (深圳勤智羅茲曼二期投資合夥企業(有限合夥)), Shenzhen Triwise Kangxin Venture Capital Partnership (Limited Partnership) (深圳勤智康信創業投資合夥企業(有限合夥)), Shenzhen Lucky-source III Venture Capital Center (Limited Partnership) (深圳瑞享源三號創業投資中心(有限合夥)), Gongqingcheng Jiayin Lucky-source Equity Investment Partnership (Limited Partnership) (共青城佳銀瑞享源股權投資合夥企業(有限合夥)), Shenzhen Lucky-source IV Venture Capital Center (Limited Partnership) (深圳瑞享源肆號創業投資中心(有限合夥)), Hangzhou Zhongmei Huadong Pharmaceutical Co., Ltd. (杭州中美華東製藥有限公司), Matrix Partners China VI, L.P., Matrix Partners China VI-A, L.P., Suzhou Guan hong Venture Capital Center (Limited Partnership) (蘇州冠鴻創業投資中心(有限合夥)), Shenzhen Yuanzhi Fuhai New Industry II Investment Co., Ltd. (深圳遠致富海新興產業二期投資企業(有限合夥)), Xinyu Tongchuang Guosheng Science and Innovation Industry Investment Partnership (Limited Partnership) (新余市同創國盛科創產業投資合夥企業(有限合夥)), Everest No. 37 (Shenzhen) Venture Capital Center (Limited Partnership) (朗瑪三十七號(深圳)創業投資中心(有限合夥)), Shenzhen Triwise Detai New Technology Venture Capital Enterprise (Limited Partnership) (深圳勤智德泰新科技創業投資企業(有限合夥)), Gongqingcheng Triwise Huisheng Venture Capital Partnership (Limited Partnership) (共青城勤智慧升創業投資合夥企業(有限合夥)), Gongqingcheng Triwise Kangxin Venture Capital Partnership (Limited Partnership) (共青城勤智康鑫創業投資合夥企業(有限合夥)), TWVC Panglin Qyuns Investment Limited, Jiaxing Jiquan Equity Investment Partnership with (Limited Partnership) (嘉興集荃股權投資合夥企業(有限合夥)), Shenzhen Kaitian Yunqi Venture Capital Center (Limited Partnership) (深圳開天雲起創業投資中心(有限合夥)), Dr. Yu Guoliang, Dr. Li, Jianwei, Dr. Qiu Zhihua, Mr. Guo Xinjun (郭新軍) and Taizhou Xinfu Tongxin Enterprise Management Partnership (Limited Partnership) (泰州信孚同心企業管理合夥企業(有限合夥)), pursuant to which the shareholders' rights were agreed among the parties; and
- (f) [REDACTED].

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2. Our Intellectual Property Rights

(a) Trademarks

As of the Latest Practicable Date, our Group was the registered proprietor of the following trademarks which, in the opinion of our Directors, were material to our business:

No.	Trademark	Class	Name of Registered Proprietor	Place of Registration	Registration Number	Date of Registration	Date of Expiry
1.	A 	1, 5, 35, 40, 42	Our Company	Hong Kong	305824503	December 7, 2021	December 6, 2031
	B 						
2.	荃芙宁	42	Our Company	PRC	48692689	March 21, 2021	March 20, 2031
3.	荃肤宁	42	Our Company	PRC	48688148	March 21, 2021	March 20, 2031
4.	荃芙宁	35	Our Company	PRC	48686982	March 21, 2021	March 20, 2031
5.	荃肤宁	35	Our Company	PRC	48683358	March 21, 2021	March 20, 2031
6.	荃芙宁	5	Our Company	PRC	48677697	April 7, 2021	April 6, 2031
7.	荃肤宁	5	Our Company	PRC	48668717	June 7, 2021	June 6, 2031
8.		42	Our Company	PRC	36352193	August 28, 2020	August 27, 2030
9.		35	Our Company	PRC	36347607	October 28, 2020	October 27, 2030
10.	荃信生物	5	Our Company	PRC	36304631	February 14, 2020	February 13, 2030
11.		5	Our Company	PRC	36304630	May 7, 2020	May 6, 2030
12.		5	Our Company	PRC	36304629	May 7, 2020	May 6, 2030
13.		5	Our Company	PRC	64606076	November 7, 2022	November 6, 2032

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No.	Trademark	Class	Name of Registered Proprietor	Place of Registration	Registration Number	Date of Registration	Date of Expiry
14.		35	Our Company	PRC	64596347	November 7, 2022	November 6, 2032
15.		42	Our Company	PRC	64598929	December 28, 2023	December 27, 2033
16.	荃信生物	35	Our Company	PRC	64616067	November 7, 2022	November 6, 2032
17.	荃信生物	42	Our Company	PRC	64613592	November 14, 2022	November 13, 2032
18.	QYUNS	5	Our Company	PRC	64619869	November 7, 2022	November 6, 2032
19.	QYUNS	42	Our Company	PRC	64593196	October 28, 2022	October 27, 2032
20.	赛孚士	5	Cellularforce	PRC	49124859	March 28, 2021	March 27, 2031
21.	赛孚士	42	Cellularforce	PRC	49134830	March 28, 2021	March 27, 2031
22.		5	Cellularforce	PRC	53300424	November 28, 2021	November 27, 2031
23.		42	Cellularforce	PRC	53314092	December 14, 2021	December 13, 2031
24.		42	Cellularforce	PRC	62456201	June 14, 2023	June 13, 2033
25.		42	Cellularforce	PRC	62449913	June 14, 2023	June 13, 2033

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(b) Patents

As of the Latest Practicable Date, our Group had registered the following patents which, in the opinion of our Directors, were material to our business:

No.	Patent	Type	Place of Registration	Patent Number	Name of Registered Proprietor	Date of Application	Date of Expiry
1.	Anti-human interleukin 17A monoclonal antibody and application thereof (抗人白介素17A單克隆抗體及其應用)	Invention	PRC	201810473679.4	Our Company	May 17, 2018	May 17, 2038
2.	Anti-human interleukin-4 receptor α monoclonal antibody and application thereof (抗人白介素4受體 α 單克隆抗體及其應用)	Invention	PRC	201811592427.X	Our Company	December 25, 2018	December 25, 2038
3.	Anti-human interleukin 23 monoclonal antibody and application thereof (抗人白介素23單克隆抗體及其應用)	Invention	PRC	202010534153.X	Our Company	June 12, 2020	June 12, 2040
4.	Cell strain for producing biosimilar drug of ustekinumab and production method thereof (用於生產烏司奴單抗的生物類似藥的細胞株及生產方法)	Invention	PRC	202110099804.1	Our Company	January 25, 2021	January 25, 2041
5.	Anti-human interferon α receptor 1 monoclonal antibody and application thereof (抗人干擾素 α 受體1單克隆抗體及其應用)	Invention	PRC	202110586032.4	Our Company	May 27, 2021	May 27, 2041

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No.	Patent	Type	Place of Registration	Patent Number	Name of Registered Proprietor	Date of Application	Date of Expiry
6.	Anti-human interleukin 17A monoclonal antibody and application thereof	Invention	Australia	AU2018423921	Our Company	May 17, 2018	May 17, 2038
7.	Anti-human interleukin 17A monoclonal antibody and application thereof (抗ヒトインターロイキン 17Aモノクローナル抗體およびその使用)	Invention	Japan	JP2020565275	Our Company	May 17, 2018	May 17, 2038
8.	Monoclonal antibody against human interleukin-4 receptor alpha and use thereof	Invention	Australia	AU2019416486	Our Company	December 25, 2019	December 25, 2039
9.	Monoclonal antibody against human interleukin-4 receptor alpha and use thereof (抗ヒトインターロイキン-4受容體αのモノクローナル抗體およびその使用)	Invention	Japan	JP2021537939	Our Company	December 25, 2019	December 25, 2039
10.	Anti-human interleukin-33 monoclonal antibody and application thereof (抗人白介素-33單克隆抗體及其應用)	Invention	PRC	202111031678.2	Our Company	September 3, 2021	September 3, 2041
11.	An anti-human TSLP monoclonal antibody and application thereof (一種抗人 TSLP單克隆抗體及其應用)	Invention	PRC	202111031653.2	Our Company	September 3, 2021	September 3, 2041

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<u>No.</u>	<u>Patent</u>	<u>Type</u>	<u>Place of Registration</u>	<u>Patent Number</u>	<u>Name of Registered Proprietor</u>	<u>Date of Application</u>	<u>Date of Expiry</u>
12.	Anti-human interleukin 17A monoclonal antibody and application thereof	Invention	Europe	EP18919093.7	Our Company	May 17, 2018	May 17, 2038
13.	Anti-human interleukin 23 monoclonal antibody and application thereof	Invention	Australia	AU2020453086	Our Company	September 9, 2020	September 9, 2040
14.	Anti-human interleukin 23 monoclonal antibody and application thereof	Invention	Japan	JP2022576348	Our Company	September 9, 2020	September 9, 2040

As of the Latest Practicable Date, we had applied for the registration of the following patents which, in the opinion of our Directors, material to our business:

<u>No.</u>	<u>Patent</u>	<u>Type</u>	<u>Place of Application</u>	<u>Application Number</u>	<u>Applicant</u>	<u>Date of Application</u>
1.	Anti-human interleukin 17A monoclonal antibody and application thereof	Invention	United States	US17/055,789	Our Company	May 17, 2018
2.	Anti-human interleukin 17A monoclonal antibody and application thereof	Invention	Canada	CA3100092	Our Company	May 17, 2018
3.	Monoclonal antibody against human interleukin-4 receptor alpha and use thereof	Invention	United States	US17/418,571	Our Company	December 25, 2019
4.	Monoclonal antibody against human interleukin-4 receptor alpha and use thereof	Invention	Canada	CA3124726	Our Company	December 25, 2019

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No.	Patent	Type	Place of Application	Application Number	Applicant	Date of Application
5.	Monoclonal antibody against human interleukin-4 receptor alpha and use thereof	Invention	Europe	EP19902812.7	Our Company	December 25, 2019
6.	Anti-human interleukin 23 monoclonal antibody and application thereof	Invention	United States	US18/009,849	Our Company	September 9, 2020
7.	Anti-human interleukin 23 monoclonal antibody and application thereof	Invention	Europe	EP20940419.3	Our Company	September 9, 2020
8.	Anti-human interleukin 23 monoclonal antibody and application thereof	Invention	Canada	CA3186988	Our Company	September 9, 2020
9.	Cell strain for producing biosimilar drug of ustekinumab and production method therefor	Invention	PCT-US	US18/273,891	Our Company	March 23, 2021
10.	Cell strain for producing biosimilar drug of ustekinumab and production method therefor	Invention	PCT-CA	CA3209089	Our Company	March 23, 2021
11.	Cell strain for producing biosimilar drug of ustekinumab and production method therefor	Invention	PCT-IN	IN202317050438	Our Company	March 23, 2021
12.	Cell strain for producing biosimilar drug of ustekinumab and production method therefor	Invention	PCT-SG	SG11202305574Q	Our Company	March 23, 2021
13.	Cell strain for producing biosimilar drug of ustekinumab and production method therefor	Invention	PCT-JP	JP2023-544164	Our Company	March 23, 2021

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No.	Patent	Type	Place of Application	Application Number	Applicant	Date of Application
14.	Cell strain for producing biosimilar drug of ustekinumab and production method therefor	Invention	PCT-AU	AU2021422014	Our Company	March 23, 2021
15.	Cell strain for producing biosimilar drug of ustekinumab and production method therefor	Invention	PCT-EP	EP21920449.2	Our Company	March 23, 2021
16.	Anti-human interleukin-33 monoclonal antibody and application thereof	Invention	PCT	PCT/CN2021/136755	Our Company	December 9, 2021
17.	An anti-human TSLP monoclonal antibody and application thereof	Invention	PCT	PCT/CN2021/136757	Our Company	December 9, 2021
18.	Anti-human interleukin 36 receptor monoclonal antibody and application thereof (抗人白介素36受體單克隆抗體及其應用)	Invention	PRC	202211288779.2	Our Company	October 20, 2022
19.	Anti-human interleukin 36 receptor monoclonal antibody and application thereof	Invention	PCT	PCT/CN2022/134732	Our Company	November 28, 2022
20.	Anti-human interferon α receptor 1 monoclonal antibody and application thereof	Invention	PCT-AU	AU2021447156	Our Company	August 27, 2021
21.	Anti-human interferon α receptor 1 monoclonal antibody and application thereof	Invention	PCT-US	US18/564,002	Our Company	August 27, 2021
22.	Anti-human interferon α receptor 1 monoclonal antibody and application thereof	Invention	PCT-EP	EP21942597.2	Our Company	August 27, 2021

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No.	Patent	Type	Place of Application	Application Number	Applicant	Date of Application
23.	Anti-human interferon α receptor 1 monoclonal antibody and application thereof	Invention	PCT-JP	JP2023-573257	Our Company	August 27, 2021
24.	Anti-human interferon α receptor 1 monoclonal antibody and application thereof	Invention	PCT-CA	CA3219713	Our Company	August 27, 2021
25.	Anti-human interleukin 13 monoclonal antibody and application thereof (抗人白介素13單克隆抗體及其應用)	Invention	PRC	2023117813732	Our Company	December 22, 2023
26.	Anti-human CD117 monoclonal antibody and application thereof (抗人CD117單克隆抗體及其應用)	Invention	PRC	202410059200.8	Our Company	January 15, 2024

(c) Domain names

As of the Latest Practicable Date, our Group had registered the following domain names which, in the opinion of our Directors, were material to our business:

No.	Domain name	Name of Registered Proprietor	Date of Registration	Date of Expiry
1	qyuns.net	Our Company	July 1, 2015	July 1, 2025
2	cellularforce.net	Cellularforce	November 5, 2018	November 5, 2028

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C. FURTHER INFORMATION ABOUT DIRECTORS, SUPERVISORS AND SUBSTANTIAL SHAREHOLDERS

1. Disclosure of interests

(a) Interests and short positions of the Directors, Supervisors and the chief executive of our Company in the registered capital of our Company and its associated corporations

Immediately following the completion of the [REDACTED] and conversion of [REDACTED] Shares into H Shares, the interests or short positions of Directors, Supervisors or chief executive of our Company in the Shares, underlying Shares and debentures of our Company or its associated corporations (within the meaning of Part XV of the SFO) which will be required to be notified to our Company and the Stock Exchange pursuant to Divisions 7 and 8 of Part XV of the SFO (including interests or short positions which they were taken or deemed to have under such provisions of the SFO) or which will be required, under section 352 of the SFO, to be entered in the register referred to in that section, or which will be required, under the Model Code for Securities Transactions by Directors of Listed Issuers as set out in Appendix 10 to the Listing Rules (the “Model Code”), to be notified to our Company and the Stock Exchange once the H Shares are [REDACTED] will be as follows:

Interest in Shares of our Company

<u>Name</u>	<u>Nature of interest</u>	<u>Type of Shares</u>	<u>Number of Shares⁽¹⁾</u>	<u>Approximately percentage of shareholding in the relevant type of Shares</u>	<u>Approximate percentage of shareholding in the total issued share capital</u>
Mr. Qiu ⁽²⁾⁽³⁾⁽⁴⁾⁽⁵⁾	Beneficial owner	[REDACTED] Shares	[10,000,000] (L)	[REDACTED]%	[REDACTED]%
	Interest in controlled corporations	H Shares	[60,550,000] (L)	[REDACTED]%	

Notes:

- (1) The letter “L” denotes the person’s long position in our Shares.
- (2) Hangzhou Quanyi is owned as to 50% by Mr. Qiu and 50% by Mr. Yu Guo’an, both being its general partners acting in concert pursuant to the supplemental partnership agreement of Hangzhou Quanyi. For details, see “Relationship with Our Controlling Shareholders—Overview” in this document. By virtue of the SFO, each of Mr. Qiu and Mr. Yu Guo’an is deemed to be interested in the Shares held by Hangzhou Quanyi.
- (3) Mr. Qiu is the general partner who holds approximately 7.20% interest in Xinfu Tongxin. By virtue of the SFO, Mr. Qiu is deemed to be interested in the Shares held by Xinfu Tongxin.

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- (4) Mr. Qiu is the general partner who holds approximately 45.71% interest in Shanghai Quanyou. Shanghai Quanyou holds 5,000,000 Shares, representing approximately 2.38% and [REDACTED]% of our Shares in issue immediately prior to and following the completion of the [REDACTED]. By virtue of the SFO, Mr. Qiu is deemed to be interested in the Shares held by Shanghai Quanyou.
- (5) Mr. Qiu directly holds 10,000,000 Shares, representing approximately 4.76% and [REDACTED]% of our Shares in issue immediately prior to and following the completion of the [REDACTED].

(b) Substantial Shareholders

Save as disclosed in the section headed “Substantial Shareholders” in this document, our Directors are not aware of any persons (other than our Directors, Supervisors and chief executive of our Company) who will, immediately following the completion of the [REDACTED], will have or be deemed or taken to have interests and/or short position in our Shares or underlying Shares which would be required to be disclosed under the provisions of Divisions 2 and 3 of Part XV of the SFO, or who is, directly or indirectly, interested in 10% or more of the nominal value of any types of the issued voting shares of any member of our Group.

2. Particulars of Directors’ and Supervisors’ service agreements and letters of appointment

Each of our Directors and Supervisors has entered into a service agreement or letter of appointment with our Company. The principal particulars of these service agreements and letters of appointment comprise (a) the term of the service; (b) termination provisions; and (c) dispute resolution provision. The service agreements and letters of appointment may be renewed in accordance with our Articles of Association and the applicable laws, rules and regulations from time to time.

Save as disclosed above, none of our Directors or Supervisors has or is proposed to have a service agreement with any member of our Group (other than contracts expiring or determinable by the relevant employer within one year without the payment of compensation (other than statutory compensation)).

3. Directors’ and Supervisors’ remuneration

For the two years ended December 31, 2022 and the nine months ended September 30, 2023, the aggregate remuneration (including salaries, allowances, benefits in kind, discretionary bonuses, retirement scheme contributions and share-based payments) paid or payable to our Directors and Supervisors were approximately RMB11.86 million, RMB32.66 million and RMB61.03 million, respectively. For details, please refer to note 8 of the Accountants’ Report set out in Appendix I to this document.

Under the arrangement currently in force, the aggregate remuneration (including salaries, allowances, benefits in kind, discretionary bonuses, retirement scheme contributions and share-based payments) of our Directors and Supervisors for the year ending December 31, 2024 is estimated to be no more than RMB55 million.

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4. Agency fees or commissions received

Save as disclosed in “[REDACTED]” in this document, no commissions, discounts, agency fee, brokerages or other special terms were granted in connection with the issue or sale of any capital of any member of our Group within the two years immediately preceding the date of this document.

5. Disclaimers

- (a) save as disclosed in this section, none of our Directors, Supervisors or chief executive of our Company has any interest or short position in our shares, underlying shares or debentures of our Company or any of its associated corporation (within the meaning of the SFO) which will have to be notified to our Company and the Stock Exchange pursuant to Division 7 and 8 of Part XV of the SFO or which will be required, pursuant to section 352 of the SFO, to be entered in the register referred to therein, or which will be required to be notified to our Company and the Stock Exchange pursuant to the Model Code for Securities Transactions by Directors of Listed Issuers once our H Shares are [REDACTED] on the Stock Exchange;
- (b) within the two years immediately preceding the date of this document, save for the property leasing by our Group from Ms. Wang Yujiao, our Supervisor, with a total GFA of 91.71 sq.m. for staff dormitory use and a rent of RMB2,250 per month until December 31, 2023, none of our Directors or Supervisors nor any of the experts referred to under “—E. Other Information—6. Qualifications and consents of experts” in this appendix has any direct or indirect interest in the promotion of our Company, or in any assets which have been acquired or disposed of by or leased to any member of our Group, or are proposed to be acquired or disposed of by or leased to any member of our Group;
- (c) none of our Directors or Supervisors nor any of the experts referred to under “—E. Other Information—6. Qualifications and consents of experts” in this appendix, is materially interested in any contract or arrangement subsisting at the date of this document which is significant in relation to the business of our Group taken as a whole;
- (d) save as disclosed in this section, none of our Directors or Supervisors has any existing or proposed service contracts with any member of our Group (excluding contracts expiring or determinable by the employer within one year without payment of compensation (other than statutory compensation));
- (e) save as disclosed in “Substantial Shareholders” and “—C. Further information about Directors, Supervisors and Substantial Shareholders—1. Disclosure of interests” above, none of our Directors or Supervisors knows of any person (not being a Director, Supervisor or chief executive of our Company) who will, immediately following the completion of the [REDACTED], have an interest or short position in our Shares or underlying Shares which would fall to be disclosed under the provisions of Division 2 and 3 of Part XV of SFO or be interested, directly or indirectly, in 10% or more of the issued voting shares of any member of our Group; and

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- (f) so far as is known to our Directors as of the Latest Practicable Date, none of our Directors, Supervisors or their respective close associates (as defined under the Listing Rules) or our Shareholders who are interested in more than 5% of the issued share capital of our Company has any interests in any of our top five suppliers.

D. EMPLOYEE SHARE INCENTIVE SCHEME

The following is a summary of the principal terms of the Employee Share Incentive Scheme as approved and adopted by the resolutions of our Shareholders at the extraordinary general meeting of our Company held on September 15, 2022 (the “Scheme”). The Employee Share Incentive Scheme comprised two parts, (i) certain participants shall have the right to invest in our Company by way of becoming limited partners of Xinfu Tongxin or Xinfu Quanxin, our employee share incentive platforms, and making capital contribution to our Company through Xinfu Tongxin; and (ii) Mr. Qiu, Dr. Li Jianwei and Dr. Yu Guoliang shall have the right to make capital contribution to our Company directly and become our Shareholders. The terms of the Scheme are not subject to the provisions of Chapter 17 of the Listing Rules as the Scheme does not involve the grant of share awards by our Company after the [REDACTED].

(a) Purpose

The purpose of the Scheme is to establish and improve the long-term incentive mechanism of our Group, better retain and motivate the employees and consultants of our Group and share the growth in earnings of our Group with the Participants (as defined below).

(b) Participants of the Scheme

Eligible participants of the Scheme (the “Participants”) are principally core management members and core personnel of our Group, which shall be determined by the management of our Company from time to time on factors such as the contribution, position and years of service of the Participants and taking into account the business objectives and performance of our Company.

(c) Maximum number of the incentive Shares

The maximum number of incentive Shares under the Scheme, which are restricted shares of the Company is [REDACTED] Shares, representing approximately [REDACTED]% of the total issued share capital of our Company immediately following the completion of the [REDACTED], which shall be held by Xinfu Tongxin and/or directly held by Mr. Qiu, Dr. Li Jianwei and Dr. Yu Guoliang, and shall be granted to the Participants in one or more tranches.

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(d) Grant price and grant of Shares

The grant price per Share under the Scheme is RMB1. A Participant may subscribe for the incentive Shares by signing the grant instrument and become a limited partner of our employee share incentive platforms or our Shareholder. A Participant shall pay the grant price in full to our employee share incentive platforms or our Company pursuant to the relevant provisions of the grant instrument, and shall be entitled to the property rights corresponding to the incentive Shares (including but not limited to the rights to receive cash dividends and proceeds from transfer) on the basis of his or her actual capital contribution.

Given that certain Participants hold the Shares indirectly through our employee share incentive platforms, such Participants shall not have voting rights as our Shareholders, and the executive partner of Xinfu Tongxin shall, on behalf of Xinfu Tongxin, exercise such voting rights, make decisions on the transfer and disposal of the Shares held by Xinfu Tongxin and execute agreements and documents in relation to such transfer or disposal.

(e) Lock-up period and releasing restrictions on the incentive Shares

Unless otherwise permitted by the general manager, Mr. Qiu or any person designated by him (collectively the “Administrator”), a Participant shall not create a pledge or other security rights over the incentive Shares.

A Participant may be required to achieve certain performance appraisal targets or to satisfy certain requirements for his or her service period with the Group before the incentive Shares held by him or her are released. The Shares directly or indirectly held by a Participant pursuant to the Scheme are subject to lock-up period (the “Lock-up Period”) from the date of receipt of the incentive Shares to the later of (a) the date of completion of three years of service of the Participant with our Group after the date of joining or the date of receipt of the incentive Shares; and (b) the expiry of all lock-up periods of the relevant incentive Shares in accordance with laws, regulations and requirements of the CSRC and the Stock Exchange after [REDACTED] and release of all restrictions (if any) on the incentive Shares received by the Participants.

(f) Disposal of incentive Shares

After the expiry of the Lock-up Period and release of all restrictions on the incentive Shares pursuant to the Scheme, the Participants may, subject to the laws, regulations and the relevant provisions or requirements of the CSRC or the Stock Exchange, dispose the incentive Shares directly or indirectly held by him or her to obtain investment returns.

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After the expiry of the Lock-up Period and release of all restrictions on the incentive Shares pursuant to the Scheme, if a Participant intends to dispose the incentive Shares indirectly held by him or her through our employee share incentive platforms, such disposal shall be conducted in the following manner:

- (a) the Administrator shall, in due course on a quarterly basis, make an announcement to the Participants concerning the specific time slot (the “Window Period”) for the disposal of the incentive Shares held by our employee share incentive platforms (if the trading of Shares is suspended, the Window Period shall be extended accordingly, subject to the time as notified by the Administrator);
- (b) a Participant shall submit an application to the Administrator for the transfer of his or her interest in our employee share incentive platforms during the Window Period. The Administrator shall during the Window Period, according to the application of the Participant and based on the total number of Shares held by our employee share incentive platforms, determine the corresponding number of Shares to be sold. The specific date of sale of such Shares shall be determined by the Administrator; and
- (c) after deducting the relevant taxes and expenses, the remaining sale price shall be paid to the designated account of the relevant Participant who applied for the transfer by reducing his or her corresponding interest in our employee share incentive platforms.

(g) *Repurchase of incentive Shares*

The table below sets out the arrangement in relation to the repurchase of incentive Shares directly or indirectly held by the Participants under certain repurchase events:

Repurchase events

(the “Repurchase Events”)

Repurchase price

- | | |
|---|---|
| (a) violation of relevant laws, regulations, rules or policies, causing economic losses to our Company; | The repurchase price shall be equal to the actual amount of capital contribution paid by such Participant for the incentive Shares to be repurchased. |
| (b) violation of the relevant provisions of the Articles of Association, partnership agreement of our employee share incentive platforms, grant agreement or key management regulations of our Company; | |
| (c) serious dereliction of duty or malpractice; | |

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Repurchase events

(the “Repurchase Events”)

Repurchase price

- (d) request for or acceptance of commercial bribery, embezzlement of property, theft, disclosure of trade secrets, materialization of related party transactions and other acts that cause harm in the interests and image of our Company;
- (e) direct or indirect engagement in any business which is the same as, similar to or in competition with the existing business of our Company through direct investment, equity participation, provision of technical or service support, service for or receipt of remuneration from third parties; or breach of non-competition agreements or confidentiality agreements with our Company (consultants of our Group are not subject to this provision);
- (f) major economic losses caused by any other act of such Participant;
- (g) dismissal by our Company due to the above matters;
- (h) refusal to perform or unreasonably delaying the performance of his or her obligations under the partnership agreement of our employee share incentive platforms or the grant agreement;

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Repurchase events

(the “Repurchase Events”)

Repurchase price

- | | |
|---|---|
| <p>(i) termination of labor or employment relationship with our Company due to voluntary resignation;</p> <p>(j) expiry and non-renewal of employment or labor contract with our Company;</p> <p>(k) changes in ownership of the incentive Shares held as a result of property division under special circumstances such as divorce or for any other reasons;</p> <p>(l) termination or cancelation of labor or employment relationship with our Company due to serious diseases (with certificates issued by a medical institution), death or declaration of death according to laws; or</p> <p>(m) termination of labor contract or employment contract with our Company for any reason other than fault on part of such Participant (such as layoff or dismissal).</p> | <p>The repurchase price shall be determined as follows:</p> <p>(1) prior to the completion of the [REDACTED], the repurchase price shall be equal to the actual amount of capital contribution paid by such Participant for the incentive Shares to be repurchased;</p> <p>(2) after the [REDACTED] but prior to the expiry of the Lock-up Period: (i) for the incentive Shares owned by such Participant on which the restrictions (if any) have been released, they shall be divided into two equal portions, and the repurchase price for each portion shall be calculated separately, in which case the repurchase price shall be equal to the average closing price of the Shares for the 20 trading days prior to the repurchase for one portion and nil for another portion; and (ii) for the incentive Shares on which restrictions (if any) have not been released, the repurchase price shall be equal to the actual capital contribution paid by such Participant for the incentive shares to be repurchased; and</p> <p>(3) after the expiry of the Lock-up Period and the release of restrictions on the incentive Shares (if any), the repurchase price shall be equal to the average closing price of the Shares for the 20 trading days prior to the repurchase or the Administrator shall assist in selling the incentive Shares with reference to the disposal arrangement set out above (subject to determination by the Administrator at his or her sole discretion in light of the actual situation of our Company).</p> |
|---|---|

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Unless otherwise agreed in the Scheme, if any of the Repurchase Events occurs to a Participant, the Administrator has the right to repurchase the incentive Shares directly or indirectly held by such Participant in one of the following ways:

- (a) to transfer the interest in our employee share incentive platforms or the Shares held by a Participant to the Administrator or a third party designated by the Administrator (such third party shall be an employee of the Company or its subsidiaries); or
- (b) to return the interest held by a Participant in our employee share incentive platforms by reducing the total capital of our employee share incentive platforms.

Upon the occurrence of a Repurchase Event, the relevant Participant shall be deemed to have divested from our employee share incentive platforms or ceased to be a Shareholder and shall not be entitled to any rights as limited partner of our employee share incentive platforms or our Shareholder from the date on which the Administrator issues a written notice of repurchase (except for the rights of repurchase price of the relevant incentive Share). For other unspecified special circumstances, the Administrator shall identify such circumstance and finally determine how to deal with the incentive Shares under such circumstance.

Details of the incentive Shares granted under the Scheme

As of the Latest Practicable Date, 27,500,000 incentive Shares had been granted to 70 Participants, of which 15,550,000 incentive Shares were indirectly held by 68 Participants through our employee share incentive platforms and the remaining 11,950,000 incentive Shares were directly held by Mr. Qiu, Dr. Li Jianwei and Dr. Yu Guoliang at consideration of RMB1 per Share pursuant to the Scheme. As of the Latest Practicable Date, all the incentive Shares under the Scheme were granted. The incentive Shares granted under the Scheme are subject to vesting period and vesting conditions which are described under the paragraph headed “(e) Lock-up Period and releasing restrictions on the incentive Shares” and the notes as set out in the table below.

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The table below sets out the details of the incentive Shares granted under the Scheme as of the Latest Practicable Date:

Name of the Participant	Position(s) in our Group	Date of grant	Number of underlying incentive Shares granted			Approximate percentage of direct or indirect shareholding in our Company immediately following completion of the [REDACTED]
			Phase I ⁽¹⁾	Phase II ⁽²⁾	Phase III ⁽³⁾	
<i>As our Shareholder</i>						
Mr. Qiu	Executive Director, chairman of our Board, chief executive officer and general manager of our Company	October 15, 2022	2,000,000	1,000,000	7,000,000	[REDACTED]%
Dr. Li Jianwei	Chief operating officer and deputy general manager of our Company and the general manager of Cellularforce	October 15, 2022	Nil	150,000	1,300,000	[REDACTED]%
Dr. Yu Guoliang	Consultant of our Company	October 15, 2022	Nil	Nil	500,000	[REDACTED]%
<i>As a limited partner of our employee share incentive platforms</i>						
<i>Directors</i>						
Mr. Qiu	Executive Director, chairman of our Board, chief executive officer and general manager of our Company	October 15, 2022 and June 13, 2023	1,000,000	120,000	Nil	[REDACTED]%
Mr. Wu Yiliang	Executive Director and executive deputy general manager of Cellularforce	October 15, 2022	1,000,000	100,000	570,000	[REDACTED]%
Mr. Lin Weidong	Executive Director and deputy general manager of our Company	October 15, 2022	Nil	Nil	1,000,000	[REDACTED]%
<i>Supervisor</i>						
Ms. Wang Yujiao	Employee representative Supervisor and assistant to general manager of our Company	October 15, 2022	300,000	60,000	530,000	[REDACTED]%

APPENDIX VIII STATUTORY AND GENERAL INFORMATION

Name of the Participant	Position(s) in our Group	Date of grant	Number of underlying incentive Shares granted			Approximate percentage of direct or indirect shareholding in our Company immediately following completion of the [REDACTED]
			Phase I ⁽¹⁾	Phase II ⁽²⁾	Phase III ⁽³⁾	
Senior management						
Mr. Wu Shenglong	Chief business officer and deputy general manager of our Company	February 13, 2023	Nil	Nil	1,000,000	[REDACTED]%
Ms. Fang Min	Deputy general manager of our Company	October 15, 2022	500,000	100,000	380,000	[REDACTED]%
Mr. Hu Yanbao	Board secretary and joint company secretary of our Company	October 15, 2022	Nil	180,000	480,000	[REDACTED]%
Other 61 onshore employee Participants		October 15, 2022 or March 1, 2023	1,600,000	4,160,000	2,470,000	[REDACTED]%
Total			6,400,000	5,870,000	15,230,000	[REDACTED]%

Notes:

1. The incentive Shares granted under Phase I are subject to the Lock-up Period from the date of receipt of the incentive Shares to the later of (1) the date of completion of three years of service of the Participant with our Group after the date of joining; and (2) the expiry of all lock-up periods of the relevant incentive Shares in accordance with laws, regulations and requirements of the CSRC or the Stock Exchange after [REDACTED]. The incentive Shares granted under Phase I are not subject to any releasing restrictions.
2. The incentive Shares granted under Phase II are subject to the Lock-up Period from the date of receipt of the incentive Shares to the later of (1) the date of completion of three years of service of the Participant with our Group after the date of receipt of the incentive Shares by the Participant; (2) the expiry of all lock-up periods of the relevant incentive Shares in accordance with laws, regulations and requirements of the CSRC or the Stock Exchange after [REDACTED]; and (3) the release of all restrictions on the incentive Shares received by the participant pursuant to the Scheme.

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The release arrangements of the incentive Shares granted under Phase II are as follows:

- (1) first tranche (30% of the incentive Shares granted under Phase II): (a) if the Participant achieves Grade A in his/her individual performance appraisal result for 2023, restrictions on all of the 30% of the incentive Shares granted under Phase II shall be released; (b) if the Participant achieves Grade B in his/her individual performance appraisal result for 2023, restrictions on 80% of the 30% of the incentive Shares granted under Phase II shall be released and the remaining 20% shall not be released; (c) if the Participant achieves Grade C in his/her individual performance appraisal result for 2023, restrictions on 70% of the 30% of the incentive Shares granted under Phase II shall be released and the remaining 30% shall not be released; and (d) if the Participant achieves below Grade C in his/her individual performance appraisal result for 2023, none of the 30% of the incentive Shares granted shall be released;
 - (2) second tranche (30% of the incentive Shares granted under Phase II): (a) if the Participant achieves Grade A in his/her individual performance appraisal result for 2024, restrictions on all of the 30% of the incentive Shares granted under Phase II shall be released; (b) if the Participant achieves Grade B in his/her individual performance appraisal result for 2024, restrictions on 80% of the 30% of the incentive Shares granted under Phase II shall be released and the remaining 20% shall not be released; (c) if the Participant achieves Grade C in his/her individual performance appraisal result for 2024, restrictions on 70% of the 30% of the incentive Shares granted under Phase II shall be released and the remaining 30% shall not be released; and (d) if the Participant achieves below Grade C in his/her individual performance appraisal result for 2024, none of the 30% of the incentive Shares granted shall be released; and
 - (3) third tranche (40% of the incentive Shares granted under Phase II): (a) if the Participant achieves Grade A in his/her individual performance appraisal result for 2025, restrictions on all of the 40% of the incentive Shares granted under Phase II shall be released; (b) if the Participant achieves Grade B in his/her individual performance appraisal result for 2025, restrictions on 80% of the 40% of the incentive Shares granted under Phase II shall be released and the remaining 20% shall not be released; (c) if the Participant achieves Grade C in his/her individual performance appraisal result for 2025, restrictions on 70% of the 40% of the incentive Shares granted under Phase II shall be released and the remaining 30% shall not be released; and (d) if the Participant achieves below Grade C in his/her individual performance appraisal result for 2025, none of the 40% of the incentive Shares granted shall be released.
3. The incentive Shares granted under Phase III are subject to the Lock-up Period from the date of receipt of the incentive Shares to the later of (1) the date of completion of three years of service of the Participant with our Group after the date of joining; (2) the expiry of all lock-up periods of the relevant incentive Shares in accordance with laws, regulations and requirements of the CSRC or the Stock Exchange after [REDACTED]; and (3) the release of all restrictions on the incentive Shares received by the participant pursuant to the Scheme.

The release arrangements of the incentive Shares granted under Phase III are as follows:

- (1) first tranche: restrictions on 30% of the incentive Shares granted under Phase III shall be released after the date of completion of one year of service of the participant with our Group;
- (2) second tranche: restrictions on 30% of the incentive Shares granted under Phase III shall be released after the date of completion of two years of service of the participant with our Group; and
- (3) third tranche: restrictions on 40% of the incentive Shares granted under Phase III shall be released after the date of completion of three years of service of the participant with our Group.

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E. OTHER INFORMATION

1. Estate duty

Our Directors have been advised that currently no material liability for estate duty is likely to fall on our Company or any of our subsidiaries in the PRC.

2. Litigation

During the Track Record Period and up to the Latest Practicable Date, we had not been involved in any litigation, arbitration or administrative proceedings which could have a material adverse impact on our business, financial condition or results of operations. As of the Latest Practicable Date, we were not aware of any pending or threatened litigation, arbitration or administrative proceedings against us which may have a material and adverse impact on our business, financial condition or results of operations.

3. Sole Sponsor

The Sole Sponsor satisfies the independence criteria applicable to sponsors as set out in Rule 3A.07 of the Listing Rules. The Sole Sponsor will receive an aggregate fee of US\$500,000 for acting as the sponsor for the [REDACTED].

The Sole Sponsor has made an application on behalf of our Company to the Stock Exchange for the [REDACTED] of, and permission to [REDACTED], the H Shares to be converted from [REDACTED] Shares and the H Shares to be issued pursuant to the [REDACTED].

4. Preliminary expenses

As of the Latest Practicable Date, our Company has not incurred any material preliminary expenses.

5. Promoters

The promoters of our Company are as follows:

<u>No.</u>	<u>Name of promoters of our Company</u>
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- | | |
|----|--|
| 1. | Hangzhou Quanyi Investment Management Partnership (General Partnership)
(杭州荃毅投資管理合夥企業(普通合夥)) |
| 2. | Shenzhen Qianhai Efung Taihe Equity Investment Fund Enterprise (Limited Partnership) (深圳市前海倚鋒太和股權投資基金企業(有限合夥)) |

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No.	Name of promoters of our Company
3.	Shanghai Quanyou Fanyue Investment Management Partnership (Limited Partnership) (上海荃友凡悅投資管理合夥企業(有限合夥))
4.	Nanjing Yuzhijia Pharmaceutical Technology Partnership (Limited Partnership) (南京裕之華醫藥科技合夥企業(有限合夥))
5.	Taizhou China Medical City Rongjianda Venture Capital Co., Ltd. (泰州中國醫藥城融健達創業投資有限公司)
6.	Taizhou Jianxin Venture Capital Co., Ltd. (泰州健鑫創業投資有限公司)
7.	Nanjing Tongren Boda Equity Investment Center (limited Partnership) (南京同人博達股權投資中心(有限合夥))
8.	Shanghai Shuochen Investment Management Co., Ltd. (上海碩臣投資管理有限公司)
9.	Taizhou Hongtai Health Investment Management Center (Limited Partnership) (泰州洪泰健康投資管理中心(有限合夥))
10.	Suzhou Hefu Ruitai Equity Investment Center (Limited Partnership) (蘇州合富瑞泰股權投資中心(有限合夥))
11.	Shenzhen Triwise Rozman Phase II Investment Partnership (Limited Partnership) (深圳勤智羅茲曼二期投資合夥企業(有限合夥))
12.	Shenzhen Triwise Kangxin Venture Capital Partnership (Limited Partnership) (深圳勤智康信創業投資合夥企業(有限合夥))
13.	Shenzhen Lucky-source III Venture Capital Center (Limited Partnership) (深圳瑞享源三號創業投資中心(有限合夥))
14.	Gongqingcheng Jiayin Lucky-source Equity Investment Partnership (Limited Partnership) (共青城佳銀瑞享源股權投資合夥企業(有限合夥))
15.	Shenzhen Lucky-source IV Venture Capital Center (Limited Partnership) (深圳瑞享源肆號創業投資中心(有限合夥))
16.	Hangzhou Zhongmei Huadong Pharmaceutical Co., Ltd. (杭州中美華東製藥有限公司)
17.	Matrix Partners China VI Hong Kong Limited
18.	Suzhou Guan hong Venture Capital Center (Limited Partnership) (蘇州冠鴻創業投資中心(有限合夥))
19.	Shenzhen Yuanzhi Fuhai New Industry II Investment Enterprise (Limited Partnership) (深圳遠致富海新興產業二期投資企業(有限合夥))
20.	Xinyu Tongchuang Guosheng Science and Innovation Industry Investment Partnership (Limited Partnership) (新余市同創國盛科創產業投資合夥企業(有限合夥))
21.	Everest No. 37 (Shenzhen) Venture Capital Center (Limited Partnership) (朗瑪三十七號(深圳)創業投資中心(有限合夥))
22.	Shenzhen Triwise Detai New Technology Venture Capital Enterprise (Limited Partnership) (深圳勤智德泰新科技創業投資企業(有限合夥))

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STATUTORY AND GENERAL INFORMATION

Save as disclosed in the section headed “History and Corporate Structure”, within the two years immediately preceding the date of this document, no cash, securities or other benefit has been paid, allotted or given nor are any proposed to be paid, allotted or given to any promoters named above in connection with the [REDACTED] and the related transactions described in this document.

6. Qualifications and consents of experts

The following are the qualifications of the experts who have given opinions or advice which are contained in this document:

<u>Name</u>	<u>Qualifications</u>
China International Capital Corporation Hong Kong Securities Limited	A licensed corporation to conduct Type 1 (dealing in securities), Type 2 (dealing in futures contracts), Type 4 (advising on securities), Type 5 (advising on futures contracts) and Type 6 (advising on corporate finance) regulated activities as defined under the SFO
KPMG	Certified Public Accountants Public Interest Entity Auditor registered in accordance with the Accounting and Financial Reporting Council Ordinance
JunHe LLP	Legal advisors to our Company as to PRC law
Frost & Sullivan	Industry consultant
Asia-Pacific Consulting and Appraisal Limited	Independent property valuer

Each of the experts named above has given and has not withdrawn its respective written consent to the issue of this document with the inclusion of its reports, letters, opinions, summaries of opinions and/or references to its name included herein in the form and context in which they respectively appear.

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STATUTORY AND GENERAL INFORMATION

7. Interests of experts in our Company

Except as disclosed in this document and save for its obligations under the [REDACTED], none of the persons named in “—E. Other Information—6. Qualifications and consents of experts” above is interested beneficially or otherwise in any Shares or shares of any member of our Group or has any right or option (whether legally enforceable or not) to subscribe for or nominate persons to subscribe for any shares or securities in any member of our Group.

8. Taxation of holders of H Shares

The [REDACTED], purchase and transfer of H Shares are subject to Hong Kong stamp duty. The current rate chargeable on each of the seller and purchaser is 0.1% of the consideration or, if higher, the fair value of the H Shares being [REDACTED] or transferred. For further information in relation to taxation, see “Appendix V—Taxation and Foreign Exchange” to this document.

9. Binding effect

This document shall have the effect, if an application is made in pursuance of this document, of rendering all persons concerned bound by all of the provisions (other than the penal provisions) of sections 44A and 44B of the Companies (Winding Up and Miscellaneous Provisions) Ordinance insofar as applicable.

10. Miscellaneous

- (a) within the two years immediately preceding the date of this document:
 - (i) save as disclosed in “History and Corporate Structure” in this document, no share or loan capital of our Company or any of our subsidiaries had been issued or agreed to be issued or proposed to be fully or partly paid either for cash or for a consideration other than cash;
 - (ii) save as disclosed in “History and Corporate Structure” in this document, no share or loan capital of our Company or any of our subsidiaries is under option or is agreed conditionally or unconditionally to be put under option;
 - (iii) save as disclosed in “[REDACTED]” in this document, no commissions, discounts, brokerages or other special terms have been granted or agreed to be granted in connection with the issue or sale of any share or loan capital of our Company or any of our subsidiaries; and

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STATUTORY AND GENERAL INFORMATION

- (iv) save as disclosed in “[REDACTED]” in this document, no commission has been paid or is payable for subscription, agreeing to subscribe, procuring subscription or agreeing to procure subscription of any share in our Company or any of our subsidiaries.

- (b) there are no founder, management or deferred shares nor any debentures in our Company or any of our subsidiaries;

- (c) there has not been any interruption in the business of our Group which may have or has had a significant effect on the financial position of our Group in the 12 months preceding the date of this document;

- (d) there has been no material adverse change in the financial or trading position or prospects of our Group since September 30, 2023 (being the date to which the latest audited consolidated financial statements of our Group were prepared);

- (e) no company within our Group is presently [REDACTED] on any stock exchange or [REDACTED] on any [REDACTED] system;

- (f) all necessary arrangements have been made to enable our H Shares to be admitted into [REDACTED] for clearing and settlement;

- (g) our Company has no outstanding convertible debt securities or debentures;

- (h) there is no arrangement under which future dividends are waived or agreed to be waived; and

- (i) none of the equity and debt securities of our Company, if any, is [REDACTED] or [REDACTED] in any other stock exchange nor is any [REDACTED] or permission to [REDACTED] being or proposed to be sought.

11. Bilingual document

The English and Chinese language versions of this document are being published separately, in reliance upon the exemption provided by section 4 of the Companies (Exemption of Companies and Prospectuses from Compliance with Provisions) Notice (Chapter 32L of the Laws of Hong Kong). In case of any discrepancies between the English language version and Chinese language version of this document, the English language version shall prevail.

APPENDIX IX

**DOCUMENTS DELIVERED TO THE REGISTRAR OF
COMPANIES AND DOCUMENTS ON DISPLAY**

A. DOCUMENTS DELIVERED TO THE REGISTRAR OF COMPANIES

The documents attached to the copy of this document delivered to the Registrar of Companies in Hong Kong for registration were:

- (a) the written consents referred to in “Appendix VIII—Statutory and General Information—E. Other Information—6. Qualifications and consents of experts” to this document; and
- (b) a copy of each of the material contracts referred to in “Appendix VIII—Statutory and General Information—B. Further Information about Our Business—1. Summary of Material Contracts” to this document.

B. DOCUMENTS ON DISPLAY

Copies of the following documents will be published on the websites of the Stock Exchange (www.hkexnews.hk) and our Company (www.qyuns.net) up to and including the date which is 14 days from the date of this document:

- (a) the Articles of Association;
- (b) the Accountants’ Report from KPMG, the text of which is set out in Appendix I to this document;
- (c) the report from KPMG in respect of the unaudited *pro forma* financial information, the text of which is set out in Appendix II to this document;
- (d) the audited consolidated financial statements of our Group for the two years ended December 31, 2022 and the nine months ended September 30, 2023;
- (e) the letter, summary of property value and valuation reports relating to the property interest of our Group prepared by Asia-Pacific Consulting and Appraisal Limited, the text of which is set out in Appendix IV to this document;
- (f) the material contracts referred to in “Appendix VIII—Statutory and General Information—B. Further Information about Our Business— 1. Summary of Material Contracts” to this document;
- (g) the service agreements and letters of appointment entered into between our Company and each of our Directors and Supervisors (as applicable) referred to in “Appendix VIII—Statutory and General Information—C. Further Information about Directors, Supervisors and Substantial Shareholders—2. Particulars of Directors’ and Supervisors’ service agreements and letters of appointment” to this document;

APPENDIX IX

**DOCUMENTS DELIVERED TO THE REGISTRAR OF
COMPANIES AND DOCUMENTS ON DISPLAY**

- (h) the rules of the Employee Share Incentive Scheme;
- (i) the legal opinion issued by JunHe LLP, our PRC Legal Advisors, in respect of certain general corporate matters of our Group;
- (j) the written consents referred to “Appendix VIII—Statutory and General Information—E. Other Information—6. Qualifications and consents of experts” to this document;
- (k) the PRC Company Law, the PRC Securities Law, the Trial Administrative Measures of Overseas Securities Offering and Listing by Domestic Companies, together with their unofficial English translation; and
- (l) the industry report issued by Frost & Sullivan.