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Post Hearing Information Pack of

Sunho Biologics, Inc.
盛禾生物控股有限公司

(the "**Company**")

(A company incorporated in the Cayman Islands with limited liability)

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Sunho Biologics, Inc.
盛禾生物控股有限公司

(Incorporated in the Cayman Islands with limited liability)

[REDACTED]

Number of [REDACTED] under the [REDACTED]	**:**	**[REDACTED] Shares**
Number of [REDACTED]	**:**	**[REDACTED] Shares (subject to reallocation)**
Number of [REDACTED]	**:**	**[REDACTED] Shares (subject to reallocation)**
Maximum [REDACTED]	**:**	**HK$[REDACTED], plus brokerage fee of 1%, SFC transaction levy of 0.0027%, Stock Exchange trading fee of 0.00565% and AFRC transaction levy of 0.00015% (payable in full on [REDACTED] in Hong Kong dollars and subject to refund)**
Nominal value	**:**	**US$0.0005 per Share**
[REDACTED]	**:**	**[REDACTED]**

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The [REDACTED] may, for itself and on behalf of the [REDACTED], where considered appropriate and with the consent of our Company, reduce the number of [REDACTED] and/or the indicative [REDACTED] stated in this document at any time on or prior to the morning of the last day for lodging [REDACTED] under the [REDACTED]. In such a case, we will, as soon as practicable following the decision to make such reduction and in any event not later than the morning of the day which is the last day for lodging [REDACTED] under the [REDACTED], cause an announcement to be published on the website of the Hong Kong Stock Exchange at www.hkexnews.hk and on the website of our Company at www.sunho-bio.com.cn. See "Structure of the [REDACTED]" and "How to Apply for the [REDACTED]" for more details.

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[REDACTED]

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[**REDACTED**]

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EXPECTED TIMETABLE[1]

[**REDACTED**]

EXPECTED TIMETABLE[1]

[**REDACTED**]

EXPECTED TIMETABLE[1]

[**REDACTED**]

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SUMMARY

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

OVERVIEW

Founded in 2018, we are a clinical stage biopharmaceutical company that focuses on the discovery, development and commercialization of biologics for the treatment of cancers and autoimmune diseases. We have three Core Products, IAH0968, IAP0971 and IAE0972, all of which are developed in-house. IAH0968 is an antibody-dependent cell-mediated cytotoxicity ("**ADCC**") enhanced monoclonal antibody ("**mAb**"), and we have initiated Phase II clinical trials for biliary tract carcinoma ("**BTC**") and colorectal cancer ("**CRC**"). IAP0971 and IAE0972 are both immunocytokines and we have completed Phase I clinical trials for advanced solid tumors including non-small cell lung cancer ("**NSCLC**") and CRC. As of the Latest Practicable Date, we had nine pipeline products, in addition to our Core Products, three of which were in the clinical stage, also focusing on the treatment of cancer.

THERE IS NO ASSURANCE THAT WE WILL ULTIMATELY BE ABLE TO DEVELOP AND MARKET OUR CORE PRODUCTS OR ANY OF OUR PIPELINE PRODUCTS SUCCESSFULLY.

SUMMARY


Candidate*
MoA
Platform
Regimen
Indication (Line of treatment)
Preclinical
Phase I
Phase II
Phase III
Commercial rights
Upcoming milestone
Cancer Immunotherapy
Viral Infection
Cancer Immunotherapy
Autoimmune Diseases
IAH0968
HER2 (ADCC enhanced mAb)
AEA™
+CapeOX
HER2+ CRC (1L)
Global
Complete Phase IIb in Q4 2024
+GC
HER2+ BTC (1L)
Complete Phase II in Q3 2025
IAP0971
PD-1/IL-15 (Antibody–cytokine fusion protein)
AIC™
Mono
NSCLC (2L)
Enter Phase II in Q2 2024
+Chemo
Non-squamous NSCLC (1L)***
Global
Enter Phase II in Q3 2024
+BCG
BCG-unresponsive high risk NMIBC (2L/3L)
Complete Phase I in Q4 2024
IAP0971
PD-1/IL-15 (Antibody–cytokine fusion protein)
AIC™
+nucleoside analogues
HBV
Global
Enter Phase I in Q3 2024
IAE0972
EGFR/IL-10 (Antibody–cytokine fusion protein)
AIC™
Mono
HNSCC (2L) and CRC (3L)
Complete Phase II in 1H 2026
+Chemo
Squamous NSCLC (2L)***
Global
Enter Phase II in Q3 2024
+Chemo
HCC (1L)***
Enter Phase II in Q2 2024
IBB0979
B7H3/IL-10 (Antibody–cytokine fusion protein)
AIC™
Mono
B7H3-high expressing solid tumors (≥2L)
Global
Complete Phase I in Q4 2024
IBC0966
PD-L1/SIRPα (Bispecific antibody fusion protein)
bsFp platform
Mono
Solid tumors (≥2L)
Greater China**
Enter Phase II in Q2 2024
IBD0333
4-1BB/CD24 (Bispecific immune modulatory antibody)
bsAb platform
Mono
Solid tumors (≥2L)
Global
Complete Phase I in Q3 2025
IAN0982
Confidential (Multispecific innate effector activator)
AIM™
Mono
Solid tumors
Global
IND filing in Q2 2024
ISH0988
Confidential (Anti-inflammatory and tissue protective)
AIC™
Mono
IBD
Global
IND filing in Q2 2024
ISH0613
Confidential (Inhibit B cell activation and IFNα secretion)
AIC™
Mono
SLE
Global
IND filing in Q2 2024
Core Product
NMPA
FDA
Preclinical stage

Abbreviations: 1L = first-line; 2L = second-line; 3L = third-line; ADCC = antibody-dependent cell-mediated cytotoxicity; AEA™ = ADCC Enhanced Antibody Platform; AIC™ = Armed ImmunoCytokine Platform; AIM™ = Armed Innate Effector Multispecific Platform; BCG = Bacillus Calmette-Guerin; bsAb = bispecific antibody; bsFp = bispecific fusion protein; CapeOX= capecitabine and oxaliplatin; Chemo = chemotherapy; FDA = U.S. Food and Drug Administration; GC = gemcitabine and cisplatin; IND = Investigational New Drug; mAb = monoclonal antibody; Mono = monotherapy; NMPA = National Medical Products Administration; NSCLC = non-small cell lung cancer; NMIBC = non-muscle invasive bladder cancer; BTC = biliary tract carcinoma; CRC = colorectal cancer; HBV = hepatitis B virus; HNSCC = head and neck squamous cell carcinoma; HCC = hepatocellular carcinoma; IBD = inflammatory bowel disease; Q1 = first quarter; Q2 = second quarter; Q3 = third quarter; Q4 = fourth quarter; 1H = first half; SLE = systemic lupus erythematosus.

Notes:

* All the product candidates are administered intravenously, except for IAP0971 for the treatment of 2L/3L NMIBC, which will be administered through intravesical instillation, as well as IAP0971 for the treatment of NSCLC, which will be administered through subcutaneous injection.

** We acquired exclusive rights from ImmuneOnco Biopharmaceuticals (Shanghai) Inc. to develop, manufacture and commercialize IBC0966 in Greater China including mainland China, Hong Kong, Macau, and Taiwan, as well as 7.5% of interests in the overseas rights of IBC0966. For more information, see "Business — Collaboration Arrangement — Collaboration Agreement With ImmuneOnco in Relation to the Development of IBC0966" in this document.

*** We have completed Phase I clinical trials of relevant products as monotherapy, and plan to leverage data collected in the respective trials and directly seek IND approvals from competent regulatory authorities to conduct Phase II clinical trials of relevant products as combination therapy.

Our Business Model

Our core business model involves internally discovering, developing and commercializing immunocytokines and other immunotherapies that regulate immune microenvironment by directly modulating both the innate and adaptive immune systems to address the market needs in the fields of oncology and autoimmune diseases. We also recognize that partnerships will be a critical source to complement our internal resource and enable us to fully execute our global strategy. As such, we will actively seek collaboration opportunities with international leading pharmaceutical companies to advance clinical studies of our products abroad through out-licensing arrangements. We will also expand our international registration team to secure our global clinical development and registration plan, and strengthen our featured products, especially our immunocytokine pipeline products including IAP0971, IAE0972 and IBB0979.

OUR PRODUCT CANDIDATES

Our R&D capabilities cover development of candidates in the forms of mAbs, bispecific antibodies ("**bsAbs**"), and fusion proteins, some of which extend indications into treatment areas beyond oncology. Our Core Product IAH0968 is an ADCC enhanced mAb targeting human epidermal growth factor receptor 2 ("**HER2**") with 100% fucose knock out, which greatly enhances the binding affinity of its fragment crystallizable ("**Fc**") to its receptor FcγRIIIa. ADCC is an immune mechanism through which Fc receptor-bearing effector cells including natural killer ("**NK**") cells and CD+8 T cells can recognize and kill antibody-coated target cells expressing tumor- or pathogen-derived antigens on their surface. It is one of the most important methods for antibody drugs to kill tumor cells. The typical ADCC involves activation of NK cells by antibodies in a multi-tiered progression of immune control. A NK cell expresses Fcγ receptors ("**FcγR**"). These receptors recognize and bind to the Fc domain of an antibody, and the antigen binding fragment ("**Fab**") domain of which binds to the tumor associated antigen ("**TAA**") on the tumor cell. When both TAA and FcγR are engaged respectively by the Fab and Fc portions of the antibody, ADCC is initiated, since this creates a bridge from the tumor cell to the effector cell. However, the natural affinity between antibodies and FcγR is relatively weak, and Fc engineering to enhance affinity has become a common method.

Our featured products, immunocytokines, are designed through our proprietary and internally developed Armed ImmunoCytokine Platform ("**AIC^{TM} Platform**") by our core R&D team in researching antibody-cytokine fusion proteins. They function through diverse mechanisms of action yet share a similar structure comprising an antibody or quasi-antibody moiety that targets tumors and blocks signaling pathways regulating tumor growth and proliferation, and cytokine payloads that activate the immune system within the tumor microenvironment ("**TME**"). Such a design is expected to overcome drawbacks of conventional cytokine-based drugs, such as short half-lives, systemic cytotoxicity and modest efficacies due to cytokine pleiotropy and off-target effects. It is expected to achieve enhanced antitumor effects through the synergy between the antibody and cytokine payloads, which potentially address the needs of cancer patients who suffer from disease progression related to the immunosuppressive TME and drug resistance.

All of our Core Products are still at early stage of development and it is difficult to directly compare their clinical efficacy with other existing drugs and/or drug candidates at a similar stage.

Core Product IAH0968 – ADCC Enhanced Anti-HER2 mAb

Our Core Product IAH0968 is an internally developed, the first anti-HER2 antibody in clinical stage with 100% fucose-removal. Antibodies consist of two structural regions, Fab and Fc. Unlike Fab region, which defines the specific target of an antibody, Fc region mediates ADCC by activating the immune system through engaging various Fc receptors. Studies of the structure of the Fc region of antibodies and its receptor FcγRIIIa complex revealed that the core fucose of the Fc region is accommodated at a place that interferes with the binding between the Fc region and FcγRIIIa, and thus reducing the affinity between them and resulting in lower ADCC activity. Therefore, modifying to remove fucose is desirable to better recruit immune cells, resulting in enhanced ADCC activity. As a result, this approach has been widely attempted in the biopharmaceutical industry. However, despite numerous attempts by multiple players to modify antibodies through various approaches, such as Fc point specific mutation and fucose removal, most resulting antibodies still contain a certain percentage of core fucose. For more details on the mechanism of action of IAH0968, see "Business — Drug Candidates — Core Product: IAH0968 (ADCC enhanced anti-HER2 mAb) — Mechanism of Action" in this document.

The Phase I clinical trial showed that IAH0968 was well tolerated and exhibited antitumor activities in patients with advanced HER2+ malignant solid tumors including breast cancers, gastric cancers, CRC and BTC with drug resistance to trastuzumab, pertuzumab, cetuximab, docetaxel, oxaliplatin, capecitabine, irinotecan, nab-paclitaxel and apatinib, or anti-PD-1 mAbs. Data showed that only one DLT was found at dosage 10mg/kg, and no MTD was reached. While no head-to-head study was conducted, the Phase I clinical data showed that IAH0968 achieved significantly improved ORR and DCR in heavily pretreated metastatic CRC and BTC patients, when compared to the historical data of current treatments. For heavily pretreated metastatic CRC and BTC patients, the ORR was 40%, and DCR was 80%.

We obtained the IND approval for conducting Phase I and Phase II clinical trials of IAH0968 from the NMPA in October 2020, commenced the Phase I clinical trial in August 2021, and completed the Phase I clinical trial of using IAH0968 as a monotherapy for heavily pretreated patients with advanced HER2+ malignant solid tumors in March 2023. Based on the encouraging clinical data from the Phase I trial, we obtained IND approvals from the NMPA to conduct Phase II and Phase III clinical trials of using IAH0968 in combination with chemotherapy for first-line treatment of inoperable HER2+ advanced or metastatic CRC, and to conduct Phase II clinical trials of using IAH0968 in combination with chemotherapy for first-line treatment of HER2+ metastatic BTC patients in September 2022. We have dosed the first CRC patient of the Phase II trial in May 2023, and also have dosed the first BTC patient of the Phase II clinical trial in August 2023. We completed the Phase IIa trial in March 2024, entered a Phase IIb/III clinical trial for CRC in January 2024, and expect to complete the Phase IIb trial for CRC in the fourth quarter of 2024. We also expect to complete the Phase II clinical trial for BTC in the third quarter of 2025. For more details on the clinical development plan of IAH0968, see "Business — Drug Candidates — Core Product: IAH0968 (ADCC enhanced anti-HER2 mAb) — Clinical Development Plan" in this document.

Addressable Markets and Competitive Landscape

We are currently investigating IAH0968 for the treatment of 1L HER2+ advanced BTC and 1L HER2+ advanced CRC, and plan to further explore its potential in these indications. See "Business — Drug Candidates — Core Product: IAH0968 (ADCC enhanced anti-HER2 mAb) — Clinical Development Plan" in this document.

According to Frost & Sullivan, the global market of BTC drugs increased from US$0.5 billion in 2018 to US$0.7 billion in 2022 with a CAGR of 10.7% from 2018 to 2022. The number is projected to reach US$1.5 billion in 2026 and US$2.5 billion in 2030 with a CAGR of 21.7% and 13.3% from 2022 to 2026 and from 2026 to 2030, respectively. The China market BTC drugs increased from US$0.2 billion in 2018 to US$0.3 billion in 2022 with a CAGR of 7.9% from 2018 to 2022. The number is projected to reach US$0.8 billion in 2026 and US$1.6 billion in 2030 with a CAGR of 28.2% and 17.9% from 2022 to 2026 and from 2026 to 2030, respectively. For details related to patient population of BTC, see "Industry Overview — Immuno-Oncology Drugs Overview — Major Indications for Immuno- Oncology Therapies — BTC" in this document.

The global market of CRC drugs increased from US$16.2 billion to US$20.6 billion from 2018 to 2022, and is projected to reach US$30.9 billion in 2026 and US$43.7 billion in 2030. The China market of CRC drugs increased from US$1.5 billion to US$2.6 billion from 2018 to 2022, and is projected to reach US$5.0 billion in 2026 and US$7.8 billion in 2030. For more information related to patient population of CRC, see "Industry Overview — Immuno-Oncology Drugs Overview — Major Indications for Immuno-Oncology Therapies — CRC" in this document.

According to Frost & Sullivan, there are three anti-HER2 mAbs in clinical development for cancer treatment globally. Among them, the most advanced product is in the Phase II/III clinical stage. In China, there are four anti-HER2 mAbs in clinical development, with the most advanced ones also in the Phase II/III stage. IAH0968 stands out as the only and the most clinically advanced ADCC-enhanced anti-HER2 mAb modified through fucose removal in China and the rest of the world, which is currently in the Phase II/III clinical stage. For details, see "Industry Overview — Immuno-Oncology Drugs Overview — Overview of Antibodies — ADCC Enhanced mAbs — Anti-HER2 Antibodies — Competitive Landscape" in this document.

Competitive Advantages

The core fucose of the Fc region of an antibody interferes with the binding between the Fc region and its receptor, resulting in lower ADCC activity. We addressed this technical difficulty through constructing a new cell line with mutated FUT8, which encodes an enzyme that catalyzes the transfer of fucose residue from its donor to its target. After biological engineering, the new cell line is not able to attach fucose to any protein it produces. In such a way, we have successfully generated potentially the first anti-HER2 antibody with 100% removal of fucose from its Fc region, i.e. IAH0968. Such achievement has been verified

through glycoprotein detection and glycosylation quantification. For more details on the competitive advantages of IAH0968, see "Business — Drug Candidates — Core Product: IAH0968 (ADCC enhanced anti-HER2 mAb) — Competitive Advantages" in this document.

Core Product IAP0971 – Anti-PD-1 Antibody-IL-15/IL-15Rα Heterodimer Fusion Protein

Our Core Product IAP0971 is an internally developed, dual-moiety, anti-programmed death -1 ("**PD-1**") antibody-IL-15/IL-15Rα heterodimer dual T cell and NK cell agonist. IAP0971 is expected to synergistically strengthen the antitumor activity through blockade of the PD-1/its ligand ("**PD-L1**") signaling pathway and accumulating IL-15 at the targeted tumor site to activate its nearby immune cells, including CD8+ T cells and NK cells, directly activating both innate and adaptive immune systems. For more details on the mechanism of action of IAP0971, see "Business — Drug Candidates — Core Product: IAP0971 (PD-1/IL-15 antibody-cytokine fusion protein) — Mechanism of Action" in this document.

In July 2023, we completed Phase I clinical trial of IAP0971 for advanced malignant tumors. Phase I clinical data showed that IAP0971 exhibited a favorable safety profile at up to 200μg/kg in patients with advanced malignant tumors, with no dose-limiting toxicity ("**DLT**") and maximum tolerable dose ("**MTD**") observed. Preliminary antitumor efficacy was observed in four patients treated with IAP0971 as later-line therapy. These four patients include one with CRC, one with cervical cancer, and two with NSCLC, and those patients underwent multiple rounds of treatments including chemotherapy, targeted therapy, immunotherapy and/or their combination, and experienced disease progress and metastases. After receiving IAP0971 for two treatment cycles, all four patients achieved stable disease ("**SD**"). Especially, one NSCLC patient complicated with adrenal gland and other metastases was resistant to several prior treatments, including chemotherapy regimes such as multiple paclitaxel-containing combination, and combination therapies with targeted therapy and immunotherapy, such as erlotinib, camrelizumab, sintilizumab and bevacizumab. This patient received 120μg/kg IAP0971 for two treatment cycles and achieved SD. The other NSCLC patient complicated with pleura or pleural effusion metastases was resistant to several prior treatments, and also achieved SD after two cycles of 200μg/kg IAP0971 administration.

In January 2022 and December 2021, we obtained IND approvals from both the NMPA and the FDA for conducting Phase I and Phase II clinical trials in patients with advanced malignant tumors, respectively. We commenced the Phase I clinical trial in China in June 2022 according to a protocol approved by both the NMPA and the FDA, and completed the Phase I clinical trial in July 2023. Based on an interview conducted with a senior examiner of the NMPA with the attendance of professional parties, the NMPA had no objection for us to commence a planned Phase II clinical trial of IAP0971 as a monotherapy for locally advanced unresectable or metastatic NSCLC. We plan to initiate a Phase II clinical trial for IAP0971 in China in the second quarter of 2024. For more details on the clinical development plan of IAP0971, see "Business — Drug Candidates — Core Product: IAP0971 (PD-1/IL-15 antibody-cytokine fusion protein) — Clinical Development Plan" in this document.

Addressable Markets and Competitive Landscape

IAP0971 potentially targets a broad range of tumor types that overexpress PD-L1. We have investigated and intend to further investigate its safety and efficacy in several tumors, including 2L and 3L Bacillus Calmette-Guerin ("**BCG**")-unresponsive high risk non-muscle-invasive bladder cancer ("**NMIBC**"), 1L advanced non-squamous NSCLC, and 2L advanced NSCLC. In addition, we also plan to expand indications of IAP0971 from oncology to the anti-viral infection field, especially for the treatment of hepatitis B virus ("**HBV**") infection. For details, see "Business — Drug Candidates — Core Product: IAP0971 (PD-1/IL-15 antibody-cytokine fusion protein) — Clinical Development Plan" in this document. IAP0971 is intended for later-line treatment in certain indications, indicating that the targeted patients have failed previous standard therapies.

According to Frost & Sullivan, the global market of bladder cancer drugs increased from US$3.4 billion to US$4.8 billion with a CAGR of 8.6% from 2018 to 2022. The number is projected to reach US$9.0 billion in 2026 and US$13.9 billion in 2030 with a CAGR of 17.1% and 11.5% from 2022 to 2026 and from 2026 to 2030, respectively. In China, the bladder cancer drugs market was US$0.2 billion in 2018, and is projected to grow to US$0.3 billion in 2022, representing a CAGR of 13.1% from 2018 to 2022. The number is projected to grow to US$0.9 billion in 2026 and further to US$2.2 billion in 2030, representing a CAGR of 28.4% from 2022 to 2026, and a CAGR of 24.8% from 2026 to 2030. For details related to patient population of NMIBC, see "Industry Overview — Immuno-Oncology Drugs Overview — Major Indications for Immuno-Oncology Therapies — NMIBC" in this document.

The global market of NSCLC drugs increased from US$44.7 billion to US$72.9 billion with a CAGR of 13.0% from 2018 to 2022. The number is projected to reach US$120.4 billion in 2026 and US$168.2 billion in 2030 with a CAGR of 13.4% and 8.7% from 2022 to 2026 and from 2026 to 2030, respectively. Similarly, the China market for NSCLC drugs also experienced remarkable expansion. The China market for NSCLC drugs was US$3.9 billion in 2018, and the number increased to US$8.0 billion in 2022, representing a CAGR of 20.0% from 2018 to 2022. Forecasts suggest continued growth, with the market projected to reach US$17.1 billion in 2026 and US$23.8 billion in 2030, representing a CAGR of 20.8% from 2022 to 2026, and a CAGR of 8.6% from 2026 to 2030. For details related to patient population of NSCLC, see "Industry Overview — Immuno-Oncology Drugs Overview — Major Indications for Immuno-Oncology Therapies — NSCLC" in this document.

According to Frost & Sullivan, the global market for HBV drugs increased from US$15.6 billion to US$19.2 billion with a CAGR of 5.3% from 2018 to 2022. The number is projected to reach US$26.8 billion in 2026 and US$45.9 billion in 2030 with a CAGR of 8.7% and 14.4% from 2022 to 2026 and from 2026 to 2030, respectively. There was an overall decrease in the China HBV drug market from US$1.9 billion in 2018 to US$1.6 billion in 2022 due to the significant decrease in the price of commonly used HBV drugs and the impact of the COVID-19 epidemic. However, in 2026, the number is projected to reach US$2.9 billion, representing a CAGR of 15.5% from 2022 to 2026. In 2030, the China HBV drug market is projected to reach US$7.4 billion, representing a CAGR of 27.0% from 2026 to 2030. The

CAGR from 2018 to 2022 is based on the changes in the disease epidemiology, diagnosis rates, treatment rates, price and efficacy of approved drugs over the past period. The CAGR from 2022 to 2030 is projected based on future changes in the disease epidemiology, diagnosis rates, treatment rates, new drug approvals, and prices and efficacy of approved drugs. The impact of the COVID-19 epidemic has also been taken into account, as it affects the availability and accessibility of drugs.

According to Frost & Sullivan, currently, there is no IL-15-based immunotherapy indicated for the treatment of cancer approved for marketing worldwide. Globally, there are 14 IL-15-based immunotherapies under clinical development. Among these products, IAP0971 and the other seven product candidates are IL-15 based immunocytokines. In China, there are seven IL-15-based immunotherapies currently under clinical development, with the most clinically advanced products in Phase I/II stage. Only three products including IAP0971 are IL-15 based immunocytokines, and IAP0971 is the most clinically advanced IL-15-based immunocytokine in China. For details, see "Industry Overview — Overview of Cytokine-Antibody Based Drugs — IL-15 Based Immunotherapies — Competitive Landscape" in this document.

Competitive Advantages

The selection of IL-15 payload and PD-1 target was based on favorable individual features and the potential for great *cis*-synergy when combined. IL-15 is deemed a promising cytokine for developing immunotherapy that could cure cancers. It can promote activation and proliferation of cancer killing cells including CD8+ T cells and NK cells. In the meantime, IL-15 does not induce immune response suppression and T cell death, unlike IL-2, a cytokine that binds to similar receptors as IL-15. As such, IL-15 can stimulate CD8+ T cells and NK cells for a longer term and induce more rapid and robust immune responses compared to IL-2-based therapies.

The selection of the anti-PD-1 antibody was based on several factors, including its ability to act in the same location on the T cells and NK cells as IL-15, as well as the significantly higher expression of PD-1 on CD8+ T cells in the TME compared to peripheral blood and peripheral lymphoid organs. Therefore, the combination of IL-15 and anti-PD-1 antibody can show *cis*-synergy with lower systemic cytotoxicity. Furthermore, IAP0971 is designed to adopt the structure of an intact bivalent anti-PD-1 antibody in combination with a monovalent IL-15, which can deliver targeted and controlled amount of IL-15 directly into the TME to effectively recruits, activates and reinvigorates immune cells, leading to a significantly enhanced antitumor immunity.

The structure of IAP0971 is also optimized to improve biological activities, developability and productivity. The cytokine portion of IAP0971 is designed to adopt a structure of IL-15 combining with its receptor IL-15Rα as naturally occurs in the human body. On the one hand, the natural high affinity between IL-15 and IL-15Rα avoids the formation of unwanted side products and improves the productivity of IAP0971. On the other hand, the IL-15/IL-15Rα complex adopted in IAP0971 is reported to be more active than IL-15 alone in

stimulating proliferation and survival of memory phenotype CD8+ T cells. In addition, the spatial structure of IAP0971 is also optimized by partially embedding the IL-15/IL-15Rα heterodimer within the anti-PD-1 antibody. This structure can balance the dose of IL-15 cytokine with that of the PD-1 antibody, as well as prevent degradation of IL-15, thereby prolonging the half-life of IL-15. For more details on the competitive advantages of IAP0971, see "Business — Drug Candidates — Core Product: IAP0971 (PD-1/IL-15 antibody-cytokine fusion protein) — Competitive Advantages" in this document.

Despite the potential competitive advantages based on the mechanism of action, drug design, preclinical studies, and preliminary clinical data, the successful development of IAP0971 remains highly uncertain, primarily due to the absence of approved IL-15 based immunocytokines. Additionally, whether the anticipated clinical benefits of using anti-PD-1 antibodies in the form of immunocytokines would materialize in targeted patients is still subject to further evaluation and validation in Phase II or later phases of clinical trials.

Core Product IAE0972 – Anti-EGFR Antibody-IL-10 Homodimer Bifunctional Fusion Protein

Our Core Product IAE0972 is an internally developed, dual-moiety, anti-epidermal growth factor receptor ("**EGFR**") antibody-IL-10 homodimer bifunctional fusion protein for immune cell activation. Like IAP0971, IAE0972 is also expected to achieve synergistical antitumor activities leveraging the advantages of immunocytokine yet through a different combination of antibody target and cytokine payload. It is designed to blockade the EGFR signaling pathway and specifically deliver IL-10 to the targeted tumor site to activate CD8+ T cells, and potentially NK cells. For more details on the mechanism of action of IAE0972, see "Business — Drug Candidates — Core Product: IAE0972 (EGFR/IL-10 antibody-cytokine fusion protein) — Mechanism of Action" in this document.

In our Phase I clinical trial of IAE0972 for advanced solid tumors, we recruited 14 patients with advanced esophageal squamous cell carcinoma, rectal cancer, gastric cancer, pancreatic cancer, small cell lung cancer ("**SCLC**") or NSCLC who progressed from at least one line of treatment. We completed dose escalation for 1 μg/kg, 10 μg/kg, 100 μg/kg, 0.3mg/kg, 1.0mg/kg and 2.5mg/kg of IAE0972, and only observed one Grade 3 adverse events. No DLT occurred and MTD was not reached. Preliminary efficacy was observed in multiple heavily pretreated patients who failed all previous therapies. A CRC patient complicated by lung metastasis, who has received multiple lines of prior treatments including standard mFOLFOX6 (5-fluorouracil, leucovorin and oxaliplatin) and CapeOX (capecitabine and oxaliplatin) regimens, achieved SD after given 10μg/kg of IAE0972 for two treatment cycles. Another patient with rectal cancer and lung metastasis and lymph node metastasis, who had experienced recurrence after received two resections, achieved SD after receiving 1.0mg/kg of IAE0972 monotherapy for two cycles.

We obtained the approval for conducting Phase I and Phase II clinical trials in patients with advanced solid tumors from the FDA and the NMPA in December 2021 and January 2022, respectively, commenced the Phase I clinical trial in China in June 2022 according to a protocol approved by both the NMPA and the FDA, and completed the Phase I clinical trial in July 2023. Based on an interview conducted with a senior examiner of the NMPA with the attendance of professional parties, the NMPA had no objection for us to commence a planned Phase II clinical trials of IAE0972 as a monotherapy for 2L HNSCC and 3L CRC, and we have initiated a Phase II clinical trial of IAE0972 as monotherapy and enrolled the first HNSCC patient and the first CRC patient in July 2023 and December 2023, respectively, in China. For more details on the clinical development plan of IAE0972, see "Business — Drug Candidates — Core Product: IAE0972 (EGFR/IL-10 antibody-cytokine fusion protein) — Clinical Development Plan" in this document.

Addressable Market and Competitive Landscape

Given the encouraging preliminary efficacy observed in the Phase I clinical trial of IAE0972 and also considering the mechanism of action and clinical data for EGFR targeted therapies from other researchers, we believe IAE0972 can be potentially used for the treatment of a wide range of advanced tumors, including 2L head and neck squamous cell carcinoma ("**HNSCC**"), 3L CRC, 1L hepatocellular carcinoma ("**HCC**") and 2L squamous NSCLC. We plan to investigate IAE0972 for these indications in future clinical trials. For details, see "Business — Drug Candidates — Core Product: IAE0972 (EGFR/IL-10 antibody-cytokine fusion protein) — Clinical Development Plan" in this document. IAE0972 is intended for later-line treatment in certain indications, indicating that the targeted patients have failed previous standard therapies.

According to Frost & Sullivan, the global market of head and neck cancer drugs increased from US$2.9 billion to US$4.6 billion with a CAGR of 12.3% from 2018 to 2022, and is projected to reach US$6.4 billion in 2026 and US$8.7 billion in 2030. The China market of head and neck cancer drugs increased from US$0.3 billion to US$0.6 billion with a CAGR of 18.6% from 2018 to 2022, and is projected to reach US$1.2 billion in 2026 and US$1.8 billion in 2030 with a CAGR of 19.2% and 11.1% from 2022 to 2026 and from 2026 to 2030, respectively. For more information related to patient population of HNSCC, see "Industry Overview — Immuno-Oncology Drugs Overview — Major Indications for Immuno-Oncology Therapies — HNSCC" in this document.

For details of the market size and patient population of CRC, see "Industry Overview — Immuno-Oncology Drugs Overview — Major Indications for Immuno-Oncology Therapies — CRC" in this document.

The global market for HCC drugs increased from US$1.7 billion in 2018 to US$3.1 billion in 2022, representing a CAGR of 16.5% during this period. Projections suggest this figure will reach US$6.6 billion in 2026 and US$11.2 billion in 2030, with anticipated CAGRs of 21.0% from 2022 to 2026 and 14.0% from 2026 to 2030, respectively. Similarly, the Chinese market for HCC drugs rose from US$0.7 billion in 2018 to US $1.5 billion in 2022,

demonstrating a CAGR of 21.7% from 2018 to 2022. It is forecasted to reach US$3.7 billion in 2026 and US$6.2 billion in 2030, with projected CAGRs of 24.4% from 2022 to 2026 and 14.2% from 2026 to 2030, respectively. For more information related to patient population, see "Industry Overview — Immuno-Oncology Drugs Overview — Major Indications for Immuno-Oncology Therapies — HCC" in this document.

For details of the market size and patient population of NSCLC, see "Industry Overview — Immuno-Oncology Drugs Overview — Major Indications for Immuno-Oncology Therapies — NSCLC" in this document.

Currently, there are no approved IL-10 based immunotherapies indicated for the treatment of cancer, according to Frost & Sullivan. Both globally and in China, three IL-10 based immunotherapies are currently under clinical development with two of them from us. As of the Latest Practicable Date, our IAE0972 was in Phase II clinical stage, which is the most clinically advanced IL-10 based immunocytokines in China. For details, see "Industry Overview — Immuno-Oncology Drugs Overview — Overview of Cytokine-Antibody Based Drugs — IL-10 Based Immunotherapies — Competitive Landscape" in this document.

Competitive Advantages

The development of IAE0972 aimed to address the issue of immune cell exhaustion observed in current PD-1/PD-L1-based immunotherapies and overcome the limitations of current EGFR-based mAbs. IL-10 is a potent activator of tumor-infiltrating memory cytotoxic antigen-specific CD8+ T cells in the TME and can restore the tumor-killing activity of tumor-infiltrating terminally exhausted T cells. Because the anti-EGFR antibody fragment can specifically enrich IL-10 in the TME, IAE0972 can effectively and specifically activate the immune system by reinvigorating antigen specific CD8+ T cells and facilitating its proliferation, and inhibiting tumor growth by blocking the EGFR signaling pathway to kill EGFR-positive tumor cells. As a result, it is expected to resolve the issues of low ORR and drug resistance commonly observed with anti-EGFR antibodies.

Like IAP0971, IAE0972 also adopts the natural structure of IL-10, which is in a homodimer form, so that the natural pairing between IL-10 molecules will improve the developability and productivity of IAE0972. But unlike IAP0971, IAE0972 adopts an asymmetric structure, which consists of a monovalent anti-EGFR antibody fragment and a homodimer of IL-10. Such a design is expected to reduce the binding activity of anti-EGFR antibody on EGFR-low expression normal cells while preserving the biological activity on EGFR-high expression tumor cells and thus reduce EGFR-related skin toxicities. In addition, the spatial structure of IAE0972 employs the knobs-into-holes format in the Fc to promote asymmetric formation and improve its developability. These structural optimizations extend the half-life of IL-10 and improve its therapeutic efficacy. For more details on the competitive advantages of IAE0972, see "Business — Drug Candidates — Core Product: IAE0972 (EGFR/IL-10 antibody-cytokine fusion protein) — Competitive Advantages" in this document.

Despite the potential competitive advantages based on the mechanism of action, drug design, preclinical studies, and preliminary clinical data, the successful development of IAE0972 remains highly uncertain, primarily due to the absence of approved IL-10 based immunocytokines. Additionally, whether the anticipated clinical benefits of using anti-EGFR antibodies in the form of immunocytokines would materialize in targeted patients is still subject to further evaluation and validation in Phase II or later phases of clinical trials.

Other Pipeline Products

In addition to our product candidates mentioned above, we are developing a number of clinical stage and IND-enabling product candidates that we believe have high commercial viability. As of the Latest Practicable Date, except for IBC0966, we maintained the global rights to develop and commercialize them. For IBC0966, we have exclusive rights to develop, manufacture and commercialize in Greater China including mainland China, Hong Kong, Macau, and Taiwan and have partial overseas rights.

- **IBB0979**: IBB0979, another immunocytokine developed by us, is a clinical stage, dual-moiety, anti-B7H3 antibody-IL-10 homodimer bifunctional fusion protein for immune cell activation. It is designed to bind to B7H3 and trigger blockage of downstream signaling pathways that participate in TME shaping and development, and deliver IL-10 to activate CD8+ T cells to fight against tumors. We obtained the approval for conducting Phase I and Phase II clinical trials in patients with locally-advanced or metastatic solid tumors from the FDA and the NMPA in October 2022 and November 2022, respectively. The Phase I clinical trial is currently on-going, with the first patient dosed in July 2023. We expect to complete the Phase I clinical trial in the fourth quarter of 2024. Since B7H3 is overexpressed in a wide range of cancers including glioma, thyroid, lung, head and neck, rectal, prostate, breast, skin, renal cell, and ovarian cancers, it has the potential to become a next-generation therapy for resolving T cell exhaustion in cancer patients.

- **IBC0966**: IBC0966 is a clinical stage anti-PD-L1 antibody-SIRPα bifunctional fusion protein that simultaneously stimulates both innate and adaptive immunity to achieve strong synergistic effects and induce long-lasting tumor-specific immune responses. It is designed to bind to PD-L1 and trigger blockage of the PD-1/PD-L1 signaling pathway to enable T cells to recognize and kill targeted cancer cells, and in the meantime deliver SIRPα to the targeted TME to interact with CD47 to block the "don't eat me" signal of macrophages for tumor cell killing. In March 2021, we obtained the IND approval from the NMPA for conducting clinical trials of IBC0966. We completed the Phase I clinical trial of IBC0966 as monotherapy for advanced malignant tumors in December 2023, and expect to enter a Phase II clinical trial in the second quarter of 2024. We acquired exclusive rights from ImmuneOnco Biopharmaceuticals (Shanghai) Inc. to develop, manufacture and commercialize IBC0966 in Greater China including mainland China, Hong Kong, Macau, and Taiwan. For more information, see "Business – Collaboration Arrangement – Collaboration Agreement With ImmuneOnco in Relation to the Development of IBC0966" in this document.

- **IBD0333**: IBD0333 is a clinical stage 4-1BB and CD24 bsAb that simultaneously stimulates both innate and adaptive immunity to achieve strong synergistic effects with reduced hepatotoxicity. It is designed to bind to 4-1BB, a robust immune cell activator expressed by CD8+ T cells as well as DC cells, monocytes, B cells, mast cells, NK cells and neutrophils, and CD24, a promising target that plays a key role in tumor evasion in CD24-sialic-acid-binding Ig-like lectin 10 ("**Siglec-10**") axis and thus is highly expressed in many cancer types. We have obtained IND approvals from the FDA in June 2023 and from the NMPA in July 2023. We initiated a Phase I clinical study in March 2024 in patients with locally advanced/metastatic solid tumors, and expect to complete the Phase I study in the third quarter of 2025.

- **IAN0982**: IAN0982 is an internally developed multi-specific innate effector activator based on our AIM™ Platform. We are developing IAN0982 as a monotherapy or in combination with other therapeutics including chemotherapy and immunotherapy for the treatment of advanced solid tumors. Our IND application for IAN0982 is expected to be submitted to the NMPA and the FDA in the second quarter of 2024.

- **ISH0988**: ISH0988 is an internally developed anti-inflammatory and tissue-protective bifunctional fusion protein based on our AIC™ Platform. We are developing ISH0988 as a monotherapy for the treatment of inflammatory bowel disease. Our IND application for ISH0988 is expected to be submitted to the NMPA and the FDA in the second quarter of 2024.

- **ISH0613**: ISH0613 is an internally developed bifunctional antibody fusion protein that simultaneously inhibits B cell activation and IFNα secretion based on our AIC™ Platform. We are developing ISH0613 as a monotherapy for the treatment of systemic lupus erythematosus ("**SLE**"). Our IND application for ISH0613 is expected to be submitted to the NMPA and the FDA in the second quarter of 2024.

OUR PLATFORMS

Our commitment to innovation is evident and supported by our proprietary technology platforms, which include (i) AIC™ Platform, a scalable platform mainly concentrated on antibody-cytokine fusion protein development, (ii) ADCC Enhanced Antibody Platform ("**AEA™ Platform**"), a FUT8 knock-out cell line constructed to enhance the cytotoxicity of antibodies, and (iii) Armed Innate Effector Multi-specific Platform ("**AIM™ Platform**"), a platform that focuses on the development of innate immunity stimulator-based bispecific/multi-specific antibodies. Each of them is designed for addressing technical difficulties and drug resistance faced in developing immunotherapies and achieving optimized treatment effects. Since their launch, we have developed IAP0971, IAE0972, IBB0979, ISH0988 and ISH0613 based on AIC™ Platform, IAH0968 based on AEA™ Platform, and IAN0982 based on AIM™ Platform.

AIC™ Platform

Our AIC™ Platform is prominently positioned in the field of immunocytokine development from multiple aspects, including cytokine selection and optimization, antibody selection and engineering, structural design and engineering, and production through customized cell line. It is a comprehensive research engine that includes not only a pool of intact immunoglobulin G ("**IgG**") antibodies and cytokines, but also functional antibody fragments and other types of immune system modulators. It is able to generate products ranging from immunocytokines to other bifunctional fusion proteins. Our clinical stage drug candidates IAP0971, IAE0972 and IBB0979, and preclinical stage drug candidates ISH0988 and ISH0613 were developed based on the AIC™ Platform.

Core competencies of our AIC™ Platform include mechanism of action ("**MoA**")-based antibody-cytokine selection, biology-oriented structural design and protein engineering, and production through customized cell lines.

- MoA-based antibody-cytokine selection is the cornerstone to achieve desired synergistic effects between antibody and cytokine. For example, selection of anti-PD-1 antibody and IL-15 cytokine for developing IAP0971 is grounded on their shared action site on the same T/NK cells, leading to great *cis*-synergy. The combination of anti-EGFR antibody and IL-10 is selected based on the potential engager effects it can produce. Specifically, IAE0972 can engage CD8+ T cells through IL-10 while simultaneously targeting tumor cells through the EGFR antibody moiety.

- Structural design and protein engineering module enables us to structurally design and modify our products to achieve improved safety and efficacy profile while reducing manufacturing cost and enhancing product quality manageability. Structural modifications that we are capable to perform through our AIC™ Platform include antibody and cytokine engineering, deglycosylation, linker/spacer design and optimization, and tertiary structure alteration.

- Production through customized cell lines is another important function performed by our AIC™ Platform. The cell lines we constructed for producing immunocytokines and other bifunctional fusion proteins are obtained after undergoing multiple rounds of metabolic and growth optimization and are of high expression capacity and excellent purification yield. Coupled with unique cytokine-specific codon optimization, stably expressed vehicles with optimized expression cassettes and our high-throughput screening system, it is able to reach an expression level of 4g/L and one-step affinity chromatography purity of 86%, which is at the top level among rivals both at home and abroad, according to Frost & Sullivan.

For details, see "Business — Research and Development — R&D Platforms — Armed ImmunoCytokine Platform, AIC™" in this document.

AEA™ Platform

Our AEA™ Platform is a biologically engineered Chinese hamster ovary ("**CHO**") cell line with the FUT8 knocked-out to generate antibodies with enhanced ADCC and improved antitumor activities. Through this bioengineering modification, the CHO cell line will not be able to catalyze the transfer of fucose residue from its donor to its target, and thus is not able to produce any antibody that carries fucose. Because absence of core fucose on the Fc region has been shown to increase the Fc region's binding affinity (up to 100 times) to its receptor FcγRIIIa present on immune effector cells, fucose-negative antibodies are expected to have enhanced ADCC activities through better activating immune effector cells.

Comparing to other platforms that aim to achieve enhanced ADCC by removing fucose from antibodies, AEA™ Platform is expected to produce antibodies with 0% of fucose, which stably and thoroughly enhances the ADCC of antibodies and simplifies quality control of the products. Different biological engineering has been adopted by different platforms. However, platforms seldom achieved 100% fucose removal. To date, our AEA™ Platform and POTELLIGENT from Kyowa Kirin are the only two platforms that can achieve 100% fucose removal rate, according to Frost & Sullivan.

For details, see "Business — Research and Development — R&D Platforms — ADCC Enhanced Antibody Platform, AEA™" in this document.

AIM™ Platform

Our AIM™ Platform focuses on designing multi-functional biological products by engaging the innate immune system for cancer immunotherapy. It selects tumor associated antigen antibodies for cancer targeting, receptors agonist antibodies for innate effector activation, and cytokines and other TME factors for immune modulation to design multi-specific antibody fusion proteins, and evaluates them in terms of expression, target binding, *in vitro* and *in vivo* biological activities, as well as druggability. Currently, we have developed several categories of our proprietary AIM™ Platform that allow us to explore the combination of innate immunity stimulators with different types and numbers of targets, which provide us with abundant flexibility and diversity of various types of TME modulations for different clinical indications.

For details, see "Business — Research and Development — R&D Platforms — Armed Innate-effector Multispecific Platform, AIM™" in this document.

OUR STRENGTHS

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

- Internally developed pipeline of immunocytokines with novel mechanisms of action;
- Differentiated products developed leveraging our insights on immunology and antibody engineering;
- Proprietary platforms aimed to addressing bottlenecks of current immunotherapies continue fueling the development of differentiated biological products;
- Fully integrated, end-to-end, in-house drug development capabilities encompassing all key biologic drug development functionalities;
- Experienced management team of industry veterans with a proven record of success.

OUR STRATEGIES

We intend to capitalize on our competitive strengths by pursuing the following strategies:

- Focus on the development of immunocytokines to enhance position in this drug development field;
- Continue advancing selected pipeline products with great clinical value and commercial potential;
- Expanding our GMP-compliant manufacturing facility to enhance our production capabilities and starting to assemble our commercial team;
- Actively seeking international collaboration opportunities to maximize value of our assets and increase brand awareness on a global scale;
- Continue to focus on selecting and retaining top talents to fuel our innovation.

RESEARCH AND DEVELOPMENT

We consistently devote resources to research and development to pave for long-term growth. We believe the diversification and expansion of our product pipeline through both in-house research and development and through external collaboration are critical to our long-term competitiveness and success. Our fully-integrated biological therapeutic platform encompasses all the key biologic drug development functionalities, enabling us to identify and address potential clinical and manufacturing needs early in the development process, so we can direct our efforts towards biologics with best potential. Our platform spans from the early

phase of identifying demand, developing core technologies, managing clinical trials, to the manufacturing of products. We believe that our integrated capabilities give us the agility to formulate our innovation, registration, commercialization and product optimization strategies that can navigate us through changing market needs, enable us to improve pipeline viability and expedite product development cycle at lower cost. See "Business — Research and Development — R&D Platforms" in this document for details.

We are led by a management team with significant R&D experience and a proven track record. Our executive Director, chief executive officer and chief scientific officer, Dr. YIN Liusong, has over 16 years of experience in antibody and cytokine development and pipeline management, and has led more than 600 antibody drug discovery and optimization projects with dozens entered into clinical trials. Chairman of our Board and executive Director, Mr. ZHANG Feng is a pharmaceutical veteran with over 20 years of experience in the industry with expertise in R&D, clinical development, product launch and marketing. Our management team has an average of more than 15 years of industry experience in biologics development and business management, including antibody discovery and engineering, process development, GMP manufacturing, clinical operations and regulatory affairs. Their vision and insights are also key drivers of our success.

Our R&D team is lead by our executive Director, chief executive officer and chief scientific officer Dr. Yin. The executive Director and vice president overseeing our research and development is Ms. JIANG Xiaoling. Members of our experienced in-house R&D team come from a variety of medical backgrounds and has diverse and in-depth knowledge that is critical to strengthening our R&D capabilities. The functions of our integrated R&D team span drug discovery, *in vitro* evaluation, pharmacology and pharmacodynamics, protein engineering, process development and quality analysis.

Our research and development expenses amounted to RMB53.2 million and RMB43.0 million in 2022 and 2023, respectively. During the Track Record Period, our research and development expenses consisted of (i) contract research expenses in relation to the engagement of CROs for preclinical and clinical research services; (ii) staff costs incurred by our research and development personnel; (iii) depreciation and amortization expenses in relation to our research and development machinery and equipment; (iv) material consumed in the course of our research and development activities; (v) application fees for our patent and IND applications, (vi) share-based compensation, and (vii) other research and development expenses.

COLLABORATION ARRANGEMENT

In October 2019, we entered into a collaboration agreement (the "**IBC0966 Agreement**") with ImmuneOnco Biopharmaceuticals (Shanghai) Inc. ("**ImmuneOnco**") with respect to the technology transfer, development, manufacture and commercialization of IBC0966. ImmuneOnco is a biotechnology company primarily engaged in the development of immuno-oncology therapies and it is an Independent Third Party to us.

Pursuant to the IBC0966 Agreement, ImmuneOnco transferred to us (i) all of its rights and interests, including but not limited to development, production, regulatory filings and commercialization, in relation to IBC0966 in mainland China, Hong Kong, Macau and Taiwan (the "**Territory**"); (ii) all related patents, if applicable, registered in the Territory; and (iii) all technical data and analytical methods relating to the development of IBC0966. Accordingly, ImmuneOnco has transferred to us its invention patent in mainland China in relation to IBC0966 (patent number: CN111278865B), which invention patent covered all the key characteristics of IBC0966, and we have completed the administrative registration of the transfer. The application of this patent was filed on October 24, 2018 and the patent will expire on October 24, 2038.

We are entitled to all rights and interests of IBC0966 in the Territory and continue the development of IBC0966 including, among others, the preclinical and clinical researches, registrational applications, manufacture and commercialization of IBC0966 in the Territory at our costs, while ImmuneOnco retains the rights to develop, register and commercialize IBC0966 outside of the Territory. We do not share any R&D expenses with ImmuneOnco. We will assist ImmuneOnco in submitting IND and NDA applications in relation to IBC0966 to regulatory authorities outside of the Territory. Specifically, we will provide our clinical trial materials in relation to IBC0966 in the Territory, and application materials in relation to chemical, manufacturing and control as well as pre-clinical studies to ImmuneOnco. In return for the aforementioned efforts and assistance that we will make for ImmuneOnco's IND and NDA applications in relation to IBC0966 outside the Territory, as commercially agreed by both parties, we will be entitled to 7.5% of the interests of IBC0966 outside the Territory. In addition, should ImmuneOnco transfer or license its rights of IBC0966 outside of the Territory to a third party, we are entitled to 7.5% of the resulting proceeds garnered by ImmuneOnco.

In exchange of our rights, we are obligated to pay RMB20.0 million assignment fee by installments. As of the Latest Practicable Date, the rights and interests of IBC0966 as well as the related documents and materials had been duly transferred to us and we had paid ImmuneOnco an assignment fee of RMB10.0 million. The remaining RMB10.0 million will be payable upon our obtainment of the marketing approval of IBC0966 from the NMPA. In addition, ImmuneOnco is entitled to low single-digit percentage royalties based on the annual net sales of IBC0966 in the Territory until the earlier of the tenth year after the initial launch of IBC0966 or the expiration of the patents for IBC0966 molecule sequences. As of the Latest Practicable Date, we did not owe any royalties to ImmuneOnco.

The IBC0966 Agreement shall remain effective from execution until termination of the agreement. Either party may terminate the IBC0966 Agreement if the other party is in breach of its obligations under this agreement, and fails to take rectification measures after the non-breaching party gives a 30 days' written notice. The IBC0966 Agreement can also be terminated upon mutual consent if IBC0966 fails to obtain IND approval or reach the clinical endpoint due to reasons related to druggability. In addition, in the occurrence of pre-specified safety issues resulting in the aforementioned failure of IBC0966, we are entitled to a 50% payment return and ImmuneOnco is entitled to restitutions of the transferred rights and interests of IBC0966 upon the termination of the IBC0966 Agreement. The termination of this

Agreement shall not release either party from any obligations or liabilities that have arisen under this agreement prior to such termination, nor shall it prevent either party from asserting any rights and remedies that it may have under this agreement or at law.

Apart from the rights and obligations under the IBC0966 Agreement, we procured a limited amount of raw materials (namely, cell culture medium) from ImmuneOnco. Other than the foregoing, there is no past or present relationships or dealings (including family, business, employment, trust, financing or otherwise) between the Group and ImmuneOnco, their respective substantial shareholders, directors or senior management, or any of their respective associates.

RELATIONSHIP WITH CROS AND CONTRACT SERVICE PROVIDERS

As is customary in the pharmaceutical industry, we use CROs and other contract service providers to support our preclinical studies and/or clinical trials under our close supervision and overall management. During the Track Record Period and up to the Latest Practicable Date, all the CROs and other contract service providers that we collaborate with were Independent Third Parties.

INTELLECTUAL PROPERTY RIGHTS

As of the Latest Practicable Date, we owned 14 issued patents and 124 patent applications, including 54 patent applications in China, nine patent applications in the U.S., and 61 patent applications under the Patent Cooperation Treaty ("**PCT**"), relating to certain of our product candidates and technologies. As of the Latest Practicable Date, the material patent and patent applications for our Core Products included (i) three patents and three patent applications in China, and two material patent applications under PCT for IAH0968; (ii) one patent and five patent applications in China, one patent application in the U.S. for IAP0971; and (iii) five patent applications in China, and one patent application under PCT for IAE0972. In addition, we had three material patent applications in the U.S., three material patent applications in China for AIM™ Platform, four material patent applications in China, and one material patent application under PCT for AIC™ Platform, and one material patent application in China for AEA™ Platform. For further details on our intellectual property rights, see "Business — Intellectual Property" in this document.

MANUFACTURING

We have established our own global GMP-compliant manufacturing facilities, which meet both clinical and commercial production demands to quantity, quality and dosage form of our product candidates. We currently have four active drug substance production lines up to a total capacity of 1,600L, including three 200L and one 1,000L disposable bioreactors. We have successfully completed over 30 production batches of immunocytokines, mAbs, bsAbs and fusion proteins, which fulfilled the needs for performing preclinical studies, pilot production of antibody drugs and conducting early phase clinical trials. We have completed the installation of a production line for 5,000L bioreactor capacity, and completed the qualification in

November 2023. When putting into operation, it will enable us to manufacture our drug candidates for Phase III clinical trials and commercialization in-house. Our drug product facility includes one commercial-scale liquid injection filing production line and one commercial scale lyophilized powder production line, which enables us to prepare biological products into various dosage forms according to different needs.

SUPPLIERS

During the Track Record Period, our purchases mainly include third-party contract services for preclinical evaluation and clinical trials of our product candidates, premise leases, equipment procurement and others. In 2022 and 2023, our purchases from our five largest suppliers amounted to RMB17.0 million and RMB11.3 million, respectively, representing 54.1% and 49.9% of our total purchases for the same years, respectively. In 2022 and 2023, our purchases from our largest supplier amounted RMB11.1 million and RMB2.7 million, respectively, representing 35.2% and 12.0% of our total purchases for the same periods, respectively. To the best of our knowledge, all of our five largest suppliers in each year during the Track Record Period were Independent Third Parties, except for Nanjing Bode which was a related party to us during the Track Record Period but has become an Independent Third Party since July 2023, further details of which are set out in the paragraph headed "Relationship with Our Controlling Shareholders — Clear Delineation of Business — Nanjing Bode" in this document.

For more details, see "Business — Suppliers and Raw Materials — Suppliers" in this document.

OUR CONTROLLING SHAREHOLDERS

As of the Latest Practicable Date, Mr. Zhang is able to exercise approximately 81.62% voting rights in our Company through Sunho Fortune, Innovalue Investments, Sunho Wisdom, No5XJR and Sunho Stellar. Immediately upon completion of the [**REDACTED**], Mr. Zhang will be able to exercise approximately [**REDACTED**]% voting rights in our Company. Therefore, Mr. Zhang, Sunho Fortune, Innovalue Investments, Sunho Wisdom, No5XJR and Sunho Stellar will be considered as a group of Controlling Shareholders under the Listing Rules.

As of the Latest Practicable Date, apart from the interest in our Group, Mr. Zhang was the chairman of the board of directors of, and through his controlled entities, was entitled to exercise approximately 50.37% voting rights in, Nanjing Yoko, which is principally engaged in the R&D, manufacturing and sales of chemical drugs. There is a clear delineation of business between our Group and Nanjing Yoko and the business of Nanjing Yoko does not compete and is unlikely to compete, directly or indirectly, with the business of our Group. For details, see "Relationship with Our Controlling Shareholders" in this document.

PRE-[REDACTED] INVESTORS

We received the Pre-[**REDACTED**] Investments from the Pre-[**REDACTED**] Investors which are venture capital funds. Efung Capital is our sophisticated investor under paragraph 10 of Chapter 2.3 of the Guide for New Listing Applicants. Upon completion of the [**REDACTED**], Efung Capital, through its affiliates, will hold approximately [**REDACTED**]% of the total issued Shares. For details, see "History, Reorganization and Corporate Structure — Pre-[**REDACTED**] Investments" in this document.

SUMMARY OF HISTORICAL FINANCIAL INFORMATION

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

The following table sets forth our consolidated statements of profit or loss and other comprehensive income for the years indicated, derived from the Accountants' Report set out in Appendix I to this document.

	Year Ended December 31,	
	2022	**2023**
	RMB'000	*RMB'000*
Other income	13,795	21,005
Other expenses	(1,258)	(70)
Other gains and losses, net	97	(49,615)
Research and development expenses	(53,171)	(43,041)
Administrative expenses	(5,558)	(40,701)
[**REDACTED**]	[**REDACTED**]	[**REDACTED**]
Finance costs	(5,074)	(692)
Loss before tax	(51,988)	(132,701)
Income tax expense	–	–
Loss and total comprehensive expense for the year	(51,988)	(132,701)

For more information, see "Financial Information — Description of Major Components of Our Results of Operations" in this document.

Our loss for the year increased substantially from RMB52.0 million in 2022 to RMB132.7 million in 2023, primarily due to (i) change from other gains of RMB97.0 thousand in 2022 to other losses of RMB49.6 million in 2023, due to the recognition of RMB41.3 million of loss from fair value change of financial liabilities at fair value through profit or loss ("**FVTPL**"); (ii) a significant increase in our administrative expenses of RMB35.1 million, primarily resulting from an increase in share-based compensation in relation to RSUs transferred to Mr. Zhang in May 2023; an increase in our other administrative expenses in relation to our general

operations, such as fees paid for our purchase of office supplies and traveling fees; and an increase in professional service fees paid for auditing and legal services; and (iii) an increase in [**REDACTED**] of RMB[**REDACTED**] in connection with the [**REDACTED**]. For detailed discussion of the fluctuation of our net loss, see "Financial Information — Description of Major Components of Our Results of Operations" in this document.

Our research and development expenses decreased from RMB53.2 million in 2022 to RMB43.0 million 2023, primarily in line with the evolving progress of preclinical studies and clinical trial status of different product candidates during the respective years. For details, see "Financial Information — Description of Major Components of Our Results of Operations — Research and Development Expenses" in this document. With respect to the research and development expenses incurred for the Core Products, we recorded RMB10.7 million and RMB17.4 million 2022 and 2023, respectively, accounting for 20.1% and 40.4% of the total research and development expenses in the corresponding years. The following table sets forth a breakdown of our research and development expenses incurred on the Core Products and other product candidates for the years indicated.

	Year Ended December 31,			
	2022		2023	
	RMB'000	*%*	*RMB'000*	*%*
IAH0968	7,428	14.0	6,895	16.0
IAP0971	2,078	3.9	3,705	8.6
IAE0972	1,172	2.2	6,783	15.8
Core products	10,678	20.1	17,383	40.4
IBB0979	7,637	14.4	1,692	3.9
IBC0966	3,396	6.4	234	0.5
IBD0333	12,644	23.8	5,369	12.5
IAN0982	876	1.6	38	0.1
ISH0988	825	1.6	1,433	3.3
ISH0613	754	1.4	1,824	4.2
Other products candidates	26,132	49.2	10,590	24.6
Others[(1)]	16,361	30.7	15,068	35.0
Total	**53,171**	**100.0**	**43,041**	**100.0**

Note:

(1) Others include R&D expenses incurred for our other in-house-developed early-stage biologics.

Selected Items of Our Consolidated Statements of Financial Position

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

	As of December 31,	
	2022	**2023**
	RMB'000	*RMB'000*
Total non-current assets	56,229	63,309
Total current assets	14,632	227,141
Total assets	**70,861**	**290,450**
Total current liabilities	66,154	387,663
Net current liabilities	**(51,522)**	**(160,522)**
Total non-current liabilities	6,206	6,896
Total liabilities	**72,360**	**394,559**
Net liabilities	**(1,499)**	**(104,109)**
Capital and reserves		
Share capital	322	322
Treasury stock	(29)	(19)
Reserves	(1,792)	(104,412)
Total deficit	**(1,499)**	**(104,109)**

For more information, see "Financial Information — Discussion of Certain Selected Items From the Consolidated Statements of Financial Position" in this document.

We had net current liabilities and net liabilities positions as of December 31, 2022, primarily due to borrowings obtained from a related party and our designation of the Series A Preferred Shares during the Track Record Period while we have not started to generate any revenue. We also had net current liabilities and net liabilities positions as of December 31, 2023, primarily due to our financial liabilities at FVTPL resulted from Pre-[**REDACTED**] Investments. Our net current liabilities increased from RMB51.5 million as of December 31, 2022 to RMB160.5 million as of December 31, 2023, primarily attributable to (i) an increase in financial liabilities at FVTPL resulted from Pre-[**REDACTED**] Investments; and (ii) an increase in other payables due to Nanjing Bode. For details, please see "Financial Information Consolidated Statements of Financial Position — Trade and Other Payables" in this document.

The net liabilities increased from RMB1.5 million as of December 31, 2022 to RMB104.1 million as of December 31, 2023, due to (i) loss and total comprehensive expense of RMB132.7 million in 2023; and (ii) recognition of equity-settled share-based payments expenses of RMB30.1 million for the same period. For further details on the equity movement of our Group, see "Consolidated Statements of Changes in Equity" of the Accountants' Report set out in Appendix I to this document.

We expect to improve our net current liabilities and net liabilities positions in the future and turn into net assets position upon [**REDACTED**], taking into account the estimated net [**REDACTED**] from the [**REDACTED**], and that the carrying amount of the financial liabilities of the convertible redeemable preferred shares of RMB316.9 million as of February 29, 2024 will be derecognized and credit to equity as a result of the automatic conversion into ordinary Shares upon the [**REDACTED**].

Summary Consolidated Statements of Cash Flows

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

	Year Ended December 31,	
	2022	**2023**
	RMB'000	*RMB'000*
Cash used in operations before movements in working capital	(36,171)	(47,124)
Changes in working capital	1,585	6,471
Net cash flows used in operating activities	(34,586)	(40,653)
Net cash flows used in investing activities	(1,362)	(83,888)
Net cash flows generated from financing activities	27,104	255,497
Net increase (decrease) in cash and cash equivalents	(8,844)	130,956
Cash and cash equivalents at the beginning of the year	10,665	1,821
Effect of foreign exchange rate changes	–	(7,703)
Cash and cash equivalents at the end of the year	**1,821**	**125,074**

For details of our cash flows, see "Financial Information — Liquidity and Capital Resources — Cash Flows" in this document.

We recorded net operating outflows during the Track Record Period due to losses incurred in relation to our research and development activities. Our net operating outflows increased from RMB34.6 million in 2022 to RMB40.7 million in 2023, primarily in line with the fluctuation of our administrative expenses, which increased from RMB5.6 million in 2022 to RMB40.7 million in 2023.

Our Directors are of the opinion that, taking into account the financial resources available to our Group, including cash and cash equivalents and the estimated net [**REDACTED**] from the [**REDACTED**], as well as cash burn rate, we have available sufficient working capital to cover at least 125% of the Group's costs, including general, administrative and operating costs (including any production 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 the average monthly amount of net cash used in operating activities, capital expenditures, and other scheduled cash payment. Assuming an average cash burn rate going forward of 6.5 times the level in 2023, taking into account the scheduled payment of indebtedness, we estimate that our cash at bank and on hand, together with other financial assets and time deposits as of December 31, 2023 will be able to maintain our financial viability for 9 months, or, if we also take into account the estimated net [**REDACTED**] (based on the [**REDACTED**] of HK$[**REDACTED**] per Share, being the low-end of the indicative [**REDACTED**]), [**REDACTED**]. Our Directors and our management team will continue to monitor our working capital, cash flows, and our business development progress.

KEY FINANCIAL RATIO

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

	As of December 31,	
	2022	**2023**
Current ratio[(1)]	0.2	0.6

Note:

(1) Current ratio equals to current assets divided by current liabilities as of the same date.

For reasons for fluctuations of the above ratio, see "Financial Information — Key Financial Ratio" in this document.

SUMMARY OF MATERIAL RISK FACTORS

We believe that there are certain risks involved in our operations, many of which are beyond our control. These risks are set out in the section headed "Risk Factors" in this document. Some of the major risks we face include:

- We may encounter difficulties in recruiting patients for clinical trials of late line treatment targeting late-stage cancers;

- Market opportunities for some of our products may be smaller than we anticipated considering the low incidence of the indications targeted by our products, as well as patients' preference in spending;

- Our business and financial prospects depend substantially on the success of our clinical stage and preclinical stage drug candidates. However, if we are unable to successfully complete their clinical development, obtain their regulatory approvals and achieve their commercialization, or if we experience significant delays in doing any of the foregoing, our business will be materially harmed;

- We invest substantial resources in research and development in order to develop, enhance or adapt to new technologies and methodologies, which may not be successful attempts;

- We have limited experience in manufacturing therapeutic biologic products on a large commercial scale, and our business could be materially and adversely affected if we encounter problems in manufacturing our future drug products;

- We face intense competition and our competitors may discover, develop or commercialize competing drugs faster or more successfully than we do, which may adversely affect our ability to successfully commercialize our drug candidates;

- We have a limited operating history and have incurred net losses since inception. We expect to continue to incur net losses for the foreseeable future and may not be able to generate sufficient revenue to achieve or maintain profitability;

- If we are unable to obtain and maintain adequate patent and other intellectual property protection for our drug candidates throughout the selected markets in the world, or if the scope of such intellectual property rights obtained is not sufficiently broad, third parties could develop and commercialize drug candidates and technologies similar or identical to ours and compete directly against us, and our ability to successfully develop and commercialize any of our drug candidates or technologies would be materially and adversely affected; and

- If we are unable to build and manage sales network, or maintain sufficient sales and marketing capabilities, either by ourselves or through third parties, we may not be able to successfully create or increase market awareness of our products or sell our products, which will materially affect our ability to generate product sales revenue.

For more details, see "Risk Factors" in this document.

[**REDACTED**] STATISTICS

The [**REDACTED**] consists of:

- the [**REDACTED**] of initially [**REDACTED**], for [**REDACTED**] by the [**REDACTED**] in Hong Kong, referred to in this document as the [**REDACTED**]; and

- the [**REDACTED**] of initially [**REDACTED**], outside the U.S. (including to professional, institutional and other [**REDACTED**] within Hong Kong) in offshore transactions in reliance on Regulation S, referred to in this document as the [**REDACTED**].

	Based on the [REDACTED] of HK$[REDACTED]	**Based on the [REDACTED] of HK$[REDACTED]**
[**REDACTED**] of our Shares[(1)]	HK$[REDACTED]	HK$[REDACTED]
Unaudited [**REDACTED**] adjusted net tangible assets per Share[(2)(3)]	HK$[REDACTED]	HK$[REDACTED]

Notes:

(1) The calculation of [**REDACTED**] is based on [**REDACTED**] Shares, including shares of Pre-[**REDACTED**] Investment and treasury stock under the employee incentive scheme, and immediately upon completion of the [**REDACTED**].

(2)

[**REDACTED**]

(3)

[**REDACTED**]

[**REDACTED**]

DIVIDENDS

No dividend has been declared or paid by entities comprising our Group. We currently expect to retain all future earnings for use in operation and expansion of our business, and do not have any dividend policy to declare or pay any dividends in the foreseeable future. Any declaration and payment by our Company as well as the amount of dividends will be subject to our constitutional documents and the Cayman Companies Act. The declaration and payment of any dividends in the future will be determined by our Board, in its discretion, and will depend on a number of factors, including our earnings, capital requirements, overall financial condition and contractual restrictions. Our Shareholders in a general meeting may approve any declaration of dividends, which must not exceed the amount recommended by our Board. Under the laws of the Cayman Islands, a Cayman Islands company may pay a dividend out of its profits or the credit standing to its share premium account, provided that immediately after the date on which the dividend is proposed to be paid, the company will be able to pay its debts as they fall due in the ordinary course of business. As advised by our legal adviser as to Cayman Islands laws, a position of accumulated losses does not necessarily restrict us from declaring and paying dividends to our Shareholders, as dividends may still be declared and paid out of our share premium account, provided that, immediately after payment of the dividend, we are able to pay our debts as they fall due in the ordinary course of business.

For more information, see "Financial Information — Dividends" in this document.

USE OF [REDACTED]

We estimate that we will receive net [**REDACTED**] from the [**REDACTED**] of approximately HK$[**REDACTED**], after deducting [**REDACTED**] and other estimated expenses paid and payable by us in connection with the [**REDACTED**], assuming an [**REDACTED**] of HK$[**REDACTED**] per Share, being the mid-point of the indicative [**REDACTED**] of HK$[**REDACTED**] to HK$[**REDACTED**] per Share in this document. We currently intend to apply these net [**REDACTED**] for the following purposes:

- [28.1]%, or approximately HK$[**REDACTED**], will be used for ongoing and planned clinical trials of IAH0968 in China;
- [36.1]%, or approximately HK$[**REDACTED**], will be used for ongoing and planned clinical trials of IAP0971 in China;
- [35.8]%, or approximately HK$[**REDACTED**], will be used to fund ongoing and planned clinical trials of IAE0972 in China.

For more details, see "Future Plans and Use of [**REDACTED**]" in this document.

[REDACTED]

[**REDACTED**] to be borne by us are estimated to be approximately HK$[**REDACTED**] (assuming an [**REDACTED**] of HK$[**REDACTED**] per Share, being the mid-point of the indicative [**REDACTED**] of HK$[**REDACTED**] to HK$[**REDACTED**] per Share), representing approximately [**REDACTED**]% of the estimated gross [**REDACTED**] from the [**REDACTED**]. The [**REDACTED**] consist of (i) [**REDACTED**] expenses, including [**REDACTED**], of approximately HK$[**REDACTED**] (representing approximately [**REDACTED**]% of the estimated gross [**REDACTED**] from the [**REDACTED**]), and (ii) [**REDACTED**] expenses of approximately HK$[**REDACTED**], comprising (a) fees and expenses of our legal advisors and reporting accountants of approximately HK$[**REDACTED**], and (b) other fees and expenses of approximately HK$[**REDACTED**]. During the Track Record Period, the [**REDACTED**] charged to our consolidated statements of profit or loss were RMB[**REDACTED**] (HK$[**REDACTED**]) and the [**REDACTED**], which was recognized as prepayments and are expected to be deducted from equity upon the [**REDACTED**], were RMB[**REDACTED**] (HK$[**REDACTED**]). After the Track Record Period, approximately HK$[**REDACTED**] is expected to be charged to our consolidated statements of profit or loss, and approximately HK$[**REDACTED**] is expected to be accounted for as a deduction from equity upon the [**REDACTED**]. We do not believe any of the above fees or expenses are material or are unusually high to our Group. The [**REDACTED**] above are the latest practicable estimate for reference only, and the actual amount may differ from this estimate.

RECENT DEVELOPMENTS AND NO MATERIAL ADVERSE CHANGE

Our recent developments of our drug candidates since the end of the Track Record Period and up to the Latest Practicable Date include:

1. In January 2024, we entered a Phase IIb clinical trial for IAH0968 in combination with CapeOX in HER2+ advanced or metastatic CRC patients as first line therapy.

2. In March 2024, we completed the Phase IIa clinical trial for IAH0968 in combination with CapeOX in HER2+ advanced or metastatic CRC patients.

3. In March 2024, we initiated a Phase I clinical trial and dosed the first patient for IAP0971 in high risk NMIBC patients who have failed BCG treatment.

4. In March 2024, we initiated a Phase I clinical trial and dosed the first patient for IBD0333 in locally advanced or metastatic solid tumors.

In addition, we completed the Pre-[**REDACTED**] Investments and raised RMB270.18 million. For details, see "History, Reorganization and Corporate Structure — Pre-[**REDACTED**] Investments" in this document.

We expect an increase in forecast loss in the year ending December 31, 2024, primarily because we expect to incur increasing research and development expenses as we continue to conduct and expand our clinical development programs and advance the research and development of pipeline product candidates that are at preclinical stages.

Our Directors confirm that, there has been no material adverse change in our business, financial condition and results of operations since December 31, 2023, being the latest balance sheet date of our consolidated financial statements as set out in the Accountants' Report included in Appendix I to this document, and up to the date of this document.

IMPACT OF THE COVID-19

During the Track Record Period and up to the Latest Practicable Date, we had not experienced material disruptions in our operations as a result of the COVID-19 pandemic. Although our planned subject enrollment of Phase I clinical trials of IAP0971 and IAE0972 encountered temporary slow-down for around one month due to the reoccurrence of the pandemic in Shanghai in May 2022, we did not experience any delay of these clinical trials from the pandemic and theses clinical trials were completed within the original timetable. The overall impact of the COVID-19 pandemic on our clinical activities, drug development timeline, business and results of operations has been immaterial, and especially as the COVID-19 pandemic has come under control as of the Latest Practicable Date and our Directors are of the view that it is unlikely that COVID-19 pandemic will have material adverse impact on our business going forward.

REGULATORY DEVELOPMENTS ON OVERSEAS LISTING

On February 17, 2023, the CSRC published the new regulations for the filing-based administration for overseas securities offerings and listings by domestic companies, which came into effect on March 31, 2023. The newly released set of regulations consists of Overseas Listing Trial Measures and relevant guidelines. As advised by our PRC Legal Adviser, our proposed [**REDACTED**] and [**REDACTED**] falls within the scope of indirect overseas [**REDACTED**] of PRC domestic companies as provided for in the Overseas Listing Trial Measures, and therefore we will be subject to the filing procedures with the CSRC. According to the Overseas Listing Trial Measures, initial public offerings or listings in overseas markets shall be filed with the CSRC within three working days after the relevant application is submitted overseas. We had filed with the CSRC within three working days after we submitted the [**REDACTED**] to the [**REDACTED**], and we had not received any inquiry, notice, warning, or order prohibiting us from getting [**REDACTED**] on the [**REDACTED**] from the CSRC or any other PRC government authorities.

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

"Accountants' Report"	the accountants' report of our Company for the Track Record Period prepared by Deloitte Touche Tohmatsu, the text of which is set out in Appendix I to this document
"affiliate(s)"	with respect to any specified person, any other person, directly or indirectly, controlling or controlled by or under direct or indirect common control with such specified person
"AFRC"	the Accounting and Financial Reporting Council of Hong Kong (formerly known as the Financial Reporting Council of Hong Kong)
"Articles" or "Articles of Association"	the articles of association of our Company conditionally adopted on [●] and will come into effect upon [**REDACTED**] (as amended, supplemented or otherwise modified from time to time), a summary of which is set out in Appendix III to this document
"associate(s)"	has the meaning ascribed to it under the Listing Rules
"Audit Committee"	the audit committee of our Board
"Board of Directors", "Board" or "our Board"	the board of Directors
"Business Day"	a day on which banks in Hong Kong are open generally for normal banking business to the public and which is not a Saturday, Sunday or public holiday in Hong Kong
"BVI"	the British Virgin Islands

[**REDACTED**]

"Cayman Companies Act" or "Companies Act"	the Companies Act (As Revised) of the Cayman Islands, Cap. 22 (Law 3 of 1961), as amended or supplemented or otherwise modified from time to time
"CCASS"	the Central Clearing and Settlement System established and operated by HKSCC
"China" or "PRC"	the People's Republic of China, which only in the context of describing PRC rules, laws, regulations, regulatory authority, and any PRC entities or citizens under such rules, laws and regulations and other legal or tax matters in this document, excludes Taiwan, Hong Kong and the Macau Special Administrative Region of the PRC
"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", "our Company" or "the Company"	Sunho Biologics, Inc. (盛禾生物控股有限公司), an exempted company with limited liability incorporated in the Cayman Islands on May 14, 2021
"connected person(s)"	has the meaning ascribed to it under the Listing Rules
"Controlling Shareholders"	has the meaning ascribed to it under the Listing Rules and unless the context otherwise requires, refers to Mr. Zhang, Sunho Fortune, Innovalue Investments, Sunho Wisdom, No5XJR and Sunho Stellar, further details of which are set out in the section headed "Relationship with Our Controlling Shareholders" in this document
"core connected person(s)"	has the meaning ascribed to it under the Listing Rules
"Core Product(s)"	has the meaning ascribed to it under Chapter 18A of the Listing Rules and in this context, refers to IAH0968, IAP0971 and/or IAE0972

"COVID-19"	a viral respiratory disease caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)
"CSRC"	China Securities Regulatory Commission (中國證券監督管理委員會)
	[**REDACTED**]
"Director(s)"	the director(s) of our Company
"Extreme Conditions"	extreme conditions caused by a super typhoon as announced by the government of Hong Kong
"FDA"	U.S. Food and Drug Administration
	[**REDACTED**]
"Frost & Sullivan" or "Industry Consultant"	Frost & Sullivan (Beijing) Inc., Shanghai Branch Co., our industry consultant
"Frost & Sullivan Report"	the industry report commissioned by our Company and independently prepared by Frost & Sullivan, a summary of which is set forth in the section headed "Industry Overview" in this document
"General Rules of HKSCC"	the General Rules of HKSCC as may be amended or modified from time to time and where the context so permits, shall include the HKSCC Operational Procedures
	[**REDACTED**]
"Group", "our Group", "we", "us" or "our"	our Company and its subsidiaries from time to time or, where the context so requires, in respect of the period prior to our Company having become the holding company of its present subsidiaries, such subsidiaries as if they were subsidiaries of our Company at the relevant time

"Guide for New Listing Applicants"	the Guide for New Listing Applicants published by the Stock Exchange
"HK$" or "Hong Kong dollars"	Hong Kong dollars, the lawful currency of Hong Kong
"HKSCC"	Hong Kong Securities Clearing Company Limited, a wholly-owned subsidiary of Hong Kong Exchanges and Clearing Limited

[**REDACTED**]

"HKSCC Nominees"	HKSCC Nominees Limited, a wholly-owned subsidiary of HKSCC
"HKSCC Operational Procedures"	the operational procedures of HKSCC, containing the practices, procedures and administrative or other requirements relating to HKSCC's services and the operations and functions of CCASS, FINI or any other platform, facility or system established, operated and/or otherwise provided by or through HKSCC, as from time to time in force
"HKSCC Participant"	a participant admitted to participate in CCASS as a direct clearing participant, a general clearing participant or a custodian participant
"Hong Kong" or "HK"	the Hong Kong Special Administrative Region of the People's Republic of China

[**REDACTED**]

[**REDACTED**]

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

[**REDACTED**]

"Independent Third Party(ies)"	any person(s) or entity(ies) who/which is not a connected person of our Company within the meaning of the Listing Rules
"Innovalue Investments"	Innovalue Investments Limited, a company incorporated in the BVI with limited liability on April 8, 2021 and one of our Controlling Shareholders

[**REDACTED**]

[**REDACTED**]

"Latest Practicable Date"	March 31, 2024, being the latest practicable date for the purpose of ascertaining certain information contained in this document before 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 Committee"	the listing committee of the Stock Exchange

[**REDACTED**]

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

"Main Board"	the stock market (excluding the option market) operated by the Stock Exchange which is independent from and operated in parallel with the GEM of the Stock Exchange
"Memorandum" or "Memorandum of Association"	the memorandum of association of our Company conditionally adopted on [●] and will come into effect upon [**REDACTED**], a summary of which is set out in Appendix III to this document
"MOF"	the Ministry of Finance of the PRC (中華人民共和國財政部)
"MOFCOM"	the Ministry of Commerce of the PRC (中華人民共和國商務部)
"Mr. Zhang"	Mr. ZHANG Feng (張峰), an executive Director, the chairman of our Board and one of our Controlling Shareholders
"Nanjing Sunho"	Nanjing Sunho Medical Technology Co., Ltd (南京盛禾醫學技術有限公司), a limited liability company established under the laws of the PRC on August 13, 2020 and an indirect wholly-owned subsidiary of our Company
"Nanjing Yoko"	Nanjing Yoko Pharmaceutical Co., Ltd. (南京優科生物醫藥股份有限公司), a joint stock company established in the PRC in February 2002 and was indirectly controlled as to approximately 50.37% by Mr. Zhang as of the Latest Practicable Date
"NDRC"	the National Development and Reform Commission of the PRC (中華人民共和國國家發展和改革委員會)
"NMPA"	the National Medical Products Administration of the PRC (國家藥品監督管理局), the successor to the China Food and Drug Administration (國家食品藥品監督管理總局)
"No5XJR"	No5XJR Limited, a company incorporated in the BVI with limited liability on April 14, 2021 and one of our Controlling Shareholders
"Nomination Committee"	the nomination committee of our Board

"NPC"	the National People's Congress of the PRC (中華人民共和國全國人民代表大會)

[**REDACTED**]

"Overseas Listing Trial Measures"	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》) promulgated by the CSRC on February 17, 2023 and effective on March 31, 2023
"PBOC"	the People's Bank of China (中國人民銀行), the central bank of the PRC
"PRC Legal Adviser"	Jingtian & Gongcheng, the legal adviser to our Company as to the PRC laws
"Pre-[**REDACTED**] Investment(s)"	the investment(s) in our Group before the [**REDACTED**], details of which are set out in the paragraph headed "History, Reorganization and Corporate Structure – Pre-[**REDACTED**] Investments" in this document
"Pre-[**REDACTED**] Investor(s)"	the investor(s) who acquired interest in our Group pursuant to the relevant share subscription agreement, details of which are set out in the section headed "History, Reorganization and Corporate Structure" in this document

[**REDACTED**]

[**REDACTED**]

"R&D"	research and development
"Regulation S"	Regulation S under the U.S. Securities Act
"Remuneration Committee"	the remuneration committee of our Board
"Reorganization"	the reorganization undertaken by our Group in preparation for the [**REDACTED**], details of which are set out in the paragraph headed "History, Reorganization and Corporate Structure — Reorganization" in this document
"RMB" or "Renminbi"	Renminbi, the lawful currency of China
"RSU"	restricted share unit
"RSU Scheme"	the RSU scheme approved and adopted by our Company on August 2, 2023, the principal terms of which are set out in the paragraph headed "Appendix IV — Statutory and General Information — D. RSU Scheme" in this document
"SAFE"	the State Administration of Foreign Exchange of the PRC (中華人民共和國國家外匯管理局)
"SAFE Circular 37"	the Circular on Relevant Issues Concerning Foreign Exchange Control on Domestic Residents' Offshore Investment and Financing and Roundtrip Investment 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》) promulgated by the SAFE on July 14, 2014

"SAMR"	the State Administration for Market Regulation of the PRC (中華人民共和國國家市場監督管理總局), the predecessors of which is the State Administration of Industry and Commerce of the PRC (中華人民共和國國家工商行政管理總局)
"SASAC"	the State-owned Assets Supervision and Administration Commission of the State Council (國務院國有資產監督管理委員會)
"SAT"	the State Administration of Taxation of the PRC (中華人民共和國國家税務總局)
"Series A Preferred Shares"	the 22,515,000 series A preferred shares in the share capital of our Company with a par value of US$0.0005 each, which are held by the Pre-[**REDACTED**] Investor(s) as of the date of this document
"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
"Share(s)"	ordinary share(s) in the share capital of our Company with a par value of US$1.00 each before the Share Subdivision and US$0.0005 each after the Share Subdivision
"Shareholder(s)"	holder(s) of our Shares
"Share Subdivision"	the subdivision of each of the issued and unissued shares of our Company with a par value of US$1.00 into 2,000 shares of the corresponding class with a par value of US$0.0005 each, details of which are set out in the paragraph headed "History, Reorganization and Corporate Structure — Major Shareholding Changes in Our Company" in this document

[**REDACTED**]

[**REDACTED**]

"Sole Sponsor", "[**REDACTED**]" or "[**REDACTED**]"	China International Capital Corporation Hong Kong Securities Limited
"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
"Sunho bio Investments"	Sunho bio Investments Limited, a company incorporated in the BVI with limited liability on June 1, 2021 and an indirect wholly-owned subsidiary of our Company
"SunHo (China) BioPharmaceutical"	SunHo (China) BioPharmaceutical Co. Ltd (盛禾(中國)生物製藥有限公司), a limited liability company established under the laws of the PRC on April 2, 2018 and an indirect wholly-owned subsidiary of our Company
"Sunho Fortune"	Sunho Fortune Investments Limited, a company incorporated in the BVI with limited liability on April 9, 2021 and one of our Controlling Shareholders
"Sunho HK"	Sunho (HK) Limited, a limited company incorporated under the laws of Hong Kong on July 9, 2021 and an indirect wholly-owned subsidiary of our Company
"Sunho Pharmaceutical Technology"	Sunho Pharmaceutical Technology (Zhejiang Anji) Co., Ltd. (盛禾醫藥科技(浙江安吉)有限公司) (formerly known as Sunho Pharmaceutical Technology (Nanjing) Co., Ltd. (盛禾醫藥科技(南京)有限公司)), a company established under the laws of the PRC on December 30, 2021 and an indirect wholly-owned subsidiary of our Company
"Sunho Stellar"	Sunho Stellar Investments Limited, a company incorporated in the BVI with limited liability on April 9, 2021, our share incentive platform and one of our Controlling Shareholders

"Sunho Wisdom"	Sunho Wisdom Investments Limited, a company incorporated in the BVI with limited liability on April 14, 2021 and one of our Controlling Shareholders
"SunHo (Zhejiang) BioPharmaceutical"	SunHo (Zhejiang) BioPharmaceutical Co., Ltd. (盛禾(浙江)生物製藥有限公司), a limited liability company established under the laws of the PRC on March 17, 2023 and an indirect wholly-owned subsidiary of our Company
"Takeovers Codes"	the Codes on Takeovers and Mergers and Share Buy-backs published by the SFC, as amended, supplemented or otherwise modified from time to time
"Track Record Period"	the two financial years ended December 31, 2022 and 2023
	[**REDACTED**]
"United States" or "U.S."	the United States of America, its territories and possessions, any State of the United States, and the District of Columbia
"U.S. Securities Act"	the United States Securities Act of 1933, as amended, supplemented or otherwise modified from time to time
"US$" or "USD" or "U.S. dollars"	United States dollars, the lawful currency of the United States
	[**REDACTED**]
"%"	per cent

GLOSSARY OF TECHNICAL TERMS

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

"activator"	a substance which initiates a physiological response when combined with a receptor
"ADA"	anti-drug antibody, is an antibody produced by the human immune system to respond to exogenous drugs (such as antibody and protein drugs)
"ADCC"	antibody-dependent cell-mediated cytotoxicity, an immune mechanism through which Fc gamma receptor-bearing effector cells can kill target cells expressing tumor- or pathogen-derived antigens on their surface through antibody-binding effect
"ADCP"	antibody-dependent cellular phagocytosis, the mechanism by which antibody-opsonized target cells activate the FcγRs on the surface of macrophages to induce phagocytosis, resulting in internalization and degradation of the target cell through phagosome acidification
"ADCs"	antibody-drug conjugates, a substance made up of a monoclonal antibody chemically linked to a cytotoxic drug
"AE" or "adverse events"	any undesirable experience associated with the use of a medical product in a patient
"AEA™ Platform"	ADCC Enhanced Antibody Platform
"affinity"	the extent or fraction to which a drug binds to receptors at any given drug concentration or the firmness with which the drug binds to the receptor. Affinity describes the strength of the attraction between two chemicals, or an antigen and an antibody
"agglutination"	the clumping of particles together, is an antigen-antibody reaction that occurs when an antigen is mixed with its corresponding antibody at a suitable pH and temperature

GLOSSARY OF TECHNICAL TERMS

"AIC™ Platform"	Armed ImmunoCytokine Platform
"AIM™ Platform"	Armed Innate Effector Multi-specific Platform
"ALK"	anaplastic lymphoma kinase, a receptor tyrosine kinase protein that plays a role in the development and function of the nervous system
"amino acid"	organic compounds that form proteins when combined
"angiogenesis"	the formation of new blood vessels
"anlotinib"	a molecular targeted therapy for tumors
"antiangiogenic"	having to do with reducing the growth of new blood vessels
"antibody"	a blood 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
"antibody fusion protein"	constructs that combine an antibody targeted to a specific antigen, typically a tumor-related antigen, with a protein that is able to amplify the immune response or induce direct damage to the cancer cell
"antibody-cytokine fusion protein"	often referred to as immunocytokines, consisting of cytokines fused to an antibody to improve cytokine targeting
"antigen"	molecule that stimulates an immune response by activating lymphocytes
"antitumor functions"	preventing or inhibiting the formation or growth of tumors
"apatinib"	a medicine that is used to treat a certain type of lung cancer (non-small cell lung cancer)

GLOSSARY OF TECHNICAL TERMS

"APC"	antigen presenting cells, a heterogeneous group of immune cells that mediate the cellular immune response by processing and presenting antigens for recognition by certain lymphocytes such as T cells
"apoptosis"	a type of cell death in which a series of molecular steps in a cell lead to its death
"asparagine-linked GlcNAc"	the attachment of N-acetylglucosamine (GlcNAc) sugar molecules to specific asparagine residues within proteins. This process plays a crucial role in protein folding, stability, trafficking, and function
"autoimmune"	with respect to any disorder or disease, the response that occurs when the immune system goes awry and attacks the body itself. Autoimmunity, present to some extent in everyone, is usually harmless but it can cause a broad range of human illnesses, known collectively as "autoimmune diseases"
"B7H3"	anti- B7 homolog 3 protein
"BCG"	Bacillus Calmette Guerin, a live attenuated strain of Mycobacterium bovis
"bioreactors"	vessels or tanks in which whole cells or cell-free enzymes transform raw materials into biochemical products and/or less undesirable by-products
"bsAbs"	bispecific antibody, antibody or antibody-constructs that have dual-specificity in their binding arms
"BTC"	biliary tract carcinoma, a type of cancer that originates in the bile ducts, usually comprising cholangiocarcinomas and gallbladder carcinomas
"CAGR"	compound annual growth rate
"capecitabine treatment"	a type of chemotherapy that is used to treat breast, colon, or rectal cancer

GLOSSARY OF TECHNICAL TERMS

"CapeOX"	a chemotherapy regime that combines capecitabine and oxaliptin to treat colon cancer
"carboplatin chemotherapy"	a chemotherapy drug containing the metal platinum that can stop or slow the growth of cancer cells and other rapidly growing cells by damaging their DNA
"CAR-T"	chimeric antigen receptor T-cell
"CC"	cervical cancer, a type of cancer that occurs in the cells of the cervix – the lower part of the uterus that connects to the vagina
"CCA(s)"	bile duct cancer, also called cholangiocarcinoma, a cancer that forms in the slender tubes (bile ducts) that carry the digestive fluid bile
"CDMO"	Contract Design & Manufacture Organization
"cetuximab"	an anti-cancer targeted therapy
"chemotherapy"	the use of drugs to destroy cancer cells
"CHO"	Chinese hamster ovary
"CIS"	carcinoma in situ, a condition in which abnormal cells that look like cancer cells under a microscope are found only in the place where they first formed and haven't spread to nearby tissue
"cisplatin chemotherapy"	a type of chemotherapy drug that damages the DNA of dividing cells in a way that cannot be repaired to stop or slow the growth of cancer cells
"*cis*-synergy"	the phenomenon occurs when two agents of bifunctional antibody act in the same location and on the same cells at the same time, which will further improve the effectiveness
"clinical trial" or "clinical study"	a kind of clinical research designed to evaluate and test new interventions such as psychotherapy or medications
"CMC"	chemistry, manufacturing and controls

GLOSSARY OF TECHNICAL TERMS

"Combo" or "combination therapy"	treatment in which a patient is given two or more drugs (or other therapeutic agents) for a single disease
"CRC"	colorectal cancer, is the development of cancer from the colon or rectum (parts of the large intestine)
"CRPC"	castration-resistant prostate cancer, prostate cancer that keeps growing even when the amount of testosterone in the body is reduced to very low levels
"CRR"	complete response rate, is the rate of the disappearance of all signs of cancer in response to treatment
"cytokine"	small secreted proteins released by cells have a specific effect on the interactions and communications between cells
"cytotoxic"	toxic to living cells, causing cell damage or death
"cytotoxicity"	the term for how toxic a substance is to cells, a cytotoxic compound can cause cell damage or death, either through necrosis or apoptosis
"DCR"	disease control rate, the percentage of patients whose disease shrinks or remains stable over a certain time period
"deglycosylation"	a process that removes glycans from glycoproteins
"DLT"	dose-limiting toxicity, toxicities of a drug or other treatment that are serious enough to prevent an increase in dose or level of that treatment
"docetaxel"	a type of chemotherapy that treats a variety of cancer
"DoR"	duration of response, commonly defined as the time from onset of response to progression or death due to any reason, whichever occurs earlier
"drug resistance"	the reduction in effectiveness of a drug in curing a disease
"druggability"	the ability of a target to be therapeutically modulated by medicines

"EGFR"	epidermal growth factor receptor, a protein found on certain types of cells that binds to a substance called epidermal growth factor. It is involved in cell signaling pathways that control cell division and survival. Sometimes, mutations (changes) in the EGFR cause epidermal growth factor receptor proteins to be made in higher than normal amounts on some types of cancer cells
"EMA"	European Medicines Agency
"equimolar"	of or relating to an equal number of moles
"erythrocyte"	a type of blood cell that is made in the bone marrow and found in the blood
"ESG"	environmental, social and governance
"Fab"	antigen binding fragment, a region on an antibody that binds to antigens, consisting of a light chain and a VH and a CH1 of the heavy chain
"Fast-to-Market Strategy"	our ongoing strategy of seeking accelerated regulatory approvals and market launches for various drug candidates under development for the treatment of serious or life-threatening disease conditions, fulfillment of unmet medical needs, and/or satisfaction of other requirements or designations that enable qualification of an expedited regulatory review process
"Fc"	fragment crystallizable, which is the tail region of an antibody that interacts with cell surface receptors called Fc receptors and some proteins of the complement system
"FcγR"	Fc-gamma receptors, a receptor for the Fc region of immunoglobulin
"FDA"	Food and Drug Administration of the United States
"first-line treatment"	the first treatment given for a disease that is often part of a standard set of treatments

GLOSSARY OF TECHNICAL TERMS

"fucose"	a methylpentose found in small quantities in glycoproteins, glycolipids and gangliosides, the presence of which reduces the antibody-dependent cellular cytotoxicity of therapeutic antibodies
"fusion protein"	a protein consisting of at least two domains which are different proteins being transcribed and translated as a single unit, producing a single polypeptide
"gastric cancer"	a cancer that develops from the inner lining of the stomach. It causes bloating stomach pain, difficulty in swallowing, nausea, vomiting, fatigue and weight loss
"GBC"	gallbladder carcinoma, an abnormal growth of cells that begins in the gallbladder
"gemcitabine"	a medicine that is used to treat cancers of the pancreas, lung, ovary and breast
"glycoprotein"	molecules that comprise protein and carbohydrate chains that are involved in many physiological functions including immunity
"GMP"	good manufacturing practice, a system for ensuring that products are consistently produced and controlled according to quality standards, which is designed to minimize the risks involved in any pharmaceutical production that cannot be eliminated through testing the final product. It is also the practice required in order to conform to the guidelines recommended by agencies that control the authorization and licensing of the manufacture and sale of pharmaceutical products
"granzyme-mediated programmed cell death"	a specific mechanism of cell death induced by cytotoxic lymphocytes, particularly natural killer (NK) cells and cytotoxic T lymphocytes (CTLs)
"haematotoxicity"	adverse effects on blood and blood-forming tissues
"half-life"	the period of time required for the concentration or amount of a drug in the body to be reduced to exactly one-half of a given concentration or amount of such drug

"HCC"	hepatocellular carcinoma, the most common type of primary liver cancer
"hepatotoxicity"	injury to the liver or impairment of the liver function caused by exposure to xenobiotics
"HER2"	human epidermal growth factor receptor 2
"heterodimer(s)"	a protein composed of two polypeptide chains differing in the sequence, number and kind of their amino acid residues
"hinge region"	a flexible amino acid stretch in the central part of the heavy chains of the IgG and IgA immunoglobulin classes, which links these 2 chains by disulfide bonds
"HNSCC"	head and neck squamous cell carcinoma
"homodimer(s)"	a protein composed of two polypeptide chains that are identical in the sequence, number and kind of their amino acid residues
"HPV"	human papillomaviruses, a deoxyribonucleic acid (DNA) virus that has many types. HPV is an important cause of cervical cancer and is also associated with other types of genital cancer
"IBD"	inflammatory bowel disease, a term that describes disorders involving long-standing inflammation of tissues in digestive tract
"ICI"	immune checkpoint inhibitor, a type of drug that blocks proteins called checkpoints that are made by some types of immune system cells, such as T cells, and some cancer cells
"IFNγ"	Interferon-gamma, a dimerized soluble pro-inflammatory cytokine
"IL"	interleukin, a type of cytokine and signaling molecule in the immune system to provoke an immune response in the body of a human or other animals

"IL-10"	a cytokine with multiple, pleiotropic, effects in immunoregulation and inflammation
"IL-15"	Interleukin-15, a proinflammatory cytokine involved in the development, survival, proliferation and activation of multiple lymphocyte lineages utilizing a variety of signaling pathways
"IL-15Rα"	the high affinity receptor alpha of IL-15
"immune cell exhaustion"	a state of immune cell dysfunction that arises during many chronic infections and cancer
"immune checkpoint inhibitor(s)"	a type of drugs that blocks the immune evasion of tumor cells by certain molecules, which helps promote immune responses and allow immune cells to kill cancer cells
"immunocytokines"	fusion proteins consisting of a cytokine moiety fused to a antibody or antibody fragment with antigen targeting capabilities, representing a novel class of biopharmaceuticals that has great potential for the therapy of cancer and other serious diseases. For details regarding the immunocytokines, see "Neri et. al. (2016), Immunocytokines for cancer treatment: past, present and future, Current Opinion in Immunology, Vol. 40, pp. 96-102"
"immunoglobulin"	the glycoproteins produced by B-cells, also called antibodies or immunoglobulins, that recognize and bind free antigens and are responsible for humoral immunity
"immuno-oncology"	a type of cancer treatment that uses the power of the body's own immune system to prevent, control and eliminate cancer
"immunosuppression"	a reduction of the activation or efficacy of the immune system
"immunotherapy"	a type of therapy that involves the immune system to help the body fight cancer, infection and other diseases
"*in vitro*"	Latin for within the glass, studies using components of an organism that have been isolated from their usual biological surroundings, such as microorganisms, cells or biological molecules

GLOSSARY OF TECHNICAL TERMS

"*in vivo*"	Latin for within the living, studies in which the effects of various biological or chemical substances are tested on whole, living organisms as opposed to a partial or dead organism, or those done *in vitro*
"IND"	investigational new drug or investigational new drug application, also known as clinical trial application, or CTA, in China
"IND-enabling"	a stage where an applicant conducting studies to secure approval to conduct the first-in-human clinical trials with a new drug
"indication"	a disease condition which makes a particular treatment or procedure advisable
"inhibitor"	a chemical or substance added or applied to another substance to slow down a reaction or to prevent an unwanted chemical change
"innate-effector"	a component of the innate immune system that plays a direct role in recognizing and eliminating pathogens
"interferons"	a group of proteins that helps the body's immune system fight infection and other diseases, such as cancer
"interleukins"	a group of related proteins made by leukocytes (white blood cells) and other cells in the body that function as signaling molecules in the immune system
"irinotecan"	a medication that is used to treat cancer of the colon and rectum
"knobs-into-holes"	a heterodimerization technology for the third constant domain of an antibody
"KOLs"	key opinion leaders
"leukemia"	cancer of the body's blood-forming tissues, including the bone marrow and the lymphatic system
"leukocytes"	part of the body's immune system that help the body fight infection and other diseases

"leukocytopenia"	a condition characterized by a low number of white blood cells (leukocytes) in the blood
"Libtayo"	an immune checkpoint inhibitor used in cancer immunotherapy that targets the programmed cell PD-1 pathway
"liver-infiltrating"	conditions that affect the liver, including infiltrative hepatocellular carcinoma and infiltrative liver disease caused by solid cancer metastases
"localized (cancer)"	cancer that is found only in the tissue or organ where it first began and that has not spread to nearby lymph nodes or to other parts of the body
"lymphocyte"	a type of white blood cells that plays a crucial role in the immune response, defending the body against infections, foreign substances, and abnormal cells
"lymphocytopenia"	a disorder in which one's blood does not have enough lymphocytes
"lymphokines"	a subset of cytokines produced by lymphocyte that plays a vital role in cell signaling within the immune system
"mAb(s)"	monoclonal antibody, an antibody made by identical immune cells that are all clones of a unique parent cell, in contrast to polyclonal antibodies which are made from hundreds of different immune cells
"macrophages"	a type of white blood cells that surrounds and kills microorganisms, removes dead cells, and stimulates the action of other immune system cells
"memory phenotype CD8+ T cell"	a kind of CD8+ T cells that has responded to cognate antigen (Ag) and persists long-term, CD8+ T cells undergo unique developmental programs after activation, resulting in the generation of effector and long-lived memory T cells
"metastasis" or "metastases"	the stage that cancer has spread to a different part of your body part than where it started

"metastatic"	in reference to any disease, including cancer, disease producing organisms or of malignant or cancerous cells transferred to other parts of the body by way of the blood or lymphatic vessels or membranous surfaces
"metastatic solid tumors"	a tumor made up of cancer cells from the primary cancer site that has spread to other parts of the body
"MoA"	mechanism of action
"monocytes"	a type of white blood cell (leukocytes) that reside in blood and tissues to find and destroy germs and eliminate infected cells
"monotherapy"	therapy that uses a single drug to treat a disease or condition
"MSI-H/dMMR"	microsatellite instability-high or mismatch repair deficient, biomarkers of tumors that have an accumulation of errors in sequences that are normally repeated
"MTD"	maximum tolerable dose, the highest dose of a drug or treatment that does not cause unacceptable side effects
"nab-paclitaxel"	a taxane -type chemotherapy medicine used to treat breast cancer
"nasopharyngeal cancer"	a disease in which malignant cancer cells form in the tissues of the nasopharynx
"nedaplatin chemotherapy"	a cisplatin analog, has been developed to decrease the toxicities induced by cisplatin, such as nephrotoxicity and gastrointestinal toxicity
"NHL"	non-Hodgkin lymphoma, a disease in which malignant (cancer) cells form in the lymph system
"NK cell"	natural killer cell, a type of cytotoxic lymphocyte, which provides rapid responses to virus-infected cell and other intracellular pathogens, and respond to tumor formation
"NMIBC"	non-muscle invasive bladder cancer

"NRDL"	National Reimbursement Drug List of China, also known as Drugs Catalogue for the National Basic Medical Insurance, Work-related Injury Insurance and Maternity Insurance (《國家基本醫療保險、工傷保險和生育保險藥品目錄》), which was published by the relevant government authority on November 27, 2009 and amended from time to time
"NSCLC"	non-small cell lung cancer, any type of epithelial lung cancer other than small-cell lung cancer (SCLC)
"Opdivo"	an immune checkpoint inhibitor used in cancer immunotherapy that targets the programmed cell PD-1 pathway
"ORR"	objective response rate
"OS"	overall survival, defined as the time from treatment to death, regardless of disease recurrence
"oxaliplatin"	a medication that is used to treat advanced cancer of the colon and rectum
"pancreatic cancer"	cancer of pancreas, an organ which is behind the lower part of the stomach
"PD-1"	programmed death-1, an immune checkpoint receptor expressed on T-cells, B-cells and macrophages. The normal function of PD-1 is to turn off the T- cell mediated immune response as part of the process that stops a healthy immune system from attacking other pathogenic cells in the body. When PD-1 on the surface of a T-cell attaches to certain proteins on the surface of a normal cell or a cancer cell, the T-cell turns off its ability to kill the cell
"PD-L1"	program death ligand 1, which is a protein on the surface of a normal cell or a cancer cell that attaches to certain proteins on the surface of the T-cell that causes the T-cell to turn off its ability to kill the cancer cell
"PEG"	polyethylene glycol, a medication that is used in the management and treatment of constipation

"PEGylated"	a biochemical modification process of bioactive molecules with polyethylene glycol
"PFS"	progression-free survival, which is defined as the time from random assignment in a clinical trial to disease progression or death from any cause
"pharmacokinetic" or "PK"	the activity of drugs in the body over a period of time, including the processes by which drugs are absorbed, distributed in the body, localized in the tissues, and excreted
"Phase I"	study that is usually conducted to test the safety of a drug candidate. The goal is to find out what the drug's most frequent and serious adverse events are and, often, how the drug is metabolized and excreted
"Phase II"	study in which a drug is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases, and to determine dosage tolerance and optimal dosage
"Phase III"	study that gathers preliminary data on effectiveness (whether the drug works in people who have a certain disease or condition). For example, participants receiving the drug may be compared with similar participants receiving a different treatment, usually an inactive substance (called a placebo) or a different drug. Safety continues to be evaluated, and short-term adverse events are studied
"phosphorylation"	the addition of a phosphoryl (PO3) group to a molecule. It is vital for the cellular storage and transfer of free energy using energy carrier molecules
"pleural effusion"	the collection of fluid in the pleural cavity resulting from malignant disease
"polymorphism"	the ability of a drug substance to crystallize into more than two different forms
"PR"	partial response, a decrease in the size of a tumor, or in the extent of cancer in the body, in response to treatment

"preclinical study"	preclinical study that tests the drug on non-human subjects, to gather efficacy, toxicity, pharmacokinetic and safety information and to decide whether a drug is ready for clinical trials
"radiotherapy"	a type of cancer treatment that uses beams of intense energy to kill cancer cells
"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.
"rectal cancer"	cancer which begins in the rectum, the lower end of the large intestine.
"retroperitoneal"	having to do with the area outside or behind the peritoneum, the tissue that lines the abdominal wall and covers most of the organs in the abdomen
"RP2D"	recommended Phase II dose
"right abdominal sulcus"	the curved border or margin formed by the lower edge of the ribcage on the right side of the abdomen
"RSV"	respiratory syncytial virus, a common, contagious virus that causes infections of the respiratory tract
"SAE" or "serious adverse event"	untoward medical occurrence: (1) results in death; (2) is life-threatening; (3) requires inpatient hospitalization or causes prolongation of existing hospitalization; (4) results in persistent or significant disability/incapacity; (5) may have caused a congenital anomaly/birth defect; or (6) requires intervention to prevent permanent impairment or damage
"SCI"	Science Citation Index
"SD"	stable disease, disease that is neither decreasing nor increasing in extent or severity
"second-line treatment"	treatment that is given when initial treatment (first-line therapy) does not work, or stops working

"signaling"	the ability of a cell to receive, process and transmit signals with its environment and with itself
"SIRPα"	Signal Regulatory Protein Alpha, a receptor selectively expressed on macrophages
"SLE"	systemic lupus erythematosus, an autoimmune disease in which the immune system attacks its own tissues, causing widespread inflammation and tissue damage in the affected organs
"solid tumors"	an abnormal mass of tissue that usually does not contain cysts or liquid areas
"spatial structure"	the way a group or phenomenon is arranged
"steric hindrance"	the slowing of chemical reactions due to steric bulk, which is often exploited to control selectivity, such as slowing unwanted side-reactions
"subcutaneous murine model"	an animal model for the evaluation of molecular hypotheses that is widely used in biomedical research, especially in pharmacology
"subcutaneously administered"	a method of injecting medication under the skin, into the layer of fat or connective tissue
"synergistic"	synergistic effect, an effect arising between two or more agents, entities, factors, or substances that produces an effect greater than the sum of their individual effects
"T cell(s)" or "lymphocyte(s)"	lymphocyte(s) produced or processed by the thymus gland and actively participating in the immune response, which plays a central role in cell-mediated immunity. T cells can be distinguished from other lymphocytes, such as B cells and NK cells, by the presence of a T cell receptor on the cell surface
"TAA"	tumor-associated antigens, which derive from any protein or glycoprotein synthesized by the tumor cell
"TGI"	tumor growth inhibition, the specific reduction in growth of tumors by a chemical compound, mechanical therapy, radiation, protein therapy, ultrasound waves, light, or other treatment

"third-line treatment"	treatment that is given when both initial treatment (first-line therapy) and subsequent treatment (second-line therapy) do not work, or stop working
"TME"	tumor microenvironment, the normal cells, molecules, and blood vessels that surround and feed a tumor cell. A tumor can change its microenvironment, and the microenvironment can affect how a tumor grows and spreads
"TNFα"	tumor necrosis factor-alpha, a cell signaling protein (cytokine) involved in systemic inflammation and is one of the cytokines that make up the acute phase reaction
"toxicity"	the degree to which a substance or a mixture of substances can harm humans or animals. Acute toxicity involves harmful effects in an organism through a single or short-term exposure. It is expressed generally as a dose response
"TRAEs"	treatment-related adverse events, undesired and often unintended effects or reactions that occur as a result of medical treatment or interventions
"tumorigenesis"	a pathologic process that involves the transformation of normal cells to a neoplastic state and resulting in polyclonal or monoclonal neoplastic cell proliferation
"tumor-infiltrating"	the movement of cells from the blood into a tumor
"Tyvyt"	an immune checkpoint inhibitor used in cancer immunotherapy that targets the programmed cell PD-1 pathway
"VEGF"	vascular endothelial growth factor, a potent angiogenic factor and was first described as an essential growth factor for vascular endothelial cells
"VEGFR"	the receptor of the vascular endothelial growth factor
"xenograft(s)"	a tissue graft or organ transplant from a donor of a different species from the recipient

FORWARD-LOOKING STATEMENTS

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

- our business strategies and plans to achieve these strategies;
- our ability to complete the development and obtain the relevant requisite regulatory approvals of our products;
- our product candidates under development or planning;
- our ability to attract customers and further enhance our brand recognition;
- our future debt levels and capital needs;
- changes to the political and regulatory environment in the industry and markets in which we operate;
- changes in competitive conditions and our ability to compete under these conditions;
- future developments, trends and conditions in the industry and markets in which we operate;
- general economic, political and business conditions in the markets in which we operate;
- effects of the global financial markets and economic crisis;
- our financial conditions and performance;
- our dividend policy; and
- change or volatility in interest rates, foreign exchange rates, equity prices, volumes, operations, margins, risk management and overall market trends.

FORWARD-LOOKING STATEMENTS

In some cases, we use the words "aim", "anticipate", "believe", "can", "continue", "could", "estimate", "expect", "going forward", "intend", "ought to", "may", "might", "plan", "potential", "predict", "project", "seek", "should", "will", "would" and similar expressions to identify forward-looking statements. In particular, we use these forward-looking statements in the sections headed "Business" and "Financial Information" in this document in relation to future events, our future financial, business or other performance and development, the future development of our industry and the future development of the general economy of our key markets.

The forward-looking statements are based on our current plans and estimates and speak only as of the date they were made. We undertake no obligation to update or revise any forward-looking statements in light of new information, future events or otherwise. Forward-looking statements involve inherent risks and uncertainties and are subject to assumptions, some of which are beyond our control. We caution you that a number of important factors could cause actual outcomes to differ, or to differ materially, from those expressed in any forward-looking statements.

Our Directors confirm that the forward-looking statements are made after reasonable care and due consideration. Nonetheless, due to the risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this document might not occur in the way we expect, or at all.

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

An [**REDACTED**] *in our 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 deciding to* [**REDACTED**] *in our Shares. 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, results of operations and growth prospects. In any such an event, the* [**REDACTED**] *of our Shares could decline, and you may lose all or part of your* [**REDACTED**].

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 is as of the Latest Practicable Date unless otherwise stated, will not be updated after the date hereof, and is subject to the cautionary statements in the section headed "Forward-Looking Statements" in this document.

We believe there are certain risks and uncertainties involved in our operations, some of which are beyond our control. We have categorized these risks and uncertainties into: (i) risks relating to the research and development of our drug candidates; (ii) risks relating to manufacturing of our drug candidates; (iii) risks relating to commercialization of our drug candidates; (iv) risks relating to our intellectual property rights; (v) risks relating to our financial position and need for additional capital; (vi) risks relating to our operations; (vii) risks relating to our reliance on third parties; (viii) risks relating to government regulations; and (ix) risks relating to the [**REDACTED**].

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

RISKS RELATING TO THE RESEARCH AND DEVELOPMENT OF OUR DRUG CANDIDATES

We may encounter difficulties in recruiting patients for clinical trials of late line treatment targeting late-stage cancers.

The field of cancer treatment has advanced rapidly in recent decades, progressing from surgery and radiotherapy, to chemotherapy and, more recently, to targeted drugs and immunotherapies. Immunotherapies can be characterized as first-line, second-line or third-line based on the timing of the treatment. First-line treatment or therapy simply refers to the initial, or first treatment recommended for the cancer, which, for most people, is expected to provide the best results with the fewest number of side effects. In contrast, second-line treatments are used when the first-line treatment failed to improve a cancer, or if the first-line worked initially before and then the cancer progressed. Third-line treatment may be adopted if previous treatments failed.

For instance, our Core Products IAP0971 and IAE0972 are mainly developed to target second line or later stage of treatment for cancer patients, who have failed prior treatments, limiting its target patients group in nature. Regulatory authorities also may establish narrower definitions around when a patient is ineligible for other treatments than we have used in our clinical trials, and that would reduce the size of the patient population eligible for our drug candidates and therefore enhance our difficulties in recruiting patients for our clinical trials. Difficulties in recruiting patients may cause delay or failure of our clinical trials, or make us incur substantial costs to find proper patients. In addition, limited patient pool can affect the quality and reliability of the clinical trial data, and our overall business operations may be adversely impacted.

Market opportunities for some of our products may be smaller than we anticipated considering the low incidence of the indications targeted by our products, as well as patients' preference in spending.

We conduct our preclinical studies and clinical trials, based on our estimation of the number of patients who have the cancers we are targeting, as well as the subset of patients with these cancers who are able to receive different lines of therapies and who have the potential to benefit from the treatment with our product candidates, which information is derived from a variety of sources, including scientific literature and surveys of clinics. Our projections may prove to be incorrect and the number of potential patients may turn out to be lower than expected, as new studies may change the estimated incidence or prevalence of cancers that our product candidates target on. Additionally, the potentially addressable patient population for our Core Products may be limited or may not be amenable to treatment with such Core Products. Therefore, our market opportunities may be limited by low incidence of the indications targeted by our products.

Cancer therapies are sometimes characterized by line of therapy (first-line, second-line, third-line, etc.), and the regulatory authorities often approve new therapies initially only for a particular line or lines of use. When cancer is detected early enough, first-line therapy is sometimes adequate to cure the cancer or prolong life without a cure. Whenever first-line therapy, usually chemotherapy, antibody drugs, tumor-targeted small molecules, hormone therapy, radiation therapy, surgery or a combination of these, proves unsuccessful, then second-line therapy may be administered. Second-line or third-line therapies often consist of more invasive forms of surgery, drugs and new technologies. There is no guarantee that our product candidates, even if approved for third-line therapy, would be approved for second-line or first-line therapy.

In addition, some of our product candidates target on cancers that lack early screening or diagnosis methods. For instance, due to a lack of early cancer screening and diagnosis in China, 89% of clinically diagnosed patients with CRC are in the late stage. These late-stage cancer patients represent an insignificant subset of the overall cancer population. Moreover, late-stage cancer patients have a relatively short life expectancy and may not prefer to spend substantial financial resources to acquire expensive drugs to treat terminal or deadly diseases. Therefore, market opportunities for these drugs may be less than we expect.

Our business and financial prospects depend substantially on the success of our clinical stage and preclinical stage drug candidates. However, if we are unable to successfully complete their clinical development, obtain their regulatory approvals and achieve their commercialization, or if we experience significant delays in doing any of the foregoing, our business will be materially harmed.

Our ability to generate revenue and become profitable is substantially dependent on our ability to successfully complete the development of our drug candidates, obtain necessary regulatory approvals, and manufacture and commercialize our drug candidates. We have invested and will continue to invest substantial efforts and resources in our drug candidates. The success of our drug candidates will depend on several factors, including but not limited to:

- favorable safety, immunogenicity and efficacy data from our clinical trials and other studies;
- successful enrollment of patients in, and completion of, clinical trials, as well as completion of preclinical studies;
- sufficient resources to acquire or discover additional drug candidates and successful identification of potential drug candidates based on our research or business development methodology or search criteria and process;
- competition with other drug candidates and marketed drugs;
- obtaining sufficient supplies of any drug products or marketed drugs that are used in combination with our drug candidates, competitor drugs, or comparison drugs that may be necessary for use in clinical trials for evaluation of our drug candidates;
- 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;
- receipt of regulatory approvals from the National Medical Products Administration ("**NMPA**"), the Food and Drug Administration ("**FDA**") or other comparable regulatory authorities for our drug candidates;
- obtaining, maintaining and enforcing patent, trademark, trade secret and other intellectual property protection and regulatory exclusivity for our drug candidates;
- ensuring we do not infringe, misappropriate or otherwise violate the patents, trademarks, trade secrets or other intellectual property rights of third parties, and successfully defending against any claims by third parties that we have infringed, misappropriated or otherwise violated any intellectual property of any such third party;

- establishing sufficient commercial manufacturing capabilities;
- successfully launching commercial sales of our drug candidates, if and when approved;
- obtaining and maintaining favorable governmental and/or private reimbursement from third-party payers for our drugs, if and when approved;
- continued acceptable safety profile of our drug candidates following regulatory approval, if and when received; and
- stable and supportive domestic policies, favorable international environment and good relationships among nations.

If we do not achieve one or more of the aforementioned factors in a timely manner or at all, we could experience significant delays or difficulties in obtaining approvals for and/or successfully commercializing our drug candidates.

Some of our drug candidates represent a novel approach to therapeutic needs compared with more commonly used medical methods, which carries inherent development risks and could result in delays in clinical development, regulatory approval or commercialization. Any modification to the protocols related to the demonstration of safety or efficacy of our drug candidates may delay the clinical program, regulatory approval and/or commercialization, and we may be required to supplement, modify, or withdraw and refile our applications for the regulatory approval. This may have a material impact on our ability to generate revenue from our drug candidates, which in turn may materially and adversely affect our business, financial condition and results of operations.

As of the Latest Practicable Date, all of our drug candidates were in various phases of clinical trials and preclinical studies and we did not have any drug candidates that are at NDA/BLA stage with the relevant competent regulatory authorities. We therefore do not yet have experience in filing for regulatory approval for our drug candidates, and we have not yet demonstrated the ability to receive regulatory approval for our drug candidates. As a result, our ability to successfully obtain regulatory approval for our drug candidates may involve more inherent risk, take longer, and cost more than it would if we were a company with experience in obtaining regulatory approvals.

We may not be able to identify, discover or develop new drug candidates, or to identify additional therapeutic opportunities for our drug candidates, to expand or maintain our product pipeline.

The success of our business depends upon our ability to identify, discover, develop and commercialize drug candidates. Although we have developed proprietary technology platforms such as AIC™, AIM™, AEA™ which we believe enable us to discover, design, evaluate and select optimal candidates and continue to enrich our pipeline, we cannot guarantee that we will be successful in identifying potential new drug candidates. Furthermore, drug candidates that we identify may be shown to have harmful side effects or other characteristics that make them unmarketable or unlikely to receive regulatory approval. Some drug candidates such as Immunocytokine and BsAb drug candidates for oncology that we intend to identify could also be technically challenging to develop and manufacture. Research programs to identify new drug candidates and drug targets or to pursue the development of our drug candidates for additional indications require substantial technical, financial and human resources. Our research programs may initially show promise in identifying potential indications and/or drug candidates, yet fail to yield results for clinical development for a number of reasons, including but not limited to the following factors:

- the research methodology used may not be successful in identifying potential indications and/or new drug candidates;

- there may be a lack of transferability of experimental results obtained in the laboratory testing in cells or from animals into clinical treatment and safety outcomes in human subjects, including unexpected toxicities in humans;

- potential drug candidates may, after further study, be shown to have adverse effects or other characteristics that indicate they are unlikely to achieve desired safety and efficacy;

- it may take greater resources to identify additional therapeutic opportunities for our drug candidates or to develop suitable potential drug candidates, thereby limiting our ability to diversify and expand our drug portfolio; or

- we may not be able to manufacture the right dosage form to match the appropriate route of administration during the development of our drug candidates.

Accordingly, there can be no assurance that we will be able to identify new drug candidates or additional therapeutic opportunities for our drug candidates or to develop suitable potential drug candidates through internal research programs, which could materially and adversely affect our future growth and prospects. We may focus our efforts and resources on potential drug candidates or other potential programs that ultimately prove to be unsuccessful.

We invest substantial resources in research and development in order to develop, enhance or adapt to new technologies and methodologies, which may not be successful attempts.

The global biologics market is constantly evolving, and we must keep pace with new technologies and methodologies to maintain our competitive position. For the years ended December 31, 2022 and 2023, our research and development expenses were RMB53.2 million and RMB43.0 million, respectively. We need to continue to invest in human resources and technologies that will allow us to enhance the scope and quality of our research and development. We intend to continue to enhance our technical capabilities in drug discovery, development and manufacturing, which are capital-and-time-intensive. We cannot assure you that we will be able to develop, enhance or adapt to new technologies and methodologies, successfully identify new technological opportunities, develop and bring new or innovative drugs to market, obtain sufficient or any patent or other intellectual property protection for such new or innovative drugs, or obtain the necessary regulatory approvals in a timely and cost-effective manner, or, if such drugs are introduced to the market, that those drugs will achieve market acceptance. Any failure to do so may make our technologies obsolete, which could harm our business and prospects.

We face intense competition and our competitors may discover, develop or commercialize competing drugs faster or more successfully than we do, which may adversely affect our ability to successfully commercialize our drug candidates.

The development and commercialization of new drugs is highly competitive and subject to rapid and significant technological changes. Major pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies, universities and other research institutions have commercialized or are commercializing or pursuing the development of drugs competing with our drug candidates.

We are developing our product candidates in competition with a number of biopharmaceutical companies that currently market and sell drugs for the same indications. For instance, as of the Latest Practicable Date, on a global scale, eleven antibody-based drugs were approved for the treatment of CRC. In China, four antibody-based drugs were approved for the treatment of CRC. On a global scale, two antibody-based drugs were approved for the treatment of BTC. In China, two antibody-based drugs were approved for the treatment of BTC. On a global scale, 17 antibody-based drugs were approved for the treatment of NSCLC. In China, seven antibody-based drugs were approved for the treatment of NSCLC. On a global scale, eleven antibody-based drugs were approved for the treatment of HCC. In China, seven antibody-based drugs were approved for the treatment of HCC. On a global scale, four antibody-based drugs were approved for the treatment of HNSCC. In China, four antibody-based drugs were approved for the treatment of HNSCC.

Some of our competitors have greater financial, technical and human resources, more established commercialization infrastructure as well as more drug candidates in late-stage clinical development than we do. For example, multiple multi-national pharmaceutical companies are also developing antibodies against same targets of our drug candidates for the treatment of solid tumors. Even if our drug candidates have been successfully developed and

subsequently approved by the NMPA, the FDA or other comparable regulatory authorities, we will still face competition in terms of safety, efficacy, tolerability, the timing and scope of the regulatory approvals, the availability and cost of supply, sales and marketing capabilities, price, patent position and other factors. Our competitors may succeed in developing competing drugs and obtaining regulatory approvals before us or gain better acceptance for the same target markets as ours, which will undermine our competitive position. Disruptive technologies and medical breakthroughs may further intensify the competition and render our drug candidates obsolete or noncompetitive.

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties may compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Clinical drug development involves a lengthy and expensive process with uncertain outcomes, and we may encounter unexpected difficulties executing our clinical trials and commercializing our drug candidates on a timely basis.

To obtain regulatory approval for the sale of our drug candidates, we are required to conduct extensive clinical trials to demonstrate the safety and efficacy of our drug candidates in human. Clinical trials are expensive, difficult to design and implement, and the clinical outcomes are subject to high uncertainty. We may experience numerous unexpected events during, or as a result of, clinical trials that could delay us in or prevent us from receiving regulatory approvals for the development and commercialization of our drug candidates, including but not limited to situations whereby:

- we or our investigators may be required to commence a clinical trial or conduct a clinical trial at an unexpected trial site;
- the number of patients required for clinical trials of our drug candidates may be larger than we anticipate;
- the patient enrollment may be insufficient or slower than we anticipate or patients may drop out or fail to return for post-treatment follow-up at a higher rate than anticipated;
- our CROs may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- the supply or quality of our drug candidates or other materials necessary to conduct clinical trials of our drug candidates may be insufficient or inadequate;

- the costs of clinical trials of our drug candidates may be substantially higher than anticipated;

- our drug candidates may lack meaningful clinical responses, which may expose the participants to unacceptable health and safety risks;

- our drug candidates may cause adverse events, have undesirable side effects or other unexpected characteristics, causing us or our investigators to suspend or terminate the trials;

- regulators may require that we or our investigators suspend or terminate clinical research for reasons such as non-compliance; and

- clinical trials of our drug candidates may produce negative or inconclusive results, and we may decide, or be required, to conduct additional clinical trials or abandon drug development programs.

If we are required to conduct additional clinical trials or other testing of our drug candidates beyond those that we currently contemplate, or if we are unable to successfully complete clinical trials of our drug candidates or other testing, or if the results of these trials or tests are not positive or are only modestly positive or if they raise safety concerns, we may be delayed in obtaining regulatory approval for our drug candidates or not obtain regulatory approval at all, or obtain approval for proposed indications that are not as broad as intended. We may have the drug removed from the market even after obtaining regulatory approval. We may also be subject to additional post-marketing testing requirements and restrictions on how the drug is distributed or used.

Delays in clinical trials and other testing or approvals may result in increases in our drug development costs. We do not know whether any clinical trials will begin as planned, will need to be restructured or will be completed on schedule. Significant clinical trial delays could also shorten any periods during which we have the exclusive right to commercialize our drug candidates or allow our competitors to bring drugs to market before we do and impair our ability to commercialize our drug candidates and may have an adverse effect on our business and results of operations.

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

The successful and timely completion of clinical trials in accordance with their protocols depends on, among other things, our ability to timely enroll a sufficient number of patients who opt to participate and remain in the trial until its conclusion. We may fail to initiate or continue clinical trials for our drug candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in our clinical trials, or if there are delays in the enrollment of eligible patients as a result of the competitive clinical enrollment environment. The inability

to enroll a sufficient number of patients who meet the applicable criteria for our clinical trials would result in significant delays. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons, including but not limited to:

- the design of the trial;
- the patient eligibility criteria defined in the protocol;
- the severity of the disease under investigation;
- the size and demographics of the patient population;
- the size of the study population required for analysis of the trial's primary endpoints;
- our ability to obtain and maintain patient consents;
- the experience and competencies of our third-party contractors;
- our ability to select clinical trial sites and to recruit clinical trial investigators with the appropriate competencies and experience;
- the proximity of patients to trial sites;
- clinicians' and patients' perceptions of the potential advantages and side effects of the drug candidate being studied compared to other available therapies, including any new drugs or treatments that may be approved for the indications we are investigating;
- the risk that patients enrolled in clinical trials will not complete a clinical trial;
- the outbreak of epidemics or pandemics; and
- the availability of approved therapies that are similar in mechanism to our drug candidates.

In addition, our clinical trials may compete with other clinical trials for drug candidates that are in the same therapeutic areas as our drug candidates, and this competition will reduce the number and types of patients available to us, because some patients may opt to enroll in a trial conducted by one of our competitors instead of ours. As the number of qualified clinical investigators and clinical trial sites is limited, we may conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites.

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

Adverse events caused by our drug candidates could interrupt, delay or halt clinical trials, delay or prevent regulatory approval, limit the commercial profile of an approved drug, or result in significant negative consequences following any regulatory approval.

Undesirable adverse events caused by our drug candidates, or caused by our drug candidates when used in combination with other drugs, could cause significant negative consequences, including but not limited to the following:

- clinical trials of our drug candidates could be interrupted, delayed, or halted;
- we may be required to cease further development of, or delay or even be denied approval of, our drug candidates for any or all targeted indications if results of our trials reveal a high and unacceptable severity or prevalence of certain adverse events;
- we may be required to withdraw approvals or revoke licenses of an approved drug candidate, or we may determine to do so even if not required;
- regulatory authorities may require additional warnings on the label of an approved drug, issue safety alerts or other communications containing warnings or other safety information of such approved drug, or impose other limitations on such approved drug;
- we may suspend, delay or alter development or marketing of our drug candidates;
- we may be required to develop a risk evaluation mitigation strategy for the drug candidate, or, if one is already in place, to incorporate additional requirements under the existing strategy, or to develop a similar strategy as required by a comparable regulatory authority;
- we may be required to change the way the drug candidate is administered or conduct post-market studies;
- the patient enrollment may be insufficient or slower than we anticipate, or patients may drop out or fail to return for post-treatment follow-up at a higher rate than anticipated;
- the costs of clinical trials of our drug candidates may be substantially higher than anticipated;

- we could be required to recall our drug candidates and subject to litigation proceedings and regulatory investigations and held liable for harm caused to patients exposed to or taking our drug candidates; and

- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular drug candidate, and could significantly harm our business, results of operations and prospects.

Results of early clinical trials may not be predictive of future trial results.

The results of preclinical studies and early clinical trials may not be predictive of the success of later phase clinical trials, and favorable initial or interim results of a clinical trial do not necessarily predict successful final results. Our drug candidates in later stages of clinical trials may fail to show the desired safety, immunogenicity and efficacy traits despite having progressed through preclinical studies and initial clinical trials.

In some instances, there can be significant variability in safety, immunogenicity and/or efficacy results among different trials of the same drug candidate due to numerous factors, including, but not limited to, changes in trial procedures set forth in protocols, differences in the size and demographics of the patient populations, including genetic differences, patient adherence to the dosing regimen, other trial protocol elements and the rate of dropout among clinical trial participants. As drug candidates are developed through preclinical and clinical trials towards approval and commercialization, it is customary that various aspects of the development programs, such as manufacturing and formulation, are altered along the way in an effort to optimize processes and results. Differences in the number of clinical trial sites and countries involved may also lead to variability between earlier and later-phase clinical trials. Constantly updated standard therapies may change patient resistance, which may affect the efficacy of our medicines. Such changes carry the inherent risks that they may not necessarily achieve the intended objectives. In addition, our future clinical trial results may differ from earlier trials and may not be favorable. Even if our future clinical trial results show favorable efficacy, not all patients may benefit. Therefore, the results of planned clinical trials or other future clinical trials could be significantly different and other than as predicted, which could result in delays in the completion of clinical trials, regulatory approvals and commencement of commercialization of our drug candidates. If so, we would have expended a significant amount of capital to progress the relevant drug candidates to that stage, and would not realize any revenue on such drug candidate if it then ultimately failed to receive regulatory approval due to poor clinical trial results. Such an uncompensated expenditure could materially and adversely affect our business, financial condition, results of operations and prospects.

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 experience delays in completing, or may ultimately be unable to complete, the development and commercialization of our drug candidates.

Before obtaining regulatory approvals for the commercialization of our drug candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of our drug candidates for their proposed indications in humans. We may conduct clinical trials with larger subject sample sizes as our clinical trial plan advances, and our drug candidates may not show the promising safety, immunogenicity and efficacy results that were observed in earlier clinical trials with fewer subjects. Undesirable adverse events caused by our drug candidates could cause the interruption, delay, suspension or termination of our clinical trials and result in a more restrictive label or the delay or denial of regulatory approval. Results of our clinical trials could reveal a high and unacceptable severity or prevalence of adverse events. In such an event, our clinical trials could be suspended or terminated and we may be required to cease further development of, or deny approval of, our drug candidates for any or all targeted indications. Adverse events could affect patient recruitment or the ability of enrolled subjects to complete the trial, and result in potential product liability claims. In addition, our clinical trials may not generate meaningful clinical response or have other unexpected characteristics, such as the short-term duration of response and insufficient enhancement of overall survival benefits.

If the results of clinical trials of our drug candidates are not positive or only modestly positive for proposed indications, or if they raise safety concerns, any or some of the following would occur:

- regulatory approvals for our drug candidates would be delayed or denied;
- we may be required to conduct additional clinical trials or other testing of our drug candidates beyond our current development plan;
- we may be required to add labeling statements, such as a "boxed" warning or a contraindication;
- we may be required to create a medication guide outlining the risks of the side effects for distribution to patients;
- we may be required to implement a risk evaluation and mitigation strategy program, including but not limited to medication guides, doctor communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk management tools;
- we may not be able to obtain regulatory approvals for all the proposed indications as intended;

- we may be subject to restrictions on how the drug is distributed or used;
- we may be sued or held liable for injury caused to individuals exposed to or taking our drug candidates;
- we may be unable to obtain reimbursement for use of the drug; and
- conditional regulatory approval of our drug candidates may require us to conduct confirmatory studies to verify the predicted clinical benefit and additional safety studies. The results from such studies may not support the clinical benefit, which would result in the approval being withdrawn.

Having expended a significant amount of capital to progress our drug candidates, if such drug candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results in future clinical trials, we would not be able to realize any revenue on such drug candidates if they then or ultimately fail to receive regulatory approvals due to unsatisfactory clinical trial results, thereby materially and adversely affecting our business, financial condition, results of operations and prospects.

In addition, if one or more of our drug candidates receives regulatory approval, and we or others later identify undesirable side effects caused by such drugs, it could result in a number of potentially significant negative consequences, including but not limited to, the following situations whereby:

- we may be forced to suspend marketing of the drug;
- approvals for the commercial sales of the drug may be withdrawn;
- additional warnings on the label may be required to be added;
- we may be required to develop risk evaluation and mitigation measures for the drug or, if risk evaluation and mitigation measures are already in place, to incorporate additional requirements under the risk evaluation and mitigation measures;
- we may be required to conduct post-market studies;
- we could be required to recall our products and be sued and held liable for harm caused to subjects or patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular drug candidate, if approved, and could significantly harm our business, financial condition, results of operations and prospects.

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

As we have limited financial and managerial resources, we focus our pipeline on research platforms and drug candidates that we identify for specific indications. As a result, we may forgo or delay pursuit of opportunities with other drug candidates or for other indications that may later prove to have greater commercial potential or a greater likelihood of success. Our spending on current and future research and development platforms and drug candidates for specific indications may not yield any commercially viable products. Accordingly, our resource allocation decisions may cause us to fail to capitalize on other viable commercial products or profitable market opportunities. If we cannot accurately evaluate the commercial potential or target market for a particular drug candidate, we may relinquish valuable rights to that drug candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights.

The data and information that we gather in our research and development process could be inaccurate or incomplete, which could harm our business, reputation, financial condition and results of operations.

We collect, aggregate, process, and analyze data and information from our preclinical studies and clinical trials. We also engage in substantial information gathering following the identification of a promising drug candidate. Because data in the healthcare industry is fragmented in origin, inconsistent in format, and often incomplete, the overall quality of data collected or accessed in the healthcare industry is often subject to challenge, the degree or amount of data which is knowingly or unknowingly absent or omitted can be material, and we often discover data issues and errors when monitoring and auditing the quality of our data. If we make mistakes in the capture, input, or analysis of these data, our ability to advance the development of our drug candidates may be materially harmed and our business, prospects and reputation may suffer.

We manage and submit data to governmental entities for procurement of necessary regulatory approvals. These processes and submissions are governed by complex data processing and validation policies and regulations. Notwithstanding such policies and regulations, interim, top-line or preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data, in which case we may be exposed to liability to a patient, court or government agency that concludes that our storage, handling, submission, delivery, or display of health information or other data was wrongful or erroneous. 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.

In addition, we rely on certain third parties to monitor and manage data for some of our ongoing preclinical studies and clinical trials and control only certain aspects of their activities. If any of our CROs or other third parties do not perform to our standards in terms of data accuracy or completeness, data from those preclinical and clinical trials may be compromised as a result, and our reliance on these parties does not relieve us of our regulatory responsibilities. For details, see "— Risks Relating to Our Reliance on Third Parties — We work with various third parties to develop our drug candidates, such as those who help us conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected timelines, we may not be able to obtain regulatory approval for, or commercialize, our drug candidates, and our business could be materially harmed" in this section.

Interim and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data becomes available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary or top-line data from our preclinical studies and clinical trials, which is based on a preliminary analysis of then available data, whose results, related findings and conclusions are subject to changes following a more comprehensive review of such data. We also make assumptions, estimations, calculations and conclusions as part of our analyses progress, for which we may not necessarily receive or had the opportunity to fully and carefully evaluate all data. As a result, the top-line or preliminary results reported by us may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, top-line data should be viewed with caution until the final data are available.

We may also disclose interim data from our preclinical studies and clinical trials. Interim data from clinical trials that we may complete are subject to the risks that one or more of the clinical outcomes may materially change along with participant enrollment where more participant data become available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or our competitors could result in volatile [**REDACTED**] of our Shares after the [**REDACTED**].

Moreover, others may not accept or agree with our assumptions, estimates, calculations, conclusions analyses, or may interpret or weigh the importance of data differently, which could impact the value of our particular program, the approvability or commercialization of our particular product candidates.

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

We face an inherent risk of product liability as a result of the clinical trials and any future commercialization of our drug candidates inside and outside China. For example, we may be sued if our drug candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. 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 the claims, we may incur substantial liabilities or be required to limit commercialization of our drug candidates. Even successful defense would require significant financial and management resources.

Liability claims may result in decreased demand for our drug candidates, injury to our reputation, withdrawal of clinical trial participants and inability to continue clinical trials, initiation of investigations, costs to defend the related litigation, a diversion of management's time and our resources, substantial monetary awards to trial participants or patients, product recalls, withdrawals, or labeling, marketing or promotional restrictions, loss of revenue, exhaustion of any available insurance and our capital resources, the inability to commercialize any approved drug candidate, and a decline in the [**REDACTED**] of our Shares.

To cover such liability claims arising from clinical trials, we purchase clinical trial insurance to cover adverse events in our clinical trials. It is possible that our liabilities could exceed our insurance coverage or that our insurance will not cover all situations in which a claim against us could be made. We may not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired. Should any of these events occur, it could have a material adverse effect on our business, financial condition and results of operations.

RISKS RELATING TO MANUFACTURING OF OUR DRUG CANDIDATES

We have limited experience in manufacturing therapeutic biologic products on a large commercial scale, and our business could be materially and adversely affected if we encounter problems in manufacturing our future drug products.

As of the Latest Practicable Date, all of our drug candidates were in the research and development stage, and we mainly produce drugs that are used for preclinical studies and clinical trials. Moreover, the manufacturing of therapeutic biologics is highly complex. Problems may arise during manufacturing for a variety of reasons, including but not limited to:

- equipment malfunction;
- failure to follow specific protocols and procedures;
- changes in product specification;
- low quality or insufficient supply of raw materials;
- delays in the construction of new facilities or the expansion of our existing manufacturing facilities as a result of changes in manufacturing production sites and limits to manufacturing capacity due to regulatory requirements;
- changes in the types of drugs produced;
- advances in manufacturing techniques;
- physical limitations that could inhibit continuous supply; and
- man-made or natural disasters and other environmental factors.

Products with quality issues may have to be discarded, resulting in product shortages or additional expenses. This could lead to, among other things, increased costs, lost revenue, damage to customer relationships, time and expense spent investigating the cause and, depending on the cause, similar losses with respect to other batches or products. If problems are not discovered before the product is released to the market, recall and product liability costs may also be incurred.

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

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

In addition, the quality of our products, including drug candidates manufactured by us for research and development purposes and drugs manufactured by us for commercial use, depends significantly on the effectiveness of our quality control and quality assurance, which in turn depends on factors such as the production processes used in our manufacturing facilities, the quality and reliability of equipment used, the quality of our staff and related training programs and our ability to ensure that our employees adhere to our quality control and quality assurance protocol. However, we cannot assure you that our quality control and quality assurance procedures will be effective in consistently preventing and resolving deviations from our quality standards. We are, however, working on improving our documentation procedures for quality control and quality assurance activities. Any significant failure or deterioration of our quality control and quality assurance protocol could render our products unsuitable for use, jeopardize any GMP certifications we may have and/or harm our market reputation and relationship with business partners. Any such developments may have a material adverse effect on our business, financial condition and results of operations.

We may face damage to or disruption of our facilities, which could reduce or restrict our production capacity, or interrupt our development plans or commercialization efforts.

We currently manufacture our drug candidates for research and development purposes in Nanjing, China. Any interruption in manufacturing operations at our facilities could result in our inability to satisfy the demands of our clinical trials or commercialization. A number of factors could cause interruptions, including equipment malfunctions or failures, technology malfunctions, work stoppages, damage to or destruction of either facility due to natural disasters or other unanticipated catastrophic events, water shortages or fire, regional power shortages, product tampering or terrorist activities. Any disruption that impedes our ability to manufacture our drug candidates in a timely manner could materially harm our business, financial condition and results of operation.

If our manufacturing facilities or the equipment in them is damaged or destroyed, we may not be able to quickly or inexpensively replace our manufacturing capacity or replace it at all. In the event of a temporary or protracted loss of the facilities or equipment, we might not be able to transfer manufacturing to a third party. Even if we could transfer manufacturing to a third party, the shift would likely be expensive and time-consuming, particularly since the new facility would need to comply with the necessary regulatory requirements and we would need regulatory agency approval before selling any of our future approved drug candidates

manufactured at that facility. Such an event could delay our clinical trials or reduce our product sales if and when we are able to successfully commercialize one or more of our drug candidates. Any interruption in manufacturing operations at our manufacturing facilities could result in our inability to satisfy the demands of our clinical trials or commercialization. Any disruption that impedes our ability to manufacture our drug candidates in a timely manner could materially and adversely affect our business, financial condition, results of operations and prospects.

If our manufacturing facilities fail to meet the necessary quality standards, it could harm our business and reputation, and our revenue and profitability could be adversely affected.

Our manufacturing facilities are required to obtain and maintain regulatory approvals, and ongoing, periodic inspection to ensure compliance with GMP regulations. Further, we will be subject to continual review and inspections to assess compliance with GMP and adherence to commitments made in any NDA, other marketing application, and previous responses to any inspection observations. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. The regulations in the medical sector are relatively new and constantly evolving, and their interpretation and enforcement must be determined in accordance with the relevant laws and regulations in effect at the time. Due to the complexity of the regulatory environment and the occasional amendments to laws and regulations, we cannot assure you that our business will comply with future laws and regulations, or that we will always fully comply with applicable laws and regulations, and our failure in compliance may lead to significant delays in the availability of products for clinical or, in the future, commercial use, may result in the termination of or a hold on a clinical trial, or may delay or prevent filing or approval of marketing applications for our drug candidates or their commercialization, if approved. Failure to comply with applicable regulations could also result in sanctions being imposed on us, including fines, injunctions, civil penalties, a requirement to suspend or put on hold one or more of our clinical trials, failure to be granted with marketing approval of our drug candidates, delays, suspension or withdrawal of approvals, supply disruptions, license revocation, seizures or recalls of our drug candidates, operating restrictions and criminal prosecutions, any of which could harm our business.

In addition, to obtain the FDA approval for our products in the United States, we would need to undergo strict pre-approval inspections of our manufacturing facilities. When inspecting our manufacturing facilities, the FDA may cite GMP deficiencies. Remediating deficiencies can be laborious, time consuming and costly. Moreover, the FDA will generally re-inspect the facility to determine whether the deficiency was remediated to its satisfaction, and may note further deficiencies during re-inspection.

If we are unable to meet the increasing demand for our drug candidates and future drug products by ensuring that we have adequate manufacturing capacity, or if we are unable to successfully manage our anticipated growth or to precisely anticipate market demand, our business and financial condition would be materially and adversely affected.

To produce our drug candidates in the quantities that we believe will be required to meet anticipated market demand of our drug candidates, if approved, we will need to substantially increase, or scale up, the production process. If the scale up is delayed, the cost of this scale up is not economically feasible for us, or we cannot find a third-party supplier, we may not be able to produce our approved drug candidates in a sufficient quantity to meet future demand.

In anticipation of the commercialization of our drug candidates and market demand of our drug candidates, if approved, we may need to expand our manufacturing capacity. However, the timing and success of our capacity expansion are subject to significant uncertainty. Moreover, such plan is capital intensive and requires significant upfront investment, and there can be no assurance that we will be able to timely obtain such financing, if at all. Furthermore, we may not be able to fully utilize them immediately or within a reasonable period of time after we commence the operation. During the construction and ramp-up period, there may be significant changes in the biopharmaceutical industry, including, among others, market demand, product and supply pricing, and customer preferences. Any adverse trends in these respects could result in operational inefficiency and excess capacity in our manufacturing facilities. We may also experience various unfavorable events in the course of developing our new manufacturing facilities, such as:

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

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

RISKS RELATING TO COMMERCIALIZATION OF OUR DRUG CANDIDATES

The actual market size of our product candidates might be smaller than expected. Our drug candidates, once approved, may fail to achieve the degree of market acceptance by physicians, patients, third-party payers and others in the medical community that would be necessary for our drug candidates' commercial success.

Our drug candidates, once approved, may fail to gain sufficient market acceptance by physicians, patients, third-party payers and others in the medical community. Potential patients and their physicians may be inclined to use conventional standard-of-care treatments rather than trying out a novel approach. Further, given the novelty of our drug candidates, patients and medical personnel may need substantial education and training. In addition, physicians, patients and third-party payers may prefer other products to ours. If our drug candidates do not achieve an adequate level of acceptance, the commercialization of such drug candidates may become less successful or profitable than we had expected.

The degree of market acceptance of our drug candidates, if approved for commercial sales, will depend on a number of factors, including, but not limited to:

- the clinical indications for which our drug candidates are approved and the market demand for approved products that treat those indications;
- efficacy and safety of our drug candidates;
- the potential and perceived advantages of our drug candidates over alternative treatments;
- the prevalence and severity of any side effects;
- acceptance by physicians, operators of hospitals and clinics and patients of our products as a safe and effective treatment;
- product labeling or package insert requirements of regulatory authorities;
- limitations or warnings contained in the labeling approved by regulatory authorities;
- the timing of market introduction of our drug candidates as well as competitive drugs;
- the cost of treatment in relation to alternative treatments;
- the amount of upfront costs or training required for physicians to administer our drug candidates;

- the availability of adequate coverage, reimbursement and pricing by third-party payers and government authorities;
- price control or downward adjustment by the government authorities or other pricing pressure;
- the willingness of patients to pay out-of-pocket in the absence of coverage and reimbursement by third-party payers and government authorities;
- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies;
- adverse publicity about our products or favorable publicity about competitive products; and
- the effectiveness of our sales and marketing efforts.

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

If we are unable to build and manage sales network, or maintain sufficient sales and marketing capabilities, either by ourselves or through third parties, we may not be able to successfully create or increase market awareness of our products or sell our products, which will materially affect our ability to generate product sales revenue.

We have not yet demonstrated an ability to launch and commercialize any of our drug candidates. Our ability to successfully commercialize our drug candidates may involve more inherent risk, take longer, and cost more than it would if we were a company with experience in launching and marketing drug candidates. We will be competing with many companies that currently have commercialization teams and extensive sales and marketing operations. With limited experience in sales and marketing, we may be unable to compete successfully against these more established companies.

In the long term, if we intend to distribute our products worldwide, we would need to develop and expand our in-house marketing organization and sales force, which will require significant expenditures, management resources and time. We will have to compete with other pharmaceutical companies to recruit, hire, train and retain marketing and sales personnel.

If we are unable to, or decide not to, further develop internal sales, marketing and commercial distribution capabilities, we will likely pursue collaborative arrangements regarding the sales and marketing of our drugs. However, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or if we are able to do so, that they will have effective sales forces. Any revenue we receive will depend upon the efforts of such third parties. We would have little or no control over the marketing and sales efforts of such third parties, and our revenue from product sales may be lower than if we had commercialized our drug candidates ourselves. We will also face competition in our search for third parties to assist us with the sales and marketing efforts for our drug candidates.

There can be no assurance that we will be able to successfully develop and maintain in-house sales and commercial distribution capabilities or establish or maintain relationships with third-party collaboration partners to successfully commercialize any product, and as a result, we may not be able to generate product sales revenue.

The illegal and/or counterfeit pharmaceutical products may reduce demand for our drug candidates, which could have a negative impact on our reputation and business.

The illegal import of similar or competing products from countries where government price controls or other market dynamics result in lower prices may adversely affect the demand for our future approved drug candidates and, in turn, may adversely affect our sales and profitability in the jurisdictions where we plan to commercialize our drug candidates. Illegal imports of prescription drugs may continue to occur or even increase as the ability of patients and other customers to obtain these lower priced imports continues to grow. Furthermore, cross-border imports from lower-priced markets (parallel imports) into higher-priced markets could harm sales of our drugs and exert commercial pressure on pricing within one or more markets. Any future legislation or regulations that increase consumer access to lower priced imported medicines where we operate could have a material adverse effect on our business.

Certain pharmaceutical products distributed or sold in our target markets may be manufactured without proper licenses or approvals, or are fraudulently mislabeled with respect to their usage or manufacturers. Since counterfeit pharmaceutical products in many cases have very similar appearances compared with the authentic pharmaceutical products but are generally sold at lower prices, counterfeits of our products can quickly erode the demand for our future approved drug candidates.

Counterfeit pharmaceutical products are unlikely to meet our or our collaboration partners' rigorous manufacturing and testing standards and may even cause health damage to patients. Our reputation and business could suffer harm as a result of counterfeit pharmaceutical products sold under our or our collaboration partners' brand name(s). In addition, theft of inventory at warehouses, plants or while in-transit, which is not properly stored and which is sold through unauthorized channels, could adversely impact patient safety, our reputation and our business.

If safety, efficacy, or other issues arise with any medical product that is used in combination with our drug candidates, we may be unable to market such drug candidates or may experience supply shortages or be subjected to regulatory measures, and our business could be materially harmed.

We plan to develop certain of our drug candidates for use as combination therapies. Combination therapy development carries a higher risk of failure compared to single agent development due to greater risk of combined drug toxicity as well as lower efficacy due to drug-drug interactions as well as toxicity limitations on efficacy. The development risks of failure are even higher if both agents are investigational. There are additional regulatory requirements for combination development to ensure patient safety during development, including the requirement for separate combination IND review and the trial designs which are also more complex and require close monitoring. If any regulatory agency revokes its approval of any pharmaceutical products or therapy we intend to use in combination with our drug candidates, we will be forced to terminate or re-design the clinical trials, or will not be able to market our drug candidates in combination with such revoked pharmaceutical products or therapies. If safety or efficacy issues arise with these or other therapies that we seek to combine with our drug candidates in the future, we may be subjected to regulatory measures, and we may be required to redesign or terminate the relevant clinical trials. In addition, if manufacturing or other issues result in a supply shortage of any component of our combination drug candidates, we may not be able to complete clinical development of our drug candidates on our current timeline, or at all.

Guidelines, recommendations and studies published by various organizations could 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 our or our competitors' drugs and drug candidates. Any such guidelines, recommendations or studies that reflect negatively on our drug candidates, either directly or indirectly relative to our competitive drug candidates, could result in current or potential decreased use of, sales of, and revenues from one or more of our drug candidates. Furthermore, our success depends in part on our ability to educate healthcare providers and patients about our drug candidates, and these education efforts could be rendered ineffective by, among other things, third parties' guidelines, recommendations or studies.

The national, provincial and other third party drug reimbursement practices and drug pricing policies or regulations are evolving from time to time, which could impact our business.

The regulations that govern regulatory approvals, pricing and reimbursement for medical products vary widely from country to country. Our ability to commercialize any drug candidates will depend in part on the extent to which reimbursement for these drugs and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payers may control costs by limiting coverage and the amount of reimbursement for particular medications.

The national or local medical insurance catalogs, as well as drug reimbursement lists are reviewed and updated regularly, which affects the amounts reimbursable to program participants for their purchases of drugs. There can be no assurance that any of our future approved drugs will be included in the national, provincial or local medical insurance catalogs. Drugs or medical products included in the national, provincial or local medical insurance catalogs are generally generic and essential drugs. Innovative drugs similar to our drug candidates have historically been more limited on their inclusion in such medical insurance catalogs. Even if our drug candidates have already obtained regulatory approval, any adverse pricing limitations may hinder our ability to recoup our investment in one or more drug candidates.

In the U.S., no uniform policy of coverage and reimbursement for drugs exists among third-party payers. As a result, obtaining coverage and reimbursement approval of a drug from a government or other third-party payer is a time-consuming and costly process that could require us to provide to each payer supporting scientific, clinical and cost-effective data for the use of our future approved drugs on a payer-by-payer basis, with no assurance that coverage and adequate reimbursement will be obtained. Even if we obtain coverage for a given drug, the resulting reimbursement rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Additionally, third-party payers may not cover, or provide adequate reimbursement for, long-term follow-up evaluations required following the use of our future approved drugs. Patients are unlikely to use any of our future approved drugs unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of the drugs. Because some of our drug candidates have a higher cost of goods than conventional therapies, and may require long-term follow-up evaluations, the risk that coverage and reimbursement rates may be inadequate for us to achieve profitability may be greater.

Increasingly, third-party payers are requiring that companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any approved drug candidates that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Reimbursement may impact the demand for, or the price of, any approved drug candidates that we commercialize. Obtaining or maintaining reimbursement for our future approved drugs may be particularly difficult because of the higher prices often associated with drugs administered under the supervision of a physician. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any drug candidates that we successfully develop.

There may be delays in obtaining reimbursement for approved drug candidates, and coverage may be more limited than the purposes for which the drug candidates are approved by the regulatory authorities. Moreover, eligibility for reimbursement 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, sale and distribution. Interim payments for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Payment rates may vary according to the use of the drug and the clinical setting in which it is

used, may be based on payments allowed for lower cost drugs that are already reimbursed, and may be incorporated into existing payments for other services. Net prices for drugs may be reduced for rebates required by government healthcare programs or private payers. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payers for any future approved drug candidates and any new drugs that we develop could have a material adverse effect on our business, our operating results, and our overall financial condition.

RISKS RELATING TO OUR INTELLECTUAL PROPERTY RIGHTS

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

Our success depends in large part on our ability to protect our proprietary technologies and drug candidates from competition by obtaining, maintaining, defending and enforcing our intellectual property rights, including patent rights. We seek to protect the drug candidates and technology that we consider commercially important by filing patent applications relying on trade secrets or pharmaceutical regulatory protection or employing a combination of these methods. In particular, we have sought patents for our core and major products. For further information on our patent portfolio, see "Business — Intellectual Property" in this document. If we or our collaborators are unable to obtain and maintain patent and other intellectual property protection with respect to our drug candidates and technologies, our business, financial condition, results of operations and prospects could be materially harmed.

The patent prosecution process is expensive, time-consuming and complex, and we may not be able to file, prosecute, maintain, defend, enforce or license all necessary or desirable patents at a reasonable cost or in a timely manner in all desirable jurisdictions. As a result, we may not be able to prevent competitors or other third parties from developing and commercializing competitive drugs in all such fields and jurisdictions. Moreover, some of our patent applications may in the future be co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Furthermore, the patent position of pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain.

There is no uniform requirement or standard on patentability. Many jurisdictions have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many jurisdictions limit the enforceability of patents against government agencies or government contractors. In these jurisdictions, the patent owner may have limited remedies, which could materially diminish the value of such patents. If we or any of our collaborators are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be materially impaired and our business, financial condition, results of operations, and prospects may be adversely affected.

Patents may be invalidated and patent applications may not be granted for a number of reasons, including known or unknown prior art, deficiencies or defects in the patent applications or lack of novelty or an inventive step of the underlying invention or technology. As of the Latest Practicable Date, we owned 14 issued patents and 119 pending patent applications. We cannot assure you that all of these patent applications will be granted. For further information on our patent portfolio, see "Business — Intellectual Property" in this document. It is also possible that we will fail to identify patentable subject matter 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 subject matter of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, 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 the U.S. and other jurisdictions are typically not published until 18 months after filing, or in some cases, not at all. Therefore, we cannot be certain that we or our collaborators were the first to make the inventions claimed in our owned or licensed patents or pending patent applications or that we or our collaborators 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. If a third party can establish that we were not the first to file for patent protection of such inventions, our owned or licensed patent applications may not issue as patents and even if issued, may be challenged and invalidated or ruled unenforceable, and third parties may be granted a patent relating to a technology which we invented.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged. We may be subject to a third-party pre-issuance submission of prior art, or become involved in post-grant proceedings such as opposition, derivation, revocation and re-examination, or *inter partes* review, or interference proceedings or similar proceedings in foreign jurisdictions challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology, products or drug candidates and compete directly with us. Moreover, we may have to participate in interference proceedings declared by the intellectual property offices to determine priority of invention or in post-grant challenge proceedings, such

as oppositions in a foreign patent office, that challenge the priority of our invention or other features of patentability of our patents and patent applications. Such challenges may result in loss of patent rights, loss of exclusivity, or in patent claims being narrowed, invalidated, or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology, products and drug candidates. Such proceedings also may result in substantial costs and require significant time from our scientists, experts and management, even if the eventual outcome is favorable to us. Consequently, we do not know whether any of our technologies, products or drug candidates will be protectable or remain protected by valid and enforceable patents globally. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner.

Filing, prosecuting, maintaining, defending and enforcing patents and other intellectual property rights with respect to our drug candidates in all other jurisdictions throughout the world would be prohibitively expensive for us. Our intellectual property rights in certain jurisdictions may have a lessor or different scope and strength compared to those in our target markets. In addition, the laws of certain jurisdictions do not protect intellectual property rights to the same extent as the laws of our target markets. Consequently, in some cases, we may not be able to obtain issued patents or other intellectual property rights covering our drug candidates in jurisdictions outside our target markets and, as a result, we may not be able to prevent third parties from using our inventions in all jurisdictions outside our target markets, or from selling or importing drugs made using our inventions in and into our target markets or other jurisdictions. Competitors and other third parties may use our technologies in jurisdictions where we have not pursued and obtained patent and other intellectual property protection to develop their own drugs and further, may export otherwise infringing drugs to jurisdictions where we have patents or other intellectual property protection. These drugs may compete with our drug candidates and our patent rights or other intellectual property rights may not be effective or adequate to prevent them from competing.

Legal systems in certain jurisdictions may not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to pharmaceutical biotechnology products, which could make it difficult for us to stop the infringement, misappropriation or other violation of our patents or other intellectual property rights, or the marketing of competing drugs in violation of our proprietary rights in these jurisdictions. Proceedings to enforce our patent and other intellectual property rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents and other intellectual property rights at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a commercial advantage from the intellectual property that we develop or license. Any of the foregoing could have adverse impact our competitive position, business, financial conditions, results of operations and prospects.

Even if we obtain patent protection for our drug candidates, the term of such protection, if any, is limited, and third parties could develop and commercialize products and technologies similar or identical to ours and compete directly against us after the expiration of our patent rights, if any, and our ability to successfully commercialize any product or technology would be materially and adversely affected.

Although various adjustments and extensions may be available, the term of a patent, and the protection it affords, is limited. Even if we successfully obtain patent protection for a drug candidate, such drug candidate may face competition from generic or biosimilar medications once the patent has expired. Manufacturers of generic or biosimilar drugs may challenge the scope, validity or enforceability of our patents in court or before a patent office; thus, we may not be successful in enforcing or defending those intellectual property rights and, as a result, may not be able to develop or market the relevant drug candidate exclusively, which would have a material adverse effect on any potential sales of that drug candidate. The issued patents and pending patent applications, if issued, for our drug candidates are expected to expire on various dates. For the expiration dates of our issued patents for our drug candidates, see "Business – Intellectual Property" in this document. Upon the expiration of our issued patents or patents that may issue from our pending patent applications, we will not be able to assert such patent rights against potential competitors and our business and results of operations may be adversely affected.

Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such drug candidates might expire before or shortly after such drug candidates are commercialized. As a result, our patents and patent applications may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours, which could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects. Moreover, some of our patents and patent applications are, and may in the future be, co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing drugs and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing events could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time-consuming and unsuccessful.

Competitors or other third parties may challenge the ownership, validity and enforceability of our patents, infringe, misappropriate or otherwise violate our other intellectual property rights. To counter infringement, misappropriation or any other unauthorized use, litigation may be necessary in the future to enforce or defend our intellectual property rights, to protect our trade secrets or to determine the validity and scope of our own intellectual property rights or the proprietary rights of others. Litigation and other proceedings

in connection with any of the foregoing claims can be expensive and time-consuming and, even if resolved in our favor, may cause us to incur significant expenses and could distract management and our scientific and technical personnel from their normal responsibilities. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Any claims that we assert against perceived infringers and other violators could also provoke these parties to assert counterclaims against us alleging that we infringe, misappropriate or otherwise violate their intellectual property rights. Many of our current and potential competitors have the ability to dedicate substantially greater resources to enforce and defend their intellectual property rights than we can. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon, misappropriating or otherwise violating our intellectual property rights. An adverse result in any litigation proceeding could put our patent, as well as any patents that may issue in the future from our pending patent applications, at risk of being invalidated, held unenforceable or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. Thus, even if we were to ultimately prevail, or to settle at an early stage, such litigation could burden us with substantial unanticipated costs.

Moreover, we may not be able to uncover infringement against our patents. Even if we uncover infringement by a third party of any of our patents, we may choose not to pursue litigation against or settlement with such third party. If we later sue such third party for patent infringement, the third party may have certain legal defenses available to it, which otherwise would not be available except for the delay between when the infringement was first uncovered and when the suit was brought. Such legal defenses may make it impossible for us to enforce our patents against such third party.

Although we believe that we have conducted our patent prosecution in accordance with the duty of candor and in good faith, the outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity of our patents, for example, we cannot be certain that there is no invalidating prior art of which we, our collaboration partner, our or their patent counsel and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our drug candidates, leave our technology or drug candidates without patent protection, allow third parties to commercialize our technology or drug candidates and compete directly with us, without payment to us, or could require us to obtain license rights from the prevailing party in order to be able to manufacture or commercialize our drug candidates without infringing third party patent rights. Even if a defendant does not prevail on a legal assertion of invalidity or unenforceability, our patent claims may be construed in a manner that would limit our ability to enforce such claims against the defendant and others.

Moreover, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize our drug candidates. We may also be subject to claims that former employees, collaborators or other third parties have an interest in our owned or in-licensed (if any in the future) patents, patent applications, trade secrets or other intellectual property as an inventor or co-inventor. For example, we may have ownership or inventorship disputes arising from conflicting obligations of employees, consultants or others who are involved in developing our drug candidates or technology. Litigation may be necessary to defend against these and other claims challenging ownership or inventorship of our owned or in-licensed patents, patent applications, trade secrets or other intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of or right to use intellectual property that is important to our drug candidates. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

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

Our commercial success depends in part on our ability to avoid infringing, misappropriating, or otherwise violating intellectual property rights of third parties. However, our efforts to identify and avoid infringing on third parties' intellectual property rights may not always be successful. Defending ourselves against third parties' intellectual right infringement allegations, meritorious or not, would be expensive and time consuming, and would be a substantial diversion of our resources and our management team's attention. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, some of our confidential information could be compromised by disclosure during this type of litigation.

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

We may not be able to enjoy additional protection over drug-related patents in the U.S.

In the United States, the Federal Food Drug and Cosmetic Act, as amended by the law generally referred to as "Hatch-Waxman", provides the opportunity for limited patent term extension. Hatch-Waxman permits a patent-term restoration that provides a patent term extension of up to five years to reflect patent term lost during certain portions of product development and the FDA regulatory review process. However, a patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of drug approval; only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. The application for the extension must be submitted prior to the expiration of the patent for which extension is sought. A patent that covers multiple products for which approval is sought can only be extended in connection with one of the approvals. Depending upon the timing, duration and specifics of any FDA marketing approval process for any drug candidates we may develop, one or more of our U.S. patents may be eligible for limited patent term extension under Hatch-Waxman. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable period or the scope of patent protection afforded could be less than we request. In addition, to the extent we wish to pursue patent term extension based on a patent that we in-license from a third party, we would need the cooperation of that third party. If we fail to obtain patent term extensions or if the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and thus our revenue could be reduced.

Hatch-Waxman also has a process for patent linkage, pursuant to which the FDA will stay approval of certain follow-on applications during the pendency of litigation between the follow-on applicant and the patent holder or licensee, generally for a period of 30 months. Moreover, Hatch-Waxman provides for statutory exclusivities that can prevent submission or approval of certain follow-on marketing applications. For example, Hatch-Waxman provides a five-year period of exclusivity within the U.S. to the first applicant to obtain approval of a new chemical entity and three years of exclusivity protecting certain innovations to previously approved active ingredients where the applicant was required to conduct new clinical investigations to obtain approval for the modification. Similarly, the U.S. Orphan Drug Act provides seven years of market exclusivity for certain drugs to treat rare diseases, where the FDA designates the drug candidate as an orphan drug and the drug is approved for the designated orphan indication. However, we may not be able to enjoy those benefits if we fail to apply for them according to the FDA's relevant requirements.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our trademark registrations and trademark applications may be the subject of a governmental or third-party objection, which could prevent the registration or maintenance of the same. We cannot assure you that any currently pending trademark applications or any trademark applications we may file in the future will be approved. During trademark registration proceedings, we may receive rejections and although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in proceedings of many jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancelation proceeding may be filed against our trademarks and our trademarks may not survive such proceedings. If we are unsuccessful in obtaining trademark protection for our primary brands, we may be required to change our brand names, which could materially and adversely affect our business. Moreover, as our products mature, our reliance on our trademarks to differentiate us from our competitors will increase, and as a result, if we are unable to prevent third parties from adopting, registering or using trademarks 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 and adversely affected.

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed. We may be subject to claims that our employees, consultants or 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.

In addition to our issued patents and pending patent applications, we rely on our trade secrets and confidential information, including unpatented know-how, technology and other proprietary information, to maintain our competitive position and to protect our drug candidates. We seek to protect our trade secrets and confidential information, in part, by entering into non-disclosure and confidentiality agreements with parties that have access to

trade secrets or confidential information, such as our employees, corporate collaboration partners, outside scientific collaboration partners, sponsored researchers, contract manufacturers, consultants, advisors and other third parties that have access to them.

However, we may not be able to prevent the unauthorized disclosure or use of our trade secrets and confidential information by the parties to these agreements. Monitoring unauthorized uses and disclosures is difficult and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. Any of the parties with whom we enter into confidentiality agreements may breach the terms of any such agreements and may disclose our proprietary information, and we may not be able to obtain adequate remedies for any such breach or violation. As a result, we could lose our trade secrets and third parties could use our trade secrets to compete with our drug candidates and technology. Additionally, we cannot guarantee that we have entered into such agreements with each party that may have or has had access to our trade secrets or proprietary technology and processes. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome is unpredictable. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us and our competitive position would be harmed.

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

While we typically require our employees, consultants and contractors who may be involved in the conception or 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, even when we obtain agreements assigning intellectual property to us, 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 to determine the ownership of what we regard as our intellectual property. Furthermore, individuals executing agreements with us may have

pre-existing or competing obligations to a third party, such as an academic institution, and thus an agreement with us may be ineffective in perfecting ownership of inventions developed by that individual. 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 any of the foregoing claims, litigation could result in substantial costs and be a distraction to our management and scientific personnel.

In addition, we may in the future be subject to claims by former employees, consultants or other third parties asserting an ownership right in our owned or licensed patents or patent applications. An adverse determination in any such submission or proceeding may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar drug candidates or technology, without payment to us, or could limit the duration of the patent protection covering our drug candidates and technology. Such challenges may also result in our inability to develop, manufacture or commercialize our drug candidates without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our owned patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future drug candidates. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

Intellectual property laws and regulations are subject to change, which could impact the value of our intellectual property and impair the intellectual property protection of our drug candidates.

Our success is heavily dependent on obtaining, maintaining, enforcing and defending intellectual property rights, particularly patents. Obtaining and enforcing patents in the pharmaceutical and biopharmaceutical industry involves technological and legal complexity and is costly, time-consuming and inherently uncertain. Changes in either the patent laws or their interpretations may increase the uncertainties and costs surrounding the prosecution of our patents, diminish our ability to protect our inventions, and, more generally, affect the value of our intellectual property or narrow the scope of our patent rights.

Under the America Invents Act, enacted in 2011, the United States moved to first-to-file system in early 2013 from the previous system under which the first to make the claimed invention was entitled to the patent. Assuming the other requirements for patentability are met, the first to file a patent application is entitled to the patent. Publications of discoveries in the scientific literatures often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. 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. The Standing Committee of the National People's Congress revised the Patent Law of the PRC on October 17, 2020, which entered into force on June 1, 2021. Comparison with the Patent Law of the PRC revised on December 27, 2008 and effective October 1, 2009, the major changes in the Patent Law of the PRC (revised in 2020)

are focused on the following: (i) clarification of the incentives for inventors or designers of subject inventions; (ii) extension of the term for industrial designs; (iii) establishment of a new "open license" system; (iv) improve the allocation of the burden of proof in patent infringement cases; and (v) improve damages for patent infringement. We cannot guarantee that any other changes to intellectual property laws would not have a negative impact on our intellectual property protection.

We may not be successful in obtaining or maintaining necessary rights for our development pipeline through acquisitions and/or in-licenses.

Our pipeline portfolio includes an acquired drug candidate IBC0966, and may involve additional drug candidates that require the use of proprietary rights held by third parties, and we have obtained and may need to further acquire and maintain licenses or other rights to use these proprietary rights. However, we may be unable to acquire or in-license any compositions, methods of use or other intellectual property rights from third parties that we identify. We also face risks relating to disputes or claims from the contracting parties, including with the local government, if we do not invest in such projects in a timely manner in accordance with the terms of the aforementioned agreements, which may adversely impact our research and development progress, reputation, financial conditions and results of operations.

The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider suitable or necessary. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights, we may have to abandon development of the relevant program or drug candidates, which could have a material adverse effect on our business, financial condition, results of operations and prospects for growth.

Patent protection depends on compliance with various procedural, regulatory and other requirements, and our patent protection could be reduced or eliminated due to non-compliance with those requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and patent applications are due to be paid to the CNIPA, USPTO and other patent agencies in several stages over the lifetime of a patent. The CNIPA, USPTO and other similar governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application and maintenance process. Although an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application,

resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In any such event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

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

The intellectual property legal systems vary across different countries and regions, introducing uncertainty to the protection of corporate intellectual property. The intellectual property protection in various countries has its limitations, which may be insufficient to fully safeguard our business or enable us to maintain a competitive edge. The limitations of the intellectual property protection system include:

- others may be able to make products that are similar to any of our drug candidates or utilize similar or alternative technology that are not covered by the claims of the patents that we own or have exclusively licensed now or in the future;

- we or our current or future collaboration partners might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or may license in the future;

- we or our current or future collaboration partners might not have been the first to file patent applications covering certain of our or their inventions, which could result in the patent applications not issuing or being invalidated after issuing;

- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing, misappropriating or otherwise violating our intellectual property rights;

- it is possible that our pending patent applications or those that we may own in the future will not lead to issued patents;

- patents that may be issued from our pending patent applications may not provide us with any competitive advantages, or may be held invalid or unenforceable, including as a result of legal challenges by our competitors;

- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;

- we may obtain patents for certain compounds many years before we obtain marketing approval for products containing such compounds, and because patents have a limited life, which may begin to run prior to the commercial sales of the related product, the commercial value of our patents may be limited;

- the proprietary technologies on which we rely may not be patentable;

- the patents of others may materially and adversely affect our business; and

- we may choose not to file a patent for certain trade secrets or know-how, yet a third party may subsequently file a patent covering such intellectual property.

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

RISKS RELATING TO OUR FINANCIAL POSITION AND NEED FOR ADDITIONAL CAPITAL

We have a limited operating history and have incurred net losses since inception. We expect to continue to incur net losses for the foreseeable future and may not be able to generate sufficient revenue to achieve or maintain profitability.

Investment in the development of pharmaceutical products is highly speculative as it requires substantial upfront capital expenditures and involves significant risks that a drug candidate may fail to demonstrate efficacy or safety to gain regulatory or marketing approvals or become commercially viable. During the Track Record Period, we had financed our operating activities primarily through capital contributions from our shareholders, private equity financing and loans.

While we have other sources of income, we had not generated any revenue from commercialization of our drug candidates during the Track Record Period, and had incurred, and may continue to incur, significant research and development expenses and other expenses related to our ongoing operations. For the years ended December 31, 2022 and 2023, we had loss and total comprehensive expenses of RMB52.0 million and RMB132.7 million, respectively. Our ability to generate revenue will depend primarily on the success of the regulatory approval, manufacturing, and commercialization of the drug candidates, which is subject to significant uncertainty. Even if we obtain regulatory approval to market our drug candidates, our future revenue will depend upon other factors such as the market size for the proposed indications of our drug candidates, and our ability to achieve sufficient market acceptance.

We expect to continue to incur significant expenses and losses for the foreseeable future. We anticipate that our expenses will increase significantly if and as we:

- continue to advance the clinical trials and preclinical studies of our drug candidates;
- initiate preclinical, clinical or other studies for new drug candidates;
- construct new manufacturing facilities;
- seek regulatory approvals for our drug candidates to complete clinical development and commence commercialization;
- commercialize our drug candidates for which we have obtained marketing approvals;
- attract and retain skilled personnel, and grant equity-settled awards to our employees under our share incentive schemes;
- develop and expand our commercialization team to commercialize any drug candidates in our pipeline for which we may obtain regulatory approval;
- maintain, protect, expand and enforce our intellectual property portfolio;
- enforce and defend any intellectual property-related claims; and
- acquire or in-license other drug candidates, intellectual property assets and technologies.

The amount of our future net losses will depend, in part, on our future expenses resulted from costs and expenses incurred by our research and development programs and in relation to our operations, the cost of commercializing any approved drug candidates, our ability to generate revenues, and the timing and amount of milestone and other payments we make or receive with or through arrangements with third parties. If any of our drug candidates fails during clinical trials or does not obtain regulatory approval, or, even if approved, fails to achieve market acceptance, our business may not become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods thereafter. Our prior losses and expected future losses have had, and will continue to have, an adverse effect on our working capital and shareholders' equity.

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

We had a total deficit of RMB1.5 million and RMB104.1 million as of December 31, 2022 and 2023, respectively, and we had net current liabilities of RMB51.5 million and RMB160.5 million as of December 31, 2022 and 2023, respectively. A total deficit can expose us to the risk of shortfalls in liquidity. This in turn would require us to seek adequate financing from sources such as external debt or issuance of our equity interest, which may not be available on terms favorable or commercially reasonable to us or at all. While we believe we have sufficient working capital to fund our current operations, we may have net liabilities for the foreseeable future. If we are unable maintain adequate working capital or obtain sufficient equity or debt financings to meet our capital needs, we may be unable to continue our operations according to our plans and be forced to scale back our operations, which may have a material adverse effect on our business, financial condition, results of operations and prospects.

We had net cash outflow from operating activities during the Track Record Period and may continue to experience net operating cash outflow for the foreseeable future.

During the Track Record Period, our operations have consumed a substantial amount of cash, and accordingly our net cash used in operating activities was RMB34.6 million and RMB40.7 million for the years ended December 31, 2022 and 2023, respectively. While we believe we have sufficient working capital to cover at least 125% of our costs, for at least the next 12 months from the date of this document, we expect that we may continue to experience net cash outflows from our operating activities for the foreseeable future. If we are unable to maintain adequate working capital, we may default on our payment obligations such as the milestone payments to CROs, be unable to meet our capital expenditure requirements, be forced to scale back our operations, and/or experience other negative impacts on our operations, which may have a material adverse effect on our business, financial condition, results of operations and prospects.

Uncertainty over the fair value changes in our Shares and related valuation may materially affect our financial performance and results of operations.

As of December 31, 2022 and 2023, our financial liabilities at FVTPL amounted to nil and RMB311.5 million, respectively. The preferred shares issued to our Pre-[**REDACTED**] Investors are classified as financial liabilities at FVTPL in the consolidated statements of financial position. In addition, the fair value change of the preferred shares shall be charged to fair value change of financial liabilities in profit or loss, and therefore, directly affecting our financial performance and results of operations.

The estimated changes in fair value involve the exercise of professional judgment and the use of certain bases, assumptions and unobservable inputs, which, by their nature, are subjective and uncertain. As such, the financial liabilities valuation has been, and will continue to be, subject to uncertainties in accounting estimation, which may not reflect the actual fair value of these financial liabilities and result in significant fluctuations in profit or loss from

year to year, which could materially and adversely affect our financial performance and results of operations. The financial liabilities of such Shares will be derecognized and credit to equity as a result of the automatic conversion into ordinary shares upon the [**REDACTED**], after which we do not expect to recognize any further loss or gain on fair value changes from the convertible redeemable preferred shares.

Our financial performance during the Track Record Period was affected by certain non-recurring items.

Our financial results during the Track Record Period were affected by certain non-recurring items. During the Track Record Period, we received subsidies for our research and development activities from local governmental authorities. In 2022 and 2023, we recorded government grants of RMB0.1 million and RMB17.3 million, respectively. We are typically required to meet certain requirements or standards to be qualified to receive such government grants and the timing and amount of each grant, if any, are out of our control. Since these events are non-recurring in nature, we cannot assure you that we may record such other income in future periods and our financial performance may be adversely affected.

We may need to obtain additional financing to fund our operations even if we consummate the [REDACTED], and if we fail to obtain such financing, we may be unable to complete the development and commercialization of our primary drug candidates.

We may require additional cash resources to meet our continued operating cash requirements in the future, especially to fund our research and development activities. Our cash operating costs mainly consist of costs relating to R&D of our product candidates, including contract research expenses, staff costs, material consumed, application fees and others. For details of our cash operating costs, see "Financial Information — Cash Operating Costs" in this document. We expect to continue to spend substantial amounts of cash on drug discovery, advancing the clinical development of our drug candidates, and launching and commercializing any drug candidates for which we receive regulatory approval. If the financial resources available to us after [**REDACTED**] are insufficient to satisfy our cash requirements, we may seek additional funding through equity offerings, debt financings, collaborations and licensing arrangements. It is uncertain whether financing will be available in the amounts or on terms acceptable to us, if at all. If we were not able to obtain additional capital to meet our cash requirements in the future, our business, financial condition, results of operations and prospects could be materially and adversely affected.

We recognized a certain scale intangible assets during the Track Record Period. If we determine our intangible assets to be impaired, it would adversely affect our financial condition and results of operations.

We recorded intangible assets of RMB10.0 million and RMB10.0 million as of December 31, 2022 and 2023, respectively. For details of such intangible assets, see note 17 to the Accountants' Report in Appendix I to this document. Although we did not recognize impairment losses in respect of intangible assets during the Track Record Period, such

intangible assets is tested impairment annually based on the recoverable amount of the cash-generating unit to which the intangible asset is related. For details on the impairment assessment methods for our intangible assets, see note 19 to Appendix I to the Accountants' Report in this document. If we determine our intangible assets to be impaired, it would adversely affect our financial condition and results of operations.

Our results of operations, financial condition, and prospects may be adversely affected by fair value changes and credit risk associated with our financial assets at fair value through profit or loss.

During the Track Record Period, we had certain financial assets at fair value through profit or loss. We are exposed to risks in relation to the financial assets, which may adversely affect our net changes in their fair value. The financial assets at fair value through profit or loss are stated at fair value, and net changes in their fair value are recorded as other income or losses, and therefore directly affect our results of operations. We cannot assure you that market conditions and regulatory environment will create fair value gains and we will not incur any fair value losses on our financial assets at fair value through profit or loss in the future. If we incur such fair value losses, our results of operations, financial condition and prospects may be adversely affected.

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

We implemented share incentive plans during the Track Record Period. For the years ended December 31, 2022 and 2023, we incurred share-based payment expenses of RMB2.0 million and RMB30.1 million, respectively. To further incentivize our employees and non-employees to contribute to us, we may grant additional share-based compensation in the future. We established Sunho Stellar, an incentive platform, to provide incentives to certain eligible employees and directors. For details, see "History, Reorganization and Corporate Structure — Adoption of RSU Scheme" in this document. Issuance of additional Shares with respect to such share-based payment may dilute the shareholding percentage of our existing Shareholders. Expenses incurred with respect to such share-based payment may also increase our operating expenses and therefore have a negative effect on our financial performance.

Fluctuations in exchange rates could result in foreign currency exchange losses.

The change in the value of currencies may fluctuate and is affected by, among other things, changes of the relevant political and economic conditions and foreign exchange policies. Most of our costs, our assets (including cash and cash equivalents) will be denominated in a different currency from Hong Kong dollars, the currency that denominates our [**REDACTED**] from the [**REDACTED**]. Any significant change in the related exchange rates may adversely affect the value of and any dividends payable on, our Shares in Hong Kong dollars.

RISKS RELATING TO OUR OPERATIONS

Any failure to comply with applicable regulations and industry standards or obtain or renew certain approvals, various licenses and permits could harm our reputation and our business, results of operations and prospects.

A number of governmental agencies or industry regulatory bodies in the PRC, the U.S. and other applicable jurisdictions impose strict rules, regulations and industry standards governing biopharmaceutical research and development activities, which apply to us. Our or our CROs' failure to comply with such regulations could result in the termination of ongoing research, administrative penalties imposed by regulatory bodies or the disqualification of data for submission to regulatory authorities. This could harm our business, reputation, prospects for future work and results of operations. For example, if we or our CROs were to treat research animals inhumanely or in violation of international standards set out by the Association for Assessment and Accreditation of Laboratory Animal Care, it could revoke any such accreditation and the accuracy of our animal research data could be questioned.

Pursuant to relevant laws and regulations, we are required to obtain, maintain and renew various approvals, licenses, permits and certificates from relevant authorities to operate our business. Some of these approvals, permits, licenses and certificates are subject to periodic renewal and/or reassessment by the relevant authorities, and the standards of such renewal and/or reassessment may change from time to time. Any failure to obtain or renew any approvals, licenses, permits and certificates necessary for our operations may result in enforcement actions thereunder, including being required to take remedial actions, suspend our operations or bear fines and penalties which could materially and adversely affect our business, financial condition and results of operations. During the Track Record Period, the owner of our leased property did not obtain the sewage disposal drainage license because the industrial park where our lease property is located was under construction which resulted in the application review and approval process being temporarily put on hold. As of the Latest Practicable Date, we had not received any order of correction or any fines or penalties from the competent authority as a result of any such failure. Furthermore, as confirmed by the competent authorities, we will not be subject to penalties or encounter business suspension due to the leased property owner's failure to timely obtain such license. As advised by our PRC Legal Adviser, the likelihood that we are subject to penalties or orders to suspend or shutdown operations by the competent authority due to the leased property owner's failure to timely obtain such license during the Track Record Period is relatively low, based on the interviews with competent authorities. Furthermore, if the interpretation or implementation of existing laws and regulations changes or new regulations come into effect, we may be required to obtain any additional approvals, permits, licenses or certificates and we cannot assure you that we will be able to do so. Our failure to obtain the additional approvals, permits, licenses or certificates may restrict the conduct of our business, increase our costs, and in turn, adversely affect results of operations and prospects.

The loss of any key members of our senior management team or our inability to attract and retain highly skilled scientists, clinical and sales personnel could adversely affect our business.

Our commercial success depends significantly on the continued service of our senior management. For more details of our senior management, see "Directors and Senior Management" in this document. The loss of any of our senior management could have a material adverse effect on our business and operations. Although we have formal employment agreements with each of our executive officers, these agreements do not prevent our executives from terminating their employment with us at any time.

Although we have not historically experienced difficulties attracting and retaining qualified employees, we could experience such problems in the future. Competition for qualified employees in the pharmaceutical industry is intense and the pool of qualified candidates is limited. We may not be able to retain the services of, or attract and retain, experienced senior management or key scientific and clinical personnel in the future. The departure of one or more of our senior management or key scientific and clinical personnel, regardless of whether or not they join a competitor or form a competing company, may subject us to risks relating to replacing them in a timely manner or at all, which may disrupt our drug development progress and have a material adverse effect on our business and results of operations.

Furthermore, replacing executive officers, key employees or consultants 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 products like those we develop. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel or consultants on acceptable terms given the competition among numerous pharmaceutical and biopharmaceutical companies for similar personnel. To compete effectively, we may need to offer higher compensation and other benefits, which could materially and adversely affect our financial condition and results of operations. In addition, we may not be successful in training our professionals to keep pace with technological and regulatory standards. Any inability to attract, motivate, train or retain qualified scientists or other technical personnel may have a material adverse effect on our business, financial condition, results of operations, cash flows and prospects.

As we have significantly increased the size and capabilities of our organization since our inception, we may experience difficulties in managing our growth.

We are a growing company working on an expanding pipeline of drug candidates. Our future financial performance and our ability to commercialize our drug candidates 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. Our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

As our development and commercialization plans and strategies evolve, we must hire a significant number of additional managerial, operational, manufacturing, sales, marketing, financial and other personnel. Our recent growth and any future growth will impose significant additional responsibilities on our management, including but not limited to:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- continuing to innovate and develop advanced technologies in the highly competitive pharmaceutical industry;
- managing our relationships with third parties, including suppliers and collaboration partners;
- 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
- improving our operational, financial and management controls, reporting systems and procedures.

If we are not able to effectively manage our growth and further expand our organization by hiring new employees and expanding our groups of consultants and contractors as needed, we may not be able to successfully implement the tasks necessary to further develop and commercialize our drug candidates and, accordingly, may not achieve our research, development and commercialization goals. Our failure to do so could materially and adversely affect our business, financial condition, results of operations and prospects.

We may engage in acquisitions or strategic partnerships, which may increase our capital requirements, cause dilution for our shareholders, cause us to incur debt or assume contingent liabilities and subject us to other risks.

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

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent or unforeseen liabilities;
- the issuance of our equity securities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;

- the diversion of our management's attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;

- the loss of key employees and personnel, and uncertainties in our ability to maintain key business relationships;

- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing drugs or drug candidates and regulatory approvals; and

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

We may not be able to identify suitable targets, and we have limited experience in acquisitions. In addition, we may not be able to successfully acquire the targets identified despite spending a significant amount of time and resources on pursuing such acquisition. Furthermore, integration of an acquired company, its intellectual property or technology into our own operations is a complex, time-consuming and expensive process. The successful integration of an acquisition may require, among other things, that we integrate and retain key management, sales and other personnel, integrate the acquired technologies or services from both an engineering and a sales and marketing perspective, integrate and support preexisting supplier, distribution and customer relationships, coordinate research and development efforts, and consolidate duplicate facilities and functions. The geographic distance between companies, the complexity of the technologies and operations being integrated, and the disparate corporate cultures being combined may increase the difficulties of integrating an acquired company or technology. In addition, it is common in our industry for competitors to attract customers and recruit key employees away from companies during the integration phase of an acquisition. In addition, if we undertake acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses, and acquire intangible assets that could result in significant future amortization expense.

We face risks related to natural disasters, health epidemics and outbreaks of contagious diseases, and other factors beyond our control.

Any future occurrence of force majeure events, natural disasters or outbreaks of other epidemics and contagious diseases, including avian influenza, severe acute respiratory syndrome, swine influenza caused by the H1N1 virus, or H1N1 influenza or the Ebola virus, may materially and adversely affect our business, financial condition and results of operations. Moreover, the world has experienced natural disasters such as earthquakes, floods and droughts in the past few years. Any future occurrence of severe natural disasters may materially and adversely affect its economy and our business. We cannot assure you that any future occurrence of natural disasters or outbreaks of epidemics and contagious diseases or the measures taken in response to such contagious diseases will not seriously disrupt our operations or those of our customers, which may materially and adversely affect our business, financial condition and results of operations.

We are subject to the risks of doing business globally. Disruptions in the financial markets and economic conditions could affect our ability to raise capital.

We primarily operate and currently conduct all our clinical trials in China. As we may further our development efforts for our drug candidates in the United States in the future, our business is subject to risks associated with doing business globally. Accordingly, our business and financial results in the future could be adversely affected due to a variety of factors, including:

- changes in a specific country's or region's political and cultural climate or economic condition;
- unexpected changes in laws and regulatory requirements in local jurisdictions;
- differences between national and local practice with respect to laws and regulatory requirements in a specific jurisdiction;
- difficulty of effective enforcement of contractual provisions in certain jurisdictions;
- efforts to develop an international sales, marketing and distribution organization may increase our expenses, divert our management's attention from the acquisition or development of drug candidates or cause us to forgo profitable licensing opportunities in these geographies;
- the occurrence of economic weakness, including inflation or political instability;
- inadequate intellectual property protection in certain jurisdictions;
- difficulty of ensuring that third-party partners do not infringe, misappropriate, or otherwise violate the patent, trade secret, or other intellectual property rights of others;
- the enforcement of anti-corruption and anti-bribery laws against us;
- trade protection measures, import or export licensing requirements and fines, penalties or suspension or revocation of export privileges;
- delays resulting from difficulty in obtaining export licenses, tariffs and other barriers and restrictions, potentially longer payment cycles, and greater difficulty in accounts receivable collection;
- non-compliance with tax, employment, immigration and labor laws;
- the effects of applicable local tax regimes and potentially adverse tax consequences;

- significant adverse changes in local currency exchange rates; and

- business interruptions resulting from geo-political actions and cultural climate or economic condition, including war and acts of terrorism, natural disasters, including earthquakes, volcanoes, typhoons, floods, hurricanes and fires, or the impact of public health pandemics or epidemics.

Furthermore, global economies could suffer dramatic downturns as the result of a deterioration in the credit markets and related financial crisis as well as a variety of other factors, including extreme volatility in security prices, severely diminished liquidity and credit availability, ratings downgrades of certain investments and declining valuations of others. In the past, governments have taken unprecedented actions in an attempt to address and rectify these extreme market and economic conditions by providing liquidity and stability to the financial markets. If these actions are not successful, the return of adverse economic conditions may cause a significant impact on our ability to raise capital, if needed, on a timely basis and on acceptable terms or at all.

We may become involved in lawsuits or other legal proceedings, which could adversely affect our business, financial conditions, results of operations and reputation.

We may become subject, from time to time, to legal proceedings and claims that arise in breach of related laws and regulations in our ordinary course of business or pursuant to governmental or regulatory enforcement activity. Litigation to which we subsequently become a party might result in substantial costs and divert management's attention and resources. Furthermore, any litigations, legal disputes, claims or administrative proceedings that may initially not appear to be of material importance may escalate and become important to us due to a variety of factors, such as the facts and circumstances of the cases, the likelihood of loss, the monetary amount at stake and the parties involved. We believe that our have maintained adequate insurance to cover our key liabilities arising from such proceedings. For more details of our insurance, see "Business — Insurance" in this document. However, it is possible that our liabilities could exceed our insurance coverage or that our insurance will not cover all situations in which a claim against us could be made. We may not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise. A claim brought against us that is uninsured or underinsured could result in unanticipated costs and could have a material adverse effect on our financial condition, results of operations or reputation.

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

We maintain insurance policies that are required under the PRC laws and regulations and that we believe are in line with market practice and adequate for our business to safeguard against risks and unexpected events. Our insurance policies cover adverse events in our clinical trials. We also maintain social welfare insurance for our employees in accordance with relevant PRC laws and regulations. However, our insurance coverage may be insufficient to cover any

claims that we may have. Any liability or damage to, or caused by, our facilities or our personnel beyond our insurance coverage may result in our incurring substantial costs and a diversion of resources and may negatively impact our drug development and overall operations.

Increased labor costs could slow our growth and affect our operations.

Our success depends in part upon our ability to attract, motivate and retain a sufficient number of qualified employees, including management, technical, research and development, sales and marketing, production, quality control and other personnel. We face intense competition in recruiting and retaining qualified personnel, as competitors are competing for the same pool of qualified personnel and our remuneration packages may not be as competitive as those of our competitors. Increasing market competition may cause market demand and competition for qualified employees to intensify. If we face labor shortages or significant increases in labor costs, higher employee turnover rates or changes to labor laws and regulations, our operating costs could increase significantly, which could materially and adversely affect our results of operations. In addition, we could face labor disputes with our employees, which could lead to fines by governmental authorities and settlement costs to resolve the disputes. Labor disputes could also make it more difficult to recruit new employees due to the reputational damage caused. Any of the foregoing changes could have a material adverse effect on our business, results of operations and prospects.

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

We are subject to numerous environmental, health, and safety laws and regulations in China and the United States, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We contract with third parties for the disposal of these materials and wastes. We cannot fully eliminate the risk of accidental contamination, biological or chemical hazards or personal injury at our facilities during the process of discovery, testing, development and manufacturing of our drug candidates. In the event of such accidents, we could be held liable for damages and clean-up costs which, to the extent not covered by existing insurance or indemnification, could harm our business. We may also be forced to close or suspend operations at certain of our affected facilities temporarily or permanently. As a result, any accidental contamination, biological or chemical hazards or personal injury could have a material adverse impact on our business, financial condition, results of operations and prospects.

We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations. In addition, we may incur substantial costs in order to comply with current or future environmental, health, and safety laws and regulations. These current or future laws and regulations may impair our drug candidate R&D

program efforts. Moreover, there is increasing stakeholder pressure on companies to diligence environmental, social, and governance matters in the supply chain. Negative publicity regarding production methods, alleged practices or workplace or related conditions of any of our suppliers, CROs or other third parties who perform services for us could adversely affect our reputation and force us to locate alternatives, which could increase our costs and result in delayed supply of components for, and manufacturing of, our drug candidates, or other disruptions to our operations.

We may be unable to detect, deter and prevent all instances of fraud or other misconduct committed by our employees, principal investigators, consultants and commercial partners.

We may be exposed to fraud, bribery or other misconduct committed by our employees or third parties that could subject us to financial losses and sanctions imposed by governmental authorities, which may adversely affect our reputation. During the Track Record Period and up to the Latest Practicable Date, we were not aware of any instances of fraud, bribery, or other misconduct involving employees and other third parties that had any material adverse impact on our business and results of operations. However, we cannot assure you that there will not be any such instances in future. Although we consider our internal control policies and procedures to be adequate, we may be unable to prevent, detect or deter all such instances of misconduct. Any such misconduct committed against our interests, which may include past acts that have gone undetected or future acts, may have a material adverse effect on our business and results of operations.

Any failure to comply with the PRC regulations regarding contribution of social insurance premium or housing provident funds may subject us to fines and other legal or administrative measures.

According to the Social Insurance Law of the PRC, the Regulations on Management of Housing Provident Fund and other applicable PRC regulations, any employer operating in China must contribute social insurance premium and housing provident funds for its employees. Any failure to make timely and adequate contribution of social insurance premium or housing provident funds for its employees may trigger an order of correction from competent authority requiring the employer to make up the full contribution of such overdue social insurance premium or housing provident funds within a specified period of time, otherwise the competent authority may further impose fines or penalties. We make contributions of social insurance premiums for our employees to provide for retirement, medical, work-related injury, maternity and unemployment benefits, as well as the housing provident funds. During the Track Record Period, we were not in strict compliance with the requisite contribution requirements in relation to some of our PRC employees, which will not bring any material adverse effect to our operations or financial position. Based on the relevant rules and regulations, the shortfall of social insurance and housing provident fund contributions amounted to approximately RMB2.8 million and RMB2.8 million in 2022 and 2023, respectively. As of the Latest Practicable Date, we had not received any order of correction or any fines or penalties from the competent authority as a result of any such failure. We have

obtained certain confirmation letters issued by the relevant competent social insurance and housing provident fund authorities confirming that there is no record of any member of our Group that hires employees being imposed administrative penalties by the relevant authorities for violation of the relevant laws and regulations. As advised by our PRC Legal Adviser, the likelihood that we will be required to settle all historical social insurance premiums and housing provident funds and be subject to material administrative penalties due to our failure to make full contributions of social insurance premium and housing provident funds for some of our employees during the Track Record Period is relatively low, provided that there are no material adverse changes in the current regulatory policies and environment and no material employee complaints occur. However, we cannot assure you that the competent authority will not require us to rectify any non-compliance by making contribution of overdue social insurance premium or housing provident funds or to pay any overdue fine or penalty related thereto.

We do not own the real property for our current major operation sites and are subject to risks associated with leasing space.

We lease premises in China. The lessors of the leased properties may not have valid title or the legal rights to such leased properties or may not have complied with all the necessary property leasing procedures. In addition, as our leases expire, we may fail to obtain renewals, either on commercially acceptable terms or at all, which could compel us to close such offices or manufacturing facilities. Our inability to enter into new leases or renew existing leases on terms acceptable to us could materially and adversely affect our business, results of operations or financial condition. Pursuant to PRC laws, both lessors and lessees are required to file the lease agreements with relevant authorities for record and obtain property leasing filing certificates for their leases. As of the Latest Practicable Date, our lease in Huzhou had not been filed with competent governmental authority. The failure to file and obtain property leasing filing certificates for such lease within the prescribed time period required by the relevant PRC government authorities, as required under PRC laws, may subject us to a fine ranging from RMB1,000 to RMB10,000 for such agreement. Although non-registration of the lease agreement does not in itself invalidate the lease, we may not be able to defend this lease against bona fide third parties, which may negatively affect our ability to operate our business covered under that lease.

Our internal information technology systems, or those used by our CROs or other contractors or consultants, may fail or suffer security breaches.

In the ordinary course of our business, we collect and store sensitive data, including, among other things, legally protected patient health information, personally identifiable information about our employees, intellectual property and proprietary business information. We manage and maintain our data utilizing on-site systems. Such data encompass a wide variety of business critical information including research and development information, commercial information and business and financial information. Because information technology systems, networks and other technologies are critical to many of our operating activities, shutdowns or service disruptions pose increasing risks. Despite the implementation

of security measures, our internal information technology systems and those of our current and any future third-party vendors, collaboration partners, consultants, and third parties performing services for us, as well as our clinical sites and regulatory authorities, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, and telecommunication and electrical failures.

Although we have not experienced any such material system failure, accident, or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a disruption of our drug candidate development and our business operations, whether due to a loss of our trade secrets or other proprietary information or other similar disruptions.

For example, the loss of clinical trial data from our current or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in the theft or destruction of intellectual property, data, or other misappropriation of assets, financial loss, or otherwise compromise our confidential or proprietary information and disrupt our operations, our competitive position could be harmed, and the further development and commercialization of our drug candidates could be delayed.

We could be subject to risks caused by misappropriation, misuse, leakage, falsification, or intentional or accidental release or loss of information maintained in the information systems and networks of our company and clinical sites, including personal information of our employees and, potentially, our clinical study patients and confidential data. In addition, third parties may attempt to penetrate our systems or fraudulently induce our personnel to disclose sensitive information in order to gain access to data and systems. We may experience threats to our data and systems, including malicious codes and viruses, phishing, and other cyber-attacks. The number and complexity of these threats continue to increase over time. If a material breach of our information technology systems occurs, the market perception of the effectiveness of our security measures could be harmed and our reputation and credibility could be damaged. We could be required to expend significant amounts of money and other resources to repair or replace information systems or networks.

In addition, we could be subject to regulatory actions or claims made by individuals and groups in private litigation involving privacy issues related to data collection and use practices and other data privacy laws and regulations, including claims for misuse or inappropriate disclosure of data, as well as unfair or deceptive practices. Although we develop and maintain systems and controls designed to prevent these events from occurring, and we have a process to identify and mitigate threats, the development and maintenance of these systems, controls, and processes is costly and requires ongoing monitoring and updating as technologies change and efforts to overcome security measures become increasingly sophisticated.

Moreover, despite our efforts, the possibility of these events occurring cannot be eliminated entirely. As we engage in more electronic transactions with clinical sites and collaboration partners, and rely more on cloud-based information systems, the related security risks will increase, and we will need to expend additional resources to protect our technology and information systems. In addition, there can be no assurance that our internal information technology systems, or those of third parties with which we conduct business, will be sufficient to protect us against breakdowns, service disruption, data deterioration, or loss in the event of a system malfunction, or prevent data from being stolen or corrupted in the event of a cyberattack, security breach, industrial espionage attacks, or insider threat attacks, which could result in financial, legal, business, or reputational harm.

Our reputation is important to our business success, and damage to our reputation may adversely affect our business.

We, our Shareholders, Directors, officers, employees, collaboration partners, suppliers, or other third parties we cooperate with or rely on may be subject to negative media coverage and publicity from time to time. Such negative coverage in the media and publicity could threaten the perception of our reputation. In addition, to the extent our Shareholders, Directors, officers, employees, collaboration partners, suppliers or other third parties we work with or rely on were non-compliant with any laws or regulations, we may also suffer negative publicity or harm to our reputation. Any negative publicity regarding our industry could also affect our reputation and commercialization. As a result, we may be required to spend significant time and incur substantial costs to respond and protect our reputation, and we cannot assure you that we will be able to do so within a reasonable period of time, or at all, in which case our business, results of operations, financial condition and prospects may be materially and adversely affected.

Our risk management and internal control systems may not fully protect us against various risks inherent in our business.

We have established risk management and internal control systems consisting of the relevant organizational framework policies, risk management policies and risk control procedures to manage our risk exposures, primarily credit risk, operational risk and legal risk as well as liquidity risk. However, we may not be successful in implementing our risk management and internal control systems. While we seek to continue to enhance our risk management and internal control systems from time to time, we cannot assure you that our risk management and internal control systems are adequate or effective notwithstanding our efforts, and any failure to address any potential risks and internal control deficiencies could materially adversely affect our business, financial condition and results of operations.

Since our risk management and internal control systems depend on their implementation by our employees, we cannot assure you that all of our employees will adhere to such policies and procedures, and the implementation of such policies and procedures may involve human errors or mistakes. Moreover, our growth and expansion may affect our ability to implement stringent risk management and internal control policies and procedures as our business evolves. If we fail to timely adopt, implement and modify, as applicable, our risk management and internal control policies and procedures, our business, financial condition and results of operations could be materially adversely affected.

RISKS RELATING TO OUR RELIANCE ON THIRD PARTIES

We work with various third parties to develop our drug candidates, such as those who help us conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected timelines, we may not be able to obtain regulatory approval for, or commercialize, our drug candidates, and our business could be materially harmed.

We have worked with and plan to continue to work with third-party CROs to monitor and manage data for our ongoing preclinical and clinical programs. We work with these parties to execute our preclinical studies and clinical trials, and control only certain aspects of their activities. 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 collaboration with the CROs does not relieve us of our regulatory responsibilities. We, our CROs for our clinical programs and our clinical investigators are required to comply with GCP, which are regulations and guidelines enforced by the NMPA, the FDA, and other comparable regulatory authorities for all of our drugs in clinical development. If we or any of our CROs or clinical investigators fail to comply with applicable GCP, the clinical data generated in our clinical trials may be deemed unreliable and the NMPA, the FDA, or comparable regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. In addition, our pivotal clinical trials must be conducted with products produced under GMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms or in a timely manner. In addition, 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 non-clinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, or if they need to be replaced or if the quality or accuracy of the clinical data they or our clinical investigators obtain is compromised due to failure to adhere to our clinical protocols, regulatory requirements or for other reasons, 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 our CROs have errors or mistakes in their experimental operations, the development projects of our drug candidates may be delayed or adversely affected. As a result, our results of operations and the commercial prospects for our drug candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

Switching or adding additional CROs involves additional costs and delays, which can materially influence our ability to meet our desired clinical development timelines. There can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse effect on our business.

Our future revenues are dependent on our ability to work effectively with collaboration partners to develop our drug candidates, including to obtain regulatory approval. Our arrangements with collaboration partners will be critical to successfully bringing drug candidates to market and commercializing them. We rely on collaboration partners in various respects, including to undertake research and development programs and conduct clinical trials, manage or assist with the regulatory filings and approval process and to assist with our commercialization efforts. We do not control our collaboration partners; therefore, we cannot ensure that these third parties will adequately and timely perform all of their obligations to us. If they fail to complete the remaining studies successfully, or at all, it could delay, adversely affect or prevent regulatory approval. We cannot guarantee the satisfactory performance of any of our collaboration partners and if any of our collaboration partners breach or terminate their agreements with us, we may not be able to successfully commercialize the licensed drug which could materially and adversely affect our business, financial condition, cash flows and results of operations.

In addition, we will rely on third parties to perform certain specification tests on our drug candidates prior to delivery to patients. If these tests are not appropriately done and test data are not reliable, patients could be put at risk of serious harm and regulatory authorities could place significant restrictions on our Company until deficiencies are remedied.

We depend on a stable and adequate supply of quality materials and research and development and manufacturing equipment from our suppliers, and price increases or interruptions of such supply could have an adverse impact on our business.

Our business operations require a substantial amount of raw materials as well as equipment and other materials needed for research and development and manufacturing purposes, and are therefore exposed to various supply chain risks. During the Track Record Period, we relied on third parties to supply certain materials. We expect to continue to rely on third parties to supply such materials and equipment for the research, development, manufacturing and commercialization of our drug candidates. For details, see "Business – Suppliers and Raw Materials" in this document.

Currently, the materials and equipment are supplied by multiple source suppliers. We have agreements for the supply of drug materials with manufacturers or suppliers that we believe have sufficient capacity to meet our demands. In addition, we believe that adequate alternative sources for such supplies exist. However, there is a risk that, if supplies are interrupted, we may not be able to find alternative supplies in a timely and commercially reasonable manner, or at all, and it would materially harm our business. Any disruption in production or the inability of our suppliers to produce adequate quantities to meet our needs could impair our operations and the research and development of our drug candidates.

Moreover, we require a stable supply of materials for our drug candidates in the course of our research and development activities, and such needs are expected to increase significantly once we enter commercial production of drugs upon receipt of marketing approval, but there is no assurance that current suppliers have the capacity to meet our demand.

Any delay in receiving such materials in the quantity and quality that we need could delay the completion of our clinical trials, regulatory approval of our drug candidates or our ability to timely meet market demand for our commercialized products, as applicable. Our suppliers may not be able to cater to our growing demands or may reduce or cease their supply of materials to us at any time.

We are also exposed to the risk of increased costs, which we may not be able to pass on to customers and, as a result, lower our profitability. In the event of significant price increases for such materials, we cannot assure you that we will be able to raise the prices of our future drug products sufficiently to cover the increased costs. As a result, any significant price increase for our needed materials may have an adverse effect on our profitability.

Additionally, our suppliers may also fail to maintain adequate quality of the services, materials and equipment we need. Although we have implemented quality inspection on the materials before using them in the manufacturing process, we cannot assure you that we will be able to identify all of the quality issues. Suboptimal or even deficient supplies of services, materials and equipment may hinder the research and development of our drug candidates, subject us to product liability claims or otherwise have a material adverse effect on our operations.

In addition, we cannot assure you that these third parties will be able to maintain and renew all licenses, permits and approvals necessary for their operations or comply with all applicable laws and regulations. Their failure to do so may lead to interruption in their business operations, which in turn may result in shortage of the materials and equipment supplied to us, and cause delays in clinical trials and regulatory filings, or recall of our products. The non-compliance of these third parties may also subject us to potential product liability claims, cause us to fail to comply with the continuing regulatory requirements, and incur significant costs to rectify such incidents of non-compliance, which may have a material adverse effect on our business, financial condition and results of operations.

We have entered into collaboration with our partner and may seek further collaboration opportunities and strategic alliances or enter into licensing arrangements in the future, but we may not realize the benefits of such collaboration, alliances or licensing arrangements.

Historically we have entered into the collaboration arrangement with ImmuneOnco Biopharmaceuticals (Shanghai) Inc. ("**ImmuneOnco**") in relation to the development of our drug candidate IBC0966. Pursuant to the IBC0966 Agreement, ImmuneOnco transferred to us all rights and interests in relation to IBC0966 in the Territory, while ImmuneOnco retains the rights to develop, register and commercialize IBC0966 outside of the Territory. Since we will assist ImmuneOnco in submitting IND and NDA applications to regulatory authorities in relation to IBC0966 outside of the Territory, we will also be entitled to 7.5% of the interests of IBC0966 out of the Territory. For details, see "Business — Collaboration Arrangement" in this document. There are plenty of uncertainties in terms of regulatory requirements and local market conditions out of the Territory, if the research and development or future

commercialization of IBC0966 out of the Territory is delayed or fails, the expected interests derived from IBC0966 out of the Territory may be less than we expected. If IBC0966 out of the Territory is subject to any dispute or adverse event, the publicity or research and development activities of IBC0966 in the Territory may be negatively influenced as well.

We may in the future seek and form additional strategic alliances, joint ventures or other collaborations, including entering into licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our drug candidates and any future drug candidates that we may develop. Any of such relationships may require us to incur non-recurring and other charges, increase our short- and long-term capital expenditures, issue securities that dilute our existing shareholders, or divert the attention of our management from our normal course of business. Moreover, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. We may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our drug candidates because they may be deemed to be at too early a stage of development for collaborative effort and third parties may not view our drug candidates as having the requisite potential to demonstrate safety and efficacy or commercial viability.

If and when we collaborate with a third party for the development and commercialization of a drug candidate, we may relinquish some or all of the control over the future success of that drug candidate to the third party. If we do not accurately evaluate the commercial potential or target market for a particular drug candidate, we may relinquish valuable rights to that drug candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such drug candidate, or we may allocate internal resources to a drug candidate in a therapeutic area in which it would have been more advantageous to enter into a partnering arrangement.

Collaborations involving our drug candidates are subject to a number of risks, which may include but are not limited to the following:

- our collaboration partners have significant discretion in determining the efforts and resources that they will allocate to such collaborations or strategic alliances;

- our collaboration partners may not pursue development and commercialization of drug candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in their strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;

- our collaboration partners may delay their drug development plan, including clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a drug candidate, repeat or conduct new clinical trials or require a new formulation of a drug candidate for clinical testing;

- our collaboration partners could independently develop, or develop with other third parties, drugs that compete directly or indirectly with our drug candidates;

- our collaboration partners may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigations that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;

- collaboration partners may not always be cooperative or responsive in providing their services in a clinical trial;

- disputes may arise between us and our collaboration partners that cause the delay or termination of the research, development or commercialization of our drug candidates, or that result in costly litigation or arbitration that diverts management attention and resources;

- collaborations may be terminated if we or our collaboration partners fail to comply with our or their obligations in the collaboration agreements;

- termination of collaborations may result in a need for additional capital to pursue further development or commercialization of the relevant drug candidates;

- our collaboration partners may own or co-own intellectual property covering our drugs that results from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property; and

- our collaboration partners with marketing and distribution rights to one or more of our drug candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such drug candidates.

We cannot be certain that, following a strategic transaction, we will be able to generate the target level of revenue or profit that can justify such a transaction. If we are unable to reach agreements with suitable collaboration partners on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a drug candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, 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, results of operations and prospects.

We are exposed to risks related to concentration of suppliers.

Purchases from our five largest suppliers accounted for 54.1%, and 49.9% of our total purchase amount, respectively, in 2022 and 2023, respectively. During the Track Record Period and up to the Latest Practicable Date, we had not experienced any material shortage of supplies or services. However, we cannot assure you that these suppliers will continue to provide supplies and services at prices and on terms and conditions acceptable to us. Our reliance on our top five suppliers may also expose us to the risk of unexpected price increases for purchases, or shortage in supply of raw materials and services. In such a situation, our business, financial condition and results of operations may be materially and adversely affected.

RISKS RELATING TO GOVERNMENT REGULATIONS

All material aspects of the research, development and commercialization of pharmaceutical products are heavily regulated. Any failure to comply with existing or future regulations and industry standards or any adverse actions by drug approval authorities against us could negatively impact our reputation and our business, financial condition, results of operations and prospects.

All jurisdictions in which we intend to develop and commercialize our drug candidates and conduct other pharmaceutical-industry activities regulate these activities in great depth and detail. We adopt a global development strategy and intend to focus our activities in the major markets including China and the United States. These jurisdictions all strictly regulate the pharmaceutical industry, and in doing so they employ broadly similar regulatory strategies, including regulation of the development and approval, manufacturing, marketing, sales and distribution of pharmaceutical products. However, there are differences in the regulatory regimes that make for a more complex and costly regulatory compliance burden for a company like us that plans to operate in these regions. Our or our CROs' failure to comply with such regulations could result in the termination of ongoing research, administrative penalties imposed by regulatory bodies or the disqualification of data for submission to regulatory authorities. This could harm our business, reputation, prospects for future work and results of operations.

We are also subject to the laws and regulations as amended from time to time in all jurisdictions in which we intend to develop and commercialize our drug candidates and conduct other pharmaceutical-industry activities. For example, on September 12, 2022, the President of the United States issued "Executive Order on Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy" (the "Executive Order"), launching a national biotechnology and biomanufacturing initiative in the United States. This initiative will be comprised of various efforts by the U.S. government, including investments, programs and partnerships to advance research and development in biotechnology and biomanufacturing, as well as efforts to secure and protect the U.S. bioeconomy. The Executive Order may lead to potential changes to U.S. policies affecting the biotechnology and biomanufacturing industries. Substantially all of our operations and all of our clinical trials are conducted in China. We plan to conduct clinical trials for certain drug

candidates and explore development and/or commercialization opportunities in the United States in the future. We therefore expect that the Executive Order will have no immediate impact on our research and development activities in the United States. However, it is unknown at this time whether and what specific policies and actions will be adopted by the U.S. government. If the U.S. government were to adopt any policies that adversely impact foreign companies conducting research and development activities in the United States, our business, financial condition and results of operations could be adversely affected.

The process of obtaining regulatory approvals and maintaining compliance with appropriate laws and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable requirements at any time during the drug development process or approval process, or after approval, 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. Failure to comply with these regulations could therefore materially and adversely affect our business, financial condition, results of operations and prospects.

Moreover, the regulatory framework regarding the pharmaceutical industry is continuing to change and evolve, and we cannot guarantee that changes to the laws and regulations with regard to pharmaceutical industry in jurisdictions where we operate would not adversely affect our business and prospects. Any such changes or amendments may result in increased compliance difficulty and costs or 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 our drug candidates. Changes in government regulations or in practices relating to the pharmaceutical industry such as a relaxation in regulatory requirements or the introduction of simplified approval procedures which would lower the entry barrier for potential competitors, or an increase in regulatory requirements which may increase the difficulty for us to satisfy such requirements, may have a material adverse impact on our business, financial condition, results of operations and prospects.

Changes in government regulations or in practices relating to the biopharmaceutical industry may affect our business.

Changes in government regulations or in practices relating to the biopharmaceutical industry, such as a relaxation in regulatory requirements, or the introduction of simplified approval procedures, which would lower the entry barrier for potential competitors, or an increase in regulatory requirements, which may increase the difficulty for us to satisfy such requirements, and may impact our business, financial condition, results of operations, and prospects. In response to emergent situations for public interests, governments in the world may take actions to protect their citizens that could affect our ability to control the production and export of medical products or otherwise impose burdensome regulations on our business.

The regulatory approval processes relating to the marketing of our drug candidates are lengthy, time-consuming and can be changed. If we are unable to obtain without undue delay any regulatory approval for our drug candidates in our targeted markets, our business may be substantially harmed.

We are subject to risks associated with obtaining regulatory approvals. Difficulties and failures in doing so may expose us to various harms. Significant time, effort and expense are required to bring our drug candidates to market in compliance with the regulatory process, and we cannot assure you that any of our drug candidates will be approved for sale. The time required to obtain approvals from the NMPA, the FDA, and other comparable regulatory authorities may be different depending on different programs, but typically takes 10 to 15 years following the commencement of preclinical studies and clinical trials and depends on numerous factors, including the substantial discretion of the regulatory authorities. In addition, regulations, approval policies and requirements for clinical data may change during the clinical development process of a drug candidate and may vary among jurisdictions. It is not uncommon that the NMPA, the FDA or a comparable regulatory authority may require more information, including additional analysis, reports, data, non-clinical studies and clinical trials, or questions regarding interpretations of data and results, to support approval, which may increase our costs, prolong, delay or prevent approval and our commercialization plans, or we may decide to abandon the development programs. We cannot assure you that we will be able to meet regulatory requirements of different jurisdictions or that our drug candidates will be approved for sale in those jurisdictions. Additional time, effort and expense may be required to bring our drug candidates, upon regulatory approval, to the international markets in compliance with different regulatory processes.

Our drug candidates could fail to receive regulatory approval in a timely manner for many reasons, including but not limited to:

- failure to begin or complete clinical trials due to disagreements with regulatory authorities in the design or implementation of our clinical trials;
- failure to demonstrate that a drug candidate is safe and potent for its proposed indications or, if it is a biologic, that it is safe, pure and potent for its proposed indication;
- failure to demonstrate that the clinical and other benefits of a drug candidate outweigh its safety risks;
- failure of clinical trial results to meet the level of statistical and medical significance required for approval;
- data integrity issues related to our clinical trials;
- disagreement with our interpretation of data from preclinical studies or clinical trials;

- insufficiency of data from clinical trials of our drug candidates to support the filing of the submission or to obtain regulatory approval;

- failure to conduct a clinical trial in accordance with regulatory requirements or our clinical trial protocols;

- clinical sites, investigators or other participants in our clinical trials deviating from a trial protocol, failing to conduct the trial in accordance with regulatory requirements, or dropping out of a trial resulting in failure to pass audits carried out by the NMPA, the FDA or other comparable regulatory authorities and a potential invalidation of our research data;

- failure of our clinical trial process to keep abreast with any scientific or technological advancements required by regulations or approval policies; and

- findings by the NMPA, the FDA or other comparable regulatory authorities of deficiencies related to our manufacturing processes or the manufacturing facilities of third-party manufacturers from whom we procure clinical and commercial supplies.

Changes in regulatory requirements and guidance may also occur, and we may need to amend clinical trial protocols submitted to competent regulatory authorities to reflect these changes. Resubmission may impact the costs, timing or successful completion of a clinical trial. The policies of the NMPA, the FDA and other comparable regulatory authorities may also change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our drug candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any regulatory approval that we may have obtained and we may not achieve or sustain profitability.

Moreover, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval procedures vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking regulatory approvals in various jurisdictions could result in significant delays, difficulties and costs for us and may require additional preclinical studies or clinical trials which would be costly and time-consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. Satisfying these and other regulatory requirements is costly, time-consuming, uncertain and subject to unanticipated delays. In addition, our failure to obtain regulatory approval in any country may delay or have negative effects on the process for regulatory approval in other countries.

We may experience delays in the completion of, or the termination of, a clinical trial of any of our drug candidates. Any delays in completing our clinical trials will increase our costs, slow down our drug candidate development and approval process, and jeopardize our ability to commence product sales and generate related revenues for that candidate. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our drug candidates, and may cause reputational damage.

We cannot assure you that we can satisfy all regulatory requirements to obtain regulatory approvals in a timely manner, or at all, or to obtain regulatory approvals with an ideal scope of indications, which may have an adverse impact on our reputation and the commercial prospects of our drug candidates, and eventually may harm our business, financial condition and prospects significantly.

Adverse events caused by our drug candidates could interrupt, delay or halt clinical trials, delay or prevent regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following any regulatory approval.

Adverse events caused by our drug candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials, or a significant change in our clinical protocol or our development plan and could result in a more restrictive label or the delay or denial of regulatory approval by the NMPA, the FDA or other comparable regulatory authorities, or could result in limitations or withdrawal following approvals.

If results of our trials reveal a high and unacceptable severity or prevalence of certain adverse events, our trials could be suspended or terminated and the NMPA, the FDA or other comparable regulatory authorities could order us to cease further development of, or deny approval of, our drug candidates for any or all targeted indications.

Adverse events caused by our drug candidates, including when used in combination therapy, which may involve unique adverse events that could be exacerbated compared with adverse events from monotherapies, and off-label use of our drug candidates could potentially cause significant negative consequences for our Company, including:

- clinical trials could be delayed or halted;
- we may suspend, delay or alter development or marketing of the drug candidates;
- approvals or licenses of an approved drug candidate could be withdrawn or revoked, or we may determine to do so even if not required;
- additional warnings could be required to be added on the label of an approved drug candidate;

- we may be required to develop a risk evaluation and mitigation strategy for the drug candidate, or, if one is already in place, to incorporate additional requirements under the risk evaluation and mitigation strategy, or to develop a similar strategy as required by a comparable regulatory authority;

- we may be required to conduct post-market studies;

- we could be subject to litigation proceedings and held liable for harm caused to subjects or patients;

- the patient enrollment may be insufficient or slower than we anticipate or patients may drop out or fail to return for post-treatment follow-up at a higher rate than anticipated;

- the costs of clinical trials of our drug candidates may be substantially higher than anticipated; and

- our reputation may suffer.

We primarily conduct clinical trials for our drug candidates in China, while FDA or comparable foreign regulatory authorities may not accept data from such trials.

We primarily conduct clinical trials for our drug candidates in China. The acceptance of trial data from clinical trials conducted outside the United States or another jurisdiction by the FDA or comparable foreign regulatory authorities may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application for marketing approvals on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; and (ii) the trials were performed by clinical investigators of recognized competence and pursuant to Good Clinical Practice, or GCP, regulations. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There is no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which could be costly and time-consuming and delay our business plan, and may result in product candidates that we may develop not receiving approval for commercialization in the relevant jurisdiction.

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

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

The PRC authorities promulgated a series of laws and regulations governing the various aspects of information security, data collection and privacy protection, including, among others, the Cybersecurity Law of the PRC, the Provisions on Protection of Personal Information of Telecommunication and Internet Users, the Cybersecurity Review Measures, the Data Security Law of the PRC, and the Personal Information Protection Law of the PRC. Under the Personal Information Protection Law of the PRC, in case of any personal information processing, such individual prior consent shall be obtained, unless otherwise specified. Further, any data processing activities that are in relation to the sensitive personal information such as biometrics, medical health and personal information of teenagers under fourteen years old, are not allowed, unless such activities have a specific purpose, are highly necessary and strictly protective measures have been taken. In addition, the Measures for the Security Assessment of Outbound Data Transfer took effect on September 1, 2022, which apply to the security assessment of data processors' provision of important data and personal information collected and generated in their operations within the territory of the PRC to overseas recipients, and require relevant data processors to submit a data security assessment to the regulatory authority for review prior to the outbound data transfer activities in order to prevent illegal data transfer activities. In addition, certain industry-specific laws and regulations affect the collection and transfer of data in China. The Regulations on the Administration of Human Genetic Resources of the PRC or the HGR Regulation, was promulgated by the State Council in May 2019 and came into effect in July 2019. It stipulates that foreign organizations, individuals, and the entities established or actually controlled by foreign organizations or individuals are forbidden to collect, preserve and export China's human genetic resources. Foreign organizations and the entities established or actually controlled by foreign organizations or individuals may only utilize and be provided with China's human genetic resources after satisfaction of all regulatory requirements, such as (i) China's human genetic resources being utilized only in international cooperation with Chinese scientific research institutions, universities, medical

institutions, and enterprises for scientific research and clinical trials after completion of requisite approval or filing formalities with competent governmental authorities, and (ii) China's human genetic resources information being provided after required security review, filing and information backup procedures have been gone through. In October 2020, the SCNPC promulgated the Biosecurity Law of the PRC, which became effective in April 2021. The Biosecurity Law of the PRC reaffirms the regulatory requirements stipulated by the HGR Regulation while potentially increasing the administrative sanctions where China's human genetic resources are collected, preserved, exported or used in international cooperation in violation of applicable laws. The interpretation and implementation of the HGR Regulation and the related laws and regulations may vary from time to time. Given such circumstance, although we have made great efforts to comply with mandatory requirements of laws and government authorities in this regard, we cannot assure you that we will be deemed at all times in full compliance with the HGR Regulation, the Biosecurity Law of the PRC and other applicable laws in our utilizing of and dealing with China's human genetic resources. As a result, we may be exposed to compliance risks under the HGR Regulation and the Biosecurity Law of the PRC and the applicable laws and regulations.

Numerous U.S. federal and state laws and regulations relate to the privacy and security of personal information. In particular, regulations promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996, or HIPAA, establish privacy and security standards that limit the use and disclosure of individually identifiable health information, known as "protected health information," and require the implementation of administrative, physical and technological safeguards to protect the privacy of protected health information and ensure the confidentiality, integrity and availability of electronic protected health information. Determining whether protected health information has been handled in compliance with applicable privacy standards and our contractual obligations may require complex factual and statistical analyses and may be subject to changing interpretation. Although we take measures to protect sensitive data from unauthorized access, use or disclosure, our information technology and infrastructure may be vulnerable to attacks by hackers or viruses or breached due to employee error, malfeasance or other malicious or inadvertent disruptions. Any such breach or interruption could compromise our networks and the information stored there could be accessed by unauthorized parties, manipulated, publicly disclosed, lost or stolen. Any such access, breach or other loss of information could result in legal claims or proceedings, and liability under federal or state laws that protect the privacy of personal information, such as the HIPAA, the Health Information Technology for Economic and Clinical Health Act, and regulatory penalties. Notice of breaches must be made to affected individuals, the Secretary of the Department of Health and Human Services, and for extensive breaches, notice may need to be made to the media or State Attorneys General. Such a notice could harm our reputation and our ability to compete.

Complying with all applicable laws, regulations, standards and obligations relating to data privacy, security, and transfers may cause us to incur substantial operational costs or require us to modify our data processing practices and processes. Non-compliance could result in proceedings against us by data protection authorities, governmental entities or others, including class action privacy litigation in certain jurisdictions, which would subject us to

significant fines, penalties, judgments and negative publicity. In addition, if our practices are not consistent or viewed as not consistent with legal and regulatory requirements, including changes in laws, regulations and standards or new interpretations or applications of existing laws, regulations and standards, we may become subject to audits, inquiries, whistleblower complaints, adverse media coverage, investigations, loss of export privileges, severe criminal or civil sanctions and reputational damage. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

In addition, our clinical trials also frequently involve professionals from third-party institutions working on-site with our staff and enrolled subjects. We cannot ensure that such persons will always comply with our data privacy measures. We also cooperate with third parties including principal investigators, hospitals, CROs, and other third-party contractors and consultants for our clinical trials and operations. Any leakage or abuse of patient data by our third-party partners may be perceived by the patients as our fault, negligence or a result of our failure. Furthermore, any change in such laws and regulations could affect our ability to use medical data and subject us to liability for the use of such data for previously permitted purposes. Complying with all applicable laws, regulations, standards and obligations relating to privacy and data security may cause us to incur substantial operational costs or require us to modify our data processing practices and processes. Noncompliance could result in proceedings against us by data protection authorities, governmental entities or others, including class action privacy litigation in certain jurisdictions, which would subject us to significant fines, penalties, judgments and negative publicity. Any failure or perceived failure by us to prevent information security breaches or to comply with privacy policies or privacy-related legal obligations, or any compromise of information security that results in the unauthorized release or transfer of personally identifiable information or other patient data, could have a material adverse effect on our business, financial condition and results of operations.

We are subject to registration, review and other requirements of the regulatory authorities for cross-border sales or licensing of technology as well as operations related to genetics and data safety.

Under the Regulations on Administration of Imports and Exports of Technologies promulgated by the State Council, which were amended in November 2020, technology import and export is defined to include, among others, the transfer or licensing of patents and know-how, and the provision of services related to technology. Depending on the nature of the relevant technology, the import and export of technology require either approvals by or registration with the relevant PRC governmental authorities. The Measures for the Administration of Registration of Technology Import and Export Contracts, issued by the MOFCOM in February 2009, specify registration requirements related to the import and export of technology. We may in the future enter into agreements with CROs in the United States for their technical support to assist us with the development of individual drug candidates, which may be deemed to constitute the import of technology under the regulations. As a result, such transfers are may be required to be registered with applicable governmental authorities. We are

also subject to regulatory supervision over genetics and data-related operations. To carry out clinical trials, as a foreign-invested enterprise, we are required to obtain approval from the Office of Human Genetic Resources Management under the Ministry of Science and Technology who will conduct genetics and data safety review. There is no assurance that we will be able to obtain such approval in a timely manner, or at all. In addition, we may also be subject to similar requirements of overseas regulatory authorities.

On March 17, 2018, the General Office of the State Council promulgated the Measures for the Management of Scientific Data, or the Scientific Data Measures, which provides that enterprises in China must seek governmental approval before any scientific data involving a state secret or individual privacy may be transferred abroad or to foreign parties. Further, any researcher conducting research funded at least in part by the government authority is required to submit relevant scientific data for management by the entity to which such researcher is affiliated before such data may be published in any foreign academic journal. If and to the extent our research and development of drug candidates will be subject to the Scientific Data Measures and any relevant laws as required by the relevant government authorities, we cannot assure you that we can always obtain relevant approvals for sending scientific data (such as the results of our preclinical studies or clinical trials conducted within China) abroad. If we are unable to obtain necessary approvals in a timely manner, or at all, our research and development of drug candidates may be hindered, which may materially and adversely affect our business, results of operations, financial condition and prospects. If the relevant government authorities consider the transmission of our scientific data to be in violation of the requirements under the Scientific Data Measures, we may be subject to fines and other administrative penalties imposed by those government authorities.

Even if we receive regulatory approval for our drug candidates, we will be subject to ongoing or additional regulatory obligations and continued regulatory review, which may result in significant additional expenses and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our drug candidates.

If the NMPA, the FDA or a comparable regulatory authority approves any of our drug candidates, the manufacturing processes, labeling, packaging, storage, distribution, adverse event reporting, advertising, promotion, sampling, recordkeeping and post-marketing studies for the drug will be subject to extensive and ongoing or additional regulatory requirements on pharmacovigilance. These requirements include submissions of safety and other post-marketing information and reports, registration, random quality control testing, adherence to any chemistry, manufacturing and controls ("**CMC**"), variations, continued compliance with GMPs, cGMPs, GCPs, good storage practices and good vigilance practices and potential post-approval studies for the purposes of license renewal.

Any regulatory approvals that we receive for our drug candidates may also be subject to limitations on the approved indicated uses for which the drug may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing studies for the surveillance and monitoring of the safety and efficacy of the drug.

In addition, once a drug is approved, it is possible that there could be a subsequent discovery of previously unknown problems with the drug, including problems with third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements. If any of the foregoing occurs with respect to our drug candidates, it may result in, among other things:

- restrictions on the marketing or manufacturing of the drug, withdrawal of the drug from the market, or voluntary or mandatory drug recalls;
- fines, warning letters or holds on our clinical trials;
- refusal to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of drug license approvals;
- refusal to accept any of our other IND approvals, NDAs or BLAs;
- suspension or revocation of existing drug license approvals;
- drug seizure or detention, or refusal to permit the import or export of drugs; and
- injunctions or the imposition of civil, administrative or criminal penalties.

Regulatory authorities strictly regulate the marketing, labeling, advertising and promotion of drugs that are placed on the market. Drugs may be promoted only for their approved indications and for use in accordance with the provisions of the approved label. The regulatory authorities actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. Any government investigation of alleged violations of law could require us to expend significant time and resources and could generate negative publicity. Moreover, regulatory policies may change or additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our drug candidates. If we are not able to maintain regulatory compliance, we may lose the regulatory approvals that we have already obtained and may not achieve or sustain profitability, which in turn could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may be directly or indirectly subject to applicable anti-kickback, anti-bribery, false claims laws, physician payment transparency laws, fraud and abuse laws or similar healthcare and security laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and others play a primary role in the recommendation and prescription of any products for which we obtain regulatory approval. Our operations are subject to various applicable anti-kickback, false claims laws, physician payment transparency laws, fraud and abuse laws or similar healthcare and security laws and regulations in China and the United States. These laws 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 governments.

In addition, we are subject to similar healthcare laws in other jurisdictions, some of which may be broader in scope or stricter than others, and if we fail to comply with any such requirements, we could be subject to penalties.

Efforts to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. Governmental authorities could conclude that our business practices may not comply with statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and if we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in governmental healthcare programs, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and have a significant impact on our businesses and results of operations.

In addition, we are subject to anti-bribery laws that generally prohibit companies and their intermediaries from making payments to government officials for the purpose of obtaining or retaining business or securing any other improper advantage. Moreover, although currently our primary operating business is in China, we are subject to the Foreign Corrupt Practices Act, which generally prohibits us from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business. Although we have policies and procedures designed to ensure that we, our employees and our agents comply with anti-bribery laws, there is no assurance that such policies or procedures will prevent our agents, employees and intermediaries from engaging in bribery activities. Failure to comply with anti-bribery laws could disrupt our business and lead to severe criminal and civil penalties, including imprisonment, criminal and civil fines, loss of our export licenses, suspension of our ability to do business with the government, denial of government reimbursement for our products and/or exclusion from participation in government healthcare programs. Other remedial measures could include further changes or enhancements to our procedures, policies, and controls and potential personnel changes and/or disciplinary actions, any of which could have a material adverse effect on our business, financial condition, results of operations and liquidity. We could also be adversely affected by any allegation that we violated such laws.

The pharmaceutical industry is highly regulated and such regulations are subject to change which may affect approval and commercialization of our drugs.

The pharmaceutical industry where our business located is subject to comprehensive government regulation and supervision, encompassing the approval, registration, manufacturing, packaging, licensing and marketing of new drugs. In recent years, the regulatory framework in China regarding the pharmaceutical industry has been revolving. Any such changes or amendments may cause changes in compliance costs on our business, the successful development or commercialization of our drug candidates and the benefits we believe are available to us from developing and manufacturing drugs. For example, the Clinical Value-oriented Guiding Principles on the Clinical Study for Antineoplastic Drugs ("**Clinical Guidelines**") issued by the CDE on November 19, 2021, states that the fundamental purpose of the drug market is to address the needs of patients, and emphasizes that drug research and development should be based on patient needs and clinical value. The Clinical Guidelines discourage repetitive research and development of "me-too drugs" (drugs with identical mechanisms of actions) and disorderly waste. If we are unable to comply with, or are deemed to be in violation of the Clinical Guidelines' detailed provisions and principles, our clinical development activities and overall business operations may be adversely impacted.

Changes in the political and economic policies, as well as the interpretation and enforcement law, rules and regulations, may affect our business, financial condition, results of operations and prospects.

Due to our extensive operations in the PRC, our business, financial condition, results of operations and prospects are affected by economic, political, and legal developments in the PRC. The overall economic growth is influenced by the governmental regulations and policies in relation to resource allocation, monetary policies, regulations of financial services and institutions, preferential treatment to particular industries or companies and others. Any of the foregoing would affect our business, financial condition, results of operations and prospects.

Laws, rules and regulations in relation to economic matters are promulgated from time to time, including those related to such as foreign investment, corporate organization and governance, commerce, taxation, finance, foreign exchange and trade, so as to develop a comprehensive system of commercial law. In addition, the interpretation and implementation of the laws and regulations relating to pharmaceutical industry also evolve from time to time. The NMPA's recent reform of the drug approval system could has impacts on our commercialization of drug candidates in a timely manner. For example, the NHC issued the Administrative Measures for Clinical Use of Anti-Oncology Drugs (Trial), effective from March 1, 2021, requiring the oncology drugs, as classified into the "restricted-use" and "normal-use" categories, to be rationally used or prescribed by the medical institutions and medical practitioners. In June 2021, the NHC further issued the Administrative Measurements for Rational Clinical Use of Oncology Drugs, which specifies the calculation formula for the administrative measurements used for gauging the rational use of restricted-use oncology drugs, while not yet setting any numeric limits on the measurements. We currently do not experience or foresee any potential material adverse impact of these regulations on our business operations. However, as such administrative regulations are newly released and relevant measures are generally evolving, we cannot assure you if our business operations will not be adversely affected in the future.

Changes in U.S. and international trade policies may cause significant disruptions to our drug candidate manufacturing and other operations.

The U.S. government has recently made significant changes in its trade policy and has taken certain actions that may materially impact international trade, such as imposing several rounds of tariffs. It is unknown whether and to what extent new tariffs (or other new laws or regulations) will be adopted, or the effect that any such actions would have on us or our industry.

While we have not started commercialization of any of our drug candidates, any unfavorable government policies on international trade, such as capital controls or tariffs, may affect the demand for our future drug products, the competitive position of our future drug products, the hiring of scientists and other research and development personnel, and import or export of raw materials in relation to drug development, or may prevent us from selling our future drug products in certain countries. If any new tariffs, legislation and regulations are implemented, or if existing trade agreements are renegotiated, such changes could have an adverse effect on our business, financial condition and results of operations.

The evolving trade disputes may escalate going forward and may result in certain types of goods, such as advanced research and development equipment and materials, becoming significantly more expensive to procure from overseas suppliers or even becoming illegal to export. Furthermore, there can be no assurance that our existing or potential service providers or collaboration partners will not alter their perception of us or their preferences as a result of adverse changes to the state of political relationships among the relevant countries or regions. Trade disputes, tensions and political concerns among the relevant countries or regions may therefore adversely affect our business, financial condition, results of operations, cash flows and prospects.

The interpretation and implementation of the PRC Foreign Investment Law may evolve from time to time, which may impose new burdens on us.

The PRC Foreign Investment Law, or the FIL, was enacted by the National People's Congress of the PRC on March 15, 2019, and became effective on January 1, 2020. The FIL replaces a trio of previous laws regulating foreign investment in China, namely, the Sino-foreign Equity Joint Venture Enterprise Law, the Sino-foreign Cooperative Joint Venture Enterprise Law and the Wholly Foreign-invested Enterprise Law, together with their implementation rules and ancillary regulations. The FIL embodies an expected PRC regulatory trend to rationalize its foreign investment regulatory regime in line with prevailing international practice and the legislative efforts to unify the corporate legal requirements for both foreign and domestic investments. The Implementation Rules to the Foreign Investment Law were promulgated by the State Council on December 26, 2019 and became effective on January 1, 2020. However, the changes in interpretation and implementation of the FIL and its Implementation Rules may increase our compliance costs or set higher standards on our corporate governance practice. For instance, the FIL imposes information reporting requirements on foreign investors or foreign-invested enterprises. Failure to take timely and appropriate measures to cope with any of these or other regulatory compliance requirements under the FIL may lead to rectification obligations, penalties or other regulatory sanctions on us.

Any failure by the Shareholders or beneficial owners of our Shares to make required applications and filings pursuant to regulations relating to offshore investment activities could restrict our ability to distribute profits and subject us to liabilities.

The State Administration of Foreign Exchange has promulgated several regulations requiring PRC residents to register before engaging in direct or indirect offshore investment activities, including the Circular on Relevant Issues Concerning the Administration of Foreign Exchange on Domestic Residents' Overseas Investment, Financing and Roundtrip Investment through Special Purpose Vehicles, or SAFE Circular 37, issued and effective on July 4, 2014. SAFE Circular 37 requires PRC residents (including PRC individuals and PRC corporate entities as well as foreign individuals that are deemed as PRC residents for foreign exchange administration purpose) to register with local branches of the SAFE in connection with their direct establishment or indirect control of an offshore entity, for the purpose of overseas investment and financing, with onshore or offshore assets or equity interests held by the PRC residents, referred to in SAFE Circular 37 as a "special purpose vehicle." SAFE Circular 37 further requires amendment to the registration in the event of any significant changes with respect to the special purpose vehicle. If a shareholder who is a PRC resident does not complete the required registration or update the previously filed registration, the PRC subsidiaries of the special purpose vehicle may be prohibited from distributing their profits and proceeds from any reduction in capital, share transfer or liquidation to the special purpose vehicle, and the special purpose vehicle may be subject to restrictions when making additional capital contributions to its PRC subsidiaries. Moreover, failure to comply with the various SAFE registration requirements described above may result in liabilities for the PRC subsidiaries of the special purpose vehicle under PRC laws for evasion of applicable foreign exchange restrictions, including (1) the requirement by the SAFE to return the foreign exchange remitted overseas within a period of time specified by the SAFE, with a fine of up to 30% of the total amount of foreign exchange remitted overseas and deemed to have been evasive, and (2) in circumstances involving serious violations, a fine of no less than 30% of and up to the total amount of remitted foreign exchange deemed evasive.

According to the Notice of the State Administration of Foreign Exchange on Issuing the Provisions on the Foreign Exchange Administration of the Overseas Direct Investments, or SAFE Circular 30, Administrative Measures for the Outbound Investment of Enterprises and other regulations, if our Shareholders who are PRC entities do not complete their registration with the competent SAFE, NDRC or MOFCOM branches, our PRC subsidiaries may be prohibited from distributing their profits and proceeds from any reduction in capital, share transfer or liquidation to us, and we may be restricted in our ability to contribute additional capital to our PRC subsidiaries. In addition, our Shareholders may be required to suspend or stop the investment and complete the registration within a specified time, and may be warned or prosecuted for relevant liability. Moreover, failure to comply with the SAFE registration described above could result in liability under PRC laws for evasion of applicable foreign exchange restriction.

On February 13, 2015, SAFE promulgated the Notice on Further Simplifying and Improving Policies for the Foreign Exchange Administration of Direct Investment, or SAFE Circular 13, which came into effect on June 1, 2015, pursuant to which local banks shall review and handle foreign exchange registration for overseas direct investment, including the initial foreign exchange registration and amendment registration under SAFE Circular 37 and SAFE Circular 30, while the application for remedial registrations shall still be submitted to, reviewed and handled by the relevant local branches of SAFE.

We are committed to complying with and to ensuring that our Shareholders who are subject to the regulations will comply with the relevant SAFE rules and other regulations. However, we may not always be fully aware or informed of the identities of our beneficiaries who are PRC nationals or entities, and may not be able to compel them to comply with SAFE Circular 37, SAFE Circular 30 or other regulations. We cannot assure you that all of our Shareholders or beneficiaries will at all times comply with, or in the future make or obtain any applicable registrations or approvals required by SAFE rules or other regulations. Failure by any such shareholders to comply with SAFE rules or other regulations may result in restrictions on the foreign exchange activities of our PRC subsidiaries and may also subject the relevant PRC resident or entity to penalties under the PRC foreign exchange administration regulations.

We may rely on dividends and other distributions on equity paid by our PRC subsidiaries to fund any cash and financing requirements we may have, and any limitation on the ability of our PRC subsidiaries to make payments to us could affect our ability to conduct our business.

We are a holding company incorporated as an exempted company in the Cayman Islands, and we may rely on dividends and other distributions on equity paid by our PRC subsidiaries for our cash and financing requirements, including the funds necessary to pay dividends and other cash distributions to our Shareholders or to service any debt we may incur. If any of our PRC subsidiaries incurs debt on its own behalf in the future, the instruments governing the debt may restrict its ability to pay dividends or make other distributions to us. Under PRC laws and regulations, our PRC subsidiaries may pay dividends only out of their respective accumulated profits as determined in accordance with PRC accounting standards and regulations. In addition, a wholly foreign-owned enterprise is required to set aside at least 10% of its accumulated after-tax profits each year, if any, to fund a certain statutory reserve fund, until the aggregate amount of such fund reaches 50% of its registered capital. Such reserve funds cannot be distributed to us as dividends. In addition, the ability of our PRC subsidiaries to make payments to us is subject to any changes in the laws and regulations relating to the currency conversion, capital outflow management and cross-border transactions.

Dividends paid by our PRC subsidiaries to us may be subject to PRC withholding taxes.

The PRC Enterprise Income Tax Law ("**Enterprise Income Tax Law**") and its implementation rules provide that China-sourced income of foreign enterprises, such as dividends paid by a PRC subsidiary to its equity holders that are non-PRC resident enterprises, will normally be subject to PRC withholding tax at a rate of 10%, unless any such foreign investor's jurisdiction of incorporation has a tax treaty with China that provides for a different withholding arrangement. As a result, dividends paid to us by our PRC subsidiaries are expected to be subject to the PRC withholding tax at a rate of 10%.

Pursuant to the Arrangement between Mainland China and Hong Kong Special Administrative Region for the Avoidance of Double Taxation and Prevention of Fiscal Evasion with respect to Taxes on Income, the withholding tax rate on dividends paid by our PRC subsidiary to our Hong Kong subsidiary would generally be reduced to 5%, provided that our Hong Kong subsidiary is a Hong Kong tax resident as well as the beneficial owner of our PRC-sourced income, and it directly holds 25% or more interests in our PRC subsidiaries. On February 3, 2018, the State Administration of Taxation issued the Announcement on Certain Issues Concerning the Beneficial Owners in a Tax Agreement, also known as Circular 9, which provides guidance for determining whether a resident of a contracting state or region is the "beneficial owner" of an item of income under China's tax treaties and similar arrangements. According to Circular 9, a beneficial owner generally must be engaged in substantive business activities and an agent will not be regarded as a beneficial owner. There is no assurance that the reduced withholding tax rate will be available to any of our Hong Kong subsidiaries.

We may be treated as a resident enterprise for PRC tax purposes under the PRC Enterprise Income Tax Law and become subject to tax liabilities.

Under the Enterprise Income Tax Law, an enterprise established outside the PRC with "de facto management bodies" within China is considered a "resident enterprise," meaning that it is treated in a manner similar to a Chinese enterprise for the PRC enterprise income tax ("**EIT**") purposes. The implementing rules of the Enterprise Income Tax Law define "de facto management bodies" as "management bodies that exercise substantial and overall management and control over the production and operations, personnel, accounting, and properties" of the enterprise. In addition, the Notice Regarding the Determination of Chinese-Controlled Offshore Incorporated Enterprises as PRC Tax Resident Enterprises on the Basis of De Facto Management Bodies, or Circular 82, specifies that certain Chinese-controlled offshore incorporated enterprises, defined as enterprises incorporated under the laws of foreign countries or territories and that have PRC enterprises or enterprise groups as their primary controlling shareholders, will be classified as resident enterprises if all of the following are located or resident in China: (i) senior management personnel and departments that are responsible for daily production, operation and management; (ii) financial and personnel decision-making bodies; (iii) key properties, accounting books, company seal and minutes of board meetings and shareholders' meetings; and (iv) half or more of senior management or directors having voting rights. State Administration of Taxation of the PRC has subsequently provided further guidance on the implementation of Circular 82.

If the PRC tax authorities determine that our Cayman Islands holding company or any of our non-PRC subsidiaries is a resident enterprise for PRC EIT purposes, a number of tax consequences could follow. First, we and our non-PRC subsidiaries may be subject to EIT at a rate of 25% on our worldwide taxable income, as well as to PRC EIT reporting obligations. Second, although under the EIT Law and its implementing rules, dividends paid by a PRC tax resident enterprise to an offshore incorporated PRC tax resident enterprise controlled by a PRC enterprise or enterprise group would qualify as tax-exempted income, we cannot assure that dividends paid by our PRC subsidiaries to us will not be subject to a 10% withholding tax. Finally, dividends paid by us to our non-PRC shareholders, and any gain realized from the transfer of our Shares by our non-PRC shareholders, may be treated as income derived from sources within China. As a result, dividends paid to our non-PRC resident enterprise shareholders may be subject to PRC withholding tax and gains realized by our non-PRC resident enterprise shareholders from the transfer of our Shares may be subject to PRC tax. Similarly, these unfavorable consequences could apply to our other offshore companies if they are classified as a PRC resident enterprise.

We and our Shareholders face uncertainties with respect to indirect transfers of equity interests in PRC resident enterprises or other assets attributed to a PRC establishment of a non-PRC company.

Pursuant to the Bulletin on Issues of Enterprise Income Tax Concerning Indirect Transfers of Assets by Non-PRC Resident Enterprises, or Bulletin 7, an "indirect transfer" of "PRC taxable assets," including equity interests in a PRC resident enterprise, by non-PRC resident enterprises may be recharacterized and treated as a direct transfer of PRC taxable assets, if such arrangement does not have a reasonable commercial purpose and was established for the purpose of avoiding payment of PRC EIT. As a result, gains derived from such indirect transfer may be subject to PRC EIT. When determining whether there is a "reasonable commercial purpose" for the transaction arrangement, factors to be taken into consideration mainly include: whether the main value of the equity interest of the relevant offshore enterprise derives from PRC taxable assets; whether the assets of the relevant offshore enterprise mainly consists of direct or indirect investment in China or if its income mainly derives from China; whether the offshore enterprise and its subsidiaries directly or indirectly holding PRC taxable assets have real commercial nature which is evidenced by their actual function and risk exposure; the duration of existence of the business model and organizational structure; the replicability of the transaction by direct transfer of PRC taxable assets; and the tax situation of such indirect transfer and applicable tax treaties or similar arrangements. Gains derived from the sale of shares by investors through a public stock exchange are not subject to the PRC EIT pursuant to Bulletin 7 where such shares were acquired in a transaction through a public stock exchange. As such, the sale of the Shares on a public stock exchange will not be subject to PRC EIT pursuant to Bulletin 7. However, the sale of our Shares by a non-PRC resident enterprise outside a public stock exchange may be subject to PRC EIT under Bulletin 7.

Bulletin 7 may be determined by the tax authorities to be applicable to sale of the shares of our offshore subsidiaries or investments where PRC taxable assets are involved. The transferors and transferees may be subject to the tax filing and withholding or tax payment obligation, while our PRC subsidiaries may be requested to assist in the filing. Furthermore, we, our non-PRC resident enterprises and PRC subsidiaries may be required to spend resources to comply with Bulletin 7 or to establish that we and our non-PRC resident enterprises should not be taxed under Bulletin 7, for our previous and future restructuring or disposal of shares of our offshore subsidiaries.

The PRC tax authorities make adjustments to the taxable capital gains based on the difference between the fair value of the taxable assets transferred and the cost of investment under Bulletin 7. If the PRC tax authorities make adjustments to the taxable income of the transactions under Bulletin 7, our income tax costs associated with such potential acquisitions or disposals may increase.

Our ability to utilize our revenue is subject to regulatory requirements over foreign currency conversion.

Currency conversion and remittance is subject to the relevant regulatory requirements. As a substantial majority of our future revenue is expected to be denominated in RMB, any shortage in availability of foreign currency may have an impact on the ability of our PRC subsidiaries to remit sufficient foreign currency to our offshore entities for distributing dividends or making other payments or satisfying our foreign currency denominated obligations. The RMB is currently convertible under the "current account," which includes dividends, trade and service-related foreign exchange transactions, but not under the "capital account," which includes foreign direct investment and loans, including loans we may secure from our onshore subsidiaries. Currently, our PRC subsidiaries may purchase foreign currency for settlement of "current account transactions," including payment of dividends to us, without the approval of SAFE by complying with certain procedural requirements. However, any existing and future changes on regulations relating to currency exchange may have an influence on our ability to utilize revenue generated in RMB to fund our business activities outside of the PRC or pay dividends in foreign currencies to holders of our Shares. Foreign exchange transactions under the capital account require approvals from, or registration with, SAFE and other relevant PRC governmental authorities. This could affect our ability to obtain foreign currency through debt or equity financing for our subsidiaries. Our inability to obtain such foreign currency could materially adversely affect our business, financial condition, results of operations and prospects.

We may face risks from transferring our scientific data.

On March 17, 2018, the General Office of the State Council promulgated the Measures for the Management of Scientific Data, or the Scientific Data Measures, which provides a broad definition of scientific data and relevant rules for the management of scientific data. According to the Scientific Data Measures, if the provision of scientific data involving "state secrets" is required in foreign exchanges and cooperation, Chinese enterprises should clarify the type, scope and purpose of the data to be used, and report to the competent authority for approval in accordance with relevant procedures of confidentiality management regulations. When publishing a paper in a foreign academic journal requires the author to submit the relevant scientific date, the author should, prior to the publication, submit such scientific data to the belonged institution for unified management if such scientific data are generated with the government funding. We cannot assure you that we can always obtain relevant approvals for sending scientific data. If we are unable to obtain necessary approvals in a timely manner, or at all, our R&D of drug candidates may be hindered, which could materially and adversely affect our business, financial condition, results of operations and prospects. If the relevant government authorities consider the transmission of our scientific data to be in violation of the requirements under the Scientific Data Measures, we may be subject to rectification and other administrative penalties imposed by those government authorities.

You may experience difficulties in effecting service of legal process, enforcing foreign judgments against us or our management named in the documents.

We are a holding company incorporated as an exempted company in the Cayman Islands with substantially all of our assets located in China. In addition, a majority of our Directors and senior management personnel reside within mainland China, and substantially all of their assets are located within the PRC. Therefore, it may be difficult for investors to directly effect service of legal process upon us or our Directors and senior management personnel in the PRC.

On July 14, 2006, the Supreme People's Court of the PRC and the government of Hong Kong Special Administrative Region entered into the Arrangement on Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Matters by the Courts of the Mainland and of the Hong Kong Special Administrative Region Pursuant to Choice of Court Agreements between Parties Concerned, or the Arrangement, which was taken into effect on August 1, 2008.

Pursuant to the Arrangement, where any designated PRC court or any designated Hong Kong court has made an enforceable final judgment requiring payment of money in a civil or commercial case under a choice of court agreement in writing, any party concerned may apply to the relevant PRC court or Hong Kong court for recognition and enforcement of the judgment. A choice of court agreement in writing is defined as any agreement in writing entered into between parties after the effective date of the Arrangement in which a Hong Kong court or a mainland court is expressly selected as the court having sole jurisdiction for the dispute.

On January 18, 2019, the Supreme People's Court and the Hong Kong SAR Government signed the Arrangement on Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Matters by the Courts of the Mainland and of the Hong Kong Special Administrative Region, or the New Arrangement, which seeks to establish a mechanism with greater clarity and certainty for recognition and enforcement of judgments in wider range of civil and commercial matters between Hong Kong SAR and the mainland China. The New Arrangement does not include the requirement for a choice of court agreement in writing by the parties. The New Arrangement will only take effect after the promulgation of a judicial interpretation by the Supreme People's Court and the completion of the relevant legislative procedures in the Hong Kong SAR. The New Arrangement will, upon its effectiveness, supersedes the Arrangement. Therefore, before the New Arrangement becomes effective, it may be difficult to enforce a judgment rendered by a Hong Kong court in China if the parties in the dispute do not agree to enter into a choice of court agreement in writing.

RISKS RELATING TO THE [REDACTED]

There has been no prior [REDACTED] for our Shares and there can be no assurance that an active [REDACTED] would develop, especially taking into account that certain of our existing Shareholders may be subject to a lock-up period, and the [REDACTED] and [REDACTED] of our Shares may be volatile.

Prior to this [**REDACTED**], there has been no [**REDACTED**] for our Shares. The [**REDACTED**] for our [**REDACTED**] was the result of negotiations among us and the [**REDACTED**] (on behalf of the [**REDACTED**]) and the [**REDACTED**] may differ significantly from the [**REDACTED**] for our Shares following this [**REDACTED**]. We have applied for [**REDACTED**] of and permission to [**REDACTED**] our [**REDACTED**] on the [**REDACTED**]. A [**REDACTED**] on the [**REDACTED**], however, does not guarantee that an active and liquid [**REDACTED**] for the Shares will develop, especially during the period when a certain portion of our Shares may be subject to lock-up, or if it does develop, that it will be sustained following the [**REDACTED**], or that the [**REDACTED**] of the Shares will not decline following the [**REDACTED**].

Normally, a [**REDACTED**] acting on behalf of the [**REDACTED**] may [**REDACTED**] or effect [**REDACTED**] or any other [**REDACTED**] with a view to [**REDACTED**] the [**REDACTED**] of the [**REDACTED**] at a level higher than that which might otherwise prevail in the [**REDACTED**]. However, given that we will not grant any [**REDACTED**] to the [**REDACTED**], no [**REDACTED**] has been appointed by us in connection to the [**REDACTED**] and it is anticipated that no [**REDACTED**] activities will be conducted by any [**REDACTED**], which may result in substantial losses for [**REDACTED**] during the period when [**REDACTED**] activities would normally have been conducted.

In addition, the [**REDACTED**] and [**REDACTED**] of the Shares may be subject to significant volatility in responses to various factors beyond our control, including the general market conditions of the securities in Hong Kong and elsewhere in the world. In particular, the business and performance and the [**REDACTED**] of the shares of other companies engaging in similar business may affect the [**REDACTED**] and [**REDACTED**] of our Shares. In

addition to market and industry factors, the [**REDACTED**] and [**REDACTED**] of our Shares may be highly volatile for specific business reasons, such as the results of clinical trials of our product candidates, the results of our applications for approval of our product candidates, regulatory developments affecting the pharmaceutical markets, healthcare, health insurance and other related matters, fluctuations in our revenue, earnings, cash flows, investments and expenditures, relationships with our suppliers, movements or activities of key personnel, or actions taken by competitors. Moreover, shares of other companies listed on the Stock Exchange have experienced price volatility in the past, and it is possible that our Shares may be subject to changes in [**REDACTED**] not directly related to our performance.

Raising additional capital may cause dilution to our Shareholders, restrict our operations or require us to relinquish rights to our technologies or drug candidates.

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

The [REDACTED] of our Shares when [REDACTED] begins could be lower than the [REDACTED].

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

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

Future sales or perceived sales of our Shares in the [REDACTED] by major Shareholders following the [REDACTED] could materially and adversely affect the [REDACTED] of our Shares.

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

Our Controlling Shareholders have substantial control over our Company and their interests may not be aligned with the interests of the other Shareholders.

Upon the completion of the [**REDACTED**], our Controlling Shareholders will be interested in approximately [**REDACTED**]% of our total issued share capital. Our Controlling Shareholders, who will remain as the Controlling Shareholders upon completion of the [**REDACTED**], will continue to have significant influence on us on various important corporate actions requiring the approval of Shareholders, such as mergers, disposal of assets, election of Directors, and timing and amount of dividends and other distributions. There may be a conflict between the interests of our Controlling Shareholders and your interests. Control by our Controlling Shareholders of a substantial percentage of our Shares may have the effect of delaying, discouraging or preventing a change in control of us, which may deprive you of opportunities to receive premiums for your Shares and may reduce the [**REDACTED**] of the Shares. If our Controlling Shareholders causes us to pursue strategic objectives that would conflict with your interests, you may also be left in a disadvantaged position.

Because we do not expect to pay dividends in the foreseeable future after the [REDACTED], you should rely on [REDACTED] appreciation of our Shares for a return on your [REDACTED].

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

We are a Cayman Islands company and, because judicial precedent regarding the rights of shareholders is more limited under the laws of the Cayman Islands than other jurisdictions, you may have difficulties in protecting your shareholder rights.

Our corporate affairs are governed by our Memorandum and Articles of Association as well as the Cayman Companies Act and the common law of the Cayman Islands. The rights of shareholders to take action against the Directors, the rights of minority shareholders to institute actions and the fiduciary responsibilities of our Directors to us under Cayman Islands law are to a large extent governed by the common law of the Cayman Islands. The common law of the Cayman Islands is derived in part from comparatively limited judicial precedent in the Cayman Islands as well as from English common law, which has persuasive, but not binding, authority on a court in the Cayman Islands. The laws of the Cayman Islands relating to the protection of the interests of minority shareholders differ in some respects from those in Hong Kong and other jurisdictions. These differences may mean that the remedies available to the Company's minority shareholders may be different from those they would have under the laws of Hong Kong or other jurisdictions. See "Appendix III — Summary of the Constitution of the Company and Cayman Islands Company Law" in this document for further information.

There can be no assurance of the accuracy or completeness of certain facts, forecasts and other statistics obtained from various government publications contained in this document.

This document, particularly the section headed "Industry Overview" contains information and statistics relating to the pharmaceutical industry. Certain information and statistics have been derived from various government publications, other third-party reports, either commissioned by us or publicly accessible, and other publicly available sources. We believe that the sources of the information are appropriate sources for such information, and we have taken reasonable care in extracting and reproducing such information. However, the information from official government sources has not been independently verified by us, the Sole Sponsor, the [**REDACTED**], the [**REDACTED**], any of their respective directors, employees, agents or advisers or any other person or party involved in the [**REDACTED**], and no representation is given as to its accuracy. Collection methods of such information may be flawed or ineffective, or there may be discrepancies between published information and market practice, which may result in the statistics being inaccurate or not comparable to statistics produced for other economies. Accordingly, the information from official government sources contained herein should not be unduly relied upon. In addition, we cannot assure you that such information is stated or compiled on the same basis or with the same degree of accuracy as similar statistics presented elsewhere. In any event, you should consider carefully the importance placed on such information or statistics.

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

This document contains certain future plans and forward-looking statements about us that are made based on the information currently available to our management. The forward-looking information contained in this document is subject to certain risk and uncertainties. Whether we implement those plans, or whether we can achieve the objectives described in this document, will depend on various factors including the market conditions, our business prospects, actions by our competitors and the global financial situations.

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

Subsequent to the date of this document but prior to the completion of the [**REDACTED**], there may be press and media coverage regarding us and the [**REDACTED**], which may contain, among other things, certain financial information, projections, valuations and other forward-looking information about us and the [**REDACTED**]. We have not authorized the disclosure of any such information in the press or media and do not accept responsibility for the accuracy or completeness of such press articles or other media coverage. We make no representation as to the appropriateness, accuracy, completeness or reliability of any of the projections, valuations or other forward-looking information about us. To the extent such statements are inconsistent with, or conflict with, the information contained in this document, we disclaim responsibility for them. Accordingly, [**REDACTED**] are cautioned to make their [**REDACTED**] decisions on the basis of the information contained in this document only and should not rely on any other information.

You should rely solely upon the information contained in this document, the [**REDACTED**] and any formal announcements made by us in Hong Kong when making your [**REDACTED**] decision regarding our Shares. We do not accept any responsibility for the accuracy or completeness of any information reported by the press or other media, nor the fairness or appropriateness of any forecasts, views or opinions expressed by the press or other media regarding our Shares, the [**REDACTED**] or us. We make no representation as to the appropriateness, accuracy, completeness or reliability of any such data or publication. Accordingly, [**REDACTED**] should not rely on any such information, reports or publications in making their decisions as to whether to [**REDACTED**] in our [**REDACTED**]. By [**REDACTED**] to [**REDACTED**] our Shares in the [**REDACTED**], you will be deemed to have agreed that you will not rely on any information other than that contained in this document.

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

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

WAIVER IN RESPECT OF MANAGEMENT PRESENCE IN HONG KONG

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

Our headquarters and most of our business operations are based, managed and conducted in the PRC. As our executive Directors play very important roles in our business operation, it is in our best interest for them to be based in the places where our Group has significant operations. We consider it practicably difficult and commercially unreasonable for us to arrange for two executive Directors to ordinarily reside in Hong Kong, either by means of relocation of our executive Directors to Hong Kong or appointment of additional executive Directors. Therefore, we do not have, and in the foreseeable future will not have, sufficient management presence in Hong Kong for the purpose of satisfying the requirements under Rule 8.12 of the Listing Rules.

Accordingly, we have applied to the Stock Exchange for, and the Stock Exchange [has granted] us, a waiver from strict compliance with the requirements under Rule 8.12 of the Listing Rules, provided that our Company implements the following arrangements:

(a) we have appointed Mr. ZHANG Feng (張峰) and Ms. WONG Hoi Ting (黃凱婷) as our authorized representatives pursuant to Rule 3.05 of the Listing Rules. The authorized representatives will act as our principal channel of communication with the Stock Exchange. The authorized representatives will be readily contactable by phone, facsimile and email to promptly deal with enquiries from the Stock Exchange, and will also be available to meet with the Stock Exchange to discuss any matter within a reasonable period of time upon the request of the Stock Exchange;

(b) when the Stock Exchange wishes to contact our Directors on any matter, each of the authorized representatives will have all necessary means to contact all of our Directors (including our independent non-executive Directors) promptly as and when required. We will also inform the Stock Exchange promptly in respect of any changes in the authorized representatives. We have provided the Stock Exchange with the contact details (i.e. mobile phone number, office phone number (if any) and/or email address) of all Directors to facilitate communication with the Stock Exchange;

(c) all Directors who do not ordinarily reside in Hong Kong possess or can apply for valid travel documents to visit Hong Kong and can meet with the Stock Exchange within a reasonable period upon the request of the Stock Exchange;

(d) we have appointed Somerley Capital Limited as our compliance adviser upon [**REDACTED**] pursuant to Rule 3A.19 of the Listing Rules for a period commencing on the [**REDACTED**] and ending on the date on which we comply with Rule 13.46 of the Listing Rules in respect of our financial results for the first full financial year commencing after the [**REDACTED**]. Our compliance adviser will serve as the additional channel of communication with the Stock Exchange when the authorized representatives are not available and will have access at all times to our authorized representatives, our Directors and our senior management who will provide such information and assistance as our compliance adviser may need or reasonably request in connection with the performance of its duties as set out in Chapter 3A of the Listing Rules; and

(e) meetings between the Stock Exchange and our Directors could be arranged through our authorized representatives or our compliance adviser, or directly with our Directors within a reasonable time frame.

WAIVER IN RESPECT OF APPOINTMENT OF JOINT COMPANY SECRETARIES

Pursuant to Rules 3.28 and 8.17 of the Listing Rules, we must appoint a company secretary 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 the company secretary. Note 1 to Rule 3.28 of the Listing Rules provides that the Stock Exchange considers the following academic or professional qualifications to be acceptable:

(a) a member of The Hong Kong Chartered Governance Institute;

(b) a solicitor or barrister as defined in the Legal Practitioners Ordinance (Chapter 159 of the Laws of Hong Kong); and

(c) a certified public accountant as defined in the Professional Accountants Ordinance (Chapter 50 of the Laws of Hong Kong).

Note 2 to Rule 3.28 of the Listing Rules further provides that the Stock Exchange considers the following factors in assessing the "relevant experience" of the individual:

(a) length of employment with the issuer and other issuers and the roles he/she played;

(b) familiarity with the Listing Rules and other relevant laws and regulations including the SFO, the Companies Ordinance, the Companies (Winding Up and Miscellaneous Provisions) Ordinance and the Takeovers Codes;

(c) relevant training taken and/or to be taken in addition to the minimum requirement under Rule 3.29 of the Listing Rules; and

(d) professional qualifications in other jurisdictions.

Pursuant to paragraph 13 of Chapter 3.10 of the Guide for New Listing Applicants, the Stock Exchange will consider a waiver application by an issuer in relation to Rules 3.28 and 8.17 of the Listing Rules based on the specific facts and circumstances. Factors that will be considered by the Stock Exchange include:

(a) whether the issuer has principal business activities primarily outside Hong Kong;

(b) whether the issuer was able to demonstrate the need to appoint a person who does not have the Acceptable Qualification (as defined under paragraph 11 of Chapter 3.10 of the Guide for New Listing Applicants) nor Relevant Experience (as defined under paragraph 11 of Chapter 3.10 of the Guide for New Listing Applicants) as a company secretary; and

(c) why the directors consider the individual to be suitable to act as the issuer's company secretary.

Further, pursuant to paragraph 13 of Chapter 3.10 of the Guide for New Listing Applicants, such waiver, if granted, will be for a fixed period of time (the "**Waiver Period**") and on the following conditions:

(a) the proposed company secretary must be assisted by a person who possesses the qualifications or experience as required under Rule 3.28 of the Listing Rules and is appointed as a joint company secretary throughout the Waiver Period; and

(b) the waiver will be revoked if there are material breaches of the Listing Rules by the issuer.

Our Company has appointed Ms. XU Chunqin (徐春芹) ("**Ms. Xu**"), our chief financial officer, as one of our joint company secretaries. She has considerable experience in financial management as well as corporate development but presently does not possess any of the qualifications under Rules 3.28 and 8.17 of the Listing Rules, and may not be able to solely fulfill the requirements of the Listing Rules. Therefore, we have appointed Ms. WONG Hoi Ting (黃凱婷) ("**Ms. Wong**"), an associate member of both The Hong Kong Chartered Governance Institute (formerly known as The Hong Kong Institute of Chartered Secretaries) in

Hong Kong and The Chartered Governance Institute in the United Kingdom, who fully meets the requirements stipulated under Rules 3.28 and 8.17 of the Listing Rules to act as the other joint company secretary and to provide assistance to Ms. Xu for an initial period of three years from the [**REDACTED**] to enable Ms. Xu to acquire the "relevant experience" under Note 2 to Rule 3.28 of the Listing Rules so as to fully comply with the requirements set forth under Rules 3.28 and 8.17 of the Listing Rules.

Given Ms. Wong's professional qualifications and experience, she will be able to explain to both Ms. Xu and us the relevant requirements under the Listing Rules and other applicable Hong Kong laws and regulations. Ms. Wong will also assist Ms. Xu in organizing Board meetings and Shareholders' meetings of our Company as well as other matters of our Company which are incidental to the duties of a company secretary. Ms. Wong is expected to work closely with Ms. Xu and will maintain regular contact with Ms. Xu, our Directors and the senior management of our Company. In addition, Ms. Xu will comply with the annual professional training requirement under Rule 3.29 of the Listing Rules to enhance her knowledge of the Listing Rules during the three-year period from the [**REDACTED**]. She will also be assisted by our compliance adviser and our legal adviser as to Hong Kong laws on matters in relation to our ongoing compliance with the Listing Rules and the applicable laws and regulations.

Since Ms. Xu does not possess the formal qualifications required of a company secretary under Rule 3.28 of the Listing Rules, we have applied to the Stock Exchange for, and the Stock Exchange [has granted], a waiver from strict compliance with the requirements under Rules 3.28 and 8.17 of the Listing Rules such that Ms. Xu may be appointed as a joint company secretary of our Company. The waiver is valid for an initial period of three years from the [**REDACTED**] on the conditions that (a) Ms. Xu must be assisted by Ms. Wong who possesses the qualifications and experience required under Rule 3.28 of the Listing Rules and is appointed as a joint company secretary throughout the Waiver Period; and (b) the waiver will be revoked immediately if and when Ms. Wong ceases to provide assistance to Ms. Xu as a joint company secretary or if there are material breaches of the Listing Rules by our Company.

Before the expiration of the initial three-year period, the qualifications of Ms. Xu will be re-evaluated to determine whether the requirements as stipulated in Rules 3.28 and 8.17 of the Listing Rules can be satisfied and whether the need for ongoing assistance will continue. We will liaise with the Stock Exchange to enable it to assess whether Ms. Xu, having benefited from the assistance of Ms. Wong for the preceding three years, will have acquired the skills necessary to carry out the duties of company secretary and the relevant experience within the meaning of Note 2 to Rule 3.28 of the Listing Rules so that a further waiver will not be necessary.

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

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

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

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

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

Section 342A(1) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance provides that the SFC may issue, subject to such conditions (if any) as the SFC thinks fit, a certificate of exemption from the 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 would otherwise be unnecessary or inappropriate.

Rule 4.04(1) of the Listing Rules requires that the consolidated results of the issuer and its subsidiaries in respect of each of the three financial years immediately preceding the issue of the listing document or such shorter period as may be acceptable to the Stock Exchange be included in the accountants' report in the listing document.

Rule 18A.03(3) of the Listing Rules requires that a biotech company must have been in operation in its current line of business for at least two financial years prior to listing under substantially the same management. Rule 18A.06 of the Listing Rules requires that a biotech company must comply with Rule 4.04 of the Listing Rules modified so that references to "three

financial years" or "three years" in Rule 4.04 of the Listing Rules shall instead be references to "two financial years" or "two years", as the case may be. Further, pursuant to Rule 8.06 of the Listing Rules, the latest financial period reported on by the reporting accountants for a new applicant must not have ended more than six months from the date of the listing document.

In compliance with the abovementioned requirements under the Listing Rules, the Accountants' Report as set out in Appendix I to this document has been prepared to cover the two financial years ended December 31, 2022 and 2023.

Accordingly, an application has been made to the SFC for, and SFC [has granted], a certificate of exemption from strict compliance with the requirements under section 342(1)(b) 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 regarding the inclusion of the accountants' report covering the full three financial years immediately preceding the issue of this document on the following grounds:

(a) our Company is primarily engaged in the R&D, application and commercialization of biotech products, and falls within the scope of biotech company as defined under Chapter 18A of the Listing Rules. Our Company will fulfill the additional conditions for [**REDACTED**] required under Chapter 18A of the Listing Rules;

(b) the Accountants' Report for each of the two financial years ended December 31, 2022 and 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) notwithstanding that the financial results as set out in this document are only for the two financial years ended December 31, 2022 and 2023 in accordance with Chapter 18A of the Listing Rules, 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; and

(d) the Accountants' Report covering the two financial years ended December 31, 2022 and 2023, together with other disclosures in this document, have already provided adequate and reasonable up-to-date information in the circumstances for the [**REDACTED**] to make an informed assessment of the business, assets and liabilities, financial position, management and prospects of our Company and to form a view on the track record of our Company. Therefore, the exemption would not prejudice the interest of the [**REDACTED**].

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

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 section 342(1)(b) 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 particulars of the exemption are set out in this document and this document will be issued on or before [**REDACTED**].

[REDACTED]

[REDACTED]

[**REDACTED**]

[**REDACTED**]

[REDACTED]

Name	Address	Nationality
Executive Directors		
Mr. ZHANG Feng (張峰)	Room 601, No. 81 Yincheng Dongyuan Xuanwu District, Nanjing City Jiangsu Province PRC	Chinese
Dr. YIN Liusong (殷劉松)	Room 1005, Siya Capital No. 166 Baixia Road Qinhuai District, Nanjing City Jiangsu Province PRC	Chinese
Ms. JIANG Xiaoling (姜曉玲)	Room 304, Unit 1, Building 7 No. 100 Tianhua East Road Pukou District, Nanjing City Jiangsu Province PRC	Chinese
Non-executive Director		
Mr. FAN Rongkui (范融奎)	Room 401, No. 61 China Railway Yidu Phase II Lane 6161, Waiqingsong Road Qingpu District Shanghai PRC	Chinese
Independent Non-executive Directors		
Mr. CHAN Heung Wing Anthony (陳向榮)	Flat B, 16/F, Tower 6 Bel-Air on the Peak, Island South 68 Bel-Air Peak Avenue Hong Kong	Chinese (Hong Kong)
Ms. FENG Lan (馮嵐)	Room 403, Block F Huating Jiayuan No. 6 North Fourth Ring Middle Road Chaoyang District Beijing PRC	Chinese
Mr. SHI Luwen (史錄文)	No. 12, 6th Floor Building 25 No. 38 Xueyuan Road Haidian District Beijing PRC	Chinese

For further information with respect to our Directors, see "Directors and Senior Management" in this document.

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**]

Legal Advisers to our Company

As to Hong Kong and U.S. laws

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1 Connaught Road Central
Hong Kong

As to PRC laws

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Wanchai
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As to PRC intellectual property laws

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77 Jianguo Road
Chaoyang District
Beijing
PRC

As to U.S. intellectual property laws

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401 North Michigan Avenue
Suite 1200
Chicago, IL 60611
United States

Legal Advisers to the Sole Sponsor and the [REDACTED]

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Hong Kong

As to PRC laws

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158 Fuxing Men Nei Street
Xicheng District
Beijing
PRC

Reporting Accountants and Auditor	**Deloitte Touche Tohmatsu** *Certified Public Accountants* *Registered Public Interest Entity Auditor* 35/F, One Pacific Place 88 Queensway Hong Kong
Industry Consultant	**Frost & Sullivan (Beijing) Inc., Shanghai Branch Co.** 2504 Wheelock Square 1717 Nanjing West Road Shanghai 200040 PRC
Compliance Adviser	**Somerley Capital Limited** 20/F, China Building 29 Queen's Road Central Hong Kong

[**REDACTED**]

CORPORATE INFORMATION

Registered Office	PO Box 309 Ugland House Grand Cayman, KY1-1104 Cayman Islands
Headquarters	Room 302, Building 3 No. 198 Peninsula Middle Road, Dipu Street Anji County, Huzhou City Zhejiang Province PRC No. 5 Xingjian Road Nanjing Economic and Technological Development Zone PRC
Principal Place of Business in China	No. 5 Xingjian Road Nanjing Economic and Technological Development Zone PRC
Principal Place of Business in Hong Kong	31/F, Tower Two Times Square 1 Matheson Street Causeway Bay Hong Kong
Company's Website	**www.sunho-bio.com.cn** *(Information contained on this website does not form part of this document)*
Joint Company Secretaries	**Ms. XU Chunqin (徐春芹)** Room 204, Building 10 No. 61 Gujiaying Road Xuanwu District, Nanjing City Jiangsu Province PRC **Ms. WONG Hoi Ting (黃凱婷)** *(ACG and HKACG)* 31/F, Tower Two Times Square 1 Matheson Street Causeway Bay Hong Kong

Authorized Representatives	**Mr. ZHANG Feng (張峰)** Room 601, No. 81 Yincheng Dongyuan Xuanwu District, Nanjing City Jiangsu Province PRC **Ms. WONG Hoi Ting (黃凱婷)** *(ACG and HKACG)* 31/F, Tower Two Times Square 1 Matheson Street Causeway Bay Hong Kong
Audit Committee	Mr. CHAN Heung Wing Anthony (陳向榮) *(Chairperson)* Ms. FENG Lan (馮嵐) Mr. SHI Luwen (史錄文)
Remuneration Committee	Ms. FENG Lan (馮嵐) *(Chairperson)* Mr. ZHANG Feng (張峰) Mr. SHI Luwen (史錄文)
Nomination Committee	Mr. ZHANG Feng (張峰) *(Chairperson)* Ms. FENG Lan (馮嵐) Mr. SHI Luwen (史錄文)

[**REDACTED**]

Principal Bankers

Bank of Communications Co., Ltd., Nanjing Xingang Development Zone Branch
No. 10 Xingzhi Road
Qixia District, Nanjing City
Jiangsu Province
PRC

China Merchants Bank Co., Ltd., Zhujiang Road Sub-branch
No. 280 Zhujiang Road
Xuanwu District, Nanjing City
Jiangsu Province
PRC

Industrial Bank Co., Ltd., Nanjing Hongwu Sub-branch
2nd Floor, Newspaper Building
No. 233 Longpan Middle Road
Qinhuai District, Nanjing City
Jiangsu Province
PRC

The information and statistics set out in this section and other sections of this document were extracted from the report prepared by Frost & Sullivan, which was commissioned by us, and from various official government publications and other publicly available publications. 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**]*, any of their respective directors, employees, agents or advisers or any other person or party involved in the* [**REDACTED**]*, and no representation is given as to its accuracy, fairness and completeness.*

IMMUNOTHERAPY OVERVIEW

Immunotherapy is the most advanced biological treatment that either activates or suppresses immune responses to effectively address diseases. It can be further categorized into immunostimulators and immunosuppressors. Since it started to draw scientists' attention in the past decade for the potential treatment of cancer, immunotherapy has rapidly developed beyond the concept stage and entered the market. Nowadays, it is one of the most promising new treatments for a wide range of diseases, including cancer and autoimmune diseases.

Based on structural differences, immunotherapy mainly includes antibodies, fusion proteins, cell products, and products developed through advanced macromolecular structural engineering technologies, such as immunocytokines and antibody-drug conjugates ("**ADCs**"). As understanding of the human immune system gets deeper, researchers became interested in developing immunotherapies that play multiple functions. Unlike traditional monospecific antibody that recognizes and interacts with only one target, bispecific or multi-specific antibody or fusion protein is designed to recognize more than one target to perform multiple functions simultaneously.

Leveraging the development of bioengineering technology, researchers recommenced studies of previously shelved products. Among them, cytokines, a group of polypeptides or glycoproteins, known to play an important role as molecular messengers in the immune system, drew special attention. Although cytokines have been known to modulate immune responses for a long time, the clinical application of cytokine-based immunotherapies is greatly limited by, among others, severe toxicities and modest efficacies due to cytokine pleiotropy and off-target effects. Currently, engineering cytokines with improved therapeutic effects and safety has emerged to address these market demands. Especially, immunocytokines represent a promising strategy to overcome these challenges.

IMMUNO-ONCOLOGY DRUGS

Cancer is a broad group of diseases in which cells divide and grow in an uncontrolled fashion. These cells may form a mass called a tumor. The tumor microenvironment ("**TME**") is the environment surrounding a tumor, including the surrounding blood vessels, immune cells, fibroblasts, signaling molecules and the extracellular matrix. The tumor and the surrounding TME are closely related and interact constantly. According to the spatial distribution of cytotoxic immune cells in the TME, a tumor can be classified into "hot" or immune-inflamed, immunosuppressed, immune-excluded, and "cold" or immune-desert tumors. The TME of a "hot" tumor is characterized by accumulation of proinflammatory cytokines and T cell infiltration, whereas the TME of an immunosuppressed, immune-excluded, or "cold" tumor is characterized by different degrees of lack of tumor antigens, antigen presenting cells ("**APC**") deficit, insufficient T cell activation or impaired trafficking and infiltration of T cells. The degree of lymphocyte infiltration in the TME exerts a critical impact on responses to treatments, especially immunotherapy.

Immuno-Oncology Drugs Overview

After going through a long development process in history, cancer treatment evolves and develops beyond the concept of directly removing and killing tumor cells, and enters the era of boosting and reviving immunity in the TME. In addition to primary treatments including surgery, radiotherapy and chemotherapy, targeted therapy and immunotherapy have become major treatments of cancer. Particularly, immunotherapy, as the state-of-the-art cancer treatment that is designed to use a person's own immune system to fight cancer, has gained significant advances in recent years. Since the launch of the first immunotherapy, ipilimumab, an immune checkpoint inhibitor ("**ICI**") that targets CTLA-4 for the treatment of melanoma approved by the FDA in 2011, immunotherapy has benefited cancer patients with superior efficacy and superior clinical responses, and showed the tendency to shift toward first-line treatment. Particularly, pembrolizumab, another ICI that targets programmed death -1 ("**PD-1**"), was approved by the FDA for the first-line treatment of patients with metastatic non-small cell lung cancer ("**NSCLC**") and head and neck squamous cell carcinomas ("**HNSCC**").

Nevertheless, it is discovered that many immunotherapies, including PD-1/its ligand ("**PD-L1**") monoclonal antibodies, have a low overall objective response rate ("**ORR**"). For example, there are only about 10%-25% of patients across almost all major cancer types can benefit from PD-1/PD-L1 monotherapy treatment. The low ORR of immunotherapy is largely due to the immunosuppressive TME. It resists immunotherapies through primary or acquired drug resistance, which leads to lack or paucity of tumor T cell infiltration and thus limits the ability of T cells to fight cancer cells. Therefore, there remains unmet needs for developing new treatments that can overcome this challenge.

Currently, all the marketed immunotherapies aim to invoke adaptive immunity, including products targeting PD-1, PD-L1 and CTLA-4. The most clinically advanced product candidates that are expected to invoke the innate immunity are under Phase III clinical trials, which include products targeting NKG2A and CD47. There is no approved treatment which can simultaneously invoke both innate and adaptive immune responses. Innate and adaptive immunity are two distinctive immune systems that cooperate to build up an integrated immune response. Innate immunity is a non-specific defense system people are born with. It protects the host against all antigens, yet has no immunologic memory. It includes physical barriers, such as skin and mucosa membrane, innate immune cells, such as phagocytes and natural killer ("**NK**") cells, and immune molecules, such as cytokines. Adaptive immunity, on the other hand, is an antigen-dependent, specific defense mechanism that a body develops to fight foreign molecules. It is able to create immunological memory so that the immune system will be able to respond more rapidly and effectively to pathogens that have been encountered previously. It includes adaptive immune cells, such as T cells and B cells, and immune molecules, such as immunoglobulins.

Simultaneous stimulation of innate and adaptive immunity can achieve a synergistic effect, which will lead to highly efficient recognition and clearance of pathogens. APCs act as the bridge between the two systems. They mainly include dendritic cells and macrophages that can phagocytose antigens, degrade them into peptides and display the processed antigen peptides on the cell surface for T cells recognition, and thereby initiating the adaptive immune responses. In turn, T cells can stimulate macrophages through the release of cytokines, and thereby stimulating the innate immunity. Therefore, when innate and adaptive immunity are both activated, an enhanced and more long-lasting immune response compared to either of them alone will be generated and will benefit cancer patients who experience drug resistance to immunotherapies due to immunosuppressive TME.

Growth Drivers of Immuno-Oncology Therapy

The growth of immuno-oncology therapy markets is primarily driven by the following factors:

- *Growing patient pool*. The increasing new cases of cancer patients, especially the treatment-naïve patients, will drive the immuno-oncology therapy development. New cases of cancer patients globally are increasing stably in the past, reaching 20.2 million in 2022. However, the enlarging patient pool is still facing limited cancer treatment options. Immuno-oncology therapy, which is able to address unmet clinical needs with durable efficacy and less side effects, represents significant market opportunity.

- *Use of combined target*. Combining two or more targets in immuno-oncology therapy is an emerging approach that has gained traction. Such therapies have demonstrated improved efficacy by targeting key pathways in a synergistic or additive manner. Ongoing trials have shown promising results with the combination of PD-1/PD-L1 inhibitors and cytokines, leading to enhanced T cell infiltration through microenvironment modulation. Further investigation into potent combinations, such as PD-1/PD-L1 inhibitors with CD47 targeted drugs, is expected to diversify treatment options and expand the immuno-oncology therapy market.

- *Emerging new targets*. Following the approval of ipilimumab, a CTLA-4 inhibitor, in 2011 and subsequent approvals of more than ten PD-1/PD-L1 inhibitors worldwide, the market for immunotherapy has experienced remarkable growth. The global and China immuno-oncology therapy markets have maintained a high CAGR of 24.3% and 80.3% from 2018 to 2022, respectively. This rapid market growth can be attributed to significant research and development efforts focused on target discovery. Currently, there is a strong emphasis on identifying new immunotherapy such as antibody-signal regulatory protein α ("**SIRPα**"), IL-15, IL-10, B7 homolog 3 protein ("**B7H3**"), among others. These emerging targets contribute to an expanding reservoir of promising candidates for targeted drug development, increasing the likelihood of future commercialization. Consequently, the immuno-oncology therapy market is expected to continue expanding in the coming years.

- *Advancement of treatment line*. On June 15, 2018 when China approved its first PD-1 mAb, the drug, Opdivo or nivolumab, was approved as second line treatment for advanced NSCLC with negative driver gene mutation. 15 months later on September 30, 2019, another PD-1 mAb Keytruda or pembrolizumab became the first mono-immunotherapy approved for first-line treatment of all locally advanced or metastatic NSCLC with positive PD-L1 expression and no epidermal growth factor receptor ("**EGFR**") or anaplastic lymphoma kinase ("**ALK**") mutation. Moving rapidly from second line to first-line treatment is a milestone for immuno-oncology therapy, indicating NMPA's recognition of its validated superior antitumor efficacy. As a result of this tendency to shift towards fronter line, immuno-oncology therapy has the potential to benefit more patients, which will drive the growth of the immuno-oncology therapy market.

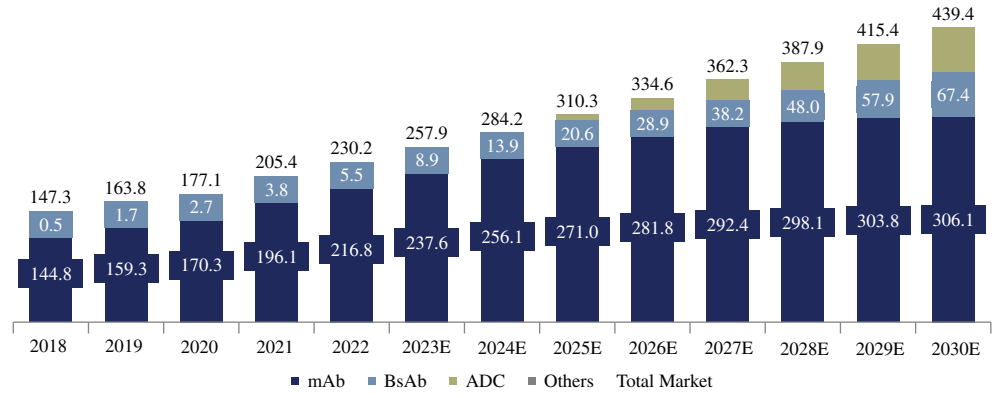
Overview of Antibodies

Antibody, also called immunoglobulin, is a protein produced by the immune system in response to the presence of pathogens such as pathogenic bacteria and viruses, which are called antigens. Antibodies recognize and latch onto antigens in order to neutralize and remove them from the body. Drugs developed based on antibody can be categorized into mAb, bispecific antibody ("**bsAb**"), ADC and fusion protein. Antibodies are currently utilized as medicines for cancer, inflammatory disease, organ transplantation, cardiovascular disease, respiratory disease and ophthalmologic disease.

mAb, bsAb, ADC and antibody fusion protein are four major types of antibodies. According to Frost & Sullivan, mAb dominated global antibody-based therapy market with a market share of over 90% from 2018 to 2022. The mAb market size is projected to reach US$281.8 billion in 2026 and US$306.1 billion in 2030. It is estimated that bsAb will have a considerable growth rate at a CAGR of 51.6% from 2022 to 2026. The global market size of bsAb is projected to reach US$67.4 billion in 2030, representing a CAGR of 23.6% from 2026 to 2030.

Global Antibody-based Drug Market, 2018-2030E

Period	CAGR				
	mAb	BsAb	ADC	Others	Total Market
2018-2022	10.6%	85.8%	40.4%	/	11.8%
2022-2026E	6.8%	51.6%	31.7%	/	9.8%
2026E-2030E	2.1%	23.6%	28.4%	87.6%	7.0%

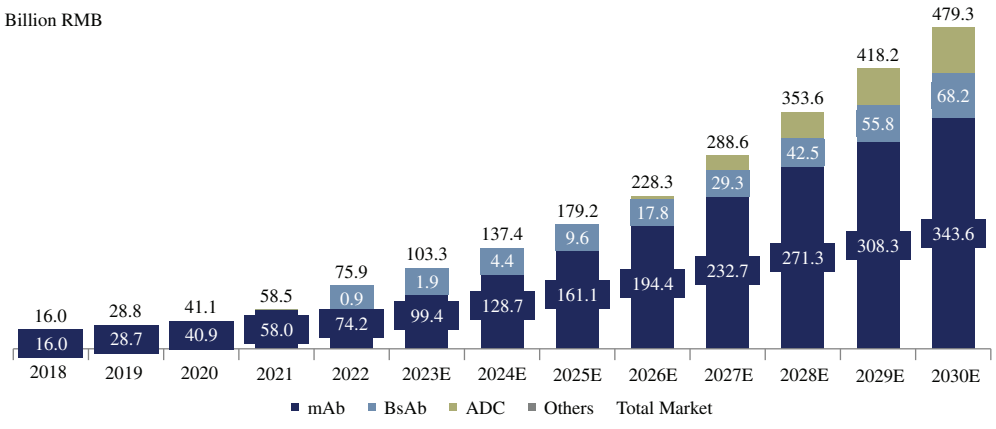


Source: Frost & Sullivan Analysis

According to Frost & Sullivan, mAb also dominated the antibody-based therapy market in China, with a market share of over 95% from 2018 to 2022. The market size of mAb in China is estimate to rise to RMB194.4 billion in 2026 and RMB343.6 billion in 2030. The market size of bsAb is projected to reach RMB17.8 billion in 2026 and RMB68.2 billion in 2030, at a CAGR of 113.6% from 2022 to 2026, and 39.8% from 2026 to 2030.

China Antibody-based Drug Market, 2018-2030E

Period	CAGR				
	mAb	BsAb	ADC	Others	Total Market
2018-2022	46.8%	/	/	/	47.7%
2022-2026E	27.2%	113.6%	109.2%	/	31.7%
2026E-2030E	15.3%	39.8%	42.8%	113.5%	20.4%



Source: Frost & Sullivan Analysis

The growth of antibodies market is primarily driven by the following factors:

- *Increasing Demand*. The rising demand for targeted and personalized therapies to effectively treat complex medical conditions is a significant driver for the growth of antibodies. These drugs offer advantages over traditional small molecule drugs, such as higher specificity, stronger affinity for target molecules, longer half-lives, and lower toxicity profiles.

- *Advancement in Biotechnology*. The rapid progress in biotechnology and protein engineering has enabled the development of more complex and diverse antibody-like drugs. Examples include bi-/multi-specific antibodies and ADCs. These advancements aim to enhance specificity, efficacy, and minimize off-target effects and drug resistance.

- *Large unmet needs*. The increasing prevalence of chronic diseases like cancer and autoimmune disorders, coupled with an aging population, is driving the growth of antibodies. This trend is expected to continue, leading to the development of more innovative and effective therapies for patients.

- *Expanding Pipeline*. The growing pipeline of antibody candidates in development is another key driver. The biopharmaceutical industry has made significant investments in research and development in this area, with many drugs currently undergoing clinical trials. As these drugs progress through clinical development and gain regulatory approval, they have the potential to significantly impact the treatment landscape for various diseases.

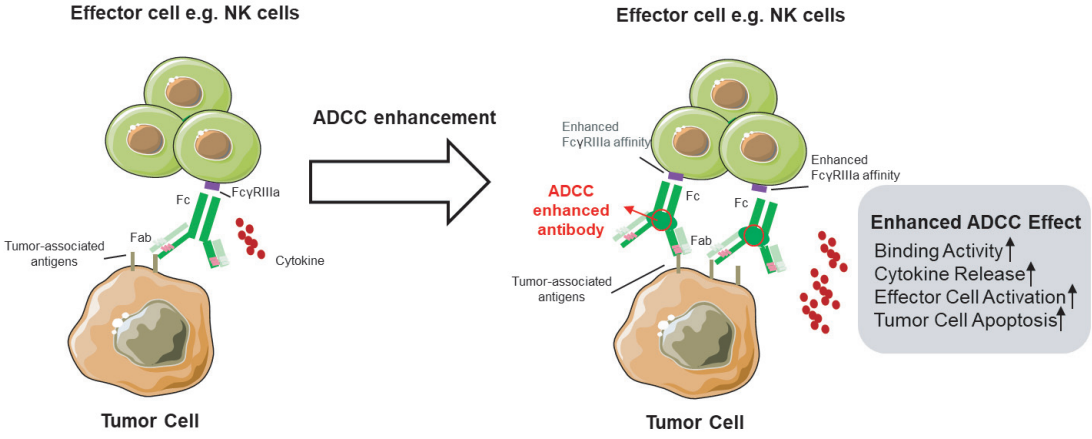
ADCC Enhanced mAbs

A monoclonal antibody is a symmetrical structure with four polypeptide chains, i.e. two heavy chains and two light chains, forming two antigen binding fragment ("**Fab**") arms containing identical domains at either end attached by a flexible hinge region to the stem of the antibody, the crystallizable fragment ("**Fc**") domain, giving the classical "Y" shape. The Fab region of antibody provides the antigen specificity of the antibody. The Fc fragment, which is composed of constant regions of heavy chains, interacts with various cell receptors and complement proteins and initiates and controls cell-mediated effector functions including ADCC, ADCP and CDC.

ADCC is an immune mechanism through which Fc receptor-bearing effector cells including NK cells and CD+8 T cells can recognize and kill antibody-coated target cells expressing tumor- or pathogen-derived antigens on their surface. It is one of the most important methods for antibody drugs to kill tumor cells. The typical ADCC involves activation of NK cells by antibodies in a multi-tiered progression of immune control. A NK cell expresses Fcγ receptors ("**FcγR**"). These receptors recognize and bind to the Fc domain of an antibody, and the Fab domain of which binds to the tumor associated antigen ("**TAA**") on the tumor cell. When both TAA and FcγR are engaged respectively by the Fab and Fc portions of the antibody,

ADCC is initiated, since this creates a bridge from the tumor cell to the effector cell. However, the natural affinity between antibodies and FcγR is relatively weak, and Fc engineering to enhance affinity has become a common method.

Mechanism of ADCC Enhanced mAbs



Source: Frost & Sullivan Analysis

The removal of core fucose has been shown to highly increase FcγRIIIa binding affinity and consequently increase ADCC. Several mutations could enhance binding to FcγRIIIa, with the most potent mutations selected from S298A/E333A/K334A/S239D/I332E/P247I/A339Q for enhanced ADCC. Fc multimerization strategies have also been shown to augment FcγR binding affinity and increase ADCC.

Different approaches have been adopted to achieve enhanced ADCC, mainly including Fc engineering, such as through amino acid alterations (e.g. margetuximab and inetetamab) and fucose removal. Fucose removal can be achieved either through the post-expression modification by enzyme digestion or through the construction of new cell lines. Studies of the structure of the Fc region of antibodies and its receptor FcγRIIIa complex revealed that the core fucose of the Fc region is accommodated at a place that interferes with the binding between the Fc region and FcγRIIIa, and thus reducing the affinity between them and resulting in lower ADCC activity. Therefore, modifying to remove fucose is desirable to better recruit immune cells, resulting in enhanced ADCC activity. As a result, this approach has been widely attempted in the biopharmaceutical industry. However, despite numerous attempts by multiple players to modify antibodies through various approaches, such as Fc point specific mutation and fucose removal, most resulting antibodies still contain a certain percentage of core fucose. To date, only IAH0968 based on AEA™ Platform from the Company and Mogamulizumab, a mAb targeting CC chemokine receptor 4, based on POTELLIGENT from Kyowa Kirin achieved complete removal of fucose residues. IAH0968 stands out as the only ADCC enhanced anti-HER2 antibody that achieves 100% fucose removal.

Anti-HER2 Antibodies

Human epidermal growth factor receptor 2 ("**HER2**") proteins are found on the surface of some tissue cells. They are involved in normal cell growth but can become overexpressed in tumor cells. The presence of overexpressed HER2 protein could cause cancer to grow and spread more quickly. Excessive cancer cells and tissue reproduction can result in a fast-growing cancer that is more likely to spread. By targeting HER2 proteins on the surface of tumor cells, the drugs can selectively kill the tumor cells. Research shows that HER2 is overexpressed in approximately 25% to 30% of breast cancers and also a number of other cancer types, including biliary tract carcinoma ("**BTC**") and colorectal cancer ("**CRC**").

Since the FDA's approval of the first anti-HER2 antibody, Herceptin or trastuzumab, developed by Roche in 1998, a total of four anti-HER2 mAbs have received marketing approval for cancer treatment in the U.S. and China, according to Frost & Sullivan. Margenza or margetuximab, Perjeta, and Herceptin are approved by the FDA. Inetetamab or 賽普汀, Perjeta, and Herceptin are approved by the NMPA. Notably, margetuximab and inetetamab possess enhanced Fc effector function through mutation of Fc region. These two antibodies are specifically indicated for HER2-positive breast cancers that have not responded to previous treatment regimens. IAH0968, developed by the Company, stands out as the only and the most clinically advanced ADCC-enhanced anti-HER2 mAb modified through fucose removal in China and the rest of the world, which is currently in the Phase II/III clinical stage.

Competitive Landscape of Anti-HER2 mAb

Drug Name	Company Name	Target	Enhanced Fc Effector Function	Indications	Clinical Stage	Approval Date/ First Posted Date	Treatment Line	Country/ Region
Margetuximab-cmkb/ Margenza®	MacroGenics	HER2	Yes (Fc mutation)	HER2+ Breast Cancer	Approved	FDA 2020/12/16; NMPA 2023/8/29	3L or above	US, China
Pertuzumab/ Perjeta®**	Roche	HER2	No	HER2+ Breast Cancer	Approved	FDA 2012/6/8; EMA 2013/3/4; PMDA 2013/6/28; NMPA 2018/12/17	1L	US, EU, Japan, China
	Roche/中外製薬株式会社			HER2+ curatively unresectable advanced or recurrent colorectal cancer*	Approved	PMDA 2022/3/28	2L	Japan
Trastuzumab/ Herceptin®**	Roche	HER2	No	HER2+ Breast Cancer, Gastric Cancer or Gastroesophageal Junction Adenocarcinoma	Approved	FDA 1998/9/25; EMA 2000/8/28; PMDA 2001/6; NMPA 2002/9/5	1L or above	US, EU, Japan, China
	Roche/中外製薬株式会社			HER2+ curatively unresectable advanced or recurrent colorectal cancer*	Approved	PMDA 2022/3/28	2L	Japan
Inetetamab/赛普汀®	Guojian Pharmaceutical	HER2	Yes (Fc mutation)	HER2+ Breast Cancer	Approved	NMPA 2020/6/19	2L or above	China
IAH0968	**SunHo (China) BioPharmaceutical**	**HER2**	**Yes (Fucose removal)**	**Metastatic colorectal cancer, biliary tract carcinoma**	**Phase II/III**	**2023/1/3**	**1L**	**China**
HLX22	Henlius	HER2	No	HER2-positive advanced or metastatic gastric cancer	Phase II	2021/6/1	1L	China
HuA21	HankeMab	HER2	No	HER2-positive locally advanced/metastatic gastric cancer	Phase I/II	2024/3/20	1L or above	China
SSGJ-612	Guojian Pharmaceutical	HER2	No	HER2-positive advanced solid tumors	Phase I	2021/10/27	2L or above	China
B002	Shanghai Pharma	HER2	No	HER2-positive recurrent or metastatic breast cancer	Phase I	2020/5/11	2L or above	China

Note: As of March 31, 2024;

* Combination therapy of Pertuzumab/Perjeta and Trastuzumab/Herceptin was approved by PMDA for HER2+ curatively unresectable advanced or recurrent colorectal cancer.

** Products have biosimilars available for marketing;

1. The listed drugs do not include ADCs and biosimilars;

2. The clinical stage refers to the most advanced stage of drug candidates;

3. The clinical trials listed above were taken from Chinadrugtrials.org.cn and Clinicaltrials.gov.

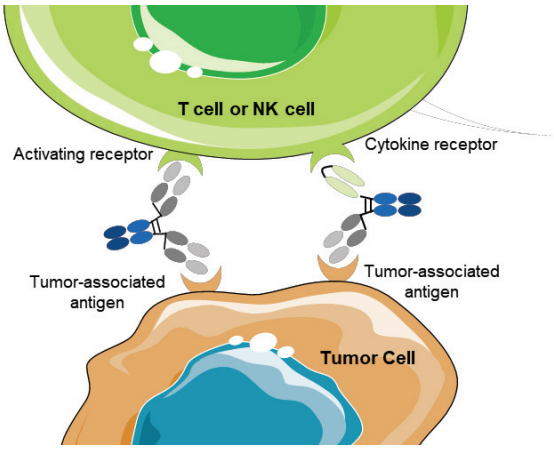
Source: FDA, NMPA, EMA, PMDA, CDE, clinicaltrials.gov, Frost & Sullivan Analysis

The global market for anti-HER2 monoclonal antibodies increased from US$10.0 billion to US$12.1 billion at a CAGR of 4.9% from 2018 to 2022. It is estimated that this market will reach US$13.6 billion in 2026 and US$14.8 billion in 2030. In China, the market for anti-HER2 monoclonal antibodies showed significant growth, increasing from RMB3.2 billion to RMB11.8 billion at a CAGR of 38.4% from 2018 to 2022. The market is expected to continue growing and reach RMB17.9 billion in 2026 and RMB21.0 billion in 2030, with a CAGR of 10.9% from 2022 to 2026 and 4.1% from 2026 to 2030.

Overview of Cytokine-Antibody Based Drugs

Cytokines are a broad and loose category of small proteins important in cell signaling and play an important role in modulating the immune system. Although cytokines have long been recognized as a promising candidate for developing cancer treatments, due to limitations including short half-life, narrow therapeutic windows, and off-target effects, the clinical application of cytokine drugs as monotherapy are greatly limited. Different approaches have been tried to overcome these technical difficulties, including covalent conjugate cytokines with polyethylene glycol ("**PEG**"), fusing cytokines with the Fc region fragment of antibodies, and developing novel cytokines through biological engineering. However, none of these approaches completely addressed the identified challenges. In recent years, immunocytokine becomes a popular approach for developing cytokine-based therapy, attributable to its strong ability to target tumors and prolong the half-life of cytokines as well as its synergistic antitumor effects of multiple targets.

Immunocytokines is a subgroup of fusion protein consisting of tumor-associated antigen recognition portion and cytokine payloads. Immunocytokine functions by bridging tumor cells and certain leukocytes (e.g., T cells and NK cells), in analogy to the function of bispecific antibodies. By activating various components of the immune system, immunocytokines are believed to show effective tumor killing effects which results from the high-density anchoring of the cytokine moiety at the tumor lesion.



Source: Frost & Sullivan Analysis

According to forms of tumor-associated antigen recognition portion, the immunocytokines could be further divided into immunocytokines with intact immunoglobulin G ("**IgG**") and immunocytokines based on antibody fragments. The below chart provides a comparison between the two subtypes of immunocytokines:

	Immunocytokines	
	Immunocytokines with intact IgG	Immunocytokines based on antibody fragments
Structure	Antibody Cytokines; Cytokines fused to different site of intact IgG antibody	Diabody*; Tribody*; Others
Half-Life	• **Long serum half-life:** Mediated by the large size and the binding to the neonatal Fc receptor (FcRn), the half-life of immucytokines with intact IgG will be prolonged through reduced renal clearance rates and impaired degradation.	• **Low serum half-life:** Due to the relatively low molecular size and lack of Fc region, the serum half-life is decreased.
Target Avidity	• **High target avidity:** The dual variable regions of intact IgG grants immunocytokines high avidity for its specific target, which contributes to high rates of retention.	• **Decreased avidity:** Since the F(ab') only has a single antigen-binding domain, the avidity for its target is decreased. However, as for F(ab')2 fragments, the high avidity and retention are still restored.
Fc-mediated Functions	• **Fc-mediated functions (ADCC, ADCP):** The binding of IgG antibodies to FcγR's, which are among others expressed on monocytes, macrophages and NK cells, can contribute to ADCC or ADCP and further enhance the tumor killing effects	• **Without Fc-mediated functions:** These fragments have no Fc region, which prevents the binding of FcγR's and the activating of ADCC or ADCP effects.

Note:

* A diabody is a dimeric variant of the scFv, while the tribody combines the diabody format with an additional F(ab') fragment.

Source: Frost & Sullivan Analysis

Immunocytokines have several advantages over monospecific mAbs or cytokine-based therapies that focus on modification of cytokine structure or combining cytokine with chemical compound or polypeptides with no target binding function. Comparing to other cytokine-based therapies, mediated by antibody direction, immunocytokines are able to target tumor lesions more precisely than cytokines, which greatly reduce the systemic toxicity. By linking to an antibody or its fragment, the half-life of cytokines is prolonged. In immunocytokines with intact IgG, the tumor killing effects can be enhanced by ADCC and ADCP effects. Comparing to monospecific mAbs, immunocytokines are able to achieve enhanced synergetic effects to kill tumor cells through combined effects of cytokines and antibodies. By increasing the number and activities of both innate and adaptive immune cells in the TME, immunocytokines could reverse the immune suppression in the TME.

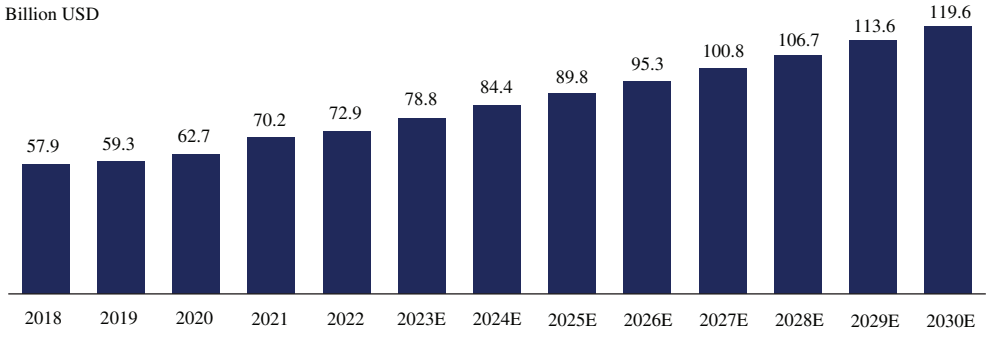
Notwithstanding the long discovery and understanding of cytokines and their functions, cytokine selection remains an important step when developing immunocytokines. Cytokines include several subcategories, including interferons (e.g. INFα, INFβ and INFγ) and interleukins (e.g. IL-2, IL-10 and IL-15). Since 1992 when the FDA approved the first IL-2 product for oncology, there had been several cytokines or cytokine-based drugs approved for the treatment of cancer. Besides IL-2, which has drawn special attention of industry players since its first FDA approval, several drug candidates based on other members of interleukin family including IL-7, IL-10, IL-15 and IL-21 are also under development for the treatment of cancer.

Market Size of Cytokine-Antibody Based Drugs Globally and in China

According to Frost & Sullivan, the global market of cytokine-antibody based drugs increased from US$57.9 billion to US$72.9 billion with a CAGR of 6.0% from 2018 to 2022. The number is projected to reach US$95.3 billion in 2026 and US$119.6 billion in 2030 with a CAGR of 6.9% and 5.8% from 2022 to 2026 and from 2026 to 2030, respectively.

Global Cytokine-Antibody Based Drugs Market, 2018-2030E

Period	CAGR
2018-2022	6.0%
2022-2026E	6.9%
2026E-2030E	5.8%

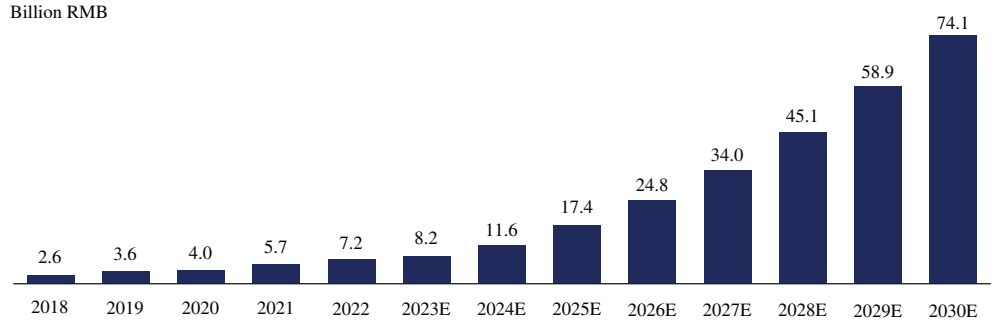


Source: Frost & Sullivan Analysis

According to Frost & Sullivan, the China market of cytokine-antibody based drugs increased from RMB2.6 billion to RMB7.2 billion with a CAGR of 28.4% from 2018 to 2022. The number is projected to reach RMB24.8 billion in 2026 and RMB74.1 billion in 2030 with a CAGR of 36.4% and 31.4% from 2022 to 2026 and from 2026 to 2030, respectively.

China Cytokine-Antibody Based Drugs Market, 2018-2030E

Period	CAGR
2018-2022	28.4%
2022-2026E	36.4%
2026E-2030E	31.4%



Source: Frost & Sullivan Analysis

Growth Drivers of Globally and China Cytokine-Antibody Based Drugs Markets

The growth of cytokine-antibody based drugs market is primarily driven by the following factors:

- *Increasing cancer incidence*. Due to factors including population aging and environmental pollution, global cancer incidence increased over past years, and it is expected to grow in the future. The total cancer incidence reached 20.2 million globally in 2022, and is expected to further increase to 22.3 million in 2026. The high incidence creates a demand for oncology drugs especially more effective immuno-oncology drugs. Currently, there is a growing interest in developing immunocytokines driven by the advantages of stimulating both innate and adaptive immunity.

- *Improving affordability*. Immunocytokine drugs, if approved, can be more expensive than traditional treatments. Improved affordability is considered important to drive the growth of the immunocytokines market in China. In this regard, on one hand, per capita disposable income is steadily increasing in China; on the other hand, reimbursement and insurance systems cover an increasing number of immuno-oncology drugs. For example in 2020, four kinds of PD-1 target drugs were listed in NRDL. As reimbursement and insurance systems mature, more patients can choose immunocytokine drugs if they are approved for marketing, and the growth of the immunocytokines market is bound to follow.

- *Favorable policy*. The Chinese government's policies create a favorable environment for R&D of innovative drugs like antibody-cytokine drugs. In July 2021, the NMPA issued Clinical Value-Oriented Guidelines for the Clinical Development of Antitumor Drugs (《以臨床價值為導向的抗腫瘤藥物臨床研發指導原則》), which could further drive the standardization of the clinical research and encourage the development of innovative antitumor drugs. In response to the policy, many large pharmaceutical companies have transformed from producing generics to innovative drug R&D, and high-quality small and medium-sized innovative biotechnology companies continue to emerge. Immunocytokine, a type of antibody-cytokine drug, is a novel class of immuno-oncology therapy that addresses the clinical demands for drug resistance. As an antibody-based innovative therapy, its development is encouraged by the Chinese government, such as "Fourteenth Five-Year Plan for the Development of the Pharmaceutical Industry (《"十四五"醫藥工業發展規劃》) (the "**Plan**") issued by nine departments including the NMPA, and Guiding Opinions on Expanding Investments in Strategic Emerging Industries and Cultivating New Growth Points and Growth Poles (《關於擴大戰略性新興產業投資培育壯大新增長點增長極指導意見》) (the "**Guiding Opinions**") issued by Ministry of Science and Technology and three other departments. Specifically, in the Plan, the Pharmaceutical Innovative Products Industrialization Project proposed to focus on the development and innovation of antibody drugs, including multi-functional antibodies, for the treatment of tumors, immune diseases, viral infections and other diseases. The Guiding Opinions proposed to accelerate the pace of biological industry innovation and development, including antibody drugs. Currently, there are several companies developing immunocytokines, which together with immunocytokines developing outside of China will drive the growth of the market if successfully commercialized. As a type of multi-functional antibody-based drug with applications in cancer treatment, immunocytokines stand to gain advantages from the favorable policies extended to antibody drugs.

- *Addressing deficiencies of existing therapies*. Conventional cytokine drugs are associated with issues of systemic toxicity and short half-life, which greatly limit the application of cytokines in cancer treatment. In the meantime, although ICI drugs has been widely applied in the treatment of various cancers, the ORR of which remains relatively low (around 30%) in many tumors because of low infiltration or activity of T cell, leaving a huge unmet clinical needs to be addressed. By combining advantages of antibodies and cytokines and reducing disadvantages of off-target toxicity and drug resistance, immunocytokines represent a potential solution for the unsatisfactory efficacy of current cancer therapies.

IL-15 Based Immunotherapies

IL-15 is a type of interleukin. It plays a vital role in the regulation of lymphocytes, especially in form of IL-15/IL-15Rα complex. It promotes the proliferation of NK/T cells and inhibits activation-induced cell death of T cells, which can improve the T cell infiltration in tumor tissues and thus potentially address the issues of immune desertification and intrinsic resistance of immunotherapy. IL-15 binds to its receptor IL-15Rα, which facilitates IL-15 trafficking through the cytoplasm and presentation of IL-15/IL-15Rα complexes on the cell surface. Then, it binds to a receptor complex composed of the IL-2/IL-15Rβγ subunit, which is highly expressed on CD8+ T cells and NK cells, to promote the proliferation of NK or T cells.

Competitive Landscape

According to Frost & Sullivan, currently, there is no IL-15-based immunotherapy indicated for the treatment of cancer approved for marketing worldwide. N-803 is currently in BLA stage, which is the only drug candidate in Phase III or later stage.

Drug Name	MoA	Company	Clinical Stage	Indications	Modality	First Posted Date	Treatment line	Mono-/Combo-therapy	Country/ region
N-803	IL-15	ImmunityBio, Inc.	BLA	BGC-unresponsive high risk NMIBC	Fusion Protein*	2023/10/26	2L/3L	Combo with BCG	U.S.
			Phase III	Stage 3 or 4 NSCLC		2018/5/11	1L	Combo with Pembrolizumab	U.S.

Notes: As of March 31, 2024; *: Fused with Fc region fragment without antigen targeting capabilities.

1. The drug candidates listed above are antibody-like drugs for cancer treatment;

2. The drug candidates listed above are in phase III or later stages of development.

Source: clinicaltrials.gov, Frost & Sullivan Analysis

Globally, there are 14 products under clinical development. Among these products, IAP0971 from the Company and the other seven product candidates are IL-15 based immunocytokines. In China, there are seven products currently under clinical development, with the most clinically advanced products in Phase I/II stage. Only three products including IAP0971 from the Company are IL-15 based immunocytokines, and IAP0971 is the most clinically advanced immunocytokine in China. As of July 2023, the Phase I clinical trial of IAP0971 for advanced malignant tumors had been completed.

Global Clinical-Stage IL-15 Based Immunotherapies

Drug Name	MoA	Company	Clinical Stage	Indications	Modality	First Posted Date
N-803	IL-15	ImmunityBio, Inc.	BLA	BCG-unresponsive NMIBC	Fusion Protein*	2023/10/26
IAP0971	**PD-1/IL-15**	**SunHo (China) BioPharmaceutical**	**Phase I/II**	**Advanced Malignant Tumors**	**Immunocytokine**	**2022/5/31**
				Advanced Malignant Tumors, NSCLC		**2024/1/25**
				High-risk NMIBC		**2024/2/13**
SHR-1501	IL-15	Hengrui Medicine	Phase I/II	High-risk NMIBC	Fusion Protein*	2022/6/08
SAR445877	PD-1/IL-15	Sanofi	Phase I/II	Advanced solid tumors	Immunocytokine	2022/10/18
JK08	CTLA4/ IL-15	Salubris Biotherapeutics	Phase I/II	Unresectable Locally Advanced or Metastatic Cancer	Immunocytokine	2022/11/17
KD033	PD-L1/IL-15	Kadmon/Sanofi	Phase I	Advanced or metastatic solid tumors	Immunocytokine	2020/1/27
BJ-001	IL-15	BJ Bioscience Inc	Phase I	Locally Advanced/Metastatic Solid Tumors	Fusion Protein*	2020/3/04
ASKG315	IL-15	AskGene Pharma	Phase I	Advanced Solid Tumors	Fusion Protein*	2022/8/22
IGM-7354	PD-L1/IL-15	IGM Biosciences	Phase I	Solid Tumor	Immunocytokine	2023/1/27
SIM0237	PD-L1/IL-15	Simcere	Phase I	Locally Advanced Unresectable or Metastatic Solid Tumor	Immunocytokine	2023/3/23
				NMIBC		2024/1/2
RC198	IL-15	RemeGen Co	Phase I	Advanced Unresectable/Metastatic Solid Tumours	Fusion Protein*	2023/5/19
ASKG915	PD-1/IL-15	AskGene Pharma	Phase I	Advanced Solid Tumors	Immunocytokine	2023/5/22
FL115	IL-15	Forlong Biotechnology	Phase I	Solid Tumor	Fusion Protein*	2023/11/14
SOT201	PD-1/IL-15	Sotio Biotech	Phase I	Solid Tumor	Immunocytokine	2023/12/8

Abbreviations: PD-1 = Programmed cell death protein 1; IL = interleukin; CTLA-4 = cytotoxic T-lymphocyte-associated protein 4.

Notes: As of March 31, 2024; *: Fused with Fc region fragment without antigen targeting capabilities.

1. The drug candidates listed above are antibody-based drugs for cancer treatment;

2. The clinical stage refers to the most advanced stage of drug candidates;

3. The clinical trials listed above were taken from clinicaltrials.gov.

Source: clinicaltrials.gov, Frost & Sullivan Analysis

China Clinical-Stage IL-15 Based Immunotherapies

Drug Name	MoA	Company	Clinical Stage	Indications	Modality	First Posted Date
IAP0971	**PD-1/IL-15**	**SunHo (China) BioPharmaceutical**	**Phase I/II**	**Advanced malignancies**	**Immunocytokine**	**2022/06/02**
				High risk non muscular invasive bladder cancer		**2023/12/18**
				Advanced solid tumor, NSCLC		**2024/01/18**
SHR-1501	IL-15	Hengrui Medicine Co., Ltd.	Phase I/II	Bladder cancer	Fusion Protein*	2022/05/31
QLF32004	PD-L1/IL-15	QILU PHARMACEUTICAL	Phase I	Advanced malignancies	Fusion Protein*	2021/10/27
ASKG315	IL-15	Aosaikang Biopharmaceutical	Phase I	Locally advanced or metastatic tumors	Fusion Protein*	2022/09/14
ASKG915	PD-1/IL-15		Phase I	Advanced malignancies	Immunocytokine	2023/09/15
SIM0237	PD-L1/IL-15	Simcere	Phase I	Locally advanced or metastatic tumors	Immunocytokine	2023/02/14
RC198	IL-15	Remegen	Phase I	Solid tumors	Fusion Protein*	2023/08/31

Abbreviations: PD-1 = Programmed cell death protein 1; IL = interleukin.

Notes: As of March 31, 2024; *: Fused with Fc region fragment without antigen targeting capabilities.

1. The drug candidates listed above are antibody-based drugs for cancer treatment;

2. The clinical stage refers to the most advanced stage of drug candidates;

3. The clinical trials listed above were taken from chinadrugtrials.org.cn.

Source: CDE, Frost & Sullivan Analysis

IL-10 Based Immunotherapies

IL-10 is a potent activator of tumor-infiltrating memory cytotoxic antigen-specific CD8+ T cells in the TME and can restore the tumor-killing activity of tumor-infiltrating terminally exhausted T cells. IL-10 is one group of proteins mainly produced by activated macrophages and certain T lymphocytes. It is a noncovalent homodimer in its natural form. IL-10 interacts with its receptor IL-10R, which is expressed on the surface of most hematopoietic cells, including T cells, B cells, and macrophages. Upon binding, IL-10 will be able to activate tumor-infiltrating memory-killing CD8+ T cells and even reactivate terminally exhausted T cells, and thereby convert the immunosuppressive TME into to pro-inflammatory TME. In addition, IL-10 has strong antitumor activities and only acts on the TME, which reduces systemic cytotoxicity and is considered safer than cytokines that enter the systemic circulation, producing immune cell activation and significant alterations in host physiology. Therefore, treatment strategies involving IL-10 may represent a potential solution for patients who suffer from primary or acquired drug resistance to immunotherapies, especially acquired drug resistance to immune checkpoint inhibitors caused by T cell exhaustion.

Competitive Landscape

Currently, there are no approved IL-10 based immunotherapies indicated for the treatment of cancer according to Frost & Sullivan. Both globally and in China, three IL-10 based immunotherapies are currently under clinical development with two of them from the Company. As of the Latest Practicable Date, the Company's products IAE0972 and IBB0979 are in Phase I/II clinical stage, which are the most clinically advanced IL-10 based immunocytokine in China. As of July 2023, the Phase I clinical trial of IAE0972 had been completed.

Global Clinical-Stage IL-10 Based Immunotherapies

Drug Name	MoA	Company or Hospital	Clinical Stage	Indications	Modality	First Posted Date
IAE0972	**EGFR/IL-10**	**SunHo (China) BioPharmaceutical**	**Phase I/II**	**Advanced solid tumors**	**Immunocytokine**	**2022/05/31**
IBB0979	**B7H3/IL-10**	**SunHo (China) BioPharmaceutical**	**Phase I/II**	**Advanced or Metastatic Solid Tumors**	**Immunocytokine**	**2023/08/14**
DK210	EGFR/IL2/ IL10	Deka Biosciences	Phase I	Locally Advanced or Metastatic EGFR+ Tumors	Immunocytokine	2023/1/30

Abbreviations: IL = interleukin; EGFR = epidermal growth factor receptor.

Notes: As of March 31, 2024.

1. The drug candidates listed above are antibody-based drugs for cancer treatment;

2. The clinical stage refers to the most advanced stage of drug candidates;

3. The clinical trials listed above were taken from clinicaltrials.gov.

Source: clinicaltrials.gov, Frost & Sullivan Analysis

China Clinical-Stage IL-10 Based Immunotherapies

Drug Name	MoA	Company	Clinical Stage	Indications	Modality	First Posted Date
IAE0972	**EGFR/IL-10**	**SunHo (China) BioPharmaceutical**	**Phase I/II**	**Advanced solid tumors**	**Immunocytokine**	**2022/5/20**
IBB0979	**B7H3/IL-10**	**SunHo (China) BioPharmaceutical**	**Phase I/II**	**Locally advanced or metastatic solid tumors**	**Immunocytokine**	**2023/03/28**
DF203	EGFR/IL-10	Dingfu Biotarget	Phase I	Advanced solid tumors	Immunocytokine	2021/2/20

Abbreviations: EGFR = epidermal growth factor receptor; IL = interleukin.

Notes: As of March 31, 2024.

1. The drug candidates listed above are antibody-based drugs for cancer treatment;

2. The clinical stage refers to the most advanced stage of drug candidates;

3. The clinical trials listed above were taken from chinadrugtrials.org.cn.

Source: CDE, Frost & Sullivan Analysis

Overview of Other Types of Immune-Regulating Fusion Proteins

Fusion protein family includes garden varieties of members created through the joining of two or more separate proteins. These proteins are joint together through recombinant DNA technology, and are transcribed and then translated into a single polypeptide. The single polypeptide, i.e. the resulting fusion protein, can offer a combination of properties that come from the original proteins.

Immunocytokine, an antibody-cytokine fusion protein, is only one example of fusion protein family. Antibody fusion protein is a recombinant protein that connects a functional protein with an antibody or its fragment. Antibody fusion protein has the characteristics of antibodies and the activity of fusion proteins, which can be used for a wide range of purposes especially for the preparation of immunotherapy drugs.

PD-L1/CD47 Dual Targeting Immunotherapies

Tumor-associated macrophages are major component of immune cells in the TME that express an array of effector molecules leading to the inhibition of antitumor immune responses. SIRPα is a myeloid-lineage inhibitory receptor that restricts phagocytosis through engagement of its ligand CD47 expressed on tumors and normal tissues. Compared to anti-CD47 therapeutics, targeting SIRPα will not bind to red blood cells to avoid severe adverse effects and even death caused by red blood cell agglutination.

Competitive Landscape

According to Frost & Sullivan, there are currently no approved PD-L1 targeting and SIRPα based immunotherapies indicated for the treatment of cancer. Among the candidates in development, the Company's product IBC0966 stands out as the most clinically advanced SIRPα based bifunctional immunotherapy globally and in China.

Global Clinical-Stage PD-L1/CD47 Dual Targeting Immunotherapies

Drug Name	MoA	Company	Clinical Stage	Indications	Modality	First Posted Date
6MW3211	PD-L1/CD47	Maiwei Bio	Phase II	Advanced Lung Cancer	BsAb	2022/6/24
				Advanced clear cell renal cell carcinoma		2022/6/30
				Relapsed or refractory lymphoma		2022/7/7
			Phase I/II	AML, MDS		2022/7/7
IBI322	PD-L1/CD47	Innovent	Phase II	Small-cell Lung Cancer	BsAb	2022/3/25
			Phase I	Advanced Malignant Tumor	BsAb	2021/6/3
IBC0966	**PD-L1/SIRPα**	**SunHo (China) BioPharmaceutical**	**Phase I/II**	**Advanced Malignant Tumors**	**Antibody fusion protein**	**2021/7/28**
PF-07257876	PD-L1/CD47	Pfizer	Phase I	Non-Small Cell Lung Cancer, Squamous Cell Carcinoma of the Head and Neck, Ovarian Cancer	BsAb	2021/5/11
BAT7104	PD-L1/CD47	Bio-Thera	Phase I	Advanced Malignant Tumor	BsAb	2023/3/14
IMM2520	PD-L1/SIRPα	ImmuneOnco	Phase I	Advanced Solid Tumor	Antibody fusion protein	2023/3/22

Abbreviations: PD-L1 = programmed death-ligand 1.

Notes: As of March 31, 2024.

1. The drug candidates listed above are antibody-based drugs for cancer treatment;

2. The clinical stage refers to the most advanced stage of drug candidates;

3. The clinical trials listed above were taken from clinicaltrials.gov.

Source: clinicaltrials.gov, Frost & Sullivan Analysis

China Clinical-Stage PD-L1/CD47 Dual Targeting Immunotherapies

Drug Name	MoA	Company	Clinical Stage	Indications	Modality	First Posted Date
6MW3211	PD-L1/CD47	Maiwei Bio	Phase II	Advanced Lung Cancer	BsAb	2022/6/13
				Advanced clear cell renal cell carcinoma		2022/6/28
				Recurrent/refractory lymphoma		2022/7/4
				AML, MDS		2023/1/31
IBC0966	**PD-L1/SIRPα**	**SunHo (China) BioPharmaceutical**	**Phase I/II**	**Advanced Malignancies**	**Antibody fusion protein**	**2021/7/8**
SG12473	PD-L1/SIRPα	SumgenBio	Phase I	Advanced Malignancies	Antibody fusion protein	2021/5/13
IBI322	PD-L1/CD47	Innovent	Phase I	Advanced Malignancies	BsAb	2021/6/7
BAT7104	PD-L1/CD47	Bio-Thera	Phase I	Advanced Malignancies	BsAb	2022/2/22
SH009	PD-L1/CD47	SanHome	Phase I	Advanced Malignancies	BsAb	2022/7/1
IMM2520	PD-L1/SIRPα	ImmuneOnco	Phase I	Advanced Solid Tumor	Antibody fusion protein	2023/2/7

Notes: As of March 31, 2024.

1. The drug candidates listed above are antibody-based drugs for cancer treatment;

2. The clinical stage refers to the most advanced stage of drug candidates;

3. The clinical trials listed above were taken from chinadrugtrials.org.cn.

Source: CDE, Frost & Sullivan Analysis

In 2019, leveraging our platform capabilities and pipeline progress, we planned to further delve into our research and development domain, particularly focusing on simultaneous activation of both the innate and adaptive immune systems. Our initial investigations into the synergistic potential of dual-targeting PD-L1 and CD47 showed promising avenues for exploration. Recognizing that ImmuneOnco Biopharmaceuticals (Shanghai) Inc. ("**ImmuneOnco**") had achieved certain advancements in the differentiated study on SIRPα, the ligand of CD47, we were particularly drawn to their drug candidate, namely IBC0966. This PD-L1/SIRPα bifunctional fusion protein matched our envisioned molecular design. With an eye on achieving a more definitive drug profile and capitalizing on the potential synergistic benefits of IBC0966 in tandem with our other pipeline drugs, we consider it commercially reasonable to enter into collaboration with ImmuneOnco.

Although IBC0966 and IMM2520 are both PD-L1 targeting and SIRPα based products, they have different amino acid sequences. As a product developed earlier than IMM2520, IBC0966 filed patent applications prior to IMM2520 and is considered prior art to IMM2520 in the patent field, and the sequence difference of IMM2520 is designed to gain patent protection considering IBC0966 as an existing technology, and/or to avoid potential patent disputes. In addition to the advantages of the earlier patent application date, compared to IMM2520, IBC0966 consists of a PD-L1 targeting portion that has been thoroughly validated for its efficacy and safety in clinical and research settings, increasing the druggability of the product. Furthermore, instead of only focusing on solid tumors, the Company is investigating IBC0966 for advanced malignancies including lymphoma, and plans to focus on NHL according to the clinical development plan. For details, see "Business — Drug Candidates — Clinical-Stage Product IBC0966 (PD-L1/SIRPα antibody fusion protein) — Clinical Development Plan" in this document.

Major Indications for Immuno-Oncology Therapies

CRC

CRC, also known as bowel cancer, colon cancer, or rectal cancer, is any cancer that affects the colon and the rectum. Most CRCs develop first as polyps, which are abnormal growths inside the colon or rectum that may later become cancerous if they are not removed. In China, the incidence and mortality of CRC rank the third and fifth respectively among all malignant tumors in 2022.

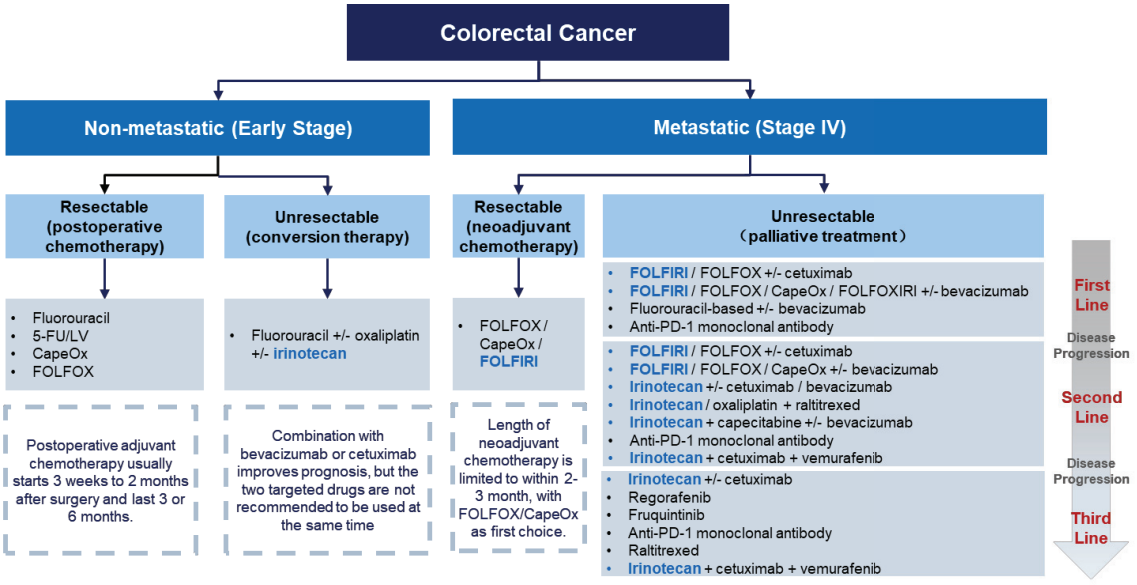
Globally, the number of new cases of CRC reached 1,981.0 thousand in 2022 and is expected to rise to 2,203.3 thousand in 2026 and 2,441.4 thousand in 2030. The number of new cases of CRC in China was 482.2 thousand in 2022. This number is projected to increase to 542.3 thousand in 2026 and 603.7 thousand in 2030, with CAGRs of 3.0% and 2.7% from 2022 to 2026 and from 2026 to 2030, respectively. Among new cases of CRC, approximately 35% are late stage cases, and the five-year survival rate can be approximately 16%.

For 3L advanced CRC, there were approximately 353.3 thousand new cases globally in 2022; the number is expected to grow to 401.4 thousand in 2026 at a CAGR of 3.2% from 2022 to 2026, and is projected to reach 452.2 thousand in 2030 at a CAGR of 3.0% from 2026 to 2030. In China, there were approximately 86.0 thousand new cases of 3L advanced CRC in 2022; the number is expected to grow to 98.8 thousand at a CAGR of 3.5% from 2022 to 2026, and is projected to reach 111.8 thousand in 2030 at a CAGR of 3.1% from 2026 to 2030.

For 1L HER2+ advanced CRC, globally, there were approximately 50.5 thousand new cases in 2022; the number is expected to grow to 57.3 thousand in 2026 at a CAGR of 3.2% from 2022 to 2026, and is projected to reach 64.6 thousand in 2030 at a CAGR of 3.0% from 2026 to 2030. In China, there were approximately 12.3 thousand new cases of 1L HER2+ advanced CRC in 2022; the number is expected to grow to 14.1 thousand in 2026 at a CAGR of 3.5% from 2022 to 2026, and is projected to reach 16.0 thousand in 2030 at a CAGR of 3.2% from 2026 to 2030.

CRC is among the most lethal and prevalent malignancies in the world. Surgery and chemotherapy have long been the first choices for cancer patients. However, the prognosis of CRC has never been satisfying, especially for patients with metastatic lesions. Targeted therapy are new optional approaches that has successfully prolonged overall survival for CRC patients.

Due to a lack of early cancer screening and diagnosis in China, 89% of clinically diagnosed patients with CRC are in the late stage, resulting in a five-year survival rate of only around 10%. This highlights an urgent need for more effective treatment options. For late-stage CRC (metastatic disease), chemotherapy alone or in combination with bevacizumab or cetuximab is recommended in the first and subsequent lines of treatment, with PD-1/PD-L1 inhibitors (pembrolizumab) only recommended for a few patients with the MSI-H/dMMR subtype in the first and second lines of treatment.



Abbreviations: FOLFOX = oxaliplatin + leucovorin + 5-FU; FOLFIRI = irinotecan + leucovorin + 5-FU; CapeOx = oxaliplatin + capecitabine.

Source: Literature Review, Frost & Sullivan Analysis

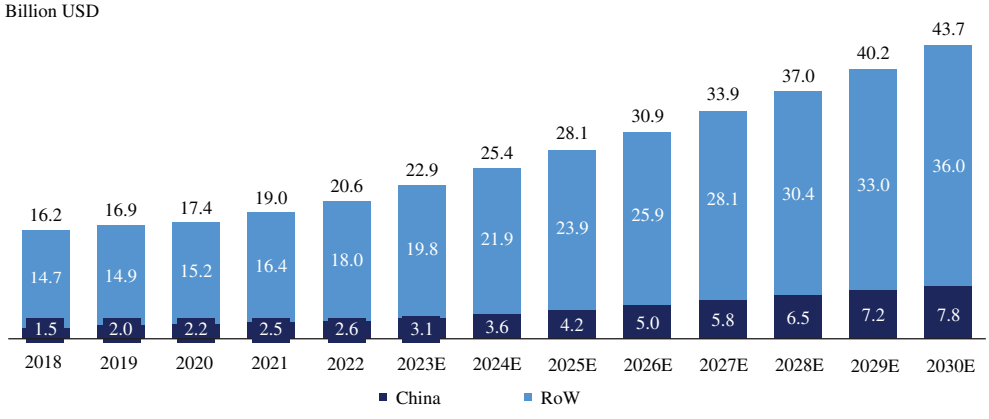
The effectiveness of currently available treatments for CRC is limited. Specifically, the therapeutic effects of bevacizumab or cetuximab in combination with chemotherapy gradually decrease as treatment progresses, with the median progression-free survival ("**mPFS**") ranging from 8.9-10.6 months in the first-line treatment and dropping to 4.1-7.5 months in the second-line treatment. Patients are left with few efficacious options if the first-line treatment of bevacizumab/cetuximab and chemotherapy fails due to drug resistance. Additionally, although PD-1 inhibitors offer another treatment option for CRC patients, it is only approved for a very small percentage (approximately 5%) of patients with MSI-H/dMMR and has not been approved for general CRC due to limited ORR of less than 10% in clinical trials. Consequently, there is a need for novel immuno-oncology therapies that can improve the immune response against tumor cells to address the unmet needs in metastatic CRC treatment, particularly by enhancing T cell and NK cell activity.

In addition, the treatment for HER2+ CRC, which accounts for approximately 5% of CRC patients, remains a significant unmet need. There is a lack of well-established HER2-expressing situation diagnosis and limited specific treatment options available. While HER2 overexpression is a well-established biomarker for HER2-targeted therapy in breast cancer and gastric cancer, no universally accepted biomarker has been established for HER2-targeted therapy in CRC. Although anti-HER2 targeted therapies have been recommended for the third-line treatment of metastatic CRC patients, there has been no approval from the NMPA or FDA for HER2-targeted therapy in HER2+ CRC patients. Additionally, the effectiveness of these agents is limited, and most patients eventually develop resistance to therapy. Therefore, there is an urgent need for novel treatment options to improve the current treatment for HER2+ CRC. Enhanced immune system engagement through ADCC shows great potential to improve the outcomes of HER2-targeted therapy.

The global market of CRC drugs increased from US$16.2 billion to US$20.6 billion with a CAGR of 6.2% from 2018 to 2022. The number is projected to reach US$30.9 billion in 2026 and US$43.7 billion in 2030 with a CAGR of 10.6% and 9.1% from 2022 to 2026 and from 2026 to 2030, respectively. The China market of CRC drugs increased from US$1.5 billion to US$2.6 billion with a CAGR of 14.6% from 2018 to 2022. The number is projected to reach US$5.0 billion in 2026 and US$7.8 billion in 2030 with a CAGR of 17.1% and 11.8% from 2022 to 2026 and from 2026 to 2030, respectively.

Global CRC Drug Market, 2018-2030E

Period	CAGR		
	China	RoW	Total
2018-2022	14.6%	5.2%	6.2%
2022-2026E	17.1%	9.6%	10.6%
2026E-2030E	11.8%	8.5%	9.1%



Note: The CAGR from 2018 to 2022 is based on the changes in the disease epidemiology, diagnosis rates, treatment rates, price and efficacy of approved drugs over the past period. The CAGR from 2022 to 2030 is projected based on future changes in the disease epidemiology, diagnosis rates, treatment rates, new drug approvals, and prices and efficacy of approved drugs. The impact of the COVID-19 epidemic has also been taken into account, as it affects the availability and accessibility of drugs.

Source: NCCR, Frost & Sullivan Analysis

On a global scale, as of the Latest Practicable Date, eleven antibody-based drugs were approved for the treatment of CRC. Among them, two targeted HER2, while none were IL-10 based drugs. Notably, the two approved mAbs targeting HER2, namely Perjeta and Herceptin, have exclusively been approved for use in combination therapy. This treatment is specifically indicated for cases of advanced or recurrent HER2+ CRC that are unsuitable for curative resection and have demonstrated progression following cancer chemotherapy in Japan. Additionally, there were eleven antibody-based drug candidates under development in Phase III or later clinical stages. Among them, one was an ADC candidate targeting HER2, which is SHR-A1811 from Hengrui Medicine/Suncadia Biopharmaceuticals, and none were IL-10 based candidates.

Competitive Landscape of Global HER2 Targeting Antibody-based Drug Pipeline Indicating for CRC

Drug Name	Brand Name	MoA	Company	Clinical Stage	Indications	Modality	Approval Date	Treatment Line	Mono-/Combo-Therapy	Country/ Region
Pertuzumab	Perjeta®	HER2	Roche/ 中外製薬株式会社	Approved by PMDA	HER2+ curatively unresectable advanced or recurrent colorectal cancer	mAb	2023/3/28	2L	Combo therapy	Japan
Trastuzumab	Herceptin®	HER2				mAb				

Notes: As of March 31, 2024.

1. The drug candidates listed above are antibody-based drugs for CRC treatment;

2. The drug candidates listed above are in Phase III or later stages of development;

3. The list does not include ADC.

Source: PMDA, Frost & Sullivan Analysis

In China, as of the Latest Practicable Date, four antibody-based drugs were approved for the treatment of CRC. None of them targeted HER2 or were IL-10 based drugs. Similarly, there were eleven antibody-based drug candidates under development in Phase III or later clinical stages. Among them, one targeted HER2, which is SHR-A1811 from Hengrui Medicine/Suncadia Biopharmaceuticals, and none were IL-10 based candidates.

SHR-A1811 from Hengrui Medicine/Suncadia Biopharmaceuticals is an ADC product with its antibody moiety targeting HER2 but mainly exerts antitumor effects through toxin payloads, which is a different mechanism of action than anti-HER2 mAbs or IL-10 based biologics.

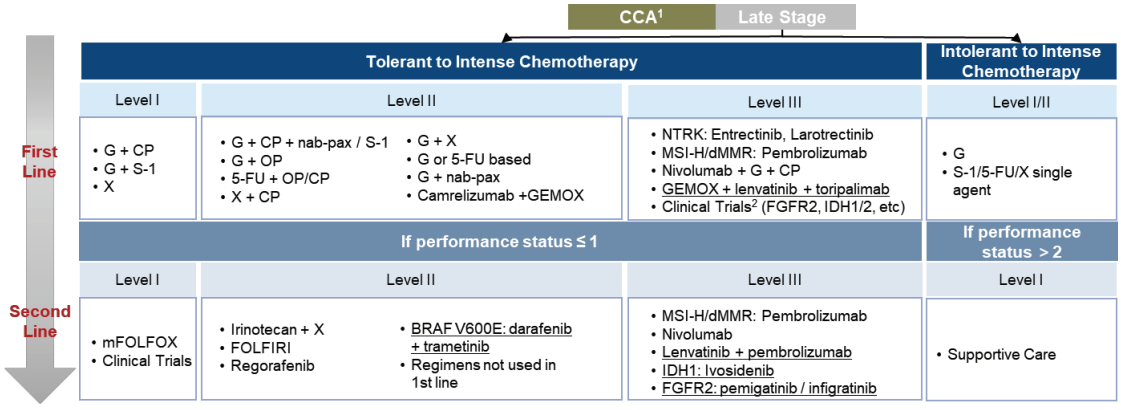
BTC

Biliary tract carcinoma ("**BTC**") is the second most prevalent type of hepatobiliary cancer globally, usually comprising cholangiocarcinomas and gallbladder carcinomas. In some cases, it may also combine with ampullary carcinoma. The primary symptom of biliary tract cancer is jaundice, which manifests as a yellow discoloration of the skin and eyes when the bile ducts become obstructed.

Globally, the number of new cases of BTC amounted to 392.3 thousand in 2022, with a projected increase to 444.4 thousand in 2026 and 501.3 thousand in 2030. The number of new BTC cases in China is projected to grow from 155.0 thousand in 2022 to 175.4 thousand in 2026 and 197.0 thousand in 2030, representing a CAGR of 3.0% between 2026 and 2030. Among new cases of BTC, approximately 75% are late stage cases, and the five-year survival rate can be extremely low, at approximately 2%.

According to Frost & Sullivan, there were approximately 63.5 thousand new cases of 1L HER2+ advanced BTC globally in 2022; the number is expected to grow to 73.4 thousand in 2026 at a CAGR of 3.7% from 2022 to 2026, and is projected to reach 84.2 thousand in 2030 at a CAGR of 3.5% from 2026 to 2030. In 2022, there were approximately 25.1 thousand new cases of 1L HER2+ advanced BTC in China; the number is expected to grow to 29.0 thousand in 2026 at a CAGR of 3.7% from 2022 to 2026, and is projected to reach 33.1 thousand in 2030 at a CAGR of 3.4% from 2026 to 2030.

BTCs are known for their clinical and pathological heterogeneity, suboptimal response to chemotherapy, and typically poor prognosis. Even among patients who have undergone surgical resection, the recurrence rate is exceptionally high. In cases of advanced unresectable or metastatic disease, systemic therapy remains the sole treatment option. As far as first-line treatment regimens go, the standard for patients with advanced or metastatic biliary tract cancer is currently gemcitabine combined with cisplatin.



Abbreviations: G = gemcitabine; CP = cisplatin; S-1 = tegafur/gimeracil/oteracil; nab-pax = nanoparticle albumin-boundpaclitaxel, OP = oxaliplatin, X = capecitabine; GEMOX = gemcitabine + oxaliplatin; 5-FU = 5-Fluorouracil; mFOLFOX =oxaliplatin + 5-FU; FOLFIRI = folinic acid, fluorouracil and irinotecan; NTRK = Neurotrophic tyrosine receptor kinase; MSI-H/dMMR = Microsatellite instability high/deficient mismatch repair, IDH1 = isocitrate dehydrogenase 1; FGFR2 = fibroblast growth factor receptor 2; BRAF V600E = V600E mutation of v-raf murine sarcoma viral oncoprotein homolog B1.

Notes: The paradigm is outlined based on CSCO 2020, taking into account the information to be updated in CSCO 2021 regarding targeted therapy, reflected by underscore. Clinical trials are recommended for all patients qualified for precision therapy, include but not limited to those ones with FGFR2 fusion, IDH1/2 mutation, PO:E/POLD mutation, and BRAC/BAP/ATM/BRAF mutation.

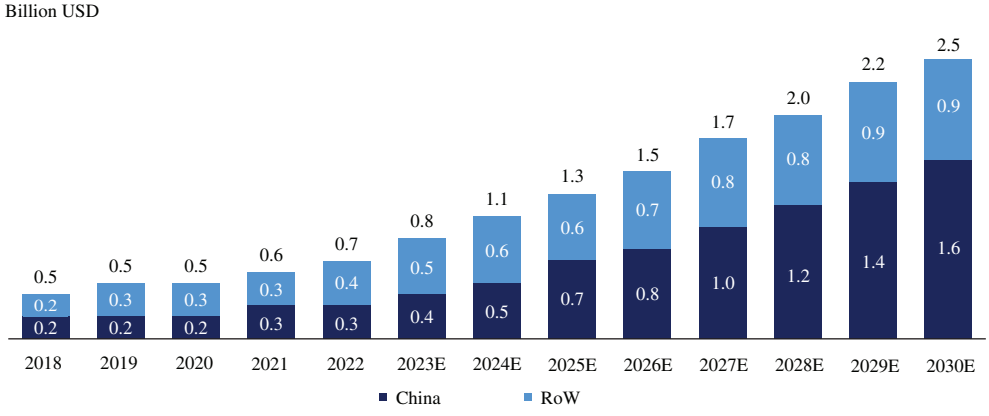
Source: Literature Review, Frost & Sullivan Analysis

In clinical practice, there is a lack of standardized treatment recommendations in the guidelines for HER2+ BTC, which accounts for approximately 20% of BTC patients. In the first-line treatment of BTC, there are no specific drugs recommended for HER2+ BTC, indicating a notable scarcity of treatment options for these patients. While HER2-targeted therapies, such as pertuzumab in combination with trastuzumab, have been recommended for second-line treatment of BTC, the development of drug resistance against HER2-targeted therapies and disease progression remain inevitable challenges. Therefore, there is an urgent need for novel treatment options to enhance the current BTC treatment landscape. Enhanced engagement of the immune system through ADCC holds significant promise in improving the outcomes of HER2-targeted therapy and should be explored as a potential avenue for advancement.

The global market of BTC drugs increased from US$0.5 billion in 2018 to US$0.7 billion in 2022 with a CAGR of 10.7% from 2018 to 2022. The number is projected to reach US$1.5 billion in 2026 and US$2.5 billion in 2030 with a CAGR of 21.7% and 13.3% from 2022 to 2026 and from 2026 to 2030, respectively. The China market BTC drugs increased from US$0.2 billion in 2018 to US$0.3 billion in 2022 with a CAGR of 7.9% from 2018 to 2022. The number is projected to reach US$0.8 billion in 2026 and US$1.6 billion in 2030 with a CAGR of 28.2% and 17.9% from 2022 to 2026 and from 2026 to 2030, respectively.

Global BTC Drug Market, 2018-2030E

Period	CAGR		
	China	RoW	Total
2018-2022	7.9%	13.2%	10.7%
2022-2026E	28.2%	15.6%	21.7%
2026E-2030E	17.9%	7.0%	13.3%



Note: The CAGR from 2018 to 2022 is based on the changes in the disease epidemiology, diagnosis rates, treatment rates, price and efficacy of approved drugs over the past period. The CAGR from 2022 to 2030 is projected based on future changes in the disease epidemiology, diagnosis rates, treatment rates, new drug approvals, and prices and efficacy of approved drugs. The impact of the COVID-19 epidemic has also been taken into account, as it affects the availability and accessibility of drugs.

Source: NCCR, Frost & Sullivan Analysis

On a global scale, as of the Latest Practicable Date, two antibody-based drugs were approved for the treatment of BTC. Among them, none targeted HER2. Additionally, there were six antibody-based drug candidates under development in Phase III or later clinical stages. Among them, none were a candidate targeting HER2.

In China, as of the Latest Practicable Date, two antibody-based drugs were approved for the treatment of BTC. None of them targeted HER2. There were three antibody-based drug candidates under development in Phase III or later clinical stages. Among them, none targeted HER2.

NSCLC

Non-small-cell lung cancer ("**NSCLC**"), which accounts for 85% of epithelial lung cancer, is any type of epithelial lung cancer other than small cell lung cancer. The most common types of NSCLC are adenocarcinoma, large cell carcinoma, and squamous cell carcinoma. All types can occur in unusual histologic variants and developed as mixed cell-type combinations. Symptoms of NSCLC include coughing, chest pain, trouble breathing, and weight loss. For more advanced NSCLC cases, symptoms include bone pain, headache, weakness and vomiting.

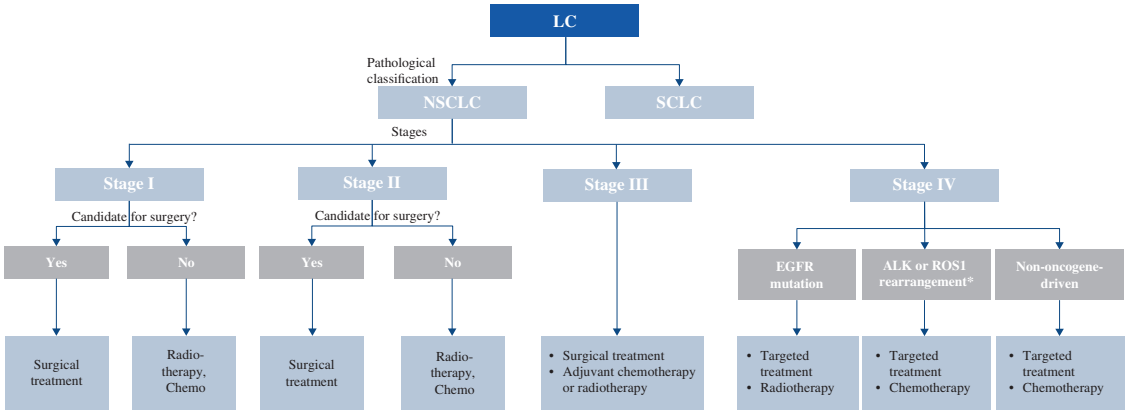
From 2018 to 2022, the number of new NSCLC cases worldwide increased from 1,779.8 thousand to 1,980.9 thousand. The number of new NSCLC cases worldwide is projected to steadily grow to 2,209.4 thousand and 2,452.2 thousand in 2026 and 2030, respectively. According to Frost & Sullivan, NSCLC has a large patient pool in China, reaching 836.8 thousand in 2022. It is projected to increase to 943.7 thousand in 2026, representing a CAGR of 3.0% from 2022 to 2026. Due to a large amount of people are following an unhealthy lifestyle including smoking, it is estimated that the number of NSCLC patients would be 1,052.4 thousand by 2030, representing a CAGR of 2.8% from 2026 to 2030. Among new cases of NSCLC, approximately 63.5% are late stage cases, and the five-year survival rate can be as low as 9%.

As to specific indications, globally, there were approximately 1,329.6 thousand new cases of 1L advanced NSCLC in 2022; the number is expected to grow to 1,514.7 thousand in 2026 at a CAGR of 3.3% from 2022 to 2026, and is projected to reach 1,709.3 thousand in 2030 at a CAGR of 3.1% from 2026 to 2030. In China, there were approximately 561.7 thousand new cases of 1L advanced NSCLC in 2022; the number is expected to grow to 646.9 thousand in 2026 at a CAGR of 3.6% from 2022 to 2026, and is projected to reach 733.6 thousand in 2030 at a CAGR of 3.2% from 2026 to 2030. For 1L advanced non-squamous NSCLC, globally, there were approximately 860.3 thousand new cases in 2022; the number is expected to grow to 980.1 thousand in 2026 at a CAGR of 3.3% from 2022 to 2026, and is expected to reach 1,106.0 thousand in 2030 at a CAGR of 3.1% from 2026 to 2030. In China, there were approximately 363.4 thousand new cases of 1L advanced non-squamous NSCLC in 2022; the number is expected to grow to 418.6 thousand in 2026 at a CAGR of 3.6% from 2022 to 2026, and is projected to reach 474.7 thousand in 2030 at a CAGR of 3.2% from 2026 to 2030.

The number of new cases of 2L advanced NSCLC was 930.7 thousand globally in 2022; the number is expected to grow to 1,060.3 thousand in 2026 at a CAGR of 3.3% from 2022 to 2026, and is anticipated to grow to 1,196.5 thousand in 2030 at a CAGR of 3.1% from 2026 to 2030. In China, the number of new cases of 2L advanced NSCLC was 393.2 thousand in 2022; the number is expected to grow to 452.9 thousand in 2026 at a CAGR of 3.6% from 2022 to 2026, and is anticipated to grow to 513.5 thousand in 2030 at a CAGR of 3.2% from 2026 to 2030. For 2L advanced squamous NSCLC, globally, there were approximately 328.5 thousand new cases in 2022; the number is expected to grow to 374.2 thousand in 2026 at a CAGR of 3.3% from 2022 to 2026, and is projected to reach 422.3 thousand in 2030 at a CAGR of 3.1% from 2026 to 2030. In China, there were approximately 138.8 thousand new cases of 2L advanced squamous NSCLC in 2022; the number is expected to grow to 159.8 thousand in 2026 at a CAGR of 3.6% from 2022 to 2026, and is projected to reach 181.2 thousand in 2030 at a CAGR of 3.2% from 2026 to 2030.

After diagnosed with NSCLC, treatment options are determined by histology, stage and general health and comorbidities of the patient. In NSCLC, the determination of stage has important therapeutic and prognostic implications. Careful initial diagnostic evaluation to define the location and to determine the extent of primary and metastatic tumor involvement is critical for the appropriate care of patients. Nevertheless, according to National Institute of Health, even stage 0 NSCLC frequently progresses to invasive cancer, and chemotherapy and radiation therapy have not been shown to improve survival in patients with stage I NSCLC that has been completely resected. Therefore, NSCLC remains a challenging disease to treat.

For early stage patients, the primary treatments are surgery, radiotherapy, and chemotherapy, and for stage IV patients, in addition to radiotherapy and chemotherapy, recommended treatments also include target therapy. For advanced (stage IV) NSCLC, the treatment is further specified by different molecular testing with more treatment options in the United States than those in China. The following diagram sets forth the treatment for NSCLC in China.



Note: The treatment paradigm for patients with BRAF V600E mutation and NTRK rearrangement can refer to the non-oncogene-driven part.

Source: Literature Review, Frost & Sullivan Analysis

In the case of NSCLC patients with EGFR mutations, the treatment paradigm is relatively well established compared to other subgroups. Small molecule targeted drugs known as EGFR-tyrosine kinase inhibitors ("**TKIs**"), such as gefitinib and osimertinib, are primarily recommended throughout the treatment process. Nevertheless, there is still room for improvement in the management of EGFR-mutated NSCLC, as drug resistance against EGFR-TKIs inevitably develops over time.

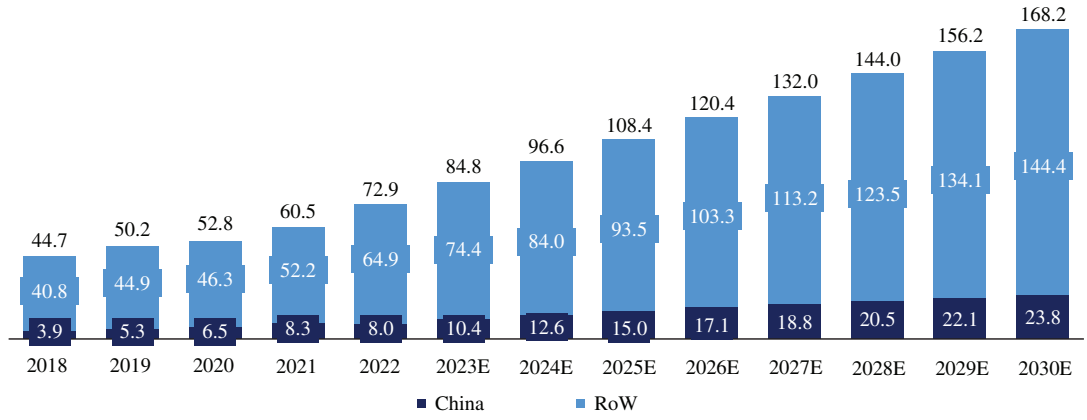
For patients with EGFR wild type NSCLC, including other types of oncogene driven (such as ALK or ROS1 rearrangement) and non-oncogene driven NSCLC, platinum-based chemotherapy has traditionally been the standard treatment for the majority of this subgroup. However, with the emergence of immuno-oncology and targeted therapies, current treatment options mainly include chemotherapy alone or in combination with antiangiogenic agents like bevacizumab, or PD-1/PD-L1 inhibitors such as pembrolizumab. Although PD-1/PD-L1 inhibitors have become the frontline treatment for the majority of EGFR wild type NSCLC patients, significant unmet needs still exist.

Specifically, when used as monotherapy, PD-1/PD-L1 inhibitors can only be administered to patients whose PD-L1 expression has reached a certain level, limiting the eligible patient population. Furthermore, even among eligible patients, the response rates to monotherapies remain relatively low, ranging from 14% to 38%, and the response rate also remains relatively low in many tumor types, which indicates either intrinsic resistance or acquired resistance to the therapy. Additionally, combining PD-1/PD-L1 inhibitors with chemotherapy to enhance the response can lead to systemic adverse events such as anaphylaxis, cytopenias and hepatotoxicity, which may result in sub-optimal dosing and shorter treatment duration. These limitations highlight the need for more effective strategies that can elicit a strong T cell response while minimizing the risk of adverse events.

According to Frost & Sullivan, the global market for NSCLC drugs has witnessed significant growth, expanding from US$44.7 billion in 2018 to US$72.9 billion in 2022, reflecting a CAGR of 13.0% during this period. Projections indicate further substantial growth, with the market expected to reach US$120.4 billion in 2026 and US$168.2 billion in 2030. This forecast corresponds to a CAGR of 13.4% from 2022 to 2026 and 8.7% from 2026 to 2030. Similarly, the China market for NSCLC drugs experienced remarkable expansion, surging from US$3.9 billion in 2018 to US$8.0 billion in 2022, demonstrating a notable CAGR of 20.0% over the same period. Forecasts suggest continued growth, with the market projected to reach US$17.1 billion in 2026 and US$23.8 billion in 2030. These estimates translate to a CAGR of 20.8% from 2022 to 2026 and 8.6% from 2026 to 2030. The rising figures reflect the increasing demand for effective therapies to combat NSCLC, highlighting the significant opportunities present in the global and China markets for NSCLC drugs.

Global NSCLC Drug Market, 2018-2030E

Period	CAGR		
	China	RoW	Total
2018-2022	20.0%	12.3%	13.0%
2022-2026E	20.8%	12.3%	13.4%
2026E-2030E	8.6%	8.7%	8.7%



Note: The CAGR from 2018 to 2022 is based on the changes in the disease epidemiology, diagnosis rates, treatment rates, price and efficacy of approved drugs over the past period. The CAGR from 2022 to 2030 is projected based on future changes in the disease epidemiology, diagnosis rates, treatment rates, new drug approvals, and prices and efficacy of approved drugs. The impact of the COVID-19 epidemic has also been taken into account, as it affects the availability and accessibility of drugs.

Source: NCCR, Frost & Sullivan Analysis

On a global scale, as of the Latest Practicable Date, 17 antibody-based drugs were approved for the treatment of NSCLC. Among them, none were IL-15 or IL-10 based drugs. Additionally, there were 38 antibody-based drug candidates under development in Phase III or later clinical stages. Among them, only one was an IL-15 based candidate, and none were IL-10 based candidates.

Competitive Landscape of Global IL-15-based and Antibody-based Drug Pipeline Indicating for NSCLC

Drug Name	MoA	Company	Clinical Stage	Indications	Modality	First Posted Date	Treatment Line	Mono-/Combo-Therapy	Country/ Region
N-803	IL-15	ImmunityBio, Inc.	Phase III	Stage 3 or 4 NSCLC	Fusion Protein*	2018/5/11	1L	Combo with Pembrolizumab	U.S.

Notes: As of March 31, 2024; *: Fused with Fc region fragment without antigen targeting capabilities.

1. The drug candidates listed above are antibody-based drugs for NSCLC treatment;

2. The drug candidates listed above are in Phase III or later stages of development;

3. The clinical trial listed above was taken from Clinicaltrials.gov.

Source: clinicaltrials.gov, Frost & Sullivan Analysis

In China, as of the Latest Practicable Date, seven antibody-based drugs were approved for the treatment of NSCLC. None of them were IL-15 or IL-10 based drugs. There were 35 antibody-based drug candidates under development in Phase III or later clinical stages. Among them, none were IL-15 or IL-10 based candidates.

NMIBC

Non-muscle invasive bladder cancer ("**NMIBC**") refers to the papillary malignant tumor of the bladder that is limited to the bladder mucosa and lamina propria without muscle invasion. Approximately 75% of all newly diagnosed cases of urothelial carcinoma of the bladder are NMIBC. NMIBC can be classified into three stages: Ta stage, which refers to noninvasive papillary carcinoma, accounting for 70%; T1, which refers to tumor spread to the connective tissue that separates the lining of the bladder from the muscles beneath yet does not involve the bladder wall muscle, accounting for 20%; and Tis, which means carcinoma is only found on or near the surface of the bladder, accounting for 10%.

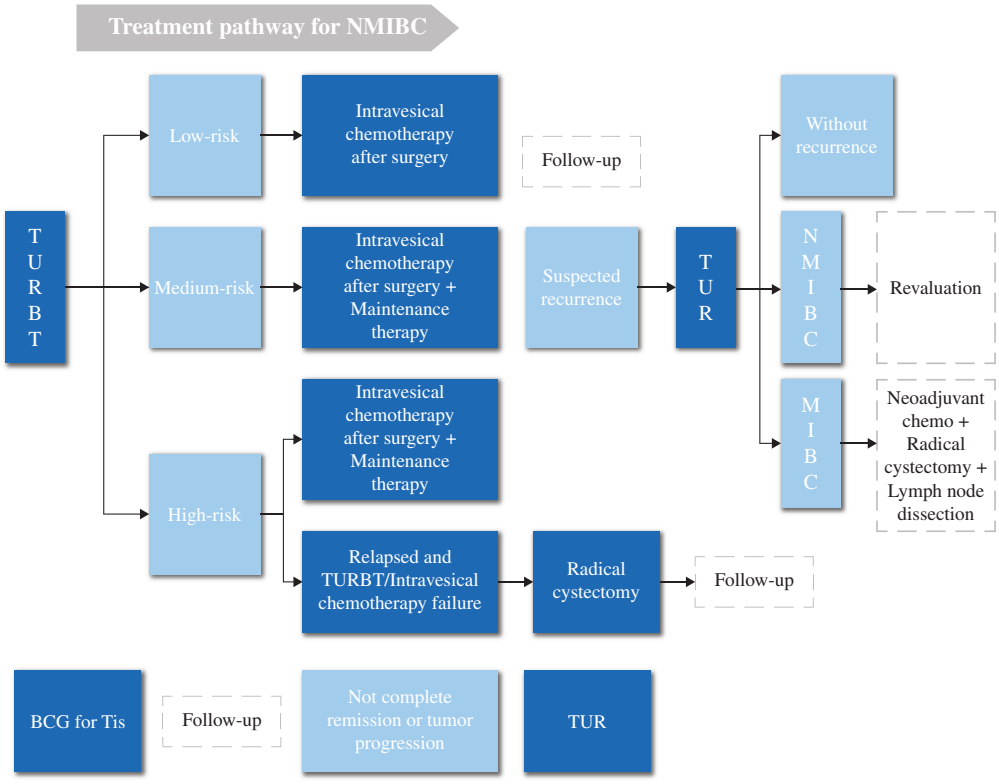
According to Frost & Sullivan, global NMIBC incidence reached 424.0 thousand in 2022. It is estimated to rise to 476.4 thousand in 2026 and 533.8 thousand in 2030, representing a CAGR of 2.9% between 2026 and 2030. Incidence of NMIBC in China reached 64.1 thousand in 2022. This number is expected to increase to 72.8 thousand in 2026 and 82.0 thousand in 2030, representing a CAGR of 3.0% from 2026 and 2030. Since NMIBC is an early stage bladder cancer, the five-year survival rate can be as high as 97%.

For BCG-unresponsive high risk NMIBC, there were approximately 118.9 thousand new cases of 2L BCG-unresponsive high risk NMIBC globally in 2022; the number is expected to grow to 136.5 thousand in 2026 at a CAGR of 3.5% from 2022 to 2026, and is projected to reach 155.5 thousand in 2030 at a CAGR of 3.3% from 2026 to 2030. The number of new cases of 3L BCG-unresponsive high risk NMIBC was 64.2 thousand globally in 2022; the number is expected to grow to 73.7 thousand in 2026 at a CAGR of 3.5% from 2022 to 2026, and is anticipated to grow to 84.0 thousand in 2030 at a CAGR of 3.3% from 2026 to 2030. In 2022, there were approximately 25.7 thousand new cases of 2L BCG-unresponsive high risk NMIBC in China; the number is expected to grow to 29.8 thousand in 2026 at a CAGR of 3.8% from 2022 to 2026, and is projected to reach 34.1 thousand in 2030 at a CAGR of 3.4% from 2026 to 2030. The number of new cases of 3L BCG-unresponsive high risk NMIBC was 13.9 thousand in China in 2022; the number is expected to grow to 16.1 thousand in 2026 at a CAGR of 3.7% from 2022 to 2026, and is anticipated to grow to 18.4 thousand in 2030 at a CAGR of 3.4% from 2026 to 2030. The five-year survival rate of late stage BCG-unresponsive high risk NMIBC is lower than NMIBC in general, which is approximately 72%.

For postoperative transurethral resection of bladder tumor ("**TURBT**") in high-risk NMIBC patients, the first-line treatment in China and the U.S. is Bacillus Calmette-Guerin ("**BCG**") intravesical instillation or radical cystectomy. Although BCG therapy can control tumor progression, the five-year recurrence rate is as high as 66%. In addition, BCG therapy

has a high incidence of adverse reactions, with 62.8%-75.2% of patients developing local complications such as urinary frequency, urgency, hematuria, cystitis and systemic complications such as fever and diarrhea.

Currently, immunotherapies such as PD-1/PD-L1 inhibitors have been demonstrated with great efficacy in treating NMIBC patients who failed BCG therapy or relapsed, and Keytruda or pembrolizumab monotherapy is approved by the FDA for BCG-unresponsive, high-risk NMIBC. However, there is no approved drug in China, and patients are at risk of radical cystectomy. Inevitably, for patients who cannot receive BCG therapy due to the shortage of BCG, or do not respond to or become relapsed/refractory ("**R/R**") of current therapies, treatment options are limited. This indicates a significant unmet need.



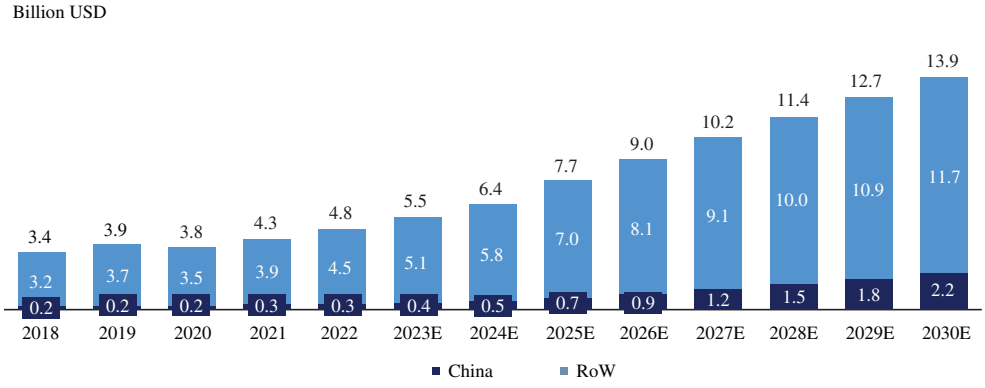
Abbreviations: TUBRT = Transurethral resection of bladder tumor; TUR = Transurethral resection.

Source: Literature Review, Frost & Sullivan Analysis

The global market of bladder cancer drugs increased from US$3.4 billion to US$4.8 billion with a CAGR of 8.6% from 2018 to 2022. The number is projected to reach US$9.0 billion in 2026 and US$13.9 billion in 2030 with a CAGR of 17.1% and 11.5% from 2022 to 2026 and from 2026 to 2030, respectively. In China, the bladder cancer market was valued at US$0.2 billion in 2018, and the number increased to US$0.3 billion in 2022 at a CAGR of 13.1%. The market value is projected to significantly increase to US$0.9 billion in 2026 and further to US$2.2 billion in 2030, representing a CAGR of 28.4% from 2022 to 2026 and a CAGR of 24.8% from 2026 to 2030.

Global Bladder Cancer Drug Market, 2018-2030E

Period	CAGR		
	China	RoW	Total
2018-2022	13.1%	8.3%	8.6%
2022-2026E	28.4%	16.1%	17.1%
2026E-2030E	24.8%	9.7%	11.5%



Note: The CAGR from 2018 to 2022 is based on the changes in the disease epidemiology, diagnosis rates, treatment rates, price and efficacy of approved drugs over the past period. The CAGR from 2022 to 2030 is projected based on future changes in the disease epidemiology, diagnosis rates, treatment rates, new drug approvals, and prices and efficacy of approved drugs. The impact of the COVID-19 epidemic has also been taken into account, as it affects the availability and accessibility of drugs.

Source: NCCR, Frost & Sullivan Analysis

On a global scale, as of the Latest Practicable Date, only one antibody-based drugs was approved for the treatment of NMIBC, which was not an IL-15 based drug. Additionally, there were seven antibody-based drug candidates under development in Phase III or later clinical stages. Among them, one was an IL-15 based candidate.

Competitive Landscape of Global IL-15 Targeting Antibody-based Drug Pipeline Indicating for NMIBC

Drug Name	MoA	Company	Clinical Stage	Indications	Modality	First Posted Date	Treatment Line	Mono-/Combo-Therapy	Country/ Region
N-803	IL-15	ImmunityBio, Inc.	BLA	BCG-unresponsive high risk NMIBC	Fusion Protein*	2023/10/26	2L/3L	Combo with BCG	U.S.

Notes: As of March 31, 2024; *: Fused with Fc region fragment without antigen targeting capabilities.

1. The drug candidates listed above are antibody-based drugs for NMIBC treatment;
2. The drug candidates listed above are in Phase III or later stages of development;
3. The clinical trial listed above was taken from Clinicaltrials.gov.

Source: clinicaltrials.gov, Frost & Sullivan Analysis

In China, as of the Latest Practicable Date, there were no antibody-based drugs approved for the treatment of NMIBC. However, there were six antibody-based drug candidates under development in Phase III or later clinical stages. Among them, none were IL-15 based candidates.

HCC

Liver cancer is the growth and spread of unhealthy cells in the liver. Hepatocellular carcinoma ("**HCC**") is the most common type of primary liver cancer (~90%), and is the most common cause of death in people with cirrhosis. The major symptoms of HCC include yellow skin, abdominal swelling due to fluid in the abdominal cavity, loss of appetite, unintentional weight loss, abdominal pain, nausea and vomiting.

There were 857.6 thousand new cases of HCC in 2022 globally. From 2022 to 2026, the number of new cases is expected to grow at a CAGR of 2.4% and reach 944.1 thousand by 2026. By 2030, the number of HCC incidence is projected to grow to 1,034.7 thousand, representing a CAGR of 2.3%. In China, there were 397.5 thousand new cases of HCC in 2022. The number is projected to grow to 435.4 thousand by 2026 with a CAGR of 2.3% from 2022 to 2026. It is expected to reach 472.2 thousand in 2030, representing a CAGR of 2.0% from 2026 to 2030. Among new cases of HCC, approximately 78.6% are late stage cases, and the five-year survival rate can be extremely low, at approximately 4%.

There were approximately 716.1 thousand new cases of 1L advanced HCC globally in 2022; the number is expected to grow to 805.1 thousand in 2026 at a CAGR of 3.0% from 2022 to 2026, and is projected to reach 897.2 thousand in 2030 at a CAGR of 2.7% from 2026 to 2030. In China, there were approximately 331.9 thousand new cases of 1L advanced HCC in 2022; the number is expected to grow to 371.3 thousand in 2026 at a CAGR of 2.8% from 2022 to 2026, and is projected to reach 409.5 thousand in 2030 at a CAGR of 2.5% from 2026 to 2030.

Therapeutic options for HCC are generally determined based on disease staging. For late-stage HCC, systemic therapies are primarily recommended for first- and second-line treatments, two major classes of which are small molecule targeted drugs, such as NEXAVAR® (sorafenib), LENVIMA® (lenvatinib) and immune checkpoint inhibitors (e.g., PD-1/PD-L1 inhibitors). The corresponding combination therapies of targeted drugs or immune checkpoint inhibitors are also commonly used in first- and second-line treatments.

Disease Stage	Recommended Therapies				
Early Stage	**Liver Resection**	**Tumor Ablation**	**Radiation Therapy**	**Radio-immunotherapy**	**Liver Transplantation**
	TACE	Immuno-modulators	Chemotherapy	Targeted Therapy (e.g. sorafenib)	
Late Stage	**Small molecule targeted therapy** (1st Line: Sorafenib, Lenvatinib, Donafenib; 2nd Line: Regorafenib, Apatinib)				
	Checkpoint inhibitors + (Monoclonal antibody) (1st Line: Atezolizumab + Bevacizumab; 2nd Line: PD-1)				
	Chemotherapy (Oxaliplatin-based, etc)				

Source: CSCO 2020, Frost & Sullivan Analysis

Due to the limited clinical outcomes associated with small molecule targeted drugs, PD-1/PD-L1 inhibitors have been introduced in the first- and second-line settings to improve treatment outcomes for HCC patients in recent years. However, current immuno-oncology therapy regimens still fail to yield material progression-free and overall survival benefits. For example, although the combination of a PD-1/PD-L1 inhibitor and anti-VEGF therapy, such as atezolizumab or sintilimab plus bevacizumab, has demonstrated certain efficacy (an overall mPFS of around 4 months), there is still room for improvement, indicating a need for more effective strategies.

The global market for HCC drugs increased from US$1.7 billion in 2018 to US$3.1 billion in 2022, representing a CAGR of 16.5% during this period. Projections suggest this figure will reach US$6.6 billion in 2026 and US$11.2 billion in 2030, with anticipated CAGRs of 21.0% from 2022 to 2026 and 14.0% from 2026 to 2030, respectively. Similarly, the Chinese market for HCC drugs rose from US$0.7 billion in 2018 to US$1.5 billion in 2022, demonstrating a CAGR of 21.7% from 2018 to 2022. It is forecasted to reach US$3.7 billion in 2026 and US$6.2 billion in 2030, with projected CAGRs of 24.4% from 2022 to 2026 and 14.2% from 2026 to 2030, respectively.

On a global scale, as of the Latest Practicable Date, eleven antibody-based drugs were approved for the treatment of HCC. Among them, none were IL-10 based drugs. Additionally, there were eight antibody-based drug candidates under development in Phase III or later clinical stages. Among them, none were IL-10 based candidates.

In China, as of the Latest Practicable Date, seven antibody-based drugs were approved for the treatment of HCC. None of them were IL-10 based drugs. There were 12 antibody-based drug candidates under development in Phase III or later clinical stages. Among them, also none were IL-10 based candidates.

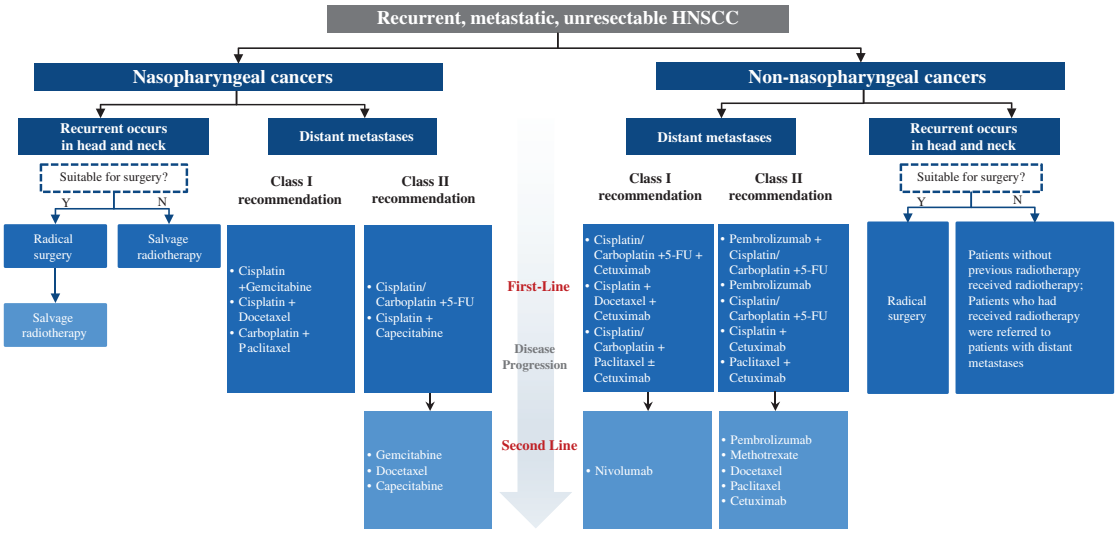
HNSCC

Head and neck cancer is a group of cancers that arise in the mouth, nose, throat, larynx, sinuses, or salivary glands. HNSCC is the most common subtype that accounts for more than 90% of head and neck cancers. It is an aggressive life-threatening disease associated with high mortality rates. While the five-year survival rate of HNSCC is approaching 50%, significantly shorter survival is observed for recurrent or metastatic HNSCC patients. Studies reported that recurrent or metastatic HNSCC has poor prognosis with a median survival of only about 12 months despite treatments.

According to Frost & Sullivan, the global HNSCC incidence reached 876.0 thousand in 2022. It is estimated to reach 954.9 thousand in 2026 and 1,035.2 thousand in 2030, representing a CAGR of 2.2% from 2022 to 2026 and a CAGR of 2.0% from 2026 to 2030. Incidence of HNSCC in China reached 134.1 thousand in 2022. To 2026, the case number is estimated to reach 144.3 thousand with a CAGR of 1.8% from 2022 to 2026. The case number is projected to reach 153.1 thousand in 2030, representing a CAGR of 1.5% from 2026 to 2030. Among new cases of HNSCC, approximately 71.4% are late stage cases, and the five-year survival rate can be approximately 40%.

There were approximately 292.2 thousand new cases of 2L advanced HNSCC globally in 2022; the number is expected to grow to 325.4 thousand in 2026 at a CAGR of 2.7% from 2022 to 2026, and is projected to reach 358.6 thousand in 2030 at a CAGR of 2.5% from 2026 to 2030. In China, there were approximately 44.7 thousand new cases of 2L advanced HNSCC in 2022; the number is expected to grow to 49.2 thousand in 2026 at a CAGR of 2.4% from 2022 to 2026, and is projected to reach 53.0 thousand in 2030 at a CAGR of 1.9% from 2026 to 2030.

In China, when it comes to treating HNSCC patients are categorized into different treatment paths based on whether they have nasopharyngeal cancer. For operable tumors, surgery followed by salvage radiotherapy is the recommended first-line treatment. Other treatments include a combination of chemotherapy and targeted therapy. For patients with metastatic HNSCC, treatment options can be limited. The first-line recommended treatment involves a combination of chemotherapy and EGFR inhibitor (cetuximab). Additionally, PD-1/PD-L1 inhibitors pembrolizumab, either alone or in combination with chemotherapy, are also suggested as first-line treatment options. In the second-line treatment, PD-1 inhibitors (pembrolizumab and nivolumab) are recommended as monotherapy for metastatic HNSCC treatment. Currently, palliative chemotherapy is the treatment for most metastatic HNSCC.



Note: Unsuitable surgery means that the patient's physical condition does not permit, CSCO refuses surgery for various reasons, or the tumor is too large to resect.

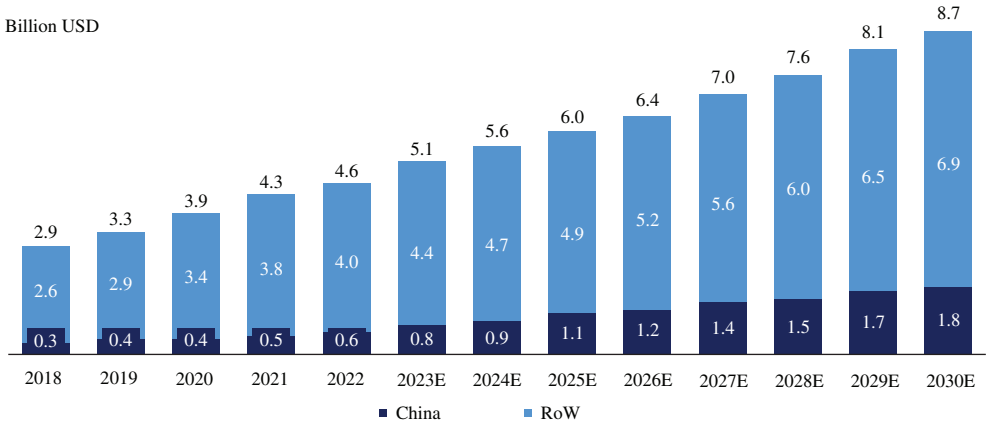
Source: Literature Review, Frost & Sullivan Analysis

While PD-1-targeted immunotherapy has been established as the preferred first-line treatment for metastatic HNSCC, surpassing the efficacy of chemotherapy combined with cetuximab, a notable proportion of patients do not experience benefits from this approach. For example, pembrolizumab, when administered in conjunction with chemotherapy, demonstrates a modest ORR of only 19% in patients exhibiting positive PD-L1 expression (Combined Positive Score, CPS $\geq$ 1). Additionally, if patients fail to respond to first-line therapy, there is a paucity of effective follow-up treatment options. Specifically, although PD-1 inhibitors are recommended as second-line treatment, their efficacy in managing HNSCC patients with disease progression remains unsatisfactory, yielding an ORR ranging from 13.3% to 16%. Consequently, there is an urgent demand for novel treatment alternatives that can enhance the response rate of PD-1-targeted immunotherapy and achieve more efficacious eradication of tumors.

The global market of head and neck cancer drugs increased from US$2.9 billion to US$4.6 billion with a CAGR of 12.3% from 2018 to 2022. The number is projected to reach US$6.4 billion in 2026 and US$8.7 billion in 2030 with a CAGR of 8.3% and 8.0% from 2022 to 2026 and from 2026 to 2030, respectively. The China market of head and neck cancer drugs increased from US$0.3 billion to US$0.6 billion with a CAGR of 18.6% from 2018 to 2022. The number is projected to reach US$1.2 billion in 2026 and US$1.8 billion in 2030 with a CAGR of 19.2% and 11.1% from 2022 to 2026 and from 2026 to 2030, respectively.

Global Head and Neck Cancer Drug Market, 2018-2030E

Period	CAGR		
	China	RoW	Total
2018-2022	18.6%	11.5%	12.3%
2022-2026E	19.2%	6.4%	8.3%
2026E-2030E	11.1%	7.3%	8.0%



Note: The CAGR from 2018 to 2022 is based on the changes in the disease epidemiology, diagnosis rates, treatment rates, price and efficacy of approved drugs over the past period. The CAGR from 2022 to 2030 is projected based on future changes in the disease epidemiology, diagnosis rates, treatment rates, new drug approvals, and prices and efficacy of approved drugs. The impact of the COVID-19 epidemic has also been taken into account, as it affects the availability and accessibility of drugs.

Source: NCCR, Frost & Sullivan Analysis

On a global scale, as of the Latest Practicable Date, four antibody-based drugs were approved for the treatment of HNSCC. Among them, none were IL-10 based drugs. Additionally, there were 13 antibody-based drug candidates under development in Phase III or later clinical stages. Among them, none were IL-10 based candidates.

In China, as of the Latest Practicable Date, four antibody-based drugs were approved for the treatment of HNSCC. None of them were IL-10 based drugs. There were five antibody-based drug candidates under development in Phase III or later clinical stages. Among them, also none were IL-10 based candidates.

AUTOIMMUNE DISEASE IMMUNOTHERAPY MARKET

Overview of Autoimmune Diseases

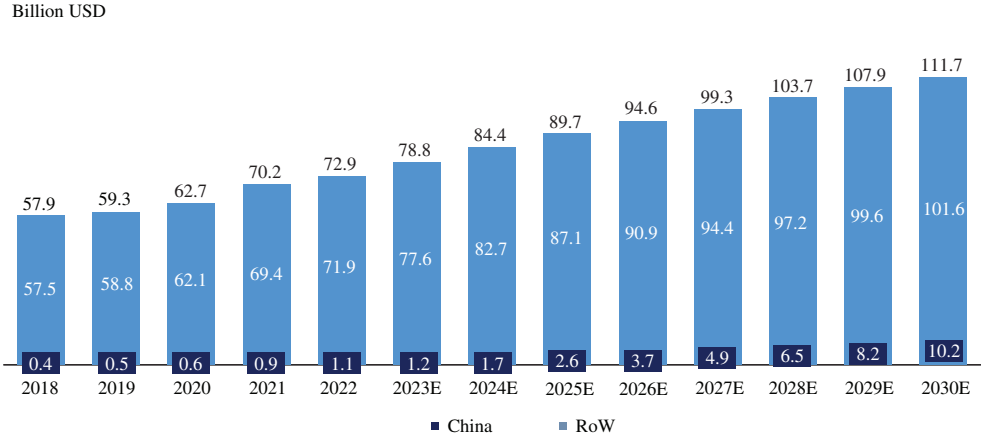
Autoimmune diseases are conditions in which the human body's immune system mistakenly attacks one's own body. There are over 100 existing types of autoimmune disorders, which can affect almost any part of the body. Both genetic and environmental factors may contribute to the development of autoimmune diseases, which can lead to symptoms of inflammation that affect patients' quality of life or even pose life-threatening risks.

There is a large patient pool in need of biologics for treatment of autoimmune diseases worldwide. The global immunotherapy market for autoimmune disease is expected to reach US$111.7 billion in 2030, growing from US$72.9 billion in 2022. The market size is expected to steadily grow at a CAGR of 6.7% from 2022 to 2026, and a CAGR of 4.2% from 2026 to 2030.

Based on the huge population, there is a large autoimmune disease patient pool in China. With the development and improvement of diagnostics for autoimmune diseases, the market demand for autoimmune disease drugs is expected to be spurred in the next few years. The China immunotherapy market for autoimmune disease is projected to reach US$3.7 billion in 2026 and US$10.2 billion in 2030, representing a CAGR of 36.2% from 2022 to 2026 and 29.0% from 2026 to 2030.

Global Immunotherapy Market for Autoimmune Disease, 2018-2030E

Period	CAGR		
	China	RoW	Total
2018-2022	27.8%	5.8%	6.0%
2022-2026E	36.2%	6.1%	6.7%
2026E-2030E	29.0%	2.8%	4.2%



Growth drivers and Future Trends of Immunotherapy Market for Autoimmune Diseases

The growth of immunotherapy market for autoimmune disease is primarily driven by the following factors:

- *Expanded patient pool of autoimmune diseases*. In recent years, the prevalence of autoimmune diseases has rapidly increased across the world. On a global scale, the prevalence rate of autoimmune disease reached 7.6%-9.4% and is considered as one of the top ten leading cause of mortality around the world, imposing a huge burden on public health service and economy. Due to the increase of diagnosis rate and treatment rate, the market size of autoimmune disease treatment is expected to expand constantly.

- *Precision diagnosis*. Due to their unspecific symptoms during the early stages, diagnosis of autoimmune diseases can be challenging and strongly relies on the identification of specific biomarkers or their combinations. Recently, novel diagnosis methods are developed to assess the development progress of the disease. As such, the accuracy and precision of autoimmune disease diagnosis are expected to be improved. Therefore, the capacity of autoimmune disease immunotherapy market will sustain rapid growth.

- *Development of novel specific therapies*. Currently available targeted immunotherapies inhibit major pro-inflammatory signaling pathways by blocking inflammatory cytokines, cell surface molecules and intracellular kinases. Despite the great success of targeted therapies in the treatment of autoimmune diseases, there are still many unmet medical needs in terms of drug efficacy and long-term safety. In addition to blocking inflammatory signaling pathways, future therapies aim to induce long-term immune tolerance while maintaining protective immune function. It is hoped that advances in biotechnology and disease knowledge will provide opportunities for the development of new drugs with better efficacy and improved safety profile.

IBD

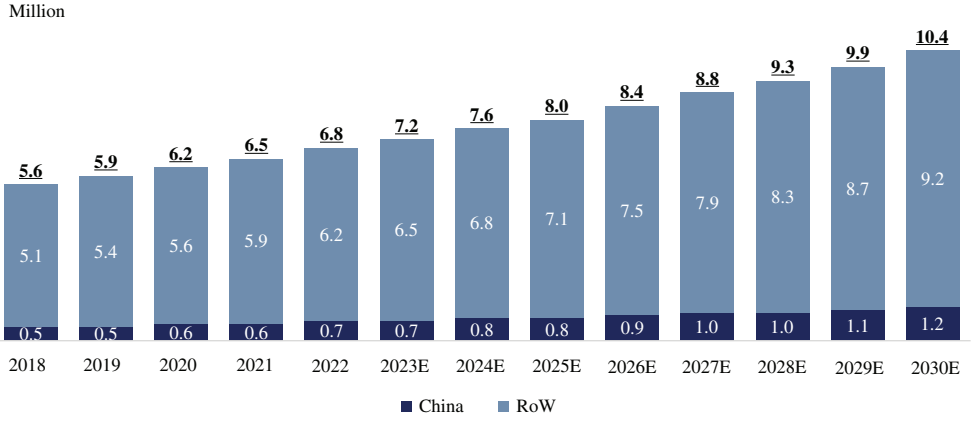
Inflammatory bowel disease ("**IBD**") is a broad term that describes conditions characterized by chronic inflammation of the gastrointestinal tract. It is one of the most common autoimmune disease in the world. The two most common inflammatory bowel diseases are ulcerative colitis and Crohn's disease. For Crohn's disease, the inflammation affects the entire digestive tract, and for ulcerative colitis, the inflammation only affects the colon. Both diseases are characterized by diarrhea, rectal bleeding, abdominal pain, fatigue and weight loss caused by abnormal immune system responses that damage one's own gastrointestinal tract.

The main objective of treating IBD is to alleviate inflammation, which triggers the associated signs and symptoms. Generally, two options are available for IBD treatment: drug therapy or surgery. Anti-inflammatory drugs are usually the first-line treatment for IBD. Immunomodulators, such as azathioprine, can help suppress the immune response, thereby reducing the release of inflammation-inducing chemicals in the intestinal lining. Biologics work by neutralizing the proteins that the immune system produces, which are recommended for moderate to severe IBD patients.

According to Frost & Sullivan, global prevalence of IBD in 2022 reached 6.8 million. It is estimated to rise to 8.4 million in 2026 and 10.4 million in 2030, representing a CAGR of 5.6% from 2026 to 2030. Prevalence of IBD in China reached 0.7 million in 2022. This number is expected to increase to 0.9 million in 2026 and 1.2 million in 2030, representing a CAGR of 7.7% from 2022 to 2026 and 7.1% from 2026 to 2030.

Global Prevalence of Inflammatory Bowel Disease, 2018-2030E

Period	CAGR		
	China	RoW	Total
2018-2022	8.4%	4.7%	5.0%
2022-2026E	7.7%	4.9%	5.2%
2026E-2030E	7.1%	5.4%	5.6%



Source: NCCR, Frost & Sullivan Analysis

SLE

Systemic lupus erythematosus ("**SLE**") is a chronic inflammatory condition caused by an autoimmune disease. Patients with lupus have distinctive antibodies in their blood that target their body tissues, leading to a multisystem autoimmune disease that can potentially cause serious organ complications and even death. Common symptoms of SLE include painful and swollen joints, fever, chest pain, hair loss, mouth ulcers, swollen lymph nodes, feeling tired, and a red rash, which is most commonly present on the face. The cause of SLE is still unclear, but it is believed to be the result of a combination of genetics and environmental factors.

Due to the significant heterogeneity of SLE, the treatment approach emphasizes early-stage diagnosis and management to prevent or delay organ lesions. In China, the treatment of SLE follows a three-stage classification system, consisting of early-stage, middle-stage, and late-stage. Distinct treatment strategies are employed for each SLE stage. For early-stage SLE, NSAIDs or antimalarials are commonly employed as first-line treatments. For middle-stage SLE, combing glucocorticoids with methotrexate or azathioprine is recommended. Finally, for late-stage SLE, glucocorticoids along with cyclophosphamide, cyclophosphamide/ciclosporin, or mycophenolate mofetil are regarded as valid options.

In 2022, the global prevalence of SLE was 8.0 million in 2022 and is expected to increase to 8.3 million in 2026 and 8.6 million in 2030. The prevalence of SLE in China was 1.0 million in 2022, and it is projected to increase to 1.1 million in 2026. The number is expected to remain stable in 2030.

REPORT COMMISSIONED BY FROST AND SULLIVAN

In connection with the [**REDACTED**], we have engaged Frost & Sullivan to conduct a detailed analysis and prepare an industry report on the therapeutic biologics market in China and the United States. 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 contract sum to Frost & Sullivan is RMB860,000 for the preparation of the Frost & Sullivan Report. The payment of such amount was not contingent upon our successful [**REDACTED**] or on the results of the Frost & Sullivan Report. Except for the Frost & Sullivan Report, we did not commission any other industry report in connection with the [**REDACTED**]. We have included certain information from the Frost & Sullivan Report in this document because we believe such information facilitates an understanding of the biologics market for potential [**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 the Frost & Sullivan Report, including those used to make future projections, are factual, correct and not misleading. Frost & Sullivan has independently analyzed the information, but the accuracy of the conclusions of its review largely relies on the accuracy of the information collected. Frost & Sullivan research may be affected by the accuracy of these assumptions and the choice of these primary and secondary sources. Our Directors confirm that, to the best of their knowledge, after taking reasonable care, there has been no adverse change in market information since the date of the Frost & Sullivan Report which may qualify, contradict or impact the information disclosed in this section.

Our business in the PRC is subject to extensive supervision and regulatory control by the PRC government. This section sets out a summary of the major relevant laws, regulations, rules and policies which may have material impact on our business.

REGULATIONS RELATING TO DRUGS IN CHINA

Primary Regulatory Authorities

Drug regulatory regime in China consists of the Standing Committee of the National People's Congress (the "**SCNPC**"), the State Council and several ministries and agencies under its authority including, among others, the NMPA, the predecessor of which is the China Food and Drug Administration (the "**CFDA**"), the National Health Commission ("**NHC**"), the predecessor of which is the National Health and Family Planning Commission of the PRC, and the National Healthcare Security Administration.

The NMPA, which inherits the drug supervision function from its predecessors, the CFDA, is the primary drug regulatory authority. The NMPA is responsible for drug registration and supervision, including non-clinical research, clinical trial, marketing approval, production, and circulation under the supervision of SAMR.

The NHC is the chief healthcare regulator of the PRC, which is primarily responsible for drafting national healthcare policies and regulating public health, medical services and health contingency system, coordinating the healthcare reform and supervising the operation of medical institutions and practicing of medical personnel.

The National Healthcare Security Administration (a new authority established in May, 2018 in accordance with the Institutional Reform Program of the State Council) is responsible for drafting and implementing policies, plans and standards on medical insurance, maternity insurance and medical assistance; administering healthcare fund; formulating a uniform medical insurance catalogue and payment standards on drugs, medical disposables and healthcare services; formulating and administering the bidding and tendering policies for drugs and medical disposables.

Drug Administration Laws and Regulations

The PRC Drug Administration Law (《中華人民共和國藥品管理法》) (the "**Drug Administration Law**") promulgated by the SCNPC on September 20, 1984, and last amended on August 26, 2019, and the Implementing Measures of the PRC Drug Administration Law (《中華人民共和國藥品管理法實施條例》) (the "**Drug Administration Law Implementing Measures**") issued by the State Council on August 4, 2002, and amended on February 6, 2016 and March 2, 2019 have together laid down the legal framework for the administration of drugs, including the research, development, manufacturing and business operation of new drugs, and administer the pharmaceutical manufacturing enterprises, pharmaceutical trading enterprises, and medicinal preparations of medical institutions, and the development, research, manufacturing, distribution, packaging, pricing and advertisements of drugs. The primary

regulation governing clinical trial applications, marketing authorization, and post-approval amendment and re-registration is known as the Administrative Measures for Drug Registration (《藥品註冊管理辦法》), promulgated by the CFDA on February 28, 2005, and last revised on January 22, 2020, by SAMR, and became effective on July 1, 2020.

Non-Clinical Research and Animal Testing

The SAMR requires preclinical data to support registration applications for imported and domestic drugs. According to the Administrative Measures for Drug Registration, non-clinical drug safety studies shall comply with the Good Laboratory Practice for Non-clinical Laboratory Studies (《藥物非臨床研究質量管理規範》) (the "**GLP**"). The GLP was issued by the CFDA on August 6, 2003 and latest revised on July 27, 2017 to improve the quality of non-clinical research, and the good laboratory practice has been implemented since September 1, 2017. Pursuant to the Circular on Administrative Measures for Certification of Good Laboratory Practice for Non-clinical Laboratory Studies (《關於印發藥物非臨床研究質量管理規範認證管理辦法的通知》) issued by the CFDA on April 16, 2007, the NMPA is responsible for the certification of non-clinical research institutions nationwide, while the local provincial medical products administrative authorities is in charge of the daily supervision of non-clinical research institution. The NMPA decides whether an institution is qualified for undertaking non-clinical pharmaceutical research by evaluating such institution's organizational administration, research personnel, equipment and facilities, and the operation and administration of non-clinical pharmaceutical projects. A GLP Certificate will be issued by the NMPA if all the relevant requirements are satisfied, which will also be published on the NMPA's website. Any entity without such certification must engage a qualified third party to conduct such non-clinical activities regulated under relevant laws and regulations.

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

Approval and Reform for Clinical Trials of New Drugs

Pursuant to the Drug Administration Law, the Drug Administration Law Implementing Measures and the Administrative Measures for Drug Registration issued by the SAMR on January 22, 2020 which became effective on July 1, 2020, new drug registration applications are subject to clinical trials. The Center for Drug Evaluation (the "**CDE**"), an institution under the NMPA, is responsible for the applications for clinical trials of new drugs.

The NMPA has taken certain measures to improve the efficiency for approving clinical trial applications, and enhanced the extent of supervising and implementation of the Good Clinical Practice for Drug Trials (《藥物臨床試驗質量管理規範》) (the "**PRC GCP**"), to ensure the completeness of the data. The PRC GCP was issued by the CFDA on August 6, 2003 and was latest revised by the NMPA and the NHC, which took effect from July 1, 2020.

The Opinions of the State Council on the Reform of Evaluation and Approval System for Drugs and Medical Devices (《國務院關於改革藥品醫療器械審評審批制度的意見》) issued by the State Council on August 9, 2015, established a reform framework of the evaluation and approval system for drugs and medical devices, and indicated the tasks of enhancing the standards of approval for, among others, drug registration, accelerating the evaluation and approval process for innovative drugs, and improving the approval for clinical trials of drugs.

The Announcement of the CFDA on Several Policies on the Evaluation and Approval of Drug Registration (《國家食品藥品監督管理總局關於藥品註冊審評審批若干政策的公告》) issued by the CFDA on November 11, 2015, further simplified the approval process of drugs that the IND of new drugs are subject to one-off umbrella approval instead of declaration, evaluation and approval by stages.

On October 8, 2017, the General Office of the Central Committee of the Communist Party of China and the General Office of the State Council jointly issued the Opinions on Deepening the Reform of the Evaluation and Approval System and Encouraging Innovation of Drugs and Medical Devices (《關於深化審評審批制度改革鼓勵藥品醫療器械創新的意見》), aiming to simplify the clinical trial procedures and shorten the time. For new drugs and medical devices urgently needed in clinical practice and drugs and medical devices used for the treatment of rare diseases, the evaluation and approval procedures for marketing shall be accelerated.

According to the Announcement of the NMPA on Adjusting the Evaluation and Approval Procedures for Clinical Trials of Drugs (《國家藥品監督管理局關於調整藥物臨床試驗審評審批程序的公告》) issued by the NMPA on July 24, 2018, which took effect therefrom, within 60 days from the acceptance of the IND and relevant fees paid up, if the applicant has not received any negative or questioning opinion from the CDE, the applicant may conduct the clinical trials for drugs pursuant to the protocol submitted.

The Priority Evaluation and Approval Procedures for Marketing Approvals of Drugs (Trial) (《藥品上市許可優先審評審批工作程序(試行)》) issued by the NMPA on July 7, 2020, further indicated that a fast track IND or drug registration pathway will be available to the innovative drugs.

Clinical Trial Registration of Drugs

According to the Administrative Measures for Drug Registration, upon obtaining the approval of IND, the applicant shall, prior to conducting the clinical trials of the drugs, register the information in relation to the clinical trial protocol on the registration and information publication platform for clinical trials of drugs.

Pursuant to the Announcement on the Drug Clinical Trial Information Platform (《關於藥物臨床試驗信息平台的公告》) issued by the NMPA on September 6, 2013, for all the clinical trials approved by the NMPA and conducted in the PRC, the applicants shall log in the registration and information publication platform for clinical trials of drugs to register, and publish the information of, the clinical trials. The applicant shall complete the pre-registration of the trials within one month after obtaining the approval for the IND, so as to obtain the unique registration number for the trial, and complete the registration of follow-up information before the enrollment of the first subject. If the applicant fails to complete the first submission and publication within one year after obtaining the approval for the IND, the applicant shall submit an explanation; if the applicant fails to complete the first submission and publication within three year after obtaining the approval for the IND, the approval for the IND will expire automatically.

Phases of Clinical Trials and Communication with the CDE

According to the Technical Guiding Principles for Clinical Trials of Antineoplastic Drugs (《抗腫瘤藥物臨床試驗技術指導原則》) issued by the CFDA on May 15, 2012, the clinical study of antineoplastic drugs usually consists of Phases I, II and III clinical trials. The primary objectives of Phase I clinical trials are the preliminary study of drug tolerance and pharmacokinetics, so as to provide data support for the design of dosage regimen in later-stage research. Phase II clinical trials are mainly exploratory studies, such as the exploration of drug administration dose, medication scheme and efficacy on tumors, as well as the observation of safety. Phase III clinical trials are intended to further confirm the clinical benefits for tumor patients on the basis of Phase II study, so as to provide sufficient evidence for obtaining the marketing approval.

According to the Administrative Measures for Drug Registration, based on the drug's characteristics and the purpose of research, clinical trials of drugs consist of Phase I, II, III and IV clinical trials, as well as the bioequivalence trials, which include clinical pharmacological research, exploratory clinical trials, confirmatory clinical trials and post-marketing research.

On November 19, 2021, the CDE issued the Clinical Value-oriented Guiding Principles on the Clinical Study for Antineoplastic Drugs (《以臨床價值為導向的抗腫瘤藥物臨床研發指導原則》), which offered suggestions on the clinical study of antineoplastic drugs from the perspective of patients' demands, in order to instruct the applicants to implement the clinical value-oriented and patient-centered study concepts during the clinical study, and provided references for the promotion of the scientific and orderly development of antineoplastic drugs.

Clinical Trials shall be conducted in accordance with the provisions of the PRC GCP, including the preparation for clinical trials, clinical trial protocols, responsibilities of sponsors and investigators, and protection of subjects.

According to the Announcement of the NMPA on Adjusting the Evaluation and Approval Procedures for Clinical Trials of Drugs (《關於調整藥物臨床試驗審評審批程序的公告》), where the clinical trials of a new drug has been approved, upon the completion of Phase I and II clinical trials and prior to Phase III clinical trials, the applicant shall apply to the CDE for a communication session, to discuss with the CDE the key technical issues including the design of Phase III clinical trials.

Pursuant to the Administrative Measures for Communication on Drug Development and Technical Reviews (《藥物研發與技術審評溝通交流管理辦法》) issued by the CDE on December 10, 2020 and effective therefrom, during the research and development, and application for registration stages of innovative drugs, the applicants may propose communication sessions with the CDE. The forms of communication can be face-to-face conference, video conference, telephone conference or written reply. The communication sessions are classified into three types. Type I sessions are held to address the key safety issues in the clinical trials of drugs and the key technical issues in the research and development of breakthrough therapeutic drugs. Type II sessions are held during the key research and development stages of drugs, mainly including the sessions held prior to the application of IND, the sessions held upon completion of Phase II clinical trials and prior to commencement of Phase III clinical trials of new drugs, the sessions held prior to application for marketing approvals of new drugs, and the risk evaluation and control sessions. Type III sessions are those sessions not falling into the categories of Type I or II sessions.

Filings for Gathering and Collecting Human Genetic Resources

To effectively protect and rationally utilize the human genetic resources in the PRC, the Ministry of Science and Technology and the Ministry of Health (the "**MOH**") jointly issued the Interim Administrative Measures on Human Genetic Resources (《人類遺傳資源管理暫行辦法》) on June 10, 1998. According to the Service Guidance for the Administrative Licensing Items of Collection, Gathering, Trading, Export or Exit 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》) issued by the Ministry of Science and Technology on July 2, 2015 and effective therefrom, and the Notice on Implementing the Administrative Licensing for Collection, Gathering, Trading, 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》) issued by the Ministry of Science and Technology on August 24, 2015 and

effective therefrom, the collection, gathering or research activities of human genetic resources participated by a foreign-invested sponsor falls within the scope of international cooperation, and the cooperating PRC organization shall apply for the approval of the China Human Genetic Resources Management Office via the online system. On October 26, 2017, the Ministry of Science and Technology issued the Circular on Optimizing the Procedures for the Administrative Examination and Approval of Human Genetic Resources (《關於優化人類遺傳資源行政審批流程的通知》), which became effective on December 1, 2017, simplifying the procedures for the examination and approval for collection and gathering of human genetic resources for marketing a drug in the PRC.

Pursuant to the Administrative Regulations on Human Genetic Resources of the PRC (《中華人民共和國人類遺傳資源管理條例》) issued by the State Council on May 28, 2019 which became effective on July 1, 2019, in order to obtain marketing approvals for the relevant drugs and medical devices in the PRC, no approval is required in the event international cooperating clinical trials are conducted at clinical institutions using the human genetic resources of the PRC but not involving the exit of human genetic resource materials. However, the cooperating parties shall file with the administrative department of science and technology under the State Council the type, quantity and purpose of the human genetic resources intended to be used prior to conducting clinical trials.

On October 17, 2020, the SCNPC promulgated the Biosecurity Law of the PRC (《中華人民共和國生物安全法》) (the "**Biosecurity Law**") which became effective on April 15, 2021, establishing a comprehensive legislative framework on the current regulations in the areas including epidemic control of human, animal and plant infectious diseases, security of biotechnology research, development and application, biosafety management of pathogenic microbiology laboratories, security management of human genetic resources and biological resources, countermeasures against microbial resistance and prevention of bioterrorism and threat of biological weapons. According to the Biosecurity Law, the high-risk and medium-risk biotechnology research and development activities shall be carried out by legal entities lawfully established in the PRC, and shall be approved or filed; the establishment of a pathogenic microbiology laboratory shall be lawfully approved or filed; (i) collecting human genetic resources of important genetic families or specific areas in the PRC, or collecting human genetic resources of which the types and quantities are subject to provisions of the competent department of science and technology under the State Council, (ii) preserving human genetic resources of the PRC, (iii) using human genetic resources of the PRC to carry out international scientific research cooperation, or (iv) transporting, mailing or exiting human genetic resource materials of the PRC, shall be approved by the competent department of science and technology.

On June 1, 2023, the Ministry of Science and Technology issued the Implementing Rules of the Administrative Regulations on Human Genetic Resources (《人類遺傳資源管理條例實施細則》) (the "**Human Genetic Resources Implementing Rules**"), which became effective on July 1, 2023, further clarifying the requirements for administrative licensing, record -filing and security review in respect of the collection, preservation, use, and outbound supply of Chinese human genetic resources, and detail the issues concerning relevant supervision, inspection and administrative penalties.

New Drug Application, Approval and Registration

According to the Administrative Measures for Drug Registration, upon completion of pharmacological and toxicological studies, clinical trials and other research supporting the marketing registration of drugs, determination of quality standards, completion of validation of commercial-scale production processes, and preparation for acceptance of verification and inspection for drug registration, the applicant may apply for the New Drug Approval (the "**NDA**"). The NMPA shall evaluate the application pursuant to applicable laws and regulations. The applicant must obtain the NDA before the drugs can be manufactured and sold in the PRC. If (i) a drug is used for the treatment of severe life-threatening diseases currently lacking effective treatment and the data of clinical trials of the drug can prove the efficacy and forecast the clinical value of the drug; (ii) a drug which is urgently needed for public health and the data of clinical trials of the drug can show the efficacy and forecast the clinical value of the drug; or (iii) a vaccine which is urgently needed to deal with major public health emergencies or deemed to be urgently needed by the NHC, and by assessment the benefit of the vaccine outweighs the risk, the applicant may apply for the conditional NDA during the clinical trials of the drug or vaccine.

According to the Administrative Provisions on Special Examination and Approval of New Drug Registration (《新藥註冊特殊審批管理規定》) issued by the CFDA on January 7, 2009 and effective therefrom, the special examination and approval by the CFDA for new drug registration applications applies when (i) the effective constituent extracted from, among others, plants, animals or minerals or the preparations thereof have never been marketed in the PRC, or the medicinal materials are newly discovered or the preparations thereof; (ii) the chemical raw medicines or the preparations thereof, or the biological products have not been approved for marketing either in the PRC or aboard; (iii) the new drugs are for the treatment of such diseases as AIDS, malignant tumors or rare diseases with distinctive clinical treatment advantages; or (iv) the new drugs are for the treatment of the diseases currently lacking effective treatment. Under the circumstances of (i) or (ii), the drug registration applicant (the "**Applicant**") may apply for the special examination and approval when submitting the application for clinical trials of the new drug; while, under the circumstances of (iii) or (iv), the Applicant may only apply for the special examination and approval when applying for production. The CFDA shall, based on the application of the Applicant, give priority to those registration applications which are determined in compliance with the aforementioned conditions after examination during the registration process, and enhance the communication with the Applicant.

According to the Announcement on Registration Classification of Biological Products and the Requirements for Application Materials (《關於發佈生物製品註冊分類及申報資料要求的通告》) issued by the NMPA on June 29, 2020 and the Registration Categories of Biological Products and the Requirements for Application Materials were implemented from July 1, 2020 and October 1, 2020 respectively, which require the registration categories of a drug shall be established at the time of filing a marketing application and further clarify the materials demand of biological products, biological products for precaution and biological therapeutic preparations.

On November 11, 2015, the NMPA issued the Circular on Several Policies of the Review and Approval of Drug Registrations (《關於藥品註冊審評審批若干政策的公告》), which provided fast-track clinical trial approvals and drug registration pathways for the following new drug applications: (i) registration of innovative drugs for the prevention or treatment of HIV, malignant tumors (cancers), severe infectious diseases and rare diseases; (ii) registration of pediatric drugs; (iii) registration of geriatric drugs for the treatment of diseases specially or commonly contracted by the senior population; (iv) registration of drugs listed in national major science and technology projects or national key research and development plan; (v) registration of innovative drugs using advanced technology or innovative treatment methods, or having distinctive clinical benefits; (vi) registration of foreign innovative drugs to be manufactured locally in China; (vii) concurrent applications for the clinical trials of new drugs which have been already approved in the United States or the European Union, or concurrent drug registration applications for drugs which are in the process of applying for marketing approvals and have passed onsite inspections by the competent review and approval authorities of drugs of the United States or the European Union, and are manufactured with the same production line in the PRC; and (viii) clinical trial applications for drugs with urgent clinical need and patent expiry within three years, and applications for manufacturing approvals of drugs with urgent clinical need and patent expiry within one year.

In addition, on May 17, 2018, the NMPA and the NHC jointly issued the Circular on Issues Concerning Optimizing the Review and Approval of Drug Registrations (《關於優化藥品註冊審評審批有關事宜的公告》), which further simplified and accelerated the drug review and approval process.

On July 7, 2020, the NMPA issued the Working Procedures for Priority Review and Approval of Drug Marketing Approvals (Trial) (《藥品上市許可優先審評審批工作程序(試行)》), which provided that during the clinical trials of drugs, for innovative drugs or improved new drugs for the prevention or treatment of severe life-threatening or life-quality-affecting diseases currently lacking effective prevention or treatment method or having obvious clinical advantages compared to the existing treatment method shown by sufficient evidence, the applicant may apply for the application of the procedures for breakthrough therapeutics during Phase I or II clinical trials, and usually no later than the Phase III clinical trials.

Drug Manufacturing License

Pursuant to the Drug Administration Law, a drug manufacturer must obtain a drug manufacturing license from the provincial medical products administration authority before manufacturing drugs. Prior to granting drug manufacturing licenses, the relevant governmental authorities shall inspect the applicant's production facilities and decide whether the sanitary conditions, quality assurance system, management structure and equipment of such facilities have met the required standards. Each drug manufacturing license will be valid for five years and the manufacturer is required to apply for renewal of the license within six months prior to the expiration date and the authorities shall reassess such application of renewal in accordance with the current legal and regulatory requirements.

Drug Operation

According to the Drug Administration Law, a drug operator shall obtain a drug operation license from the provincial drug administration department before conducting the drug wholesaling or from the county's drug administration department before conducting the drug sale. On November 17, 2017, the CFDA issued the Administrative Measures for Drug Operation Licenses (《藥品經營許可證管理辦法》), which further clarify the procedure, renewal, supervision and inspection of the drug operation licenses.

Drug Advertisements

According to the Advertising Law of the PRC (《中華人民共和國廣告法》), which was promulgated by the SCNPC in October, 1994 and last amended in April, 2021, certain contents such as statement on cure rate or efficiency shall not be included in the advertisement of drugs.

According to the Interim Administrative Measures for the Review of Advertisements for Drugs, Medical Devices, Health Food, and Formula Food for Special Medical Purposes (《藥品、醫療器械、保健食品、特殊醫學用途配方食品廣告審查管理暫行辦法》) issued by the SAMR in December, 2019 and came into effect in March, 2020, the advertisements for drugs shall not be released without being reviewed and the contents of a drug advertisement shall be based on the drug instructions approved by the drug administration departments.

GMP

The World Health Organization encourages the adoption of GMP standards in the drug production, in order to minimize the risks of failure to pass the finished product tests in the drug production.

The MOH first issued the Guidelines on Good Manufacturing Practices (《藥品生產質量管理規範》) on March 17, 1988, which was later revised on December 28, 1992. After its establishment, the NMPA revised the Guidelines on Good Manufacturing Practices on June 18, 1999, which became effective from August 1, 1999. The Guidelines on Good Manufacturing Practices revised by the MOH on October 19, 2010, which took effect on March 1, 2011 provided the basic standards for drug production, including production facilities, qualification of management personnel, production plant and facilities, documentation, material packaging and labeling, testing, production management, sales and return of products, and complaints of customers.

On August 2, 2011, the CFDA issued the Circular on Printing and Distributing the Administrative Measures for the Certification of Good Manufacturing Practice (《關於印發藥品生產質量管理規範認證管理辦法的通知》), which provided that newly established drug manufacturers, or existing drug manufacturers that wish to expand manufacturing scope or build new workshops shall apply for the GMP certification in accordance with the Drug Administration Law Implementing Measures. Those drug manufacturers that have already obtained the GMP certificates shall re-apply for the GMP certification within six months prior

to the expiration date of the GMP certificates. On December 30, 2015, the CFDA issued the Notice on Effectively Implementing the Good Manufacturing Practice (《關於切實做好實施藥品生產質量管理規範有關工作的通知》), which provided that those drug manufacturers that failed to obtain the GMP certificates shall not be granted the drug manufacturing license.

On November 29, 2019, the NMPA issued the Announcement on Matters relating to 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》), which confirmed that the GMP certification would be canceled from December 1, 2019, and no application for GMP certification would be accepted and no GMP certificate would be granted. However, according to the Drug Administrative Law, drug manufacturers shall still comply with the GMP, establish and improve the GMP system, and ensure the whole drug production process consistently in compliance with statutory requirements.

On May 24, 2021, the NMPA issued the Administrative Measures for Drug Inspection (Trial) (《藥品檢查管理辦法(試行)》) which became effective on the same day, and the Administrative Measures for the Certification of Good Manufacturing Practice was repealed. The Administrative Measures for Drug Inspection (Trial) provided that onsite inspections shall be conducted pursuant to the GMP on a drug manufacturer applying for the drug manufacturing license for the first time, while for the drug manufacturers applying for the renewal of drug manufacturing licenses, the review shall be conducted based on the risk management principles, in combination with the drug manufacturers' compliance with the laws and regulations of drug administration, and the operation of the GMP and quality management system, and inspections on the drug manufacturers' conformity to the GMP may be conducted where necessary.

Administrative Protection and Monitoring Periods for New Drugs

According to the Drug Administration Law Implementing Measures, to protect public health, the NMPA may provide for administrative monitoring periods of up to five years for new drugs approved to be manufactured, to consistently monitor the safety of such new drugs. During the monitoring period of a new drug, the NMPA will not approve any other enterprises' applications to manufacture or import a similar new drug.

REGULATIONS RELATING TO PRODUCT LIABILITY

Pursuant to the Product Quality Law of the PRC (《中華人民共和國產品質量法》) promulgated on February 22, 1993 and amended on July 8, 2000, August 27, 2009 and December 29, 2018 respectively by SCNPC, Seller shall be responsible for the repair, replacement or return of the product sold if (i) the product sold does not possess the properties for use that it should possess, and no prior and clear indication is given of such a situation; (ii) the product sold does not conform to the applied product standard as carried on the product or its packaging; or (iii) the product sold does not conform to the quality indicated by such means as a product description or physical sample. If a consumer incurs losses as a result of purchased product, the seller shall compensate for such losses.

Pursuant to the PRC Civil Code (《中華人民共和國民法典》) promulgated by the NPC on May 28, 2020 and coming into effect on January 1, 2021, where a patient suffers damage due to defects in drugs, he may seek compensation from the drug marketing authorization holder or also from the medical institution. Where the patient seeks compensation from the medical institution, the medical institution, after it has made the compensation, shall have the right to recover the compensation from the liable drug marketing authorization holder.

The Law of the PRC on the Protection of the Rights and Interests of Consumers (《中華人民共和國消費者權益保護法》) was promulgated on October 31, 1993 and was amended on August 27, 2009 and October 25, 2013 to protect consumers' rights when they purchase or use goods and accept services. All business operators must comply with this law when they manufacture or sell goods and/or provide services to customers. Under the amendments made on October 25, 2013, all business operators must pay high attention to protecting customers' personal information and must strictly keep confidential any consumer information they obtain during their business operations.

REGULATIONS ON ENVIRONMENTAL PROTECTION

Environmental Protection and Environmental Impact Assessment

The Environmental Protection Law of the PRC (《中華人民共和國環境保護法》), which was promulgated by the SCNPC on December 26, 1989, last amended on April 24, 2014 and came into effect on January 1, 2015, outlines the authorities and duties of various environmental protection regulatory agencies. The Ministry of Environmental Protection is authorized to issue national standards for environmental quality and emissions, and to monitor the environmental protection scheme of the PRC.

Pursuant to the Environmental Impact Assessment Law of the PRC (《中華人民共和國環境影響評價法》) promulgated by the SCNPC on October 28, 2002, became effective on September 1, 2003 and amended on July 2, 2016 and December 29, 2018, the State implements administration by classification on the environmental impact of construction projects according to the level of impact on the environment. The construction entity shall prepare an environmental impact report, or an environmental impact form or complete an environmental impact registration form (the "**Environmental Impact Assessment Documents**") for reporting and filing purpose. If the Environmental Impact Assessment Documents of a construction project have not been reviewed by the approving authority in accordance with the law or have not been granted approval after the review, the construction entity is prohibited from commencing construction works.

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, an 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.

Drainage and Sewage Disposal

Enterprises that engage in the activities of industry, construction, catering, and medical treatment, etc. that discharges sewage into urban drainage facilities shall apply to the relevant competent urban drainage department for the permit for discharging sewage into drainage pipelines under relevant laws and regulations, including the Regulations on Urban Drainage and Sewage Disposal (《城鎮排水與污水處理條例》), which was promulgated on October 2, 2013 and came into force on January 1, 2014, and the Measures for the Administration of Permits for the Discharge of Urban Sewage into the Drainage Network (《城鎮污水排入排水管網許可管理辦法》), which was promulgated on January 22, 2015 and last amended on December 1, 2022 and took effect on February 1, 2023. Drainage entities covered by urban drainage facilities shall discharge sewage into urban drainage facilities in accordance with the relevant provisions of the State. Where a drainage entity needs to discharge sewage into urban drainage facilities, it shall apply for a drainage license in accordance with the provisions of these Measures. The drainage entity that has not obtained the drainage license shall not discharge sewage into urban drainage facilities.

Management of Waste Discharge

Pursuant to the Catalog of Classified Management of Pollutant Discharge Permits for Stationary Pollution Sources (2019 Version) (《固定污染源排污許可分類管理名錄(2019年版)》) issued by the Ministry of Ecology and Environment of the PRC and became effective on December 20, 2019, the State implements the primary management, simplified management and registration management of pollutant discharge permits based on the pollutant production, emission amount and the extent of environmental impact of the pollutant discharge entities. A pollutant discharge unit under registration management does not need to apply for a pollutant discharge license.

Pursuant to the Regulations on the Administration of Pollutant Discharge Permits (《排污許可管理條例》) promulgated by the State Council on January 24, 2021 and became effective on March 1, 2021, based on the quantity of pollutants generated and discharged, their impacts on the environment and other factors, categorical administration of pollutant discharge permit system is implemented to regulate pollutant-discharging entities: (1) key administration of pollutant discharge permits shall be implemented for pollutant discharging entities which generate and discharge relatively large quantities of pollutants or have a relatively serious impact on the environment; and (2) administration of pollutant discharge permits shall be simplified for pollutant-discharging entities which generate and discharge relatively small

quantities of pollutants and have a relatively small impact on the environment. The entities that generate and discharge relatively small quantities of pollutants and have a relatively small impact on the environment shall fill in the waste discharge registration form (排污登記表) and are no longer required to obtain a waste discharge license (排污許可證). Entity that is required to fill in the waste discharge registration form shall report the basic information, waste discharge destination, waste discharge standards implemented, waste prevention and control measures adopted and other information to the national waste discharge license information platform. If the information reported is changed, it shall be changed in the platform within 20 days as of the date when such change occurs.

According to the Law of the PRC on the Prevention and Control of Environmental Pollution Caused by Solid Waste (《中華人民共和國固體廢物污染環境防治法》) promulgated by the SCNPC on October 30, 1995, last amended on April 29, 2020 and became effective on September 1, 2020, the entity that produces hazardous wastes shall work out a plan for managing hazardous wastes in accordance with relevant provisions and keep a hazardous waste management journal, faithfully recording relevant information, and report the types, production, destination, storage, treatment and other relevant information to the local ecology and environment department through the National Hazardous Waste Information Management System. The aforesaid management plan shall be filed with the ecology and environment department of the local people's government at or above the county level in the place where the entity that produces hazardous wastes is located, and failing to formulate a hazardous waste management plan or report information on hazardous wastes in accordance with relevant provisions issued by the state may be ordered by the environment department to take corrective action, imposed a fine, and confiscated illegal income by the authorities, and if the circumstances are serious, the ecology and environment department may order suspension of business or close-down, with the approval of the people's government with the authority to approve.

Hazardous Chemicals

Pursuant to the Regulations on the Safety Management of Hazardous Chemicals (《危險化學品安全管理條例》), which was promulgated on January 26, 2002 and last amended with effect from December 7, 2013, the production, storage, use, operation, and transportation of hazardous chemicals shall be in accordance with the safety management regulations. The hazardous chemical units shall oblige to the safety conditions required by laws and administrative regulations and state and industry standards, establish and improve safety management rules and post safety responsibility systems, and provide safety education, legal education and occupation technical training for employees. Employees shall accept such education and training and may begin working only after qualifying the relevant assessment. Where it requires employees to have certain qualification to assume a position, an enterprise shall only designated employees with such qualification to assume the position.

According to the Administrative Regulations on Precursor Chemicals (《易製毒化學品管理條例》) promulgated by the State Council on August 26, 2005 and last amended with effect from September 18, 2018, the precursor chemicals are classified into three categories. Category I refers to the major materials that may be used to produce drugs. Categories II and III refer to the chemical auxiliary substances that may be used to produce drugs. An enterprise who applies for producing the precursor chemicals in Category I shall be qualified with specific requirements and obtain the production license upon the examination and approval of the administrative department.

Fire Protection

According to the Fire Prevention Law of the People's Republic of China (《中華人民共和國消防法》) promulgated by the SCNPC on April 29, 1998 and most recently amended on April 29, 2021, and the Interim Provisions on the Administration of Examination and Acceptance of Fire Prevention Design of Construction Projects (《建設工程消防設計審查驗收管理暫行規定》) promulgated by the Ministry of Housing and Urban-Rural Development on April 1, 2020 and effective on June 1, 2020, fire acceptance should be done for special construction projects which meet certain conditions, fire filing should be done for other types of construction projects. The construction project that fails to complete the required as-built acceptance check on fire prevention shall be ordered by the relevant governmental authorities to close down and shall be imposed a fine of RMB30,000 up to RMB300,000.

REGULATIONS ON INTELLECTUAL PROPERTY RIGHTS

Trademarks

Trademarks are protected by the Trademark Law of the PRC (《中華人民共和國商標法》) which was promulgated on August 23, 1982 and subsequently amended on February 22, 1993, October 27, 2001, August 30, 2013, April 23, 2019 and took effect on November 1, 2019 as well as the Implementation Regulation of the PRC Trademark Law (《中華人民共和國商標法實施條例》) adopted by the State Council on August 3, 2002 and revised on April 29, 2014. In the PRC, registered trademarks include commodity trademarks, service trademarks, collective marks and certification marks. The Trademark Office of National Intellectual Property Administration handles trademark registrations and grants a term of 10 years to registered trademarks, renewable every 10 years where a registered trademark needs to be used after the expiration of its validity term.

Patents

According to the Patent Law of the PRC (《中華人民共和國專利法》) (the "**Patent Law**"), promulgated by the SCNPC on March 12, 1984 and further amended on September 4, 1992, August 25, 2000, December 27, 2008, October 17, 2020 and came into effect on June 1, 2021 and the Implementing Rules of the Patent Law of the PRC (《中華人民共和國專利法實施細則》), promulgated by the China Patent Bureau Council on January 19, 1985, and latest amended on December 11, 2023 and came into effect on January 20, 2024, the term

"invention-creations" refers to inventions, utility models and designs. The duration of patent right for inventions shall be twenty years, the duration of patent right for utility models shall be ten years and the duration of patent right for designs shall be fifteen years, counted from the date of filing. In the event that a dispute arises due to a patent being exploited without the prior authorization of the patentee, that is to say an infringement upon the patent right of the patentee.

Internet Domain Names

The Administrative Measures for Internet Domain Names (《互聯網域名管理辦法》), which was promulgated by the Ministry of Industry and Information Technology of the PRC (the "**MIIT**") on August 24, 2017 and became effective on November 1, 2017, regulates the ".CN" and the ". zhongguo (in Chinese character)" shall be China's national top-level domains. Any party that engages in internet information services shall use its domain name in compliance with laws and regulations and in line with relevant provisions of the telecommunications authority but shall not use its domain name to commit any violation.

REGULATIONS ON EMPLOYMENT AND SOCIAL SECURITY

Labor Laws

The Labor Law of the PRC (《中華人民共和國勞動法》), which was promulgated by the SCNPC on July 5, 1994, came into effect on January 1, 1995, and was amended on August 27, 2009 and December 29, 2018, provides that an employer shall develop and improve its rules and regulations to safeguard the rights of its workers. Labor safety and health facilities must comply with relevant national standards. Workers engaged in special operations shall have received specialized training and obtained the pertinent qualifications.

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 on June 29, 2007, came into effect on January 1, 2008, and was amended on December 28, 2012, and came into effect on July 1, 2013, and the Implementation Regulations on Labor Contract Law (《中華人民共和國勞動合同法實施條例》) which was promulgated and came into effect on September 18, 2008 by the State Council, regulate the relations of employer and the employee, and contain specific provisions involving the terms of the labor contract.

Social Security and Housing Funds

According to the Provisional Regulations on the Collection and Payment of Social Insurance Premium (《社會保險費徵繳暫行條例》), the Regulations on Work Injury Insurance (《工傷保險條例》), the Regulations on Unemployment Insurance (《失業保險條例》) and the Trial Measures on Employee Maternity Insurance of Enterprises (《企業職工生育保險試行辦法》), enterprises in China must provide benefit plans for their employees, which include basic pension insurance, unemployment insurance, maternity insurance, work injury insurance and medical insurance. An enterprise must provide social insurance by processing social insurance registration with local social insurance agencies and must pay or withhold relevant social insurance premiums for or on behalf of employees.

The PRC Law on Social Insurance (《中華人民共和國社會保險法》), which was promulgated by the SCNPC on October 28, 2010 and came into effect on July 1, 2011, and was amended on December 29, 2018 regulates basic pension insurance, unemployment insurance, maternity insurance, work injury insurance and medical insurance, and has elaborated in detail the legal obligations and liabilities of employers who do not comply with relevant laws and regulations on social insurance.

The Regulations on the Administration of Housing Provident Fund (《住房公積金管理條例》), which was promulgated on April 3, 1999 and came into effective on the same date, and was amended on March 24, 2002 and March 24, 2019, stipulates that housing provident fund contributions paid by an individual employee and housing provident fund contributions paid by his or her employer shall all belong to the individual employee.

REGULATIONS ON TAXATION

Enterprise Income Tax

According to the Enterprise Income Tax Law of the PRC (《中華人民共和國企業所得稅法》) (the "**EIT Law**"), which was promulgated by the NPC on March 16, 2007, came into effect on January 1, 2008 and amended by the SCNPC on February 24, 2017 and December 29, 2018, and the Implementation Regulations on the EIT Law (《中華人民共和國企業所得稅法實施條例》), which was promulgated by the State Council on December 6, 2007 and came into effect on January 1, 2008, and amended by the State Council on April 23, 2019 and came into effect on the same date, a uniform income tax rate of 25% will be applied to domestic enterprises, foreign-invested enterprises and foreign enterprises that have established production and operation facilities in China. These enterprises are classified as either resident enterprises or non-resident enterprises. Resident enterprises refer to enterprises that are established in accordance with PRC laws, or that are established in accordance with the laws of foreign countries but whose actual or de facto control is administered from within the PRC. Non-resident enterprises refer to enterprises that are set up in accordance with the laws of foreign countries and whose actual administration is conducted outside the PRC, but who (whether or not through the establishment of institutions in the PRC) derive income from the PRC. Under the EIT Law and relevant implementing regulations, a uniform corporate income tax rate of 25% is applicable. However, if non-resident enterprises have not established institutions or places in the PRC, or if they have established institutions or places in the PRC but there is no actual relationship between the relevant income derived in the PRC and the institutions or places set up by them, enterprise income tax is set at the rate of 10%.

Value-added Tax

The Provisional Regulations on Value-added Tax of the PRC (《中華人民共和國增值税暫行條例》), which was promulgated by the State Council on December 13, 1993, came into effect on January 1, 1994, and amended on November 10, 2008, February 6, 2016 and November 19, 2017, and the Detailed Implementing Rules of the Provisional Regulations on Value-added Tax of the PRC (《中華人民共和國增值税暫行條例實施細則》), which was promulgated by the MOF on December 25, 1993 and came into effect on the same date, and was amended on December 15, 2008 and October 28, 2011, came into effect on November 1, 2011 set out that all taxpayers selling goods or providing processing, repairing or replacement services, sales of services, intangible assets and immovable assets and importing goods in China shall pay a value-added tax. A tax rate of 17% shall be levied on general taxpayers selling goods and services, leasing of tangible movable assets or importing goods whereas the applicable rate for the export of goods by taxpayers shall be nil, unless otherwise stipulated.

On November 16, 2011, the MOF and the State Administration of Taxation (the "**SAT**") promulgated the Trial Scheme for the Conversion of Business Tax to Value-added Tax (《營業税改徵增值税試點方案》), pursuant to which, the government launched gradual taxation reforms from January 1, 2012, where a value-added tax is imposed in lieu of business tax on a trial basis in regions and industries showing strong economic performance, such as transportation and certain modern service industries.

According to the Notice of the Ministry of Finance and the State Administration of Taxation on Overall Implementation of the Pilot Program of Replacing Business Tax with Value-added Tax (《財政部、國家税務總局關於全面推開營業税改徵增值税試點的通知》), which was promulgated by the MOF and the SAT on March 23, 2016 and came into effective on May 1, 2016, amended on July 1, 2017, December 25, 2017 and March 20, 2019 and became effective on April 1, 2019, all business taxpayers in the consumer service industry shall pay value-added tax instead of business tax from May 1, 2016. If the taxpayer of the pilot project has already enjoyed tax incentives of business tax according to relevant policies and regulations before the application of the pilot collection of value-added tax in lieu of business tax, he/she may, in the remaining period of tax incentives, enjoy tax incentives of value-added tax in accordance with the relevant provisions. Medical services provided by medical institutions shall be exempted from value-added tax.

According to the Notice of the Ministry of Finance and the State Administration of Taxation on Adjusting Value-added Tax Rates (《財政部、國家税務總局關於調整增值税税率的通知》) issued on April 4, 2018 and became effective on May 1, 2018, the value-added tax rates of 17% and 11% applicable to the taxpayers who have VAT taxable sales activities or imported goods are adjusted to 16% and 10%, respectively.

According to the Notice on Relevant Policies for Deepening Value-Added Tax Reform (《關於深化增值税改革有關政策的公告》) issued on March 20, 2019 and became effective on April 1, 2019, the value-added tax rate was reduced to 13% and 9%, respectively.

REGULATIONS ON FOREIGN EXCHANGE

Foreign Exchange Regulation

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

On November 19, 2012, the SAFE issued the Circular of Further Improving and Adjusting Foreign Exchange Administration Policies on Foreign Direct Investment (《關於進一步改進和調整直接投資外匯管理政策的通知》), or 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, multiple capital accounts for the same entity may be opened in different provinces as well. 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》) in February 2015, which was partially abolished in December 2019, 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 10, 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》), or 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 on Relevant Issues Concerning the Administration of Foreign Exchange for Overseas Listing (《關於境外上市外匯管理有關問題的通知》) issued by the SAFE on December 26, 2014, the domestic companies shall register the overseas listed with the foreign exchange control bureau located at its registered address in 15 working days after completion of the overseas listing and issuance. The funds raised by the domestic companies through overseas listing may be repatriated to China or deposited overseas, provided that the intended use of the fund shall be consistent with the contents of the document and other public disclosure documents.

According to the Notice of 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》), or 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 estates 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》), or the SAFE Circular 16, which came into effect on the same day. The SAFE Circular 16 provides that discretionary foreign exchange settlement applies to foreign exchange capital, foreign debt offering proceeds and remitted foreign listing proceeds, and the corresponding RMB capital converted from foreign exchange may be used to extend loans to related parties or repay inter-company loans (including advances by third parties). 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). The 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.

According to the Circular on Optimizing Administration of Foreign Exchange to Support the Development of Foreign-related Business (《關於優化外匯管理支持涉外業務發展的通知》) issued by the SAFE on April 10, 2020, eligible enterprises are allowed to make domestic payments by using their capital funds, foreign credits and the income under capital accounts of overseas listing, without submitting the evidentiary materials concerning authenticity of such capital for banks in advance, provided that their capital use is authentic and in compliance with administrative regulations on the use of income under capital accounts. The bank in charge shall conduct post spot checking in accordance with the relevant requirements.

SAFE Circular 37

SAFE promulgated the Circular on Relevant Issues Concerning Foreign Exchange Control on Domestic Residents' Offshore Investment and Financing and Roundtrip Investment through Special Purpose Vehicles (《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》), or SAFE Circular 37, on July 4, 2014, which replaced the former circular commonly known as "SAFE Circular 75" (《關於境內居民通過境外特殊目的公司融資及返程投資外匯管理有關問題的通知》) promulgated by SAFE on October 21, 2005. SAFE Circular 37 requires PRC residents to register with local branches of SAFE in connection with their direct establishment or indirect control of an offshore entity, for the purpose of overseas investment and financing, with their legally owned assets or interests in domestic enterprises or offshore assets or interests, referred to in SAFE Circular 37 as a "special purpose vehicle." SAFE Circular 37 further requires amendment to the registration in the event of any significant changes with respect to the special purpose vehicle, such as increase or decrease of capital contributed by PRC individuals, share transfer or exchange, merger, division or other material event. In the event that a PRC shareholder holding interests in a special purpose vehicle fails to fulfill the required SAFE registration, the PRC subsidiary of that special purpose vehicle may be prohibited from making profit distributions to the offshore parent and from carrying out subsequent cross-border foreign exchange activities, and the special purpose vehicle may be restricted in its ability to contribute additional capital into its PRC subsidiary. Furthermore, failure to comply with the various SAFE registration requirements described above could result in liability under PRC law for evasion of foreign exchange controls. On February 13, 2015, SAFE released SAFE Circular 13, under which local banks will examine and handle foreign exchange registration for overseas direct investment, including the initial foreign exchange registration and amendment registration, from June 1, 2015.

REGULATIONS ON THE COMPANIES AND FOREIGN INVESTMENT IN CHINA

The Company Law and Regulations

The Company Law of the PRC (《中華人民共和國公司法》) (the "**Company Law**"), which was amended by the SCNPC on 26 October 2018 and became effective on the same day, provides for the establishment, corporate structure and corporate management of companies, which also applies to foreign-invested enterprises in PRC. Furthermore, the Company Law of the PRC was recently amended by the SCNPC on December 29, 2023 with respect to the registration, the capital contribution period and so on and will come into force on July 1, 2024,

to improve the system for company registration and facilitates the establishment and exit channels of companies, to offer greater autonomy for companies in terms of corporate structure, improve the capital system for companies, boost the responsibility system of company shareholders and management personnel, and highlight social responsibility efforts of enterprises.

Regulations relating to Foreign Investment

On March 15, 2019, the NPC promulgated the Foreign Investment Law of the PRC (《中華人民共和國外商投資法》) (the "**Foreign Investment Law**"), which took effect on January 1, 2020 and repealed the Sino-foreign Equity Joint Ventures Law of the PRC (《中華人民共和國中外合資經營企業法》), the Wholly Foreign-owned Enterprise Law of the PRC (《中華人民共和國外資企業法》) and the Sino-foreign Cooperative Joint Ventures Law of the PRC (《中華人民共和國中外合作經營企業法》). Since then, the Foreign Investment Law has become the fundamental law regulating foreign-invested enterprises wholly or partially invested by foreign investors. According to the Foreign Investment Law and the Implementation Regulations for the Foreign Investment Law of the PRC (《中華人民共和國外商投資法實施條例》) issued by the State Council on December 26, 2019 and effective from January 1, 2020, foreign investment refers to any investment activity directly or indirectly carried out by foreign natural persons, enterprises or other organizations (the "**foreign investors**") within the territory of the PRC, including the following circumstances: (i) a foreign investor establishes a foreign-funded enterprise within the territory of the PRC, either alone or together with any other investor; (ii) a foreign investor acquires shares, equities, property shares or any other similar rights and interests of a PRC enterprise; (iii) a foreign investor invests in any new project within the territory of the PRC, either alone or together with any other investor; or (iv) a foreign investor invests in any other way as stipulated under the laws or administrative regulations or provided by the State Council. The organization form and structure, and the operating rules of foreign-funded enterprises are subject to the provisions of the Company Law, the Partnership Enterprise Law of the PRC and other applicable laws.

Pursuant to the Measures for the Reporting of Foreign Investment Information (《外商投資信息報告辦法》) promulgated by the Ministry of Commerce of the PRC (the "**MOFCOM**") and the SAMR on December 30, 2019 and effective on January 1, 2020, a listed foreign-funded company may, when the change of foreign investors' shareholding ratio accumulatively exceeds 5% or the foreign party's controlling or relatively controlling status changes, report the information on the modification of investors and the shares held by them.

REGULATIONS ON M&A AND OVERSEAS LISTING

The Provisions on the Merger or Acquisition of Domestic Enterprises by Foreign Investors (《關於外國投資者併購境內企業的規定》) (the "**M&A Rules**") was jointly promulgated by six PRC governmental authorities including the the MOFCOM, the SAT, the SAFE, the PRC State Administration for Industry and Commerce, the State-owned Assets Supervision and Administration Commission of the State Council and the China Securities Regulatory Commission (the "**CSRC**") on August 8, 2006, and amended on June 22, 2009.

Foreign investors must comply with the M&A Rules when they purchase equity interests of a domestic company or subscribe the increased capital of a domestic company, and thus changing of the nature of the domestic company into a foreign-invested enterprise; or when the foreign investors establish a foreign-invested enterprise in China, purchase the assets of a domestic company and operate the asset; or when the foreign investors purchase the assets of a domestic company by agreement, establish a foreign-invested enterprise by injecting such assets, and operate the assets. According to Article 11 of the M&A Rules, where a domestic enterprise, or a domestic natural person, through an overseas company established or controlled by it/him/her, acquires a domestic enterprise which is related to or connected with it/him/her, approval from the MOFCOM is required. The M&A Rules, among other things, further purport to require that an offshore special purpose vehicle, formed for listing purposes and controlled directly or indirectly by PRC companies or individuals, shall obtain the approval of the CSRC prior to the listing and trading of such special purpose vehicle which acquires shares of or equity interests in the PRC companies in exchange for the shares of offshore companies.

The CSRC promulgated the Overseas Listing Trial Measures and five relevant guidelines on February 17, 2023, which took effect on March 31, 2023. The Overseas Listing Trial Measures comprehensively reform the regulatory regime for overseas offering and listing of PRC domestic companies' securities, either directly or indirectly, into a filing-based system.

According to the Overseas Listing Trial Measures, the PRC domestic companies that seek to offer and list securities in overseas markets, either in direct or indirect means, are required to fulfill the filing procedure with the CSRC and report relevant information. The Overseas Listing Trial Measures provide that an overseas listing or offering is explicitly prohibited, if any of the following applies: (i) such securities offering or listing is explicitly prohibited by provisions in PRC laws, administrative regulations or relevant state rules; (ii) the proposed securities offering or listing may endanger national security as reviewed and determined by competent authorities under the State Council in accordance with laws; (iii) the domestic company intending to be listed or offer securities in overseas markets, or its controlling shareholder(s) and the actual controller, have committed crimes such as corruption, bribery, embezzlement, misappropriation of property or undermining the order of the socialist market economy during the latest three years; (iv) the domestic company intending to be listed or offer securities in overseas markets is currently under investigations for suspicion of criminal offenses or major violations of laws and regulations, and no conclusion has yet been made thereof; or (v) there are material ownership disputes over equity held by the domestic company's controlling shareholder(s) or by other shareholder(s) that are controlled by the controlling shareholder(s) and/or actual controller. According to the Overseas Listing Trial Measures, initial public offerings or listings in overseas markets shall be filed with the CSRC within three working days after the relevant application is submitted overseas. We had filed with the CSRC within three working days after we submitted the [**REDACTED**] to [**REDACTED**], and we had not received any inquiry, notice, warning, or order prohibiting us from getting [**REDACTED**] on the [**REDACTED**] from the CSRC or any other PRC government authorities.

On February 24, 2023, the CSRC and other relevant government authorities promulgated the Provisions on Strengthening the Confidentiality and Archives Administration of Overseas Securities Issuance and Listing by Domestic Enterprises (《關於加強境內企業境外發行證券和上市相關保密和檔案管理工作的規定》) (the "**Provision on Confidentiality**"), which took effect on March 31, 2023. Pursuant to the Provision on Confidentiality, where a domestic enterprise provides or publicly discloses to the relevant securities companies, securities service institutions, overseas regulatory authorities and other entities and individuals, or provides or publicly discloses through its overseas listing subjects, documents and materials involving state secrets and working secrets of state organs, it shall report the same to the competent department with the examination and approval authority for approval in accordance with the law, and submit the same to the secrecy administration department of the same level for filing. Domestic enterprises providing accounting archives or copies thereof to entities and individuals concerned such as securities companies, securities service institutions and overseas regulatory authorities shall perform the corresponding procedures pursuant to the relevant provisions of the State. The working papers formed within the territory of the PRC by the securities companies and securities service institutions that provide corresponding services for the overseas issuance and listing of domestic enterprises shall be kept within the territory of the PRC, and those that need to leave the PRC shall go through the examination and approval formalities in accordance with the relevant provisions of the State.

REGULATIONS ON CYBERSECURITY AND DATA EXPORTATION SECURITY

On December 28, 2021, the Cyberspace Administration of China (the "**CAC**"), jointly with 12 other governmental authorities, promulgated the Measures for Cybersecurity Review (《網絡安全審查辦法》) (the "**Measures for Cybersecurity Review**"), which became effective on February 15, 2022, provides that critical information infrastructure operators that purchase network products and services and data processing operators engaging in data processing activities that affect or may affect national security must be subject to the cybersecurity review.

On June 13, 2023, our PRC Legal Adviser and the Sole Sponsor's PRC legal adviser consulted with the China Cybersecurity Review Technology and Certification Center (中國網絡安全審查技術與認證中心) (the "**CCRC**"), which is authorized by the Cybersecurity Review Office of CAC for receiving and accepting submissions of cybersecurity reviews and answering public inquiries relating to cybersecurity reviews. The consultation was made on a no-name basis but detailed description of our business model and our proposed [**REDACTED**] in Hong Kong was communicated to the CCRC officer during the consultation. During the consultation, the CCRC confirmed that: (i) our Company is not required to apply for cybersecurity review in connection with its proposed [**REDACTED**] under the Measures for Cybersecurity Review as "listing in Hong Kong" does not fall into the scope of "listing in a foreign country" and (ii) our Company is not required to apply for cybersecurity review because we had not been identified by the competent authority that responsible for identifying critical information infrastructure as a critical information infrastructure operators.

We and our PRC Legal Adviser are of the view that, the currently effective Measures for Cybersecurity Review would not have a material adverse impact on our business operations or the proposed [**REDACTED**], on the basis that: (i) we have implemented a set of internal policies, procedures, and measures to ensure our cybersecurity and data protection practice; (ii) as of the Latest Practicable Date, we had not received any inquiry, notice, warning, investigation, sanctions or objection regarding the proposed [**REDACTED**] plan or requesting any cybersecurity review regarding relevant regulations from relevant regulatory authorities; (iii) as of the Latest Practicable Date, we had not been subject to any material administrative penalties, mandatory rectifications, or other sanctions by any competent regulatory authorities in relation to cybersecurity and data protection, nor had there been any material cybersecurity and data protection incidents or infringement upon any third parties, or other legal proceedings, administrative or governmental proceedings, pending or, to the best of our knowledge threatened against or relating to our Group; (iv) we agree to closely monitor the legislative and regulatory development in cybersecurity and data protection, including the Measures for Cybersecurity Review, and will adjust our cybersecurity and data protection practices in a timely manner to ensure compliance with the currently effective Measures for Cybersecurity Review and other laws and regulations effective in the future.

Besides, we and our PRC Legal Adviser are of the view that the likelihood of our Group's business operations and the proposed [**REDACTED**] that might give rise to national security risks based on the factors set out in Article 10 of the Measures for Cybersecurity Review is relatively low, on the basis that, during the Track Record Period and as of the Latest Practicable Date, (i) we had implemented data collection, retention, and safeguard procedures; (ii) our Group had not experienced any data breach or violation of data protection and privacy laws and regulations that has a material adverse effect on our business operations; (iii) we had not been subject to any material investigation, inquiry, or sanction relating to cybersecurity, data security or any cybersecurity review from the CAC, the CSRC, or any other relevant government authority, and we were not required to take the initiative to apply for the cybersecurity review from the CAC as of the Latest Practicable Date; (iv) we had not been notified by any authorities of being classified as a critical information infrastructure operator; and (v) our products, services, systems and data would not be technically and managerially controlled by any foreign government, upon the completion of the proposed [**REDACTED**]. However, it is hard for our PRC Legal Adviser to preclude the possibility that new rules or regulations promulgated in the future will impose additional compliance requirements and it is ultimately subject to the review by regulatory authorities on a case-by-case basis. Our Group will closely monitor the legislative and regulatory development in cybersecurity and data protection, including the newly effective laws as well as its specific provisions or implementation standards.

As of the Latest Practicable Date, we were not subject to any investigations on cybersecurity review made by the CAC.

On July 7, 2022, the CAC issued the Measures on the Security Assessment of Cross-border Data Transfer (《數據出境安全評估辦法》) (the "**Security Assessment Measures**"), which took effect on September 1, 2022. The Security Assessment Measures generally apply to data processors that provide abroad important data or personal information that was collected or produced through operations within the PRC. Companies that are subject to the Security Assessment Measures need to conduct data mapping on cross-border data transfers, prepare the self-assessment and submission, as well as implement data classification and apply controls on cross-border data transfers.

In March 2024, the CAC issued the Provisions on Promoting and Regulating Cross-border Data Flows (《促進和規範數據跨境流動規定》), which required security assessment for the following types of cross-border data transfers, (i) for critical information infrastructure operators, the outbound transfer of personal information or important data, and (ii) for data processors that are not critical information infrastructure operators, the outbound transfer of important data or the cumulative outbound transfer within one calendar year of the personal information of over one million people or the sensitive personal information of over 10,000 people. These provisions also stipulated that, when data processors that are not critical information infrastructure operators engage in the cumulative outbound transfer within one calendar year of the personal information of over 10,000 people but less than one million people or the sensitive personal information of less than 10,000 people, the data processors must enter into a standard contract for cross-border transfer of personal information with the data recipient or obtain a certification for the protection of personal information. Furthermore, these provisions clarified that data processors do not need to treat any data as "important data" the outbound transfer of which requires security assessments, if government authorities have not declared or notified them that the data are "important data".

REGULATIONS ON THE SECURITY REVIEW OF FOREIGN INVESTMENT

On December 19, 2020, the NDRC and the MOFCOM jointly promulgated the Measures on the Security Review of Foreign Investment (《外商投資安全審查辦法》), effective on January 18, 2021, setting forth provisions concerning the security review mechanism on foreign investment, including the types of investments subject to review, the scopes of review and procedures to review, among others.

REGULATIONS RELATING TO DRUGS IN THE U.S.

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FDCA, and its implementing regulations, and biologics under the FDCA and the Public Health Service Act, or PHSA, and its implementing regulations. FDA approval is required before any new unapproved drug or dosage form, including a new use of a previously approved drug, can be marketed in the United States. Drugs and biologics are also subject to other federal, state, and local statutes and regulations. The FDA generally requires the following before drug candidates may be marketed in the United States:

- completion of extensive preclinical laboratory tests and preclinical animal studies, performed in accordance with Good Laboratory Practices, or GLP, regulations, where applicable;

- submission to the FDA of an IND, which must become effective before human clinical trials may begin;

- approval by an independent institutional review board, or IRB or ethics committee representing each clinical site before each clinical study may be initiated;

- performance of adequate and well-controlled human clinical trials in accordance with GCP, requirements to establish the safety and efficacy, or with respect to biologics, the safety, purity and potency of the drug candidate for each proposed indication;

- preparation of and submission to the FDA of a NDA, or biologics license application, or BLA;

- potential review of the product application by an FDA advisory committee, where appropriate and if applicable;

- a determination by the FDA within 60 days of the initial submission of an NDA or BLA to accept the application for formal review;

- satisfactory completion of an FDA pre-approval inspection of the manufacturing facilities where the proposed drug product is produced to assess compliance with current Good Manufacturing Practices, or cGMP, and audits of selected clinical trial sites to ensure compliance with GCP; and

- FDA review and approval of an NDA or BLA prior to any commercial marketing or sale of the drug in the United States.

An IND is a request for authorization from the FDA to administer an investigational drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol or protocols for preclinical studies and clinical trials. The IND also includes results of animal and *in vitro* studies assessing the toxicology, PK, pharmacology and pharmacodynamic characteristics of the product, chemistry, manufacturing and controls, information, and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials may begin. Upon the date of submission of the initial IND, the sponsor must wait 30 days to allow for FDA review and comment (e.g., protocol design, proposed starting dose) before dosing the first patient under the IND. If the FDA accepts the sponsor's response to all queries, the sponsor is given agency approval via an "OK to proceed letter" for the clinical trial. If questions are not answered appropriately or the FDA has concerns, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCP, which includes the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. An amendment to the existing IND or initiation of a new, separate IND must be made for each successive clinical trial or amendment to the information contained in the IND for the existing clinical trial. Furthermore, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site, and must monitor the study until completed. Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing preclinical studies and clinical trials and clinical results to public registries.

The clinical investigation of a drug is generally divided into three phases. Although the phases are usually conducted sequentially, they may overlap or be combined.

- **Phase I.** The investigational product is initially introduced into healthy human subjects or patients with the target disease or condition. These studies are designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, the side effects associated with increasing doses, if possible.

- **Phase II.** The investigational product is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages, and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase II clinical trials may be conducted to obtain information prior to beginning larger Phase III clinical trials.

- **Phase III.** The investigational product is administered to an expanded patient population to further evaluate potential dose regimen(s), to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval.

A clinical investigation may fail at any phase. In some cases, the FDA may conditionally approve an NDA or BLA for a drug candidate on the sponsor's agreement to conduct additional clinical studies after approval, called a post-marketing requirement, or PMR or a post-marketing commitment, or PMC. The stipulations of the PMR and/or PMCs are outlined in the FDA approval letter. Concurrent with clinical trials, companies may complete additional animal studies and develop additional information about the biological characteristics of the drug candidate, and must finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug candidate and, among other things, must develop methods for testing the identity, strength, quality, and purity of the final product, or for biologics, the safety, purity and potency.

NDA and BLA Review Process

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, nonclinical studies and clinical trials are submitted to the FDA as part of an NDA or BLA requesting approval to market the product for an indication. The NDA or BLA must include all relevant data available from pertinent preclinical studies and pivotal and supporting clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing and controls and proposed labeling. Data can come from company-sponsored clinical studies intended to test the safety and effectiveness of the product, or from a number of alternative sources, including studies initiated and sponsored by investigators. The initial indication submission of a NDA or BLA requires payment per US regulatory under the Prescription Drug User Fee Act, or the PDUFA. Subsequent submissions for additional indications, called supplements, do not have a fee associated with the Agency review.

Within 60 days following submission of the application, the FDA will determine if the application is substantially complete before the agency accepts it for filing. The FDA may refuse to file any NDA or BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the NDA or BLA must be resubmitted with the additional information. Once an NDA or BLA has been accepted for filing, the FDA's goal is to review standard applications within ten months after the filing date, or, if the application qualifies for priority review, six months after the FDA accepts the application for filing. In both standard and priority reviews, the review process may also be extended by FDA requests for additional information or clarification. The FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is sufficient to assure and preserve the product's identity, strength, quality, and purity. Ninety (90) days after submission, the FDA generally requires the sponsor provide a safety update report which updates more recent safety information from the patients being evaluated in the NDA or BLA. The FDA reviews a BLA to determine, among other things, whether a product is safe, pure, and potent and the facility in which it is manufactured, processed, packed, or held meets standards designed to assure the product's continued safety, purity, and potency. When reviewing an NDA or BLA, the FDA may convene an advisory committee to provide clinical insight on application review questions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA or BLA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA or BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP.

After the FDA evaluates the NDA or BLA and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced, the FDA may issue an approval letter or a Complete Response Letter, or CRL. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A CRL will describe deficiencies that the FDA identified in the NDA or BLA, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the CRL without first conducting required inspections, testing submitted product lots and/or reviewing proposed labeling. In issuing the CRL, the FDA may recommend actions that the applicant might take to place the NDA or BLA in condition for approval, including requests for additional information or clarification. The FDA may delay or refuse approval of an NDA or BLA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

If regulatory approval of a product is granted, such approval will be granted for the indication supported by the data included in the NDA or BLA and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the NDA or BLA with a Risk Evaluation and Mitigation Strategy, or REMS, to ensure the benefits of the product outweigh its risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a product and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace.

Expedited Development and Review Programs

The FDA offers a number of expedited development and review programs for qualifying drug candidates. For example, the fast track program is intended to expedite or facilitate the process for reviewing new products that meet certain criteria. Specifically, drug candidates are eligible for fast track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast track designation applies to the combination of the drug candidate and the specific indication for which it is being studied. The sponsor of a fast track drug candidate has opportunities for more frequent interactions with the review team during product

development and, once an NDA or BLA is submitted, the application may be eligible for priority review. A fast track drug candidate is eligible for rolling review, where the FDA may consider for review sections of the NDA or BLA on a rolling basis, with the NDA or BLA being considered complete upon submission of the final module(s). The sponsor pays any required user fees upon submission of the first section of the NDA or BLA.

A drug candidate intended to treat a serious or life-threatening disease or condition may also be eligible for breakthrough therapy designation to expedite its development and review. A product can receive breakthrough therapy designation if preliminary clinical evidence indicates that the product, alone or in combination with one or more other drugs or biologics, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the fast track program features, as well as more intensive FDA interaction and guidance beginning as early as Phase I and an organizational commitment to expedite the development and review of the drug candidate, including involvement of senior managers.

Any marketing application for a drug or biologic submitted to the FDA for approval, including a drug candidate with a fast track designation and/or breakthrough therapy designation, may be eligible for other types of FDA programs intended to expedite the FDA review and approval process, such as priority review and accelerated approval. A drug candidate is eligible for priority review if it has the potential to provide a significant improvement in the treatment, diagnosis or prevention of a serious disease or condition. For new- molecular-entity NDAs and original BLAs, priority review designation means the FDA's goal is to take action on the marketing application within six months of the 60-day filing date (as compared to ten months under standard review).

Additionally, drug candidates studied for their safety and effectiveness in treating serious or life- threatening diseases or conditions may receive accelerated approval upon a determination that the drug candidate has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of accelerated approval, the FDA will generally require the sponsor to perform adequate and well- controlled post-marketing clinical studies to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. Products receiving accelerated approval may be subject to expedited withdrawal procedures if the sponsor fails to conduct the required post-marketing studies or if such studies fail to verify the predicted clinical benefit. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

Fast track designation, breakthrough therapy designation, priority review, and accelerated approval do not change the standards for approval but may expedite the development or approval process. Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Post-approval Requirements

Any products manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use or first publication. Further, if there are any modifications to the drug or biologic, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new BLA or BLA supplement, which may require the development of additional data or preclinical studies and clinical trials. There also are continuing user fee requirements, under which the FDA assesses an annual program fee for each product identified in an approved NDA or BLA. Drug and biologic manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMPs. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMPs. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain compliance with cGMPs and other aspects of regulatory compliance.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including AEs of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of a product, complete withdrawal of the product from the market or product recalls; fines, warning letters or holds on post-approval clinical studies;

- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of existing product approvals;

- product seizure or detention, or refusal of the FDA to permit the import or export of products;

- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;

- mandated modification of promotional materials and labeling and the issuance of corrective information;

- the issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product; or

- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of drug products and biologics. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising, and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products.

Drug Product Marketing Exclusivity

Market exclusivity provisions authorized under the FDCA can delay the submission or the approval of certain marketing applications. For example, the FDCA provides a five-year period of non-patent data exclusivity within the United States to the first applicant to obtain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not approve or even accept for review an abbreviated new drug application, or ANDA, or an NDA submitted under Section 505(b)(2), or 505(b)(2) NDA, submitted by another company for another drug based on the same active moiety, regardless of whether the drug is intended for the same indication as the original innovative drug or for another indication, where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA by the innovator NDA holder.

The FDCA alternatively provides three years of marketing exclusivity for an NDA, or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the modification for which the drug received approval on the basis of the new clinical investigations and does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for drugs containing the active agent for the original indication or condition of use. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to any preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

FDA Acceptance of Foreign Clinical Studies

Pursuant to 21 CFR 312.120 and 314, FDA recognizes that sponsors may choose to conduct multinational clinical studies under a variety of scenarios. Multinational studies may include domestic sites conducted under an IND, foreign sites conducted under an IND, and/or foreign sites not conducted under an IND. Some sponsors may even seek to rely solely on foreign clinical data as support for an IND or application marketing approval in the U.S.

An application based solely on foreign clinical data meeting U.S. criteria for marketing approval may be approved if: (1) the foreign data are applicable to the U.S. population and U.S. medical practice; (2) the studies have been performed by clinical investigators of recognized competence; and (3) the data may be considered valid without the need for an on-site inspection by FDA or, if FDA considers such an inspection to be necessary, FDA is able to validate the data through an on-site inspection or other appropriate means. Failure of an application to meet any of these criteria will result in the application not being approvable based on the foreign data alone. FDA will apply this policy in a flexible manner according to the nature of the drug and the data being considered.

OVERVIEW

We are a biopharmaceutical company committed to the discovery, development and commercialization of biologics that regulate immune microenvironment by directly modulating both the innate and adaptive immune systems. Our Company was incorporated in the Cayman Islands as an exempted company with limited liability on May 14, 2021. Through the Reorganization as further disclosed below, our Company has become the holding company of our Group.

The origin of our Group can be traced back to April 2018 when our principal operating subsidiary, SunHo (China) BioPharmaceutical, was founded by Mr. Zhang through his holding vehicles. Mr. Zhang is our executive Director and the chairman of our Board. For further details of the background and experience of Mr. Zhang, see "Directors and Senior Management" in this document.

BUSINESS MILESTONES

The following table summarizes the key milestones in our business development:

Year	Milestone
2018	SunHo (China) BioPharmaceutical, our principal operating subsidiary, was established in the PRC
	We commenced the R&D of our Armed ImmunoCytokine AIC™ Platform and ADCC-Enhanced AEA™ Platform
	We established one 200L production line and one 1,000L production line for GMP-compliant drug substance manufacturing for performing preclinical study, pilot production, and conducting early stage clinical trials, as well as clinical to commercial-scale drug product production lines for liquid injection and lyophilized powder that fulfill different dosage forms
2019	We commenced the R&D of our Armed Innate-effector Multispecific AIM™ Platform
	We further established two 200L production lines for GMP-compliant drug substance manufacturing for performing preclinical study, pilot production, and conducting early stage clinical trials
	We acquired exclusive rights from ImmuneOnco Biopharmaceuticals (Shanghai) Inc. to develop, manufacture and commercialize IBC0966 in Greater China including mainland China, Hong Kong, Macau and Taiwan, as well as 7.5% of interests in the overseas rights of IBC0966

Year	Milestone
2020	We obtained the IND approval from the NMPA for conducting Phase I and Phase II clinical trials of our Core Product, IAH0968
2021	Our Company was incorporated in the Cayman Islands
	We obtained the IND approval from the NMPA for conducting Phase I and Phase II clinical trials of IBC0966, and the IND approvals from the FDA for conducting Phase I and Phase II clinical trials in solid tumors for our Core Products, IAE0972 and IAP0971
	We commenced the Phase I clinical trials for IAH0968 and for IBC0966 in the PRC
2022	We obtained IND approvals from the NMPA for conducting Phase I and Phase II clinical trials in patients with locally advanced or metastatic malignant tumors for IAP0971 and IAE0972
	We commenced the Phase I clinical trials for IAP0971 and IAE0972
	We received approvals from the NMPA for conducting a Phase II clinical trial for IAH0968 in HER2+ advanced or metastatic BTC, and Phase II and Phase III clinical trials for IAH0968 in HER2+ metastatic CRC
	We obtained the IND approvals from the FDA and the NMPA for conducting Phase I and Phase II clinical trials of IBB0979 in locally advanced or metastatic solid tumors
2023	We completed the Phase I clinical trial of IAH0968 and initiated two Phase II clinical trials to evaluate IAH0968 in combination with chemotherapy in HER2+ metastatic CRC and HER2+ advanced or metastatic BTC
	We obtained the IND approvals from the NMPA and the FDA for conducting Phase I and Phase II clinical trials of IAP0971 for NMIBC
	We obtained the IND approvals from the FDA and the NMPA for conducting Phase I and Phase II clinical trials of IBD0333 in locally advanced solid tumors

Year	Milestone
	We completed the Phase I clinical trials of IAP0971 and IAE0972 used as monotherapy for heavily pretreated patients
	We commenced the Phase I clinical trial for IBB0979
	We completed the Pre-[**REDACTED**] Investments and raised RMB270.18 million
	We obtained the IND approval from the NMPA for conducting Phase II and Phase III clinical trials of IAE0972 in combination with lenvatinib for HCC
	We completed the qualification of a 5,000L bioreactor for commercial scale drug substance manufacturing
	We commenced the Phase II clinical trial of IAE0972 for HNSCC and CRC
	We completed the Phase I clinical trial of IBC0966 for advanced malignant tumors
2024	We commenced the Phase IIb clinical trial for IAH0968 in combination with CapeOX in HER2+ advanced or metastatic CRC patients as first line therapy
	We completed the Phase IIa clinical trial for IAH0968 in combination with CapeOX in HER2+ advanced or metastatic CRC patients
	We dosed the first patient for the Phase I clinical trials of IAP0971 in high risk NMIBC patients who have failed BCG treatment and IBD0333 in locally advanced or metastatic solid tumors, respectively

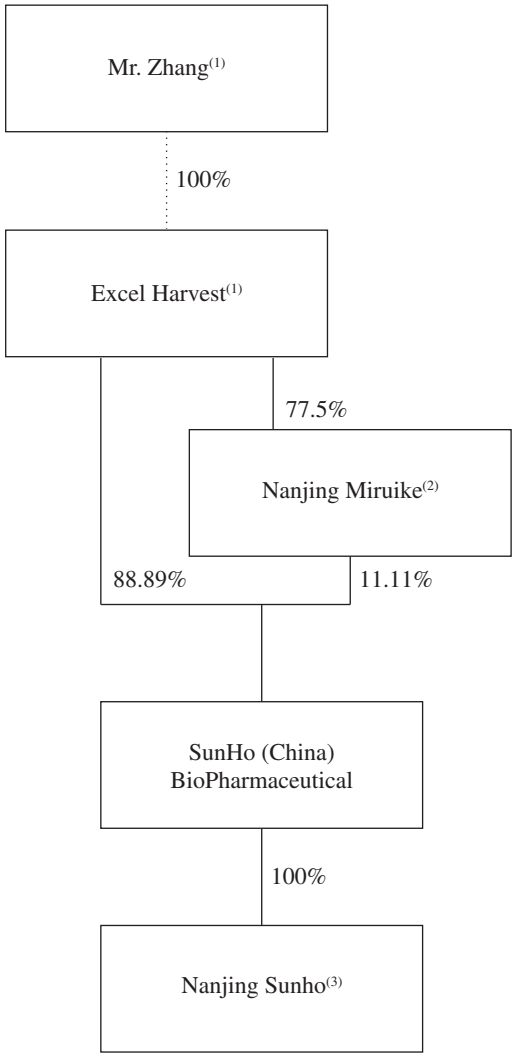
CORPORATE ESTABLISHMENT AND DEVELOPMENT

We substantially operate our business through our principal operating subsidiary, SunHo (China) BioPharmaceutical, in the PRC.

SunHo (China) BioPharmaceutical was established in the PRC as a limited liability company on April 2, 2018 with an initial registered capital of RMB160 million. Upon its establishment, SunHo (China) BioPharmaceutical was wholly owned by Excel Harvest Holding Limited ("**Excel Harvest**"), which was indirectly wholly owned by Mr. Zhang at the time of the establishment of SunHo (China) BioPharmaceutical.

On September 11, 2020, SunHo (China) BioPharmaceutical increased its registered capital from RMB160 million to RMB180 million with the additional registered capital of RMB20 million being subscribed for by Nanjing Miruike Biotechnology Co., Ltd. (南京米瑞柯生物科技有限公司) ("**Nanjing Miruike**"). Nanjing Miruike is a limited liability company established in the PRC and was wholly owned by Excel Harvest at the time of its subscription of the registered capital of SunHo (China) BioPharmaceutical.

The following chart sets forth the shareholding structure of our Group immediately prior to the Reorganization:



Notes:

(1) Immediately prior to the Reorganization, Excel Harvest was indirectly wholly owned by Mr. Zhang.

(2) Upon its establishment, Nanjing Miruike was wholly owned by Excel Harvest. On December 18, 2020, Excel Harvest transferred 22.5% equity interest in Nanjing Miruike to Dr. YIN Liusong (殷劉松), our executive Director, chief executive officer and chief scientific officer, as an incentive for his joining of our Group. Upon completion of the equity transfer, Dr. YIN Liusong had an indirect interest of 2.5% in SunHo (China) BioPharmaceutical through his equity interest in Nanjing Miruike and the equity interest in SunHo (China) BioPharmaceutical ultimately held by Mr. Zhang were reduced to 97.5%.

(3) Nanjing Sunho is a limited liability company established in the PRC on August 13, 2020 with a registered capital of RMB5 million. As of the Latest Practicable Date, Nanjing Sunho had not commenced any business activities.

REORGANIZATION

In preparation for the [**REDACTED**], we underwent the following Reorganization, pursuant to which our Company became the holding company of our Group.

1. Incorporation of Our Company

On May 14, 2021, our Company was incorporated as an exempted company with limited liability in the Cayman Islands. Upon its incorporation, our Company had an authorized share capital of US$100,000 divided into 100,000 ordinary shares with a par value of US$1.00 each, and one Share was allotted and issued to the initial subscriber, which was then transferred to Sunho Wisdom at par value. On the same date, our Company further allotted and issued 42,499 Shares to Sunho Wisdom and 3,000 Shares to No5XJR at par value. Upon completion of the share transfer and issuance, the shareholding structure of our Company was as follows:

Shareholder	**Number of Shares**	**Shareholding Percentage** *(approximation)*
Sunho Wisdom[(1)]	42,500	93.41%
No5XJR[(2)]	3,000	6.59%
Total	45,500	100%

Notes:

(1) Sunho Wisdom is a company incorporated in the BVI with limited liability on April 14, 2021. At the time of its subscription of Shares, it was indirectly wholly owned by Mr. Zhang through Innovalue Investments, a company incorporated in the BVI with limited liability on April 8, 2021.

(2) No5XJR is a company incorporated in the BVI with limited liability on April 14, 2021 and is owned as to 8.34% by Innovalue Investments and 91.66% by OriTure Limited, respectively. No5XJR has a weighted voting rights structure, under which each of the 8.34 class A ordinary shares held by Innovalue Investments would entitle Innovalue Investments to exercise 30 votes, and each of the 91.66 class B ordinary shares held by OriTure Limited would entitle OriTure Limited to exercise one vote, respectively, on any resolution tabled at general meetings of No5XJR. As such, Innovalue Investments is entitled to exercise approximately 73.19% voting rights in No5XJR. The weighted voting rights structure pertaining to No5XJR has been in place since its establishment so as to ensure that the voting rights attached to the Shares held by No5XJR are controlled by Mr. Zhang while allowing the beneficial owners of OriTure Limited to enjoy a vast majority of the economic benefits through their indirect interests in our Company as an incentive.

OriTure Limited is a company incorporated in the BVI with limited liability on April 8, 2021. As of the Latest Practicable Date, OriTure Limited was owned as to 90.9% by Dr. YIN Liusong (our executive Director, chief executive officer and chief scientific officer) and 9.1% by Mr. ZHU Zhenfei (朱振飛), respectively. Mr. ZHU Zhenfei has not held any positions within our Group but has been an external legal consultant to our Group since the establishment of SunHo (China) BioPharmaceutical in April 2018 and an Independent Third Party. He has been assisting our Group with various legal matters, such as providing advice on legal compliance of our operation, providing advice on our transactions and cooperations with other parties, and reviewing transaction documents. The indirect interests in our Company held by Dr. YIN Liusong and Mr. ZHU Zhenfei served as an incentive for Dr. YIN Liusong to further promote our development and recognition of the contribution by Mr. ZHU Zhenfei to our Group.

2. Incorporation of Sunho bio Investments

On June 1, 2021, Sunho bio Investments was incorporated in the BVI with limited liability, which was authorized to issue no more than 50,000 shares of US$1.00 each. Upon its incorporation, one ordinary share was allotted and issued to our Company at par value.

3. Incorporation of Sunho HK

On July 9, 2021, Sunho HK was incorporated in Hong Kong with limited liability. Upon its incorporation, one ordinary share was allotted and issued to Sunho bio Investments at a consideration of HK$1.00.

4. Establishment of Personal Trust

On September 20, 2021, Mr. Zhang, as the settlor, established a trust with Trident Trust Company (HK) Limited acting as an independent professional trustee for personal estate planning purpose (the "**Sunho Fortune Trust**"). On November 3, 2021, Sunho Wisdom allotted and issued 999 shares to Innovalue Investments, which were subsequently transferred to Sunho Fortune. Upon completion of the share transfer on November 11, 2021, Sunho Wisdom was owned as to 99.9% by Sunho Fortune (as a nominee which is wholly owned by the Sunho Fortune Trust) and 0.1% by Innovalue Investments, respectively. Pursuant to the Sunho Fortune Trust, Trident Trust Company (HK) Limited holds the equity interest in our Company through Sunho Fortune on trust for the benefit of Mr. Zhang.

5. Incorporation of Sunho Stellar and Issuance of Shares by Our Company to Sunho Stellar

On November 3, 2021, our Company further allotted and issued 4,500 Shares to Sunho Stellar at par value. Upon completion of the share issuance, our Company was owned as to 85% by Sunho Wisdom, 6% by No5XJR and 9% by Sunho Stellar, respectively.

Sunho Stellar was incorporated in the BVI with limited liability on April 9, 2021 and serves as the share incentive platform of our Company. For further details, see "— Adoption of RSU Scheme" in this section.

6. Establishment of Sunho Pharmaceutical Technology

On December 30, 2021, Sunho Pharmaceutical Technology was established in the PRC as a limited liability company with an initial registered capital of RMB5 million. Since its establishment, Sunho Pharmaceutical Technology has been wholly owned by Sunho HK.

7. Acquisition of SunHo (China) BioPharmaceutical by Sunho Pharmaceutical Technology

Pursuant to the equity transfer agreements dated December 29, 2021, Sunho Pharmaceutical Technology acquired the entire equity interest held by Excel Harvest in SunHo (China) BioPharmaceutical at a consideration of RMB0.89 and the entire equity interest held by Nanjing Miruike in SunHo (China) BioPharmaceutical at a consideration of RMB0.11. The considerations for such equity transfers were determined with reference to the negative net asset value of SunHo (China) BioPharmaceutical as of June 30, 2021 as appraised by an independent valuer on December 31, 2021. Upon completion of the equity transfers on January 11, 2022, SunHo (China) BioPharmaceutical became a wholly-owned subsidiary of Sunho Pharmaceutical Technology.

MAJOR SHAREHOLDING CHANGES IN OUR COMPANY

1. Equity Transfer in May 2023

On May 16, 2023, Sunho Stellar transferred 1,500 Shares to Sunho Wisdom at par value, considering such Shares are not expected to be granted as part of the potential employee incentive arrangements under deliberation.

2. Series A Financing in August 2023

On May 31, 2023, (i) our Company, (ii) Huzhou Efung Ansheng Venture Capital Partnership (Limited Partnership) (湖州市倚鋒安盛創業投資合夥企業(有限合夥)) ("**Efung Ansheng**"), (iii) Huzhou Efung Anhe Venture Capital Partnership (Limited Partnership) (湖州市倚鋒安禾創業投資合夥企業(有限合夥)) ("**Efung Anhe**"), (iv) Sunho Wisdom, (v) Mr. Zhang, (vi) Sunho Stellar, and (vii) No5XJR entered into a share subscription agreement, pursuant to which Efung Ansheng agreed to subscribe for 5,833.33 Shares at a consideration of RMB140,000,000 and Efung Anhe agreed to subscribe for 2,916.67 Shares at a consideration of RMB70,000,000 ("**Series A Financing**"). Upon completion of the share subscription on August 2, 2023, our Company was owned as to approximately 74.89% by Sunho Wisdom, 5.11% by Sunho Stellar, 5.11% by No5XJR, 9.93% by Efung Ansheng, and 4.96% by Efung Anhe, respectively. For further details of Series A Financing, see "— Pre-[**REDACTED**] Investments" in this section.

3. Re-designation of Share Capital, Repurchase of Shares, Issuance of Series A Preferred Shares and Share Subdivision in August 2023

On August 30, 2023, 11,257.5 authorized but unissued Shares with a par value of US$1.00 each were re-designated and reclassified into 11,257.5 Series A Preferred Shares with a par value of US$1.00 each (the "**Re-designation of Share Capital**"). Following the Re-designation of Share Capital, the authorized share capital of our Company became US$100,000 divided into 88,742.5 Shares with a par value of US$1.00 each and 11,257.5 Series A Preferred Shares with a par value of US$1.00 each.

Upon completion of the Re-designation of Share Capital, on the same date, our Company repurchased (i) the 5,833.33 Shares each held by Efung Ansheng in consideration of the issuance and allotment of 5,833.33 Series A Preferred Shares to Efung Ansheng, and (ii) the 2,916.67 Shares held by Efung Anhe in consideration of the issuance and allotment of 2,916.67 Series A Preferred Shares to Efung Ansheng (the "**Repurchase of Shares**").

Following the Repurchase of Shares, on the same date, each of the authorized issued and unissued Shares with a par value of US$1.00 each was subdivided into 2,000 Shares with a par value of US$0.0005 each, and each of the authorized issued and unissued Series A Preferred Shares with a par value of US$1.00 each was subdivided into 2,000 Series A Preferred Shares with a par value of US$0.0005 each. Upon completion of the Share Subdivision, (i) the authorized share capital of our Company became US$100,000 divided into 177,485,000 Shares with a par value of US$0.0005 each and 22,515,000 Series A Preferred Shares with a par value of US$0.0005 each, and (ii) Sunho Wisdom, Sunho Stellar, No5XJR, Efung Ansheng and Efung Anhe held 88,000,000 Shares, 6,000,000 Shares, 6,000,000 Shares, 11,666,660 Series A Preferred Shares and 5,833,340 Series A Preferred Shares, respectively.

4. Series A+ Financing in October 2023

On August 30, 2023, our Company issued a warrant to Beijing Yuehe Enterprise Management Development Center (Limited Partnership) (北京越禾企業管理發展中心(有限合夥)) ("**Beijing Yuehe**"), pursuant to which Beijing Yuehe is entitled to subscribe for up to 5,015,000 Series A Preferred Shares at a total consideration of RMB60,180,000 or equivalent U.S. dollars.

On October 10, 2023, our Company alloted and issued 5,015,000 Series A Preferred Shares to Beijing Yuehe following the full exercise of the warrant by Beijing Yuehe ("**Series A+ Financing**"). For further details of Series A+ Financing, see "— Pre-[**REDACTED**] Investments" in this section.

ADOPTION OF RSU SCHEME

In recognition of the contributions of our employees and to incentivize them to further promote our development, Sunho Stellar was established as our share incentive platform.

On August 2, 2023, our Company adopted the RSU Scheme. An award of RSU(s) under the RSU Scheme gives the grantee a conditional right upon vesting of the award to obtain either Shares or an equivalent value in cash with reference to the market value of the Shares on or about the date of vesting, as determined by the Board at its absolute discretion, less any tax, fees, levies, stamp duty and other applicable charges. RSUs representing all the 3,000 Shares (6,000,000 Shares as adjusted after the Share Subdivision) held by Sunho Stellar have been granted to eligible participants under the RSU Scheme.

As of the Latest Practicable Date, Sunho Stellar is wholly owned by Trident Trust Company (HK) Limited, an independent professional trustee appointed to administer the trust for the benefits of employees who have been granted awards under the RSU Scheme. Pursuant to the trust deed, the trustee shall exercise all voting rights attached to the Shares held by Sunho Stellar in accordance with the instructions of Mr. Zhang.

For details and principal terms of the RSU Scheme, see "Appendix IV — Statutory and General Information — D. RSU Scheme" in this document.

PRE-[REDACTED] INVESTMENTS

Principal terms of the Pre-[REDACTED] Investments

The following table summarizes the principal terms of the Pre-[**REDACTED**] Investments:

	Series A Financing	**Series A+ Financing**
Date of agreement	May 31, 2023	August 30, 2023
Amount of consideration paid	RMB210,000,000	Equivalent U.S. dollars of RMB60,180,000
Date of payment of full consideration	August 2, 2023	September 27, 2023
Post-money valuation of our Company *(approximation)*[(1)]	RMB1.41 billion	RMB1.47 billion
Cost per Series A Preferred Share paid under the Pre-[REDACTED] Investments	RMB12[(3)]	RMB12
Discount to the [REDACTED] *(approximation)*[(2)]	[**REDACTED**]%	[**REDACTED**]%
Basis of determination of the valuation and consideration	The valuation and consideration for the Pre-[**REDACTED**] Investments were determined based on arm's length negotiations between the relevant parties after taking into consideration the timing of the investments and the business, operations and status of our business and operating entities.	
Lock-up period	Any equity securities of our Company held by Efung Ansheng and Efung Anhe will be subject to a lock-up period of six months from the [**REDACTED**]. There is no lock-up arrangement for Beijing Yuehe.	

	Series A Financing	Series A+ Financing
Use of proceeds from the Pre-[REDACTED] Investments	We shall utilize the proceeds from the Pre-[**REDACTED**] Investments for the principal business of our Company, including but not limited to the research and development activities and general working capital purposes. As of the Latest Practicable Date, approximately 22.3% of the net proceeds from the Pre-[**REDACTED**] Investments had been utilized.	
Strategic benefits of the Pre-[REDACTED] Investments to our Group	At the time of the Pre-[**REDACTED**] Investments, our Directors were of the view that our Company could benefit from the additional funds provided by the investments in our Company and the knowledge and experience of the Pre-[**REDACTED**] Investors.	

Notes:

(1) Calculated on the [**REDACTED**] of HK$[**REDACTED**], being the mid-point of the indicative [**REDACTED**], the valuation of our Company upon [**REDACTED**] will be approximately HK$[**REDACTED**]. The increase in valuation of our Company upon [**REDACTED**] from Series A Financing and Series A+ Financing has taken into account: (i) advancements in our business and drug candidates since December 31, 2022, being the reference date based on which the consideration of Series A Financing and Series A+ Financing was determined, for instance, (a) we completed the Phase I clinical trial of IAH0968 in March 2023, (b) we dosed the first patient for the Phase II clinical trial of IAH0968 in HER2+ metastatic CRC, and obtained the IND approval from the NMPA for conducting Phase I and Phase II clinical trials of IAP0971 for NMIBC in May 2023, (c) we obtained the IND approvals for conducting Phase I and Phase II clinical trials of IBD0333 in locally advanced solid tumors from the FDA, and completed the installation of a drug substance production line for 5,000L bioreactor capacity, in June 2023, (d) we completed Phase I clinical trials for IAP0971 and IAE0972, dosed the first patient for the Phase I clinical trial of IBB0979, and obtained the IND approval for conducting Phase I and Phase II clinical trials of IBD0333 in locally advanced solid tumors from the NMPA, and enrolled the first HNSCC patient for the Phase II clinical trial of IAE0972 in July 2023, (e) we dosed the first patient for the Phase II clinical trial of IAH0968 in HER2+ advanced or metastatic BTC in August 2023, (f) we obtained the IND approval from the FDA for conducting Phase I and Phase II clinical trials of IAP0971 in NMIBC in August 2023, (g) we obtained the IND approval from the NMPA for conducting Phase II and Phase III clinical trials of IAE0972 in combination with lenvatinib for HCC in November 2023, (h) we completed the qualification of a 5,000L bioreactor for commercial scale drug substance manufacturing in November 2023, (i) we enrolled the first CRC patient for the Phase II clinical trial of IAE0972 in December 2023, (j) we completed the Phase I clinical trial of IBC0966 for advanced malignant tumors in December 2023, (k) we commenced the Phase IIb clinical trial for IAH0968 in combination with CapeOX in HER2+ advanced or metastatic CRC patients as first line therapy in January 2024, (l) we completed the Phase IIa clinical trial for IAH0968 in combination with CapeOX in HER2+ advanced or metastatic CRC patients in March 2024, and (m) we dosed the first patient for the Phase I clinical trials of IAP0971 in high risk NMIBC patients who have failed BCG treatment and IBD0333 in locally advanced or metastatic solid tumors, respectively, in March 2024; (ii) the difference in risk undertaken by the Pre-[**REDACTED**] Investors investing in a private company *vis-à-vis* investors investing in a public company; (iii) the premium attached to the Shares of our Company as they become freely tradeable upon [**REDACTED**]; and (iv) the expected capital raised during the [**REDACTED**]. For details of the aforesaid advancements in our business and drug candidates, see "Business" in this document.

(2) The discount is based on the indicative price of HK$[**REDACTED**] (being the mid-point of the indicative [**REDACTED**] range as stated in this document) and the indicative exchange rate of HK$1.00 = RMB0.9066.

(3) The cost per Series A Preferred Share paid by Efung Ansheng and Efung Anhe was calculated based on the amount of investment made by Efung Ansheng and Efung Anhe and the number of Series A Preferred Shares held by them immediately upon completion of the Re-designation of Share Capital, the Repurchase of Shares, the issuance of Series A Preferred Shares and the Share Subdivision in August 2023.

Rights of the Pre-[REDACTED] Investors

The Pre-[**REDACTED**] Investors were granted customary special rights, including but not limited to information and inspection rights, right of first refusal, tag-along rights, veto right, and director appointment right. All special rights granted to the Pre-[**REDACTED**] Investors by our Company shall automatically cease to be effective upon [**REDACTED**]. There is no side agreement or arrangement entered into between our Company and the Pre-[**REDACTED**] Investors.

All Series A Preferred Shares shall be automatically converted into Shares on [a one-to-one basis] upon completion of the [**REDACTED**].

Information about the Pre-[REDACTED] Investors

1. Efung Capital

Shenzhen Efung Investment Management Enterprise (Limited Partnership) (深圳市倚鋒投資管理企業(有限合夥)) ("**Efung Capital**") has made a meaningful investment in our Company at least six months before the [**REDACTED**] through its affiliates, Efung Ansheng and Efung Anhe. Efung Ansheng is a limited partnership established in the PRC and is managed by its general partner, Efung Capital, which is indirectly controlled by Shenzhen Efung Holdings Group Co., Ltd. (深圳市倚鋒控股集團有限公司) ("**Efung Holdings**"). As of the Latest Practicable Date, Efung Ansheng was held as to approximately 99.99% by Guocheng (Zhejiang) Industrial Development Co., Ltd. (國成(浙江)實業發展有限公司) as the sole limited partner, which in turn is wholly owned by the Management Committee of Anji Economic Development Zone of Zhejiang (浙江安吉經濟開發區管理委員會). Efung Anhe is a limited partnership established in the PRC and is managed by its general partner, Hainan Efung Junma Private Equity Fund Management Co., Ltd. (海南倚鋒駿馬私募基金管理有限公司), which is controlled by Efung Holdings. As of the Latest Practicable Date, Efung Anhe had seven limited partners, and was held as to approximately 49.99% by Guocheng (Zhejiang) Industrial Development Co., Ltd. as the largest limited partner, with six other limited partners each holding less than 30% partnership interest. Efung Holdings is held as to approximately 54% by Mr. ZHU Jinqiao (朱晉橋). To the best knowledge of our Directors, save for their investments in our Company and the nomination of Mr. FAN Rongkui (范融奎) (our non-executive Director), each of Efung Ansheng and Efung Anhe and their respective general partner and limited partners is an Independent Third Party. For details of Mr. Fan's working experience in Efung Capital, see "Directors and Senior Management" in this document.

Efung Capital is a sophisticated investor under paragraph 10 of Chapter 2.3 of the Guide for New Listing Applicants with approximately RMB5 billion of assets under management as of November 30, 2023. Within the investment portfolio held by Efung Capital as of November 30, 2023, its assets under management for the medical and healthcare sectors amounted to more than RMB4.5 billion. Since November 2014, Efung Capital has invested in more than 90 pharmaceutical/healthcare/biotech companies, including 3D Medicines Inc. (a company listed on the Stock Exchange (stock code: 1244)), Ascentage Pharma Group International (亞盛醫藥

集團) (a company listed on the Stock Exchange (stock code: 6855)), HBM Holdings Limited (和鉑醫藥控股有限公司) (a company listed on the Stock Exchange (stock code: 2142)), OBiO Technology (Shanghai) Corp., Ltd. (和元生物技術(上海)股份有限公司) (a company listed on the Science and Technology Innovation Board (科創板) of the Shanghai Stock Exchange (the "**SSE STAR Market**") (stock code: 688238)), Shenzhen Chipscreen Biosciences Co., Ltd. (深圳微芯生物科技股份有限公司) (a company listed on the SSE STAR Market (stock code: 688321)), Shenzhen Lifotronic Technology Co., Ltd. (深圳普門科技股份有限公司) (a company listed on the SSE STAR Market (stock code: 688389)) and Frontier Biotechnologies Inc. (前沿生物藥業(南京)股份有限公司) (a company listed on the SSE STAR Market (stock code: 688221)).

2. Yuexiu Industrial Investment Fund

Beijing Yuehe is a limited partnership established in the PRC and is managed by its general partner, Guangzhou Yuexiu Industrial Investment Fund Management Co., Ltd. (廣州越秀產業投資基金管理股份有限公司) ("**Yuexiu Industrial Investment Fund**"). Yuexiu Industrial Investment Fund is an indirect non-wholly owned subsidiary of Guangzhou Yuexiu Capital Holdings Group Co., Ltd. (廣州越秀資本控股集團股份有限公司), which is a company listed on the Shenzhen Stock Exchange (stock code: 000987) and is controlled by Guangzhou Yue Xiu Holdings Limited (廣州越秀集團股份有限公司), which in turn is ultimately beneficially owned by the Guangzhou Municipal People's Government of the PRC. As of the Latest Practicable Date, Beijing Yuehe had three limited partners, and was held as to approximately 65.38% by Guangzhou Yuexiu Kangjian Phase II Venture Capital Fund Partnership Enterprise (Limited Partnership) (廣州越秀康健二期創業投資基金合夥企業(有限合夥)) as the largest limited partner and 32.69% by Yuexiu (Nanchang) Equity Investment Partnership Enterprise (Limited Partnership) (越秀(南昌)股權投資合夥企業(有限合夥)), with the remaining limited partner holding approximately 0.29% partnership interest. Guangzhou Yuexiu Kangjian Phase II Venture Capital Fund Partnership Enterprise (Limited Partnership) is managed by its general partner, Guangzhou Yuexiu Venture Capital Fund Management Co., Ltd. (廣州越秀創業投資基金管理有限公司) (a wholly-owned subsidiary of Yuexiu Industrial Investment Fund), and had nine limited partners each holding less than 30% partnership interest as of the Latest Practicable Date. To the best knowledge of our Directors, each of Beijing Yuehe and its general partner and limited partners is an Independent Third Party.

Yuexiu Industrial Investment Fund is the main investment management arm of Guangzhou Yuexiu Capital Holdings Group Co., Ltd. and mainly focuses on direct equity investments in companies with potential and realization of capital gains by exiting through public offerings of investee companies and trading on secondary markets. It had more than RMB100 billion of assets under management as of September 30, 2023, among which it had more than RMB2 billion of assets under management in the biopharmaceutical sector. Since January 2015, Yuexiu Industrial Investment Fund has directly invested in more than 35 companies in the biopharmaceutical sector, including Sirnaomics Ltd. (a company listed on the Stock Exchange (stock code: 2257)), HighTide Therapeutics, Inc. (a company listed on the Stock Exchange (stock code: 2511)), Beijing Mabworks Biotechnology Co., Ltd. (北京天廣實生物技術股份有限公司) (a company listed on the National Equities Exchange And Quotations

(stock code: 874070)), Yunzhou Biosciences (Guangzhou) Co., Ltd. (雲舟生物科技(廣州)股份有限公司) (a company that focuses on gene delivery products and services), BeBetter Med Inc. (廣州必貝特醫藥股份有限公司) (a company that focuses on R&D of innovative drugs for the treatment of tumors, autoimmune diseases and metabolic diseases), Guangzhou Reforgene Biotech Co. Ltd. (廣州瑞風生物科技有限公司) (a company that focuses on R&D of gene editing drugs for treatment of genetic diseases and tumors) and Shenzhen ExoRNA Bio Co., Ltd. (深圳艾碼生物科技有限公司) (a company that specializes in the in-vivo self-assembled exosome nucleic acid drug delivery platform for treatment of central nervous system diseases).

Sole Sponsor's Confirmation

On the basis that (i) the [**REDACTED**] will take place no earlier than 120 clear days after completion of the investment of the Pre-[**REDACTED**] Investors; and (ii) all special rights of the Pre-[**REDACTED**] Investors will be automatically terminated upon the completion of the [**REDACTED**], the Sole Sponsor confirms that the investments by the Pre-[**REDACTED**] Investors are in compliance with Chapter 4.2 of the Guide for New Listing Applicants.

[**REDACTED**]

Upon completion of the [**REDACTED**], (i) Mr. Zhang (our executive Director and chairman of our Board) will indirectly, through Sunho Wisdom, No5XJR and Sunho Stellar, control approximately [**REDACTED**]% of the total issued Shares, and (ii) Efung Holdings and Mr. ZHU Jinqiao (朱晉橋) will indirectly, through Efung Ansheng and Efung Anhe, control approximately [**REDACTED**]% of the total issued Shares and will be substantial shareholders of our Company. Therefore, the Shares held by Sunho Wisdom, No5XJR, Sunho Stellar, Efung Ansheng and Efung Anhe will not count towards the [**REDACTED**] for the purpose of Rule 8.08 of the Listing Rules.

Immediately upon completion of the [**REDACTED**], based on the [**REDACTED**] Shares to be [**REDACTED**] to the [**REDACTED**] pursuant to the [**REDACTED**] and an [**REDACTED**] of HK$[**REDACTED**] per Share (being the low-end of the indicative [**REDACTED**]), [**REDACTED**] Shares, representing approximately [**REDACTED**]% of our Company's total issued Shares, with a [**REDACTED**] of at least HK$375 million will be held by [**REDACTED**] in accordance with Rules 8.08(1)(a) and 18A.07 of the Listing Rules.

PRC REGULATORY REQUIREMENTS

Our PRC Legal Adviser is of the view that the Reorganization and each of the capital increase and equity transfers in relation to SunHo (China) BioPharmaceutical disclosed in this section have been conducted in compliance with applicable laws and regulations of the PRC in all material respects and duly registered with the local branch of the SAMR, and all necessary regulatory approvals have been obtained.

M&A Rules

According to the "Provisions Regarding Mergers and Acquisitions of Domestic Enterprises by Foreign Investors" (《關於外國投資者併購境內企業的規定》) (the "**M&A Rules**") jointly issued by the MOFCOM, the SASAC, the SAT, the CSRC, the SAMR and the SAFE on August 8, 2006, effective as of September 8, 2008 and amended in June 2009, where a domestic company, enterprise or natural person intends to acquire its/his/her related domestic company in the name of an offshore company which it/he/she lawfully established or controls, the acquisition shall be subject to the examination and approval of the MOFCOM; and where a domestic company or natural person holds an equity interest in a domestic company through an offshore special purpose company by paying the acquisition price with equity interests, the overseas listing of that special purpose company shall be subject to approval by the CSRC.

As advised by our PRC Legal Adviser, since SunHo (China) BioPharmaceutical had already been a foreign investment enterprise before the acquisition of its entire equity interest by Sunho Pharmaceutical Technology, the M&A Rules are not applicable to the onshore reorganization of our Group.

SAFE Registration

Pursuant to SAFE Circular 37, (a) a PRC resident must register with the local SAFE branch before he/she contributes assets or equity interests in an overseas special purpose vehicle (the "**Overseas SPV**") that is directly established or controlled by the PRC resident for the purpose of conducting investment or financing; and (b) following the initial registration, the PRC resident is required to register with the local SAFE branch for any major change in respect of the Overseas SPV, including, among other things, a change in the Overseas SPV's PRC resident shareholder, name of the Overseas SPV, term of operation or any increase or reduction of the Overseas SPV's registered capital, share transfer or swap, and merger or division. Pursuant to SAFE Circular 37, failure to comply with these registration procedures may result in penalties. Pursuant to the SAFE Circular 13, promulgated by the SAFE and which became effective on June 1, 2015, the power to accept SAFE registration was delegated from local SAFE to local banks.

As advised by our PRC Legal Adviser, each of Mr. Zhang, Dr. YIN Liusong and Mr. ZHU Zhenfei, as the relevant domestic individual residents that indirectly hold the equity interest in our Company by establishing Overseas SPVs, completed registration under SAFE Circular 37 in June 2021.

CAPITALIZATION OF OUR COMPANY

The table below is a summary of the capitalization of our Company as of the Latest Practicable Date and the [**REDACTED**]:

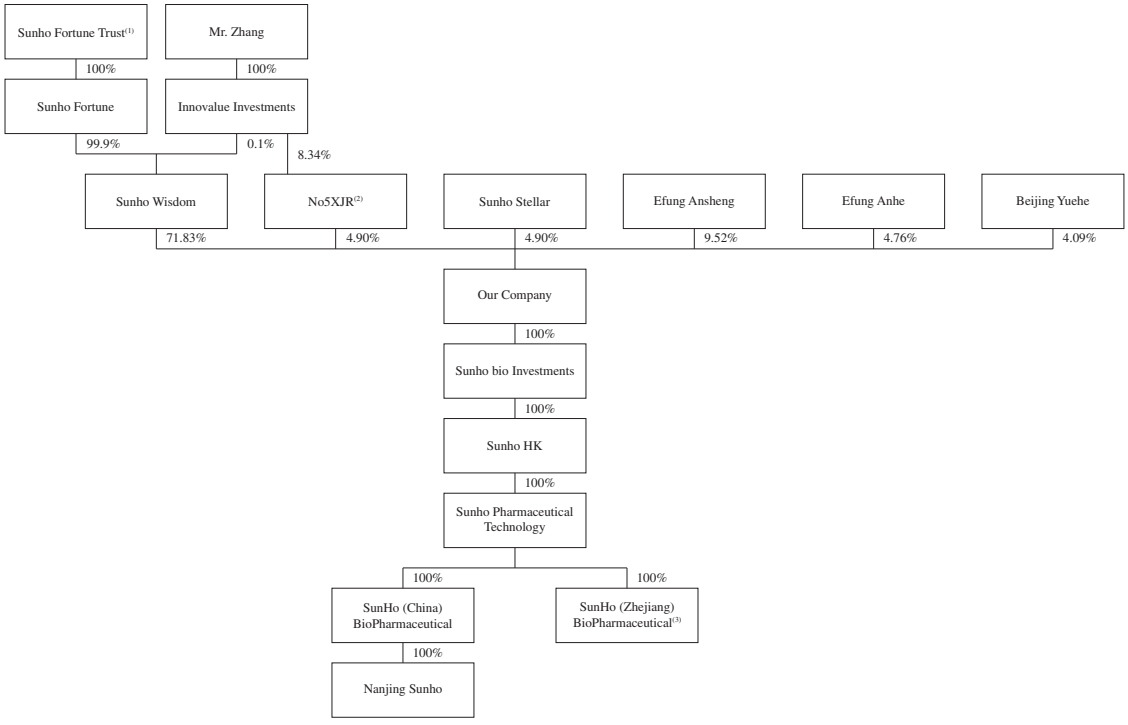
	As of the Latest Practicable Date			As of the [REDACTED]	
Shareholders	**Number of Shares**	**Number of Series A Preferred Shares**	**Shareholding percentage[(1)]** *(%)*	**Number of Shares**	**Shareholding percentage** *(%)*
Sunho Wisdom	88,000,000	–	71.83	88,000,000	[**REDACTED**]
No5XJR	6,000,000	–	4.90	6,000,000	[**REDACTED**]
Sunho Stellar	6,000,000	–	4.90	6,000,000	[**REDACTED**]
Efung Ansheng	–	11,666,660	9.52	11,666,660	[**REDACTED**]
Efung Anhe	–	5,833,340	4.76	5,833,340	[**REDACTED**]
Beijing Yuehe	–	5,015,000	4.09	5,015,000	[**REDACTED**]
Investors taking part in the [**REDACTED**]	–	–	–	[**REDACTED**]	[**REDACTED**]
Total	100,000,000	22,515,000	100	[**REDACTED**]	100

Note:

(1) Based on the assumption that all Series A Preferred Shares have been converted into Shares on a one-to-one basis.

OUR STRUCTURE IMMEDIATELY PRIOR TO THE [REDACTED]

The following chart sets forth the shareholding structure of our Group immediately prior to the [**REDACTED**] (assuming all Series A Preferred Shares have been converted into Shares on a one-to-one basis):



Notes:

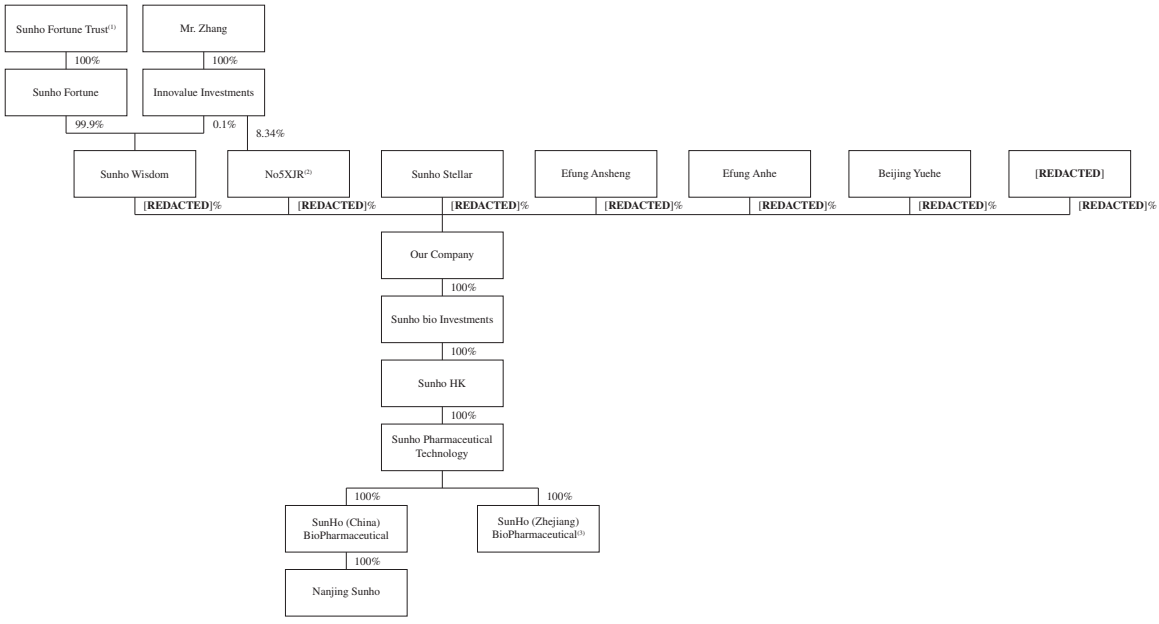
(1) The Sunho Fortune Trust is a personal trust established by Mr. Zhang with Trident Trust Company (HK) Limited acting as an independent professional trustee for personal estate planning purpose. Pursuant to the Sunho Fortune Trust, Trident Trust Company (HK) Limited holds the equity interest in our Company through Sunho Fortune on trust for the benefit of Mr. Zhang. Pursuant to the trust deed, the trustee shall exercise all voting rights attached to the Shares held by Sunho Fortune in accordance with the instructions of Mr. Zhang.

(2) No5XJR is a company incorporated in the BVI with limited liability on April 14, 2021 and is owned as to 8.34% by Innovalue Investments and 91.66% by OriTure Limited, respectively. No5XJR has a weighted voting rights structure, under which each of the 8.34 class A ordinary shares held by Innovalue Investments would entitle Innovalue Investments to exercise 30 votes, and each of the 91.66 class B ordinary shares held by OriTure Limited would entitle OriTure Limited to exercise one vote, respectively, on any resolution tabled at general meetings of No5XJR. As such, Mr. Zhang, through Innovalue Investments, is entitled to exercise approximately 73.19% voting rights in No5XJR.

(3) SunHo (Zhejiang) BioPharmaceutical is a limited liability company established in the PRC on March 17, 2023 with a registered capital of RMB30 million, and has been our indirect wholly-owned subsidiary since its establishment. As of the Latest Practicable Date, SunHo (Zhejiang) BioPharmaceutical had not commenced any business activities.

OUR STRUCTURE IMMEDIATELY FOLLOWING THE [REDACTED]

The following chart sets forth the shareholding structure of our Group immediately following completion of the [**REDACTED**]:



Note: See the notes to the paragraph headed "— Our Structure Immediately Prior to the [**REDACTED**]" in this section.

OVERVIEW

We are a biopharmaceutical company committed to the discovery, development and commercialization of biologics that regulate immune microenvironment by directly modulating both the innate and adaptive immune systems. Drawing upon our expertise in immunology, we have developed various types of immunotherapies including immunocytokines to treat cancers and autoimmune diseases. We have three Core Products, IAH0968, IAP0971 and IAE0972, all of which are developed in-house. IAH0968 is an antibody-dependent cell mediated cytotoxicity ("**ADCC**") enhanced monoclonal antibody ("**mAb**"), and we have initiated Phase II clinical trials for biliary tract carcinoma ("**BTC**") and colorectal cancer ("**CRC**"). IAP0971 and IAE0972 are both immunocytokines and we have completed Phase I clinical trials for advanced solid tumors including non-small cell lung cancer ("**NSCLC**") and CRC. We stand out for our specialized focus and expertise in the development of immunocytokine products with our IAP0971 and IAE0972 among the most clinically advanced immunocytokine candidates, according to Frost & Sullivan. We aim to develop innovative immunotherapies that overcome disadvantages of currently available treatments, including low response rates and drug resistance, and to bring perceivable benefits and affordable medicine to patients worldwide.

Since our inception in 2018, we have built fully-integrated, end-to-end, in-house R&D capabilities encompassing all the key biological drug development functionalities, including discovery, antibody and protein engineering, process development, preclinical pharmacology studies, clinical development, and good manufacturing practice ("**GMP**")-compliant manufacturing. Through our proprietary technology platforms, we have identified and developed a pipeline of nine products, with six of them in clinical stage. As a leading company in exploring antibody-cytokine fusion protein based drugs according to Frost & Sullivan, we implement a global strategy for our immunocytokine products, and have obtained investigational new drug ("**IND**") approvals for conducting clinical trials of all three immunocytokines from regulatory authorities of both China and the U.S. According to Frost & Sullivan, as of the Latest Practicable Date, these three candidates were among the most clinically advanced immunocytokines in treating cancer patients in the world.

Our R&D capabilities cover development of candidates in forms of mAbs, bispecific antibodies ("**bsAbs**"), and fusion proteins, some of which extend indications into treatment areas beyond oncology. Our Core Product IAH0968 is an ADCC enhanced mAb targeting human epidermal growth factor receptor 2 ("**HER2**") with 100% fucose knock out, which greatly enhances the binding affinity of its fragment crystallizable ("**Fc**") to its receptor FcγRIIIa. Data from preclinical study showed that IAH0968 increased the binding affinity up to 20-fold comparing to trastuzumab or Herceptin, an anti-HER2 antibody without enhanced ADCC activity. The Phase I clinical data demonstrated a 40% objective response rate ("**ORR**"), and an 80% disease control rate ("**DCR**") using IAH0968 as monotherapy for heavily pretreated metastatic BTC, and CRC patients who had failed all previous therapies. Currently, we are conducting Phase II clinical trials in patients with inoperable HER2+ advanced or metastatic BTC and HER2+ metastatic CRC as first-line treatments.

Our featured products, immunocytokines, are designed through our proprietary and internally developed Armed ImmunoCytokine Platform ("**AIC^{TM} Platform**") by our core R&D team in researching antibody-cytokine fusion proteins. They function through diverse mechanisms of action yet share a similar structure comprising an antibody or quasi-antibody moiety that targets tumors and blocks signaling pathways regulating tumor growth and proliferation, and cytokine payloads that activate the immune system within the tumor microenvironment ("**TME**"). Such a design is expected to overcome drawbacks of conventional cytokine-based drugs, such as short half-lives, systemic cytotoxicity, and modest efficacies due to cytokine pleiotropy and off-target effects. It is expected to achieve enhanced antitumor effects through the synergy between the antibody and cytokine payloads, which will potentially address market demands of cancer patients who suffer from disease progression related to the immunosuppressive TME and drug resistance.

We have received IND approvals for conducting Phase I and Phase II clinical trials for our Core Products IAP0971 (PD-1/IL-15) and IAE0972 (EGFR/IL-10) in patients with advanced solid tumors from both the NMPA and the U.S. Food and Drug Administration ("**FDA**"), and completed the Phase I clinical trials in July 2023. Phase I clinical data showed that our core immunocytokine products IAP0971 and IAE0972 were well tolerated and demonstrated encouraging preliminary antitumor activities as monotherapy in heavily pretreated patients who has failed chemotherapy, targeted therapy, immunotherapy and/or their combination.

The following chart summarizes the development status of our Core Products and other selected drug candidates as of the Latest Practicable Date.

Abbreviations: 1L = first-line; 2L = second-line; 3L = third-line; ADCC = antibody-dependent cell-mediated cytotoxicity; AEA™ = ADCC Enhanced Antibody Platform; AIC™ = Armed ImmunoCytokine Platform; AIM™ = Armed Innate Effector Multispecific Platform; BCG = Bacillus Calmette-Guerin; bsAb = bispecific antibody; bsFp = bispecific fusion protein; CapeOX= capecitabine and oxaliplatin; Chemo = chemotherapy; FDA = U.S. Food and Drug Administration; GC = gemcitabine and cisplatin; IND = Investigational New Drug; mAb = monoclonal antibody; Mono = monotherapy; NMPA = National Medical Products Administration; NSCLC = non-small cell lung cancer; NMIBC = non-muscle invasive bladder cancer; BTC = biliary tract carcinoma; CRC = colorectal cancer; HBV = hepatitis B virus; HNSCC = head and neck squamous cell carcinoma; HCC = hepatocellular carcinoma; IBD = inflammatory bowel disease; Q1 = first quarter; Q2 = second quarter; Q3 = third quarter; Q4 = fourth quarter; 1H = first half; SLE = systemic lupus erythematosus.

Notes:

* All the product candidates are administered intravenously, except for IAP0971 for the treatment of 2L/3L NMIBC, which will be administered through intravesical instillation, as well as IAP0971 for the treatment of NSCLC, which will be administered through subcutaneous injection.

** We acquired exclusive rights from ImmuneOnco Biopharmaceuticals (Shanghai) Inc. to develop, manufacture and commercialize IBC0966 in Greater China including mainland China, Hong Kong, Macau, and Taiwan, as well as 7.5% of interests in the overseas rights of IBC0966. For more information, see "— Collaboration Arrangement — Collaboration Agreement With ImmuneOnco in Relation to the Development of IBC0966" in this section.

*** We have completed Phase I clinical trials of relevant products as monotherapy, and plan to leverage data collected in the respective trials and directly seek IND approvals from competent regulatory authorities to conduct Phase II clinical trials of relevant products as combination therapy.

Our pipeline includes three Core Products: one ADCC enhanced mAb, and two immunocytokines. The ADCC enhanced mAb, IAH0968, was developed based on our ADCC Enhanced Antibody Platform ("**AEA™ Platform**"). The two immunocytokines, IAP0971 and IAE0972, were developed based on our AIC™ Platform.

- **IAH0968** is a clinical stage ADCC enhanced anti-HER2 antibody with 100% removal of fucose. Binding between the Fc region and its receptor FcγRIIIa allows antibodies to activate the immune system. Studies revealed that fucose interferes with the binding between the Fc region of an antibody and FcγRIIIa. As such, complete removal of fucose can increase the binding affinity, which is expected to improve antitumor activities of antibodies. Produced through our AEA™ Platform, which is an internally developed proprietary FUT8-knock out cell line, the Fc region of IAH0968 contains 0% of fucose. Preclinical data demonstrated that IAH0968 mediated stronger ADCC killing toxicity against HER2+ tumor cells SKBR3, BT474 and SKOV2 than an anti-HER2 antibody. Moreover, IAH0968 showed 100% TGI in a BT474 tumor cell subcutaneous murine model, superior to the anti-HER2 antibody without fucose removal modification.

  The Phase I clinical trial of using IAH0968 as a monotherapy for heavily pretreated patients with advanced HER2+ malignant solid tumors including trastuzumab resistant and ineffective patients demonstrated encouraging clinical activity and tolerated safety profiles. Data showed that only one dose-limiting toxicity ("**DLT**") was found at dosage of 10mg/kg, and no maximum tolerable dose ("**MTD**") was reached. For heavily pretreated metastatic CRC and BTC patients, the ORR was 40%, and DCR was 80%. Based on these encouraging results, we have received IND approvals from the NMPA for conducting Phase II clinical trials for IAH0968 in combination with gemcitabine and cisplatin in inoperable HER2+ advanced or metastatic solid tumors and BTC on September 28, 2022, and Phase II and Phase III clinical trials for IAH0968 in combination with CapeOX in HER2+ metastatic CRC on September 28, 2022. We have completed the Phase IIa trial for CRC in March 2024, and initiated a Phase IIb/III trial for CRC in January 2024. We expect to complete the Phase IIb trial for CRC in the fourth quarter of 2024. In addition, we initiated a Phase II trial for BTC in August 2023, and expect to complete the Phase II trial in the third quarter of 2025.

- **IAP0971** is a clinical stage, dual-moiety, anti-programmed death -1 ("**PD-1**") antibody-Interleukin-15 ("**IL-15**")/its receptor ("**IL-15Rα**") heterodimer dual T cell/natural killer ("**NK**") cell agonist. It is expected to target the PD-1/its ligand ("**PD-L1**") signaling pathway to relieve the immunosuppression in the TME, and in the meantime deliver IL-15 to the tumor, and thus locally activates and enhances antitumor functions of CD8+ T cells and NK cells. Compared to marketed cytokine-based therapies, IAP0971 may offer improved safety profile through targeted delivery of IL-15, and also achieve improved efficacy profile through the *cis*-synergy between IL-15 and anti-PD-1 antibody. Furthermore, it adopts our internally designed and developed novel structure by embedding the IL-15

heterodimer in the "hinge" region of the anti-PD-1 antibody to balance the activity of IL-15 and protect IL-15 from degradation and further prolong the half-life of IAP0971. Our preclinical study showed that IAP0971 was well tolerated at a dosage up to 1.2mg/kg in the primate animal model, which is around 40-fold higher than an IL-15-Fc fusion protein. It also achieved superior tumor inhibition rate (110.47% when treated with 0.5mg/kg of IAP0971 vs. 74% when treated with 0.5mg/kg of anti-PD-1 antibody) and complete tumor regression rate (90% when treated with 0.5mg/kg of IAP0971 vs. 50% when treated with 0.5mg/kg of anti-PD-1 antibody) in our preclinical studies.

We adopted a global registration strategy for IAP0971, and has obtained IND approvals for conducting Phase I and Phase II clinical trials for advanced solid tumors from the NMPA and the FDA. Phase I study demonstrated that IAP0971 was well tolerated in heavily pretreated patients with advanced malignant tumors up to 200ug/kg Q2W when subcutaneously administered. Preliminary efficacy was observed in multiple heavily pretreated patients, including two NSCLC, who achieved stable disease ("**SD**") after receiving 120μg/kg and 200μg/kg IAP0971 monotherapy, respectively. As of the Latest Practicable Date, we have completed the Phase I study of IAP0971 and have not received objection from the NMPA for us to conduct Phase II clinical trials for IAP0971, and expect to enter Phase II clinical stage in the second quarter of 2024 in China.

- **IAE0972** is a clinical stage, dual-moiety, anti-epidermal growth factor receptor ("**EGFR**") antibody-IL-10 homodimer bifunctional fusion protein for immune cell activation. It is designed to bind to EGFR and trigger blockage of downstream signaling pathways that contribute to cell death suppression and promote cell proliferation, and deliver IL-10 to activate CD8+ T cell in the TME. IAE0972 is designed to resolve immune cell exhaustion of current PD-1/PD-L1-based immunotherapies and lift the limitations of current EGFR-based mAbs. By specifically enriching IL-10 at EGFR-over expressing cancer, IAE0972 is expected to restore the antitumor activities of exhausted T cells. The asymmetric structure of IAE0972 employs a monovalent anti-EGFR antibody fragment to reduce its toxicity to skins. Preclinical studies showed that IAE0972 was well tolerated up to 6 mg/kg in the primate animal model, which is approximately 300 times the safe dosage of IL-10 cytokine therapy. No obvious EGFR-related skin toxicity, no significant organ changes, and no significant changes for levels of cytokines were observed. The studies showed that IAE0972 had a tumor growth inhibition ("**TGI**") rate of 83% in the mice model, which is significantly higher than an anti-EGFR antibody.

  Also following a global strategy, we have received IND approvals for conducting Phase I and Phase II clinical trials for advanced solid tumors from both the NMPA and the FDA. The clinical data from the Phase I trial indicated that IAE0972 can be safely administered to subjects at doses up to 2.5mg/kg on a weekly basis. In addition, preliminary efficacy results showed encouraging antitumor activities when IAE0972 was administered as a monotherapy in multiple heavily pretreated tumor

types including two rectal cancers. As of the Latest Practicable Date, we have concluded the Phase I study of IAE0972 and have not received objection from the NMPA for us to conduct Phase II clinical trials for IAE0972. We have initiated a Phase II clinical trial of IAE0972 as monotherapy in China, and enrolled the first HNSCC patient and the first CRC patient in July 2023 and December 2023, respectively. In addition, in November 2023, we also received the IND approval from the NMPA for conducting Phase II and Phase III clinical trials of IAE0972 in combination with lenvatinib in patients with locally advanced or metastatic HCC as first-line treatment.

In addition to our Core Products mentioned above, we are developing six other product candidates: clinical stage products IBB0979, IBC0966 and IBD0333, and preclinical stage products IAN0982, ISH0988 and ISH0613.

- IBB0979, another immunocytokine developed by us based on AIC™ Platform, received IND approvals from both the FDA and the NMPA for conducting clinical trials for B7H3-high expressing solid tumors. It is an anti-B7 homolog 3 protein ("**B7H3**") antibody-IL-10 homodimer bifunctional fusion protein for immune cell activation. It is designed to bind to B7H3 and trigger blockage of downstream signaling pathways that participate in TME shaping and development, and deliver IL-10 to activate CD8+ T cells in the TME.

- IBC0966 is a clinical stage anti-PD-L1 antibody-signal regulatory protein α ("**SIRPα**") bifunctional fusion protein. It is a therapy that stimulates both innate and adaptive immunity, leading to strong synergistic effects and long-lasting tumor-specific immune responses.

- IBD0333 also received IND approvals from both the FDA and the NMPA. It is a 4-1BB/CD24 bsAb, which simultaneously targets CD24 over expressed tumor cells and activates the stimulatory signal of 4-1BB in CD8+ T cells to induce T cell mediated antitumor immunity at the targeted tumor tissue.

- The preclinical candidates, namely IAN0982, ISH0988 and ISH0613, are currently in the IND enabling stage. IAN0982 is being developed for oncology, while ISH0988 and ISH0613 are immunosuppressors focused on autoimmune diseases.

Our commitment to innovation is evident and supported by our proprietary technology platforms, which include (1) AIC™ Platform, a scalable platform mainly concentrated on antibody-cytokine fusion protein development, (2) AEA™ Platform, a FUT8 knock-out cell line constructed to enhance the cytotoxicity of antibodies, and (3) Armed Innate Effector Multi-specific Platform ("**AIM™ Platform**"), a platform that focuses on the development of innate immunity stimulator-based bispecific/multi-specific antibodies. Each of them is designed for resolving technical difficulties and addressing drug resistance faced in developing immunotherapies and achieving optimized treatment effects. Since their launch, we have developed IAP0971, IAE0972, IBB0979, ISH0988 and ISH0613 based on AIC™ Platform, IAH0968 based on AEA™ Platform, and IAN0982 based on AIM™ Platform.

We have built our GMP-compliant manufacturing facilities, which enhance quality assurance and control of our products and fulfill clinical and potential commercial demands for our drug candidates in a cost efficient way. Our drug substance production facility is currently equipped with four production lines for a total bioreactor capacity of 1,600L. We have completed the installation of a production line for 5,000L bioreactor capacity, and completed the qualification in November 2023. Our drug product facility includes one liquid injection filing production line and one lyophilized powder production line, which enables us to prepare biological products into various dosage forms according to different needs in both clinical and commercial stages. Leveraging our GMP-compliant manufacturing capabilities, as of the Latest Practicable Date, we had successfully completed at least 30 batches with a success rate of 100%.

We are led by a management team with significant R&D experience and a proven track record. Our executive Director, chief executive officer and chief scientific officer, Dr. YIN Liusong, has over 16 years of experience in antibody and cytokine development and pipeline management, and has led more than 600 antibody drug discovery and optimization projects with dozens entered into clinical trials. Chairman of our Board and executive Director, Mr. ZHANG Feng is a pharmaceutical veteran with over 20 years of experience in the industry with expertise in R&D, clinical development, product launch and marketing. Our management team has an average of more than 15 years of industry experience in biologics development and business management, including antibody discovery and engineering, process development, GMP manufacturing, clinical operations and regulatory affairs. Their vision and insights are also key drivers of our success.

OUR STRENGTHS

Internally developed pipeline of immunocytokines with novel mechanisms of action

We are in a leading position to explore immunocytokines to modulate the TME according to Frost & Sullivan, and are experienced in overcoming technical challenges in developing them. Through insightful design of sequence, spatial structure, and protein modification, we aim to improve the safety and efficacy balancing of cytokines, which often act as a double-edge sword in modulating the immune system. Currently, our immunocytokine pipeline includes IAP0971, IAE0972 and IBB0979, all of which are drug candidates with novel mechanisms of action. All three immunocytokines have obtained IND approvals from both the FDA and the NMPA. Currently, we have concluded the Phase I study of IAP0971 and IAE0972. IAE0972 has entered the Phase II clinical phase, and IAP0971 is expected to enter the Phase II clinical phase in the second quarter of 2024. As of the Latest Practicable Date, IBB0979 was in Phase I/II clinical stage.

As potent immune mediators that play an important role in controlling the growth and activity of immune system cells, cytokines have long been deemed by researchers as a promising candidate for developing therapeutics. However, attempts to use them like conventional drugs were unsuccessful mainly due to two reasons: first, cytokines have activity on many different cell types and tissues and can cause systemic rather than localized activities; and second, cytokines are subject to biological degradation, and most of them have very short half-lives *in vivo*. As such, cytokine-based therapy with target specificity and elongated treatment window becomes a research hotspot.

We developed immunocytokines with a structure of co-expressing antibody and cytokines into a fusion protein, which is expected to overcome the drawbacks of conventional cytokine drugs and provide enhanced antitumor activities with a favorable safety profile. On one hand, the antibody portion of the fusion protein may increase the half-life and the specificity of cytokine and thus increase the treatment window and reduce the systemic toxicity. On the other hand, the cytokine portion of the fusion protein may locally activate the immune system, which will turn "cold" or immunosuppressive tumors into "hot" or immune-inflamed tumors, and thus overcome primary and acquired drug resistance.

IAP0971 – Anti-PD-1 antibody-IL-15/IL-15Rα heterodimer fusion protein

Our Core Product IAP0971 is an internally developed, dual-moiety, anti-PD-1 antibody-IL-15/IL-15Rα heterodimer dual T cell and NK cell agonist. IAP0971 is expected to synergistically strengthen the antitumor activity through blockade of the PD-1/PD-L1 signaling pathway and accumulating IL-15 at the targeted tumor site to activate its nearby immune cells, including CD8+ T cells and NK cells, directly activating both innate and adaptive immune systems. We obtained the approval for conducting Phase I and Phase II clinical trials in patients with advanced solid tumors from the NMPA and the FDA in January 2022 and December 2021, respectively.

The selection of IL-15 payload and PD-1 target was based on favorable individual features and the potential for great *cis*-synergy when combined. IL-15 can promote activation and proliferation of CD8+ T cells and NK cells, and in the meantime it does not induce regulatory T cell ("**Treg**")-related immune response suppression that is often observed for IL-2 based cytokine drugs. Also, IL-15 inhibits IL-2-induced T cell death. As such, IL-15 can stimulate CD8+ T cells and NK cells for a longer term and induce relatively fast and robust immune responses without activating Tregs or inducing apoptosis of activated T cells, which are common side effects of IL-2-based therapies.

The selection of the anti-PD-1 antibody was based on several factors, including its ability to act in the same location on the T cells and NK cells as IL-15, as well as the significantly higher expression of PD-1 on CD8+ T cells in the TME compared to peripheral blood and peripheral lymphoid organs. Therefore, the combination of IL-15 and anti-PD-1 antibody can show *cis*-synergy with lower systemic cytotoxicity. Furthermore, considering the balanced activity and dose between the PD-1 antibody and the IL-15 cytokine, IAP0971 is designed to adopt the structure of an intact bivalent anti-PD-1 antibody in combination with a monovalent IL-15. As such, the combination can deliver targeted and controlled amount of IL-15 directly into the TME, which effectively recruits, activates, and reinvigorates immune cells, leading to a significantly enhanced antitumor immunity.

Structure of IAP0971 is also optimized to improve biological activities, developability and productivities. The cytokine moiety of IAP0971 is designed to adopt a structure of IL-15 combining with its receptor IL-15Rα to form a heterodimer that resembles its natural state. On the one hand, the natural high affinity between IL-15 and IL-15Rα avoids the formation of IL-15 homodimer and half antibody fragment, and reduces the mismatch of two different heavy

chains of the anti-PD-1 antibody, which improves the productivity of IAP0971. On the other hand, the IL-15/IL-15Rα complex adopted in IAP0971 is reported to be more active than IL-15 alone in stimulating proliferation and survival of memory phenotype CD8+ T cells. In addition, the spatial structure of IAP0971 is also optimized by embedding the IL-15/IL-15Rα heterodimer in the "hinge" region of the anti-PD-1 antibody. This structure can balance the dose of IL-15 cytokine with that of the PD-1 antibody, as well as prevent degradation of IL-15, thereby prolonging the half-life of IL-15.

Preclinical data showed that IAP0971 was well tolerated up to 1.0mg/kg when subcutaneously administered in MC38 syngeneic mouse model. In the repeated-dose toxicity study in cynomolgus monkeys, IAP0971 showed a favorable safety profile even at 1.2mg/kg, around 40-fold higher than an IL-15-Fc fusion protein. Furthermore, in pharmacokinetic analysis, IAP0971 showed a half-life of 15.7 hours, which is approximately 15-fold longer than that of recombinant IL-15, and approximately 2-fold longer than that of an IL-15-Fc fusion protein. In addition, IAP0971 achieved superior tumor inhibition rate (110.47% when treated with 0.5mg/kg of IAP0971 vs. 74% when treated with 0.5mg/kg of anti-PD-1 antibody) and complete tumor regression rate (90% when treated with 0.5mg/kg of IAP0971 vs. 50% when treated with 0.5mg/kg of anti-PD-1 antibody) in our preclinical study.

In July 2023, we have completed the Phase I clinical trial of IAP0971 for advanced malignant tumors. Data showed that IAP0971 exhibited a favorable safety profile at up to 200μg/kg in patients with advanced solid tumors, with no DLT and MTD observed. Preliminary antitumor efficacy was observed in four patients treated with IAP0971 as a later-line therapy. These four patients include one with CRC, one with cervical cancer, and two with NSCLC, and these patients underwent multiple rounds of treatments including chemotherapy, targeted therapy, immunotherapy and/or their combination, and experienced disease progress and metastasis. After receiving IAP0971 for two treatment cycles, all four patients achieved stable disease ("**SD**"). Especially, one NSCLC patient complicated with adrenal gland and other metastases was resistant to several prior treatments, including chemotherapy regimes such as multiple paclitaxel-containing combination, and combination therapies with targeted therapy and immunotherapy, such as erlotinib, camrelizumab, sintilizumab and bevacizumab. This patient received 120μg/kg IAP0971 for two treatment cycles and achieved SD. The other NSCLC patient complicated with pleura or pleural effusion metastases who was resistant to several prior treatments, also achieved SD after two cycles of 200μg/kg IAP0971 administration. Based on the encouraging Phase I results and without objection from the NMPA, we expect to commence a Phase II clinical trial for IAP0971 in China in the second quarter of 2024.

IAE0972 – Anti-EGFR antibody-IL-10 homodimer bifunctional fusion protein

Our Core Product IAE0972 is an internally developed, dual-moiety, anti-EGFR antibody-IL-10 homodimer bifunctional fusion protein for immune cell activation. Like IAP0971, IAE0972 is also expected to achieve synergistical antitumor activities leveraging the advantages of immunocytokine yet through a different combination of antibody target and cytokine payload. It is designed to blockade the EGFR signaling pathway and specifically

deliver IL-10 to the targeted tumor site to activate CD8+ T cells, and potentially NK cells. We obtained the approval for conducting Phase I and Phase II clinical trials in patients with advanced solid tumors from the FDA and the NMPA in December 2021 and January 2022, respectively.

The development of IAE0972 aimed to address the issue of immune cell exhaustion observed in current PD-1/PD-L1-based immunotherapies and overcome the limitations of current EGFR-based mAbs. IL-10 is a potent activator of tumor-infiltrating memory cytotoxic antigen-specific CD8+ T cells in the TME and can restore the tumor-killing activity of tumor-infiltrating terminally exhausted T cells. Because the anti-EGFR antibody fragment can specifically enrich IL-10 in the TME, IAE0972 can effectively and specifically activate the immune system by reinvigorating antigen specific CD8+ T cells and facilitating its proliferation, and inhibiting tumor growth by blocking the EGFR signaling pathway to kill EGFR-positive tumor cells. As a result, it is expected to resolve the issues of low ORR and drug resistance commonly observed with anti-EGFR antibodies.

Like IAP0971, IAE0972 also adopts the natural structure of IL-10, which is in a homodimer form, so that the natural pairing between IL-10 molecules will improve the developability and productivity of IAE0972. But unlike IAP0971, IAE0972 adopts an asymmetric structure, which consists of a monovalent anti-EGFR antibody fragment and a homodimer of IL-10. Such a design is expected to reduce the binding activity of anti-EGFR antibody on EGFR-low expression normal cells while preserving the biological activity on EGFR-high expression tumor cells and thus reduce EGFR-related skin toxicities. In addition, the spatial structure of IAE0972 employs the knobs-into-holes format in the Fc to promote asymmetric formation and improve its developability. This optimization extends the half-life of IL-10 and improves its therapeutic efficacy.

In vivo data of the preclinical study showed that IAE0972 was well tolerated up to 6 mg/kg in cynomolgus monkeys, which is 300 times the safe dosage of IL-10 cytokine therapy. Also, no obvious EGFR-related skin toxicity, no significant organ changes for liver, thymus, adrenal gland and thyroid gland, and no significant changes for levels of IL-2, tumor necrosis factor-alpha ("**TNFα**") and Interferon-gamma ("**IFNγ**") were observed in the cynomolgus monkey repeated-dose toxicity studies. Studies showed that IAE0972 had a TGI rate of 83% in a MC38-hEGFR syngeneic mice model, which rate is significantly higher than that of an anti-EGFR antibody.

In our Phase I clinical trial of IAE0972 for advanced solid tumors, we recruited 14 patients with advanced esophageal squamous cell carcinoma, rectal cancer, gastric cancer, pancreatic cancer, SCLC or NSCLC who progressed from at least one line of treatment. We have completed dose escalation for 1μg/kg, 10μg/kg, 100μg/kg, 0.3mg/kg, 1.0mg/kg and 2.5mg/kg of IAE0972, and have only observed one Grade 3 adverse events. No DLT occurred and MTD was not reached. As of the Latest Practicable Date, preliminary efficacy was observed in multiple heavily pretreated patients who failed all previous therapies. A CRC patient complicated by lung metastasis, who has received multiple lines of prior treatments including standard mFOLFOX6 (5-fluorouracil, leucovorin and oxaliplatin) and CapeOX

(capecitabine and oxaliplatin) regimens, achieved SD after given 10μg/kg of IAE0972 for two treatment cycles. Another patient with rectal cancer and lung metastasis and lymph mode metastasis, who had experienced recurrence after two resections, achieved SD after receiving 1.0mg/kg of IAE0972 monotherapy for two cycles. The Phase I clinical trial was completed in July 2023. Based on the encouraging Phase I results and without objection from the NMPA, we have initiated a Phase II clinical trial of IAE0972 as monotherapy in China, and enrolled the first HNSCC patient and the first CRC patient in July 2023 and December 2023, respectively.

IBB0979 – an anti-B7 homolog 3 protein ("B7H3") antibody-IL-10 homodimer bifunctional fusion protein

IBB0979, another immunocytokine developed by us, is a clinical stage anti-B7H3 antibody-IL-10 homodimer bifunctional fusion protein for immune cell activation. It is designed to bind B7H3 and trigger blockage of downstream signaling pathways that participate in TME shaping and development, and deliver IL-10 to activate CD8+ T cells to fight against tumors. Preclinical study showed that IBB0979 has high affinity to both targets and exhibited potent TGI in C57BL/6J mice bearing MC38-hB7H3 cell line, with TGI of 100% at 0.3mg/kg, 1mg/kg and 3mg/kg. An *in vivo* study in cynomolgus monkeys showed that after intravenously administered with 1mg/kg, 2mg/kg and 6mg/kg of IBB0979 once a week for 29 days (5 times in total, given in days 1, 8, 15, 22 and 29), MTD was not reached up to 6 mg/kg. There was no administration-related mortality, and no donor-related changes observed.

We obtained the approval for conducting Phase I and Phase II clinical trials in patients with advanced solid tumors from the FDA and the NMPA in October 2022 and November 2022, respectively. The Phase I clinical trial is currently on-going, with the first patient dosed in July 2023. Since B7H3 is overexpressed in a wide range of cancers including glioma, thyroid, lung, head and neck, rectal, prostate, breast, skin, renal cell, and ovarian cancers, it has the potential to become a next-generation therapy for alleviating T cell exhaustion in cancer patients.

Differentiated products developed leveraging our insights on immunology and antibody engineering

In addition to our immunocytokine pipeline, we leverage our insights on immunology and our significant expertise in biologics design and antibody engineering to develop immunotherapies, which exert antitumor activities through novel mechanisms of action. These candidates are designed to achieve improved outcome comparing to currently approved drugs. IAH0968 and IBD0333 exemplify our drug design roadmap based on our understanding of immunological mechanisms of action and spatial structures of biologics, and our engineering capabilities in accomplishing the conception.

IAH0968

Our Core Product IAH0968 is an internally developed, the first anti-HER2 antibody in clinical stage with 100% fucose-removal. It is designed with an aim to achieve enhanced ADCC activities compared to current anti-HER2 antibodies. While no head-to-head study was conducted, the Phase I clinical data showed that IAH0968 achieved significantly improved ORR and DCR in heavily pretreated metastatic CRC and BTC patients, when compared to the historical data of current treatments. We obtained an IND approval from the NMPA for conducting Phase II clinical trials for IAH0968 in combination with gemcitabine and cisplatin in HER2+ patients with inoperable advanced or metastatic tumors and BTC, and another IND approval from the NMPA for conducting Phase II and Phase III clinical trials for IAH0968 in combination with CapeOX in HER2+ patients with metastatic CRC.

Antibodies consist of two structural regions, antigen binding fragment ("**Fab**") and Fc. Unlike Fab region, which defines the specific target of an antibody, Fc region mediates ADCC by activating the immune system through engaging various Fc receptors. Different approaches have been adopted to achieve enhanced ADCC, mainly including Fc point specific mutation, such as through amino acid alterations (e.g. margetuximab and inetetamab) and fucose removal. Fucose removal can be achieved either through the post-expression modification by enzyme digestion or through the construction of new cell lines. Studies of the structure of the Fc region of antibodies and its receptor FcγRIIIa complex revealed that the core fucose of the Fc region is accommodated at a place that interferes with the binding between the Fc region and FcγRIIIa, and thus reducing the affinity between them and resulting in lower ADCC activity. Therefore, modifying to remove fucose is desirable to better recruit immune cells, resulting in enhanced ADCC activity. As a result, this approach has been widely attempted in the biopharmaceutical industry. However, despite numerous attempts by multiple players to modify antibodies through various approaches, most resulting antibodies still contain a certain percentage of core fucose.

We addressed this technical difficulty through constructing a new cell line with mutated FUT8, which encodes an enzyme that catalyzes the transfer of fucose residue from its donor to its target. After biological engineering, the new cell line is not able to attach fucose to any protein it produced. In such a way, we have successfully generated potentially the first anti-HER2 antibody with 100% removal of fucose from its Fc region, i.e. IAH0968. Such achievement has been verified through glycoprotein detection and glycosylation quantification.

Produced through our AEA™ Platform, IAH0968 showed an affinity between IAH0968 and its Fc receptor ten to 20 times higher than unmodified or other ADCC enhanced anti-HER2 antibodies in preclinical studies (especially for the FcγRIIIa 158F polymorphism). *In vitro* assays demonstrated that IAH0968 mediated stronger ADCC killing toxicity against HER2+ tumor cells SKBR3, BT474 and SKOV2 than trastuzumab. Moreover, IAH0968 showed 100% TGI in a BT474 tumor cell subcutaneous murine model, superior to trastuzumab, an anti-HER2 antibody that does not go through fucose removal. In cynomolgus monkeys, IAH0968 showed an encouraging safety profile, with no observed adverse effect at a dosage over 100mg/kg.

The Phase I clinical trial showed that IAH0968 was well tolerated and exhibited antitumor activities in patients with advanced HER2+ malignant solid tumors including breast cancers, gastric cancers, CRC and BTC with drug resistance to trastuzumab, pertuzumab, cetuximab, docetaxel, oxaliplatin, capecitabine, irinotecan, nab-paclitaxel and apatinib, or anti-PD-1 mAbs. Data showed that only one DLT was found at dosage 10mg/kg and no MTD was reached. For heavily pretreated metastatic CRC and BTC patients, the ORR was 40%, and DCR was 80%. As of September 28, 2022, we had obtained IND approvals from the NMPA to conduct Phase II and Phase III clinical trials of using IAH0968 in combination with chemotherapy for first-line treatment of HER2+ advanced or metastatic CRC and BTC patients. We have dosed the first patient in May 2023 in a Phase II trial to evaluate IAH0968 in combination with chemotherapy in HER2+ metastatic CRC, completed the Phase IIa trial in March 2024, and entered a Phase IIb/III trial in January 2024. In August 2023, we have also dosed the first patient in a Phase II trial to evaluate IAH0968 in combination with gemcitabine and cisplatin in inoperable HER2+ advanced or metastatic BTC. We expect to complete the Phase IIb clinical trial for CRC in the fourth quarter of 2024, and complete the Phase II clinical trial for BTC in the third quarter of 2025.

IBD0333

IBD0333 is an internally developed, clinical stage, 4-1BB/CD24 bsAb, which simultaneously targets CD24 over expressed tumor cells and activates the stimulatory signal of 4-1BB in CD8+ T cells to induce T cell mediated antitumor immunity at the targeted tumor tissue. Developed from our proprietary bispecific antibody platform, IBD0333 exemplifies our research capabilities in designing and developing bispecific antibodies.

IBD0333 is potentially the first bsAb that targets both 4-1BB and CD24. CD24 is highly expressed in many cancers, such as ovarian and breast cancer and its high expression is often related to poor prognosis. CD24, expressed on the surface of tumor cells, and sialic-acid-binding Ig-like lectin 10 ("**Siglec-10**"), expressed on immune cells, act as an innate immune checkpoint that is essential for mediating antitumor immunity. The interaction between them promotes tumor immune escape. By specifically targeting CD24, IBD0333 will not only be able to target cancer cells that overexpress CD24, but also block the CD24/Siglec-10 interaction to prevent immune escape. 4-1BB is a costimulatory molecule expressed on immune cells including CD8+ T cells and also DC cells, monocytes, B cells, mast cells, NK cells and neutrophils. 4-1BB's activation triggers a signaling cascade that activate both innate and adaptive immune system, resulting in upregulation of antiapoptotic molecules, cytokine secretion, and enhanced effector function. Because anti-4-1BB antibody was known to have hepatotoxicity, tumor-associated antigens ("**TAA**") targeting to specifically activate immune cells in the TME is expected to enhance its safety profile.

In addition to the target selection, IBD0333 has additional structural design aiming to achieve improved safety and efficacy. For example, the anti-4-1BB moiety is designed to activate the 4-1BB signaling pathway only when IBD0333 binds to the tumor cells that overexpress CD24, which can further reduce the systemic toxicity of the product. The antibody backbone of IBD0333 is an IgG4, which binds to its receptors with lower affinity (except for

FcRI), and is a poor inducer of Fc-mediated effector functions. By adopting IgG4 as its backbone antibody, IBD0333 can further reduce the safety risk of anti-4-1BB antibody. Through targeted delivery of anti-4-1BB moiety and specific activation of the stimulatory signal of immune cells in the TME, IBD0333 can achieve not only improved safety, but also improved efficacy compared to anti-4-1BB mAbs.

Preclinical data showed that IBD0333 had excellent safety and efficacy profile. In toxicology studies of IBD0333 in both mice and cynomolgus monkeys, no obvious abnormality in mice or cynomolgus monkeys administered with IBD0333 was observed. The MTD was estimated to be greater than 200mg/kg with no severe side effects observed in the study. Benchmark anti-4-1BB mAbs, Utomilumab from Pfizer and Urelumab from BMS, were reported to show either systemic toxicity or hepatotoxicity at 30mg/kg and 0.3mg/kg in the Phase III trials, respectively. Comparing to these mAbs, the 200mg/kg MTD of IBD0333 according to the preclinical data showed that IBD0333 has great potential to achieve significantly improved safety profile. As to efficacy, IBD0333 showed excellent tumor inhibition activities in mice model with 99% tumor growth inhibition at 1mg/kg and 100% at 3mg/kg, in a dose-dependent manner. We have obtained IND approvals from the FDA on June 2, 2023 and from the NMPA on July 10, 2023, dosed the first patient of a Phase I clinical trial in March 2024, and plan to complete the Phase I trial in the third quarter of 2025.

Proprietary platforms aimed to addressing bottlenecks of current immunotherapies continue fueling the development of differentiated biological products

Our R&D capabilities are driven by our proprietary platforms, including AIC™ Platform, AEA™ Platform, and AIM™ Platform. We built our pipeline mostly based on them with our in-depth understanding of immune microenvironment.

AIC™ Platform

Our AIC™ Platform is prominently positioned in the field of immunocytokine development from multiple aspects, including cytokine selection and optimization, antibody selection and engineering, structural design and engineering, and production through customized cell line. It is a comprehensive research engine that includes not only a pool of intact immunoglobulin G ("**IgG**") antibodies and cytokines, but also functional antibody fragments and other types of immune system modulators. It is able to generate products ranging from immunocytokines to other bifunctional fusion proteins. Our clinical stage drug candidates IAP0971, IAE0972 and IBB0979, and preclinical stage drug candidate ISH0988 and ISH0613 were developed based on the AIC™ Platform.

Our AIC™ Platform successfully addresses technical difficulties for developing immunocytokines. These difficulties range from antibody and cytokine selection and optimization, to final drug production.

- Antibody/cytokine selection. Due to different spatial structure, different types of cytokines behave largely different when fused with antibodies targeting different antigens.

- Structural design. Dose ratio and activity between the selected antibody and cytokine is needed to be balanced to achieve the desired mechanism of actions ("**MoA**") and synergistic effects.

- Manufacturing capabilities. It is challenging for developing and manufacturing immunocytokine molecules, because they are structurally complicated, especially considering the degradation vulnerability of cytokines.

Core competencies of AIC™ Platform include MoA-based antibody-cytokine selection, biology-oriented structural design and protein engineering, and production through customized cell line.

- MoA-based antibody-cytokine selection is the cornerstone to achieve desired synergistic effects between antibody and cytokine. For example, selection of anti-PD-1 antibody and IL-15 cytokine for developing IAP0971 is grounded on their shared action site on the same T/NK cells, leading to great *cis*-synergy. The combination of anti-EGFR antibody and IL-10 is selected based on the potential engager effects it can produce. Specifically, IAE0972 can engage CD8+ T cells through IL-10 while simultaneously targeting tumor cells through the EGFR antibody moiety.

- Structural design and protein engineering module enable us to structurally design and modify our products to achieve improved safety and efficacy profile while reducing manufacturing cost and enhancing product quality manageability. Structural modifications that we are capable to perform through AIC™ Platform include antibody and cytokine engineering, deglycosylation, linker/spacer design and optimization, and tertiary structure alteration. Especially, developed through the AIC™ Platform, IAP0971 employs the natural pairing of IL-15/IL-15Rα, which leads to more efficient dimerization and eliminates the formation of IL-15 homodimer and half antibody fragments. Additionally, a knobs-into-holes structure is introduced in the Fc region of the anti-PD-1 antibody, reducing the mismatch of two different heavy chains. These structural designs result in improved productivity of IAP0971. Furthermore, IAP0971 is also modified by engineering the IL-15/IL-15Rα heterodimers partially embedded into the "hinge" region in the anti-PD-1 antibody. Our drug candidate is the first of this structure to enter into clinical trial, according to Frost & Sullivan. It can increase the stability of cytokine by "hiding" a substantial portion of cytokine within antibody to protect it from hydrolysis by proteases, as well as balances the activity of cytokine versus antibody by introducing steric hindrance to the cytokine, and in the meantime retains the specificity and affinity of cytokine to bind to its receptor and allows it to mediate immune responses.

- Production through customized cell lines is another important function performed by our AIC™ Platform. The cell lines we constructed for producing immunocytokines and other bifunctional fusion proteins are obtained after undergoing multiple rounds of metabolic and growth optimization and are of high expression capacity and excellent purification yield. Coupled with unique cytokine-specific codon optimization, stably expressed vehicles with optimized expression cassettes and our high-throughput screening system, it is able to reach an expression level of 4g/L and one-step affinity chromatography purity of 86%, which is at the top level among rivals both at home and abroad, according to Frost & Sullivan.

AEA™ Platform

Our AEA™ Platform is a biologically engineered Chinese hamster ovary ("**CHO**") cell line with the FUT8 knocked-out to generate antibodies with enhanced ADCC and improved antitumor activities. Through this bioengineering modification, the CHO cell line will not be able to catalyze the transfer of fucose residue from its donor to its target, and thus is not able to produce any antibody that carries fucose. Because absence of core fucose on the Fc region has been shown to increase the Fc region's binding affinity (up to 100 times) to its receptor FcγRIIIa present on immune effector cells, fucose-negative antibodies are expected to have enhanced ADCC activities through better activating immune effector cells.

Comparing to other platforms that aim to achieve enhanced ADCC by removing fucose from antibodies, AEA™ Platform is expected to produce antibodies with 0% of fucose, which rapidly, stably, and thoroughly enhances the ADCC of antibodies and simplifies quality control of the products. Different biological engineering has been adopted by different platforms. However, seldom platforms achieved 100% fucose removal. As of the Latest Practicable Date, our AEA™ Platform and POTELLIGENT from Kyowa Kirin are the only two platforms that can achieve 100% fucose removal rate, according to Frost & Sullivan.

Feasibility and advantages of AEA™ Platform have been demonstrated by IAH0968, the first complete fucose-removal anti-HER2-antibody in clinical stage developed through this platform. We have verified through glycoprotein detection and glycosylation quantification that IAH0968 does not contain any fucose. In addition, *in vitro* and *in vivo* tests showed that the affinity between IAH0968 and its Fc receptor was ten to 20 times higher than unmodified or other ADCC enhanced anti-HER2 antibodies, resulting in greater enhanced ADCC activity and antitumor efficacy.

AIM™ Platform

Our AIM™ Platform focuses on designing multi-functional biological products by engaging the innate immune system for cancer immunotherapy. It selects tumor associated antigen antibodies for cancer targeting, receptors agonist antibodies for innate effector activation, and cytokines and other TME factors for immune modulation to design multi-specific antibody fusion proteins, and evaluates them in terms of expression, target binding, *in vitro* and *in vivo* biological activities, as well as druggability. Currently, we have developed

several categories of our proprietary AIM™ Platform that allow us to explore the combination of innate immunity stimulators with different types and numbers of targets, which provide us with abundant flexibility and diversity of various types of TME modulations for different clinical indications.

By targeting innate immunity stimulators instead of adaptive immunity stimulators, which is considered more cytotoxic and easily restrained by immune escape of tumors and the immunosuppressive TME, products developed from our AIM™ Platform are expected to achieve desired clinical safety and efficacy profiles. Our preclinical product IAN0982 was developed based on the AIM™ Platform.

Fully integrated, end-to-end, in-house drug development capabilities encompassing all key biologic drug development functionalities

We have built and continue to build key capabilities and infrastructure that empower us to advance a broad portfolio of programs to the clinic. Within five years since our inception, we have established fully integrated, end-to-end, in house drug development capabilities covering functions of drug discovery and preclinical studies, process development, GMP-compliant manufacturing, clinical development, and quality control. Leverage these capabilities and through efficient execution of our R&D strategies, we have developed multiple proprietary technology platforms, from which we have generated a pipeline of nine product candidates, with six of them in the clinical stage.

Our achievement is largely attributed to our R&D team, who has profound industry experience in fields such as mechanisms of cytokine action, antibody drug discovery, protein engineering and antibody engineering, and biopharmaceutical project management. Our core R&D team members are experienced project leaders in the pharmaceutical industry. They contributed their knowledge and provided guidance to the development of our proprietary R&D platforms and drug candidates. As of the Latest Practicable Date, we have a dedicated in-house R&D team with 57.5% of team members holding masters or doctorate degrees in biology or medical related majors.

Our clinical development and regulatory affairs handling capabilities cover China and the U.S., which empower us to adopt a global strategy for the development of our product candidates. As of the Latest Practicable Date, except for IBC0966, we held global commercial rights of all of our pipeline products. Our clinical development team manages our clinical trials and carries out substantial clinical development activities, including clinical trial design, implementation, the collection and preliminary analysis of trial data, and communication with regulatory authorities. As of the Latest Practicable Date, we have successfully secured five IND approvals from the FDA by leveraging our clinical execution capabilities and through our regulatory affairs team members' broad and close communication with clinical development specialists in FDA regulations.

Our chemistry, manufacturing and controls ("**CMC**") team is experienced in GMP-compliant manufacturing. We have established our own manufacturing facilities in Nanjing, PRC in compliant with international GMP standards regulated by the NMPA, FDA and European Medicines Agency ("**EMA**"), which meet both clinical and commercial production demands of our drug candidates. Our four drug substance production lines for a total bioreactor capacity of 1,600L are currently in operation, and have successfully completed over 30 production batches of immunocytokines, mAbs, bsAbs and fusion proteins, which fulfilled the needs for performing preclinical study, pilot production of antibody drugs and conducting early phase clinical trials. We have completed the installation of a production line for 5,000L bioreactor capacity, and completed the qualification in November 2023. When putting into operation, it will enable us to manufacture our drug candidates for Phase III clinical trials and commercialization in-house. Our drug production facility includes one commercial-scale liquid injection filing production line and one commercial scale lyophilized powder production line, which enables us to prepare biological products into various dosage forms according to different needs.

Experienced management team of industry veterans with a proven record of success

We have assembled an experienced management team of successful industry veterans, who have an average of more than ten years of experience in drug development or manufacturing, or business management in well-reputed biopharmaceutical companies in China or abroad, and led the discovery, development and marketing of multiple target therapies, biologics and biosimilars.

Dr. Yin, our executive Director, chief executive officer, and chief scientific officer, has 16 years of experience in immunology and biologics development with eight years in leadership roles. He has led more than 600 of antibody drug discovery and optimization projects, many of which entered into clinical stage. He was named as an inventor of more than 70 patents directed to innovative biologics, and more than 10 projects were out-licensed to reputable biotechnology companies. As of the Latest Practicable Date, Dr. Yin has published 16 research papers in journals indexed in Science Citation Index ("**SCI**"), and these papers were cited by others for more than 500 times. In addition to his role as an industry leader, he serves as an adjunct professor at Institute of Microbiology of Chinese Academy of Sciences. Dr. Yin received his Bachelor of Science in biological sciences from University of Science and Technology of China, and Doctor of Philosophy in Biomedical Sciences in University of Massachusetts Chan Medical School in the U.S.

Chairman of our board and executive director, Mr. Zhang is experienced in R&D, clinical development, product launch, and marketing. He is a serial entrepreneur and veteran pharmaceutical professional with over 20 years of experience in the industry. Besides, Mr. Zhang has successfully obtained marketing approvals for nearly 20 drugs, manufacturing certificates for over 30 drugs, and has involved in the development of more than 50 clinical and preclinical products, 15 of which are Class 1 or Class 2 new drugs according to the drug classification standards issued by the NMPA. In addition to his leadership in the pharmaceutical industry, Mr. Zhang holds multiple positions in academia and industry

organizations. Particularly, he is a member of the sixth editorial board of Progress in Pharmaceutical Sciences 《藥學進展》, a committee member of the Antitumor Drug Committee of the Chinese Pharmaceutical Association (中國藥學會抗腫瘤藥物專業委員會), and the vice president of the Jiangsu Provincial Pharmacy Association (江蘇省醫藥行業協會).

Members of our senior management team are pragmatic and experienced industry leaders with a proven record of success in drug development. The head of R&D department, Ms. JIANG Xiaoling, has over 15 years' experience in R&D of pharmaceuticals including biosimilar drugs and antibody drugs. She led the development of about 20 innovative biologics and six biosimilars. Mr. JIANG Dongcheng, the leader of our manufacturing team, who has 10 years' experience in GMP manufacturing, has directly involved in GMP-manufacturing, scaling-up, validation of more than ten drug candidates.

OUR STRATEGIES

We aspire to be a leading global biopharmaceutical company with a focus on antibody and cytokine-based therapeutics. Our mission is to bring perceivable benefits and affordable medicine to patients both in China and globally. We intend to execute the following strategies to achieve our aspiration and mission.

Focus on the development of immunocytokines to enhance our position in this drug development field

We plan to fully explore our knowledge and experience in developing immunocytokines and rapidly advance the clinical development of our immunocytokine product candidates, including IAP0971, IAE0972 and IBB0979. We will also continue developing and further exploring our AIC™ Platform to enrich our immunocytokine pipeline.

Rapidly advance clinical development of immunocytokines

- **IAP0971**. We completed the Phase I clinical trial of IAP0971 administered subcutaneously for advanced malignant tumors in July 2023, and plan to initiate the Phase II clinical trials in 2L advanced NSCLC patients in the second quarter of 2024. In addition, we received the IND approvals for conducting Phase I and Phase II clinical trials for IAP0971 administered intravesically in patients with recurrent or metastatic non-muscle invasive bladder cancer ("**NMIBC**") from NMPA and the FDA in May 2023 and August 2023, respectively. We expect to complete the Phase I study and enter a pivotal Phase II trial in the fourth quarter of 2024. Furthermore, PD-1 or PD-L1 is significantly upregulated in the liver of chronic hepatitis B patients, skewing the immune response towards the induction of tolerance in circulating naïve T cells and attenuating the effector functions of liver-infiltrating cytotoxic T lymphocytes. To fully explore IAP0971's clinical potential, we also plan to submit the IND for conducting clinical trials of IAP0971 for the treatment of chronic HBV infections in the third quarter of 2024.

- **IAE0972**. We have completed the Phase I clinical trial of IAE0972 for locally-advanced or metastatic solid tumors in July 2023, initiated a Phase II clinical trial of IAE0972 as monotherapy in China, and enrolled the first HNSCC patient and the first CRC patient in July 2023 and December 2023, respectively. In addition, we received the IND approval from the NMPA for conducting Phase II and Phase III clinical trials of IAE0972 in combination with lenvatinib in patients with locally advanced or metastatic HCC as first-line treatment in November 2023. We expect to commence a Phase II clinical trial for HCC in the second quarter of 2024. Furthermore, we also plan to submit an IND application for and initiate a Phase II clinical trial of IAE0972 in combination with docetaxel for NSCLC in the third quarter of 2024.

- **IBB0979**. We are currently conducting a Phase I clinical trial of IBB0979 for locally-advanced or metastatic solid tumors with IND approved by both the FDA and the NMPA. We expect to complete the Phase I clinical trial, and enter Phase II clinical stage for extensive-stage small cell lung cancer ("**ES-SCLC**") and metastatic castration-resistant prostate cancer ("**mCRPC**") in the fourth quarter of 2024.

Continue developing AIC™ Platform and enriching our pipeline therefrom

We will continue scaling-up our AIC™ Platform to design and develop new molecules with innovative mechanism and novel targets, and expand indications of our immunocytokines beyond oncology. Leveraging technical advantages of our AIC™ Platform, in addition to immunocytokines, we intend to develop and are also capable of developing products containing functional groups that have a similar function of regulating inflammation signaling pathways as cytokines. IBC0966, an anti-PD-L1 antibody-SIRPα fusion protein, marks our first attempt in developing an antibody fusion protein that carries immune system modulators that play a similar role as cytokines. We have conducted preclinical studies of IBC0966 since its acquisition, completed the Phase I trial of IBC0966, and expect to enter into Phase II clinical stage in the second quarter of 2024.

In addition, our AIC™ Platform also enables us to design product candidates that suppress immune responses. Currently, our immunocytokine pipeline products are potent immunostimulants that directly activate both innate and adaptive immunity. Our AIC™ Platform is scalable to develop immunoregulators including immunosuppressors, which enables us to enrich our pipeline with candidates for the treatment of autoimmune diseases and emergency care against cytokine storm. We have developed ISH0988, an anti-inflammatory and tissue-protective bifunctional fusion protein that is currently in preclinical study phase for the treatment of inflammatory bowel disease ("**IBD**"), and ISH0613, a bifunctional antibody fusion protein that simultaneously inhibits B cell activation and IFNα secretion for the treatment of systemic lupus erythematosus ("**SLE**"), based on the AIC™ Platform. In the future, leveraging the AIC™ Platform, we plan to develop immunocytokines or other types of fusion proteins targeting pro-inflammatory signaling pathways that are associated with autoimmune diseases.

Explore new immunocytokine development platforms

In addition to continue developing our AIC™ Platform, we plan to develop a novel immunocytokine prodrug platform, which will allow us to design prodrugs that is pharmacologically inactive, and is metabolized into an active drug after it enters the human body. This platform is expected to deliver products with improved safety, prolonged therapeutic window, and more balanced profile between efficacy and safety, and thus will further enhance our current position in the immunocytokine development field.

Continue advancing selected pipeline products with great clinical value and commercial potential

In addition to our featured immunocytokines product candidates, we intend to continue advancing selected products and expanding indication coverage.

Continue advancing selected pipeline products

- **IAH0968**. We are currently conducting a Phase II clinical trial for IAH0968 in combination with CapeOX in HER2+ metastatic CRC and a Phase II clinical trial for IAH0968 in combination with gemcitabine and cisplatin in inoperable HER2+ advanced or metastatic BTC. We have completed the Phase IIa clinical trial for CRC in March 2024, commenced a Phase IIb/III clinical trial for CRC in January 2024, and plan to complete the Phase IIb trial in the fourth quarter of 2024. We also plan to submit a BLA of IAH0968 for the treatment of 1L HER2+ advanced BTC to the NMPA in the second half of 2025.

- **IBD0333**. We have received the IND approvals for conducting clinical trials of IBD0333 for locally-advanced or metastatic solid tumors from both the NMPA and the FDA in July 2023 and June 2023, respectively. We initiated a Phase I clinical trial in March 2024 in patients with locally advanced/metastatic solid tumors. We expect to complete the Phase I study in the third quarter of 2025.

- **IBC0966**. We obtained the IND approval from the NMPA for conducting Phase I and Phase II clinical trials of IBC0966 in advanced malignant tumors in March 2021. We concluded the Phase I study in December 2023, and expect to enter Phase II clinical trials for non-Hodgkin lymphomas ("**NHL**") in the second quarter of 2024.

Continue to advance and enrich our product pipeline in autoimmune diseases and viral infections

Leveraging our strong in-house R&D capabilities, we have developed two product candidates, i.e. ISH0988 and ISH0613, indicated for autoimmune diseases IBD and SLE. ISH0988 can inhibit either upstream B cell activation by anti-self antibodies or downstream INFα production by immune cells and deliver precise immunotherapy to treat the disease, while ISH0613 can achieve anti-inflammatory and tissue-protective functions. We will continue advancing these preclinical products into clinical stage, and expect to submit IND applications to both the NMPA and the FDA in the second quarter of 2024.

We will continue to discover and generate lead candidates to enrich our early-stage pipeline. These include innovative drug candidates against novel or validated targets for autoimmune diseases. We plan to continue to design and develop bifunctional biologics to modulate immune responses, like ISH0988 and ISH0613, and optimize these biologics to enhance their efficacy, safety and pharmacokinetic properties. This involves sequence optimization, spatial structural modification, and adjusting binding affinities to different targets.

We will continue developing treatments for viral infections through two approaches. The first approach is by developing immunotherapies for viral infections. Currently, we plan to develop IAP0971 for HBV infection, and submit an IND application for a Phase I trial in the second quarter of 2024. We will continue exploring immunotherapy regimen for the treatment of viral infection through modulating innate or adaptive immune responses to microbial pathogens to promote the anti-pathogen immune response or to prevent immunopathology. The second is by developing multi-valent neutralizing antibodies, leveraging our long-acting multi-valent broadly neutralizing antibody platform.

Continue developing our AIM™ Platform to further explore druggability of innate effectors

We will continue developing our AIM™ Platform to harness the potential of innate effectors in cancer treatments. Our focus is on developing antibodies that target different tumor associated antigens and incorporating different cytokines and other immune modulators into multispecific molecules to further enhance the function of innate effector cells. We will also explore different structural formats, and evaluate them in terms of expression, target binding, *in vitro* and *in vivo* biological activities, as well as developability profiles.

Expanding our GMP-compliant manufacturing facility to enhance our production capabilities and starting to assemble our commercial team

As of the Latest Practicable Date, we have three 200L production lines and one 1,000L production line for GMP-compliant drug substance manufacturing for performing preclinical study, pilot production, and conducting early stage clinical trials, as well as commercial-scale drug product lines for liquid injection and lyophilized powder that fulfill different dosage forms. We have completed the installation of a production line for 5,000L bioreactor capacity, and completed the qualification in November 2023. When putting into practice, it will enable us to manufacture our drug candidates for Phase III clinical trials and commercialization in-house.

Our commercialization strategy is to first capture market share in China followed by a gradual penetration into other target markets such as the U.S. As our drug candidates approach late clinical stage and commercialization, we intend to form our in-house core commercialization and distribution team by recruiting senior-level sales and marketing personnel who are experienced in treatment fields we focus on. We may also seek strategic collaboration opportunities for the commercialization of our drug candidates in China. In particular, we may selectively license-out, establish joint ventures or through other forms of partnerships collaborate with leading biopharmaceutical companies for executing late-stage clinical trials and/or marketing our drug candidates. The collaboration is expected to bring access to strong distribution channels, high-performing sales team, and long-term relationship with domestic players.

Actively seeking international collaboration opportunities to maximize value of our assets and increase brand awareness on a global scale

We are executing a global registration strategy for our immunocytokine candidates, and will continue implementing a global registration plan for our product candidates. We recognize that partnerships will be a critical source to complement our internal resource and enable us to fully execute our global strategy. As such, we will actively seek collaboration opportunities with international leading pharmaceutical companies to advance clinical trials abroad of our products through out-licensing arrangements. We will also expand our international registration team to secure our global clinical development and registration plan, and strengthen the leading clinical development stage of our featured products, especially our immunocytokine pipeline including IAP0971, IAE0972 and IBB0979.

We have managed to establish our technology platforms and advance multiple candidates into clinical stage through our own R&D capabilities. In the future, we intend to continue enriching our drug portfolio mainly through our internal discovery efforts leveraging our fully-integrated, end-to-end, in-house R&D capabilities to develop biologics. We will continue to focus our in-house discovery efforts on the development of novel immunotherapies especially immunocytokines in furtherance of our current position in this therapeutic development field. We will also build an in-house sales and marketing team focusing on commercializing our products in China once they get approved for marketing by the NMPA.

In the meantime, we aim to proactively enhance our brand awareness worldwide, thereby pave the way for promoting our product candidates and technologies to enter global markets. We believe that raising global awareness of our brand is an important way to promote our product candidates and technologies to enter global markets. As of the Latest Practicable Date, we had applied for 119 patent applications in major jurisdictions around the world. As of the Latest Practicable Date, we had published six papers and abstracts on influential journals, and joined over ten international conferences on cancer therapy. In addition to these ongoing efforts to increase our international presence, partnering with world's renowned pharmaceutical companies will also be a further testament to our R&D capabilities and thereby raise our profile in the pharmaceutical industry. Our current assets have already drawn attention from several MNCs, and we will actively communicate with them for potential collaborations.

Continue to focus on selecting and retaining top talents to fuel our innovation

Innovation is the core growth driver of our business, and talent is the cornerstone of innovation-driven development strategy. We place a high priority on selecting, attracting, and retaining top talent. To fully support our continued growth, we will continue to invest in attracting and retaining top talent in various aspects of our operations, including drug discovery, CMC, clinical development, regulatory affairs, and sales and marketing.

In particular, we plan to recruit more talents specialized in clinical development and sales and marketing of innovative therapeutics. Our robust product pipeline is built with our exceptional drug discovery and development expertise. To further strengthen this competitive advantage, we plan to continue to enhance the capabilities and capacity of our clinical development team both inside and beyond China, in order to advance our clinical development efforts and support regulatory affairs in our target markets.

Moreover, we are committed to the continued development of a cohesive and vibrant corporate culture that inspires and encourages innovation. We will continue to provide our employees with competitive salary package, improved performance evaluation system, and a wide variety of employee development projects, including internal and external training opportunities to help them further improve their technical and management skills.

DRUG CANDIDATES

As of the Latest Practicable Date, we had identified and developed a pipeline of nine products. Our pipeline is featured by our internally developed immunocytokines, which directly modulate both the innate and adaptive immune systems. Our immunocytokine pipeline includes (1) Core Product IAP0971, a dual-moiety, anti-PD-1 antibody-IL-15/IL-15Rα heterodimer dual T cell/NK cell agonist; (2) Core Product IAE0972, a dual-moiety, anti-EGFR antibody-IL-10 homodimer bifunctional fusion protein for immune cell activation; and (3) IBB0979, a dual-moiety, anti- B7 homolog 3 protein ("**B7H3**") antibody-IL-10 homodimer bifunctional fusion protein for immune cell activation. All three products are under clinical development with IND approvals from both the NMPA and the FDA, with IAP0971 and IAE0972 completed the Phase I clinical trials in July 2023 and IBB0979 in the Phase I/II clinical stage. Based on the Phase I clinical data, IAP0971 and IAE0972 have shown good tolerability and preliminary antitumor activities in patients with advanced solid tumors. We have initiated a Phase II clinical trial of IAE0972 as monotherapy in China, and enrolled the first HNSCC patient and the first CRC patient in July 2023 and December 2023, respectively. For IAP0971, we plan to commence Phase II clinical trials in the second quarter of 2024. For another immunocytokine, IBB0979, we dosed the first patient of the Phase I trial for B7H3-high expressing solid tumors in July 2023 in China and expect to complete the Phase I clinical study of IBB0979 in the fourth quarter of 2024 in China.

In addition to immunocytokines, we have developed candidates in forms of monoclonal antibodies ("**mAbs**"), bsAbs, and fusion proteins, which span across various stages of clinical and preclinical development. Our Core Product IAH0968 is an antibody-dependent cell-mediated cytotoxicity ("**ADCC**") enhanced mAb targeting human epidermal growth factor receptor 2 ("**HER2**") with 100% fucose knock out. Currently, we are conducting Phase II clinical trials in patients with inoperable HER2+ advanced or metastatic BTC and HER2+ metastatic CRC as the first-line treatment.

Except for the above mentioned products, we are also developing five other product candidates, i.e. IBC0966, IBD0333, IAN0982, ISH0988 and ISH0613. IBC0966 is a clinical stage, anti- PD-L1 antibody-signal regulatory protein α ("**SIRPα**") bifunctional fusion protein that simultaneously stimulates both innate and adaptive immunity to achieve strong synergistic effects and induce long-lasting tumor-specific immune responses. As of the Latest Practicable Date, IBC0966 has completed the Phase I clinical trial as a monotherapy for the treatment of advanced malignant tumors in December 2023. We expect to enter Phase II clinical trials in the second quarter of 2024. IBD0333 is an anti-CD24-anti-4-1BB bsAb that simultaneously stimulates both innate and adaptive immunity. We have obtained IND approvals from both the FDA and the NMPA on June 2 and July 10, 2023, respectively. We expect to complete the Phase I study in the third quarter of 2025. IAN0982, ISH0988 and ISH0613 are currently in the preclinical stage. We expect to file IND applications for them in 2024. The following chart summarizes the development status of our Core Products and other selected drug candidates as of the Latest Practicable Date.


Candidate*
MoA
Platform
Regimen
Indication (Line of treatment)
Preclinical
Phase I
Phase II
Phase III
Commercial rights
Upcoming milestone
Cancer Immunotherapy
Viral Infection
Cancer Immunotherapy
Autoimmune Diseases
IAH0968
HER2 (ADCC enhanced mAb)
AEA™
+CapeOX
HER2+ CRC (1L)
Global
Complete Phase IIb in Q4 2024
+GC
HER2+ BTC (1L)
Complete Phase II in Q3 2025
IAP0971
PD-1/IL-15 (Antibody–cytokine fusion protein)
AIC™
Mono
NSCLC (2L)
Enter Phase II in Q2 2024
+Chemo
Non-squamous NSCLC (1L)***
Global
Enter Phase II in Q3 2024
+BCG
BCG-unresponsive high risk NMIBC (2L/3L)
Complete Phase I in Q4 2024
IAP0971
PD-1/IL-15 (Antibody–cytokine fusion protein)
AIC™
+nucleoside analogues
HBV
Global
Enter Phase I in Q3 2024
IAE0972
EGFR/IL-10 (Antibody–cytokine fusion protein)
AIC™
Mono
HNSCC (2L) and CRC (3L)
Complete Phase II in 1H 2026
+Chemo
Squamous NSCLC (2L)***
Global
Enter Phase II in Q3 2024
+Chemo
HCC (1L)***
Enter Phase II in Q2 2024
IBB0979
B7H3/IL-10 (Antibody–cytokine fusion protein)
AIC™
Mono
B7H3-high expressing solid tumors (≥2L)
Global
Complete Phase I in Q4 2024
IBC0966
PD-L1/SIRPα (Bispecific antibody fusion protein)
bsFp platform
Mono
Solid tumors (≥2L)
Greater China**
Enter Phase II in Q2 2024
IBD0333
4-1BB/CD24 (Bispecific immune modulatory antibody)
bsAb platform
Mono
Solid tumors (≥2L)
Global
Complete Phase I in Q3 2025
IAN0982
Confidential (Multispecific innate effector activator)
AIM™
Mono
Solid tumors
Global
IND filing in Q2 2024
ISH0988
Confidential (Anti-inflammatory and tissue protective)
AIC™
Mono
IBD
Global
IND filing in Q2 2024
ISH0613
Confidential (Inhibit B cell activation and IFNα secretion)
AIC™
Mono
SLE
Global
IND filing in Q2 2024
Core Product
NMPA
FDA
Preclinical stage

Abbreviations: 1L = first-line; 2L = second-line; 3L = third-line; ADCC = antibody-dependent cell-mediated cytotoxicity; AEA™ = ADCC Enhanced Antibody Platform; AIC™ = Armed ImmunoCytokine Platform; AIM™ = Armed Innate Effector Multispecific Platform; BCG = Bacillus Calmette-Guerin; bsAb = bispecific antibody; bsFp = bispecific fusion protein; CapeOX= capecitabine and oxaliplatin; Chemo = chemotherapy; FDA = U.S. Food and Drug Administration; GC = gemcitabine and cisplatin; IND = Investigational New Drug; mAb = monoclonal antibody; Mono = monotherapy; NMPA = National Medical Products Administration; NSCLC = non-small cell lung cancer; NMIBC = non-muscle invasive bladder cancer; BTC = biliary tract carcinoma; CRC = colorectal cancer; HBV = hepatitis B virus; HNSCC = head and neck squamous cell carcinoma; HCC = hepatocellular carcinoma; IBD = inflammatory bowel disease; Q1 = first quarter; Q2 = second quarter; Q3 = third quarter; Q4 = fourth quarter; 1H = first half; SLE = systemic lupus erythematosus.

Notes:

* All the product candidates are administered intravenously, except for IAP0971 for the treatment of 2L/3L NMIBC, which will be administered through intravesical instillation, as well as IAP0971 for the treatment of NSCLC, which will be administered through subcutaneous injection.

** We acquired exclusive rights from ImmuneOnco Biopharmaceuticals (Shanghai) Inc. to develop, manufacture and commercialize IBC0966 in Greater China including mainland China, Hong Kong, Macau, and Taiwan, as well as 7.5% of interests in the overseas rights of IBC0966. For more information, see "— Collaboration Arrangement — Collaboration Agreement With ImmuneOnco in Relation to the Development of IBC0966" in this section.

*** We have completed Phase I clinical trials of relevant products as monotherapy, and plan to leverage data collected in the respective trials and directly seek IND approvals from competent regulatory authorities to conduct Phase II clinical trials of relevant products as combination therapy.

Our pipeline products modulate both innate and adaptive immunity to achieve synergistic effect on regulating immune microenvironment.

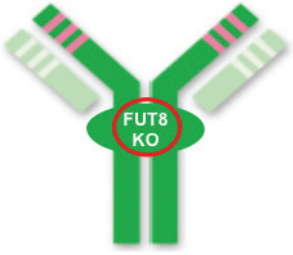
Introduction of Innate and Adaptive Immunity

The immune system comprises two main components: the innate immune system and the adaptive immune system. They are two distinctive immune systems that cooperate to build up an integrated immune response. Innate immunity is a non-specific defense system people are born with. It protects the host against all antigens, yet has no immunologic memory. It includes physical barriers, such as skin and mucosa membrane, innate immune cells, such as phagocytes and NK cells, and immune molecules, such as cytokines. Adaptive immunity, on the other hand, is an antigen-dependent, specific defense mechanism that a body develops to fight foreign molecules. It is able to create immunological memory so that the immune system will be able to respond more rapidly and effectively to pathogens that have been encountered previously. It includes adaptive immune cells, such as T cells and B cells, and immune molecules, such as immunoglobulins.

Simultaneous stimulation of innate and adaptive immunity can achieve a synergistic effect, which will lead to highly efficient recognition and clearance of pathogens. Cytokines, produced by various innate effector cells or adaptive immune cells, are essential in modulating both innate and adaptive immune systems. Antigen presenting cells ("**APC**") act as the bridge between the two systems. They mainly include dendritic cells and macrophages that can phagocytose antigens, degrade them into peptides and display the processed antigen peptides on the cell surface for T cells recognition and secrete cytokines, and thereby initiating the adaptive immune responses. In turn, T cells can stimulate macrophages and NK cells through the release of cytokines to directly kill pathogens. Therefore, when innate and adaptive immunity are both activated, an enhanced and more long-lasting immune response compared to either of them alone will be generated.

Core Product: IAH0968 (ADCC enhanced anti-HER2 mAb)

IAH0968 is a clinical stage, ADCC enhanced anti-HER2 antibody with complete removal of fucose. Removal of fucose from the Fc region of the anti-HER2 antibody moiety enables IAH0968 to bind to the receptor FcγRIIIa with a higher affinity, which will activate the immune system more efficiently comparing to the unmodified anti-HER2 antibody. The diagram below illustrates the structure of IAH0968:



Source: Company data

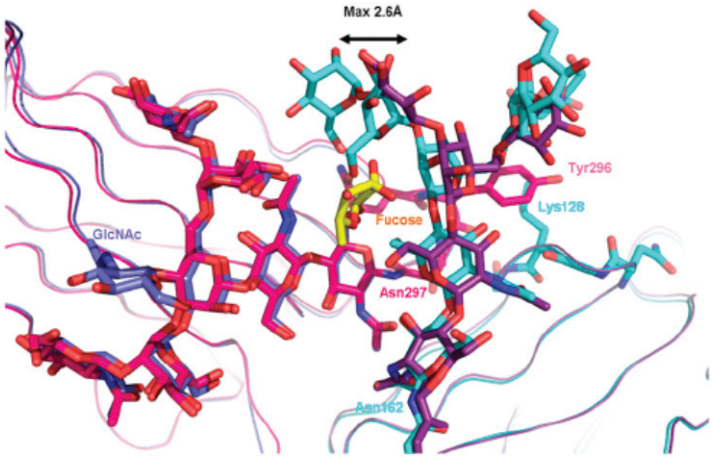
We obtained the IND approval for conducting Phase I and Phase II clinical trials of IAH0968 from the NMPA in October 2020, commenced the Phase I clinical trial in August 2021, and have completed the Phase I clinical trial of using IAH0968 as a monotherapy for heavily pretreated patients with advanced HER2+ malignant solid tumors in March 2023. On September 28, 2022, we received IND approvals from the NMPA for conducting Phase II clinical trials for IAH0968 in combination with gemcitabine and cisplatin in inoperable HER2+ advanced or metastatic BTC as first-line therapy, and Phase II and Phase III clinical trials for IAH0968 in combination with CapeOX (capecitabine + oxaliplatin) in HER2+ metastatic CRC as first-line therapy. We dosed the first patient of the Phase II clinical trial to evaluate IAH0968 in HER2+ metastatic CRC in May 2023 and also dosed the first patient of the Phase II clinical trial to evaluate IAH0968 in HER2+ advanced BTC in August 2023. We completed the Phase IIa trial for CRC in March 2024, commenced a Phase IIb/III trial for CRC in January 2024, and expect to complete the Phase IIb trial in the fourth quarter of 2024. In addition, we also expect to complete the Phase II trial for BTC in the third quarter of 2025.

Mechanism of Action

Antibodies consist of two structural regions, Fab and Fc. Unlike Fab region, which defines the specific pathogen target, Fc region binds to FcR on cell membrane, which could initiate and control cell-mediated effector functions as ADCC, antibody-dependent cellular phagocytosis ("**ADCP**"), and complement-dependent cytotoxicity ("**CDC**"). The stronger the affinity between the Fc region and FcR, the higher the activities of cell-mediated effector functions.

Different approaches have been adopted to achieve enhanced ADCC, mainly including Fc engineering, such as through amino acid alterations (i.e. margetuximab) and fucose removal, to increase the affinity between the Fc region and FcR. Studies of the structure of the Fc region of antibodies and its receptor FcγRIIIa complex revealed that the core fucose of the Fc region is accommodated at a place that interferes with the binding between the Fc region and FcγRIIIa, and thus reducing the affinity between them and resulting in lower ADCC activity. Therefore, modifying to remove fucose is desirable to better recruit immune cells, resulting in enhanced ADCC activity. As a result, this approach has been widely attempted in the biopharmaceutical industry. Fucose removal can be achieved either through the post-expression modification by enzyme digestion or through the construction of new cell lines. However, despite numerous attempts by multiple players to modify antibodies through various approaches, most resulting antibodies still contain a certain percentage of core fucose.

Antibody Core Fucose Increases the Binding Distance Between Fc and Fc Receptor

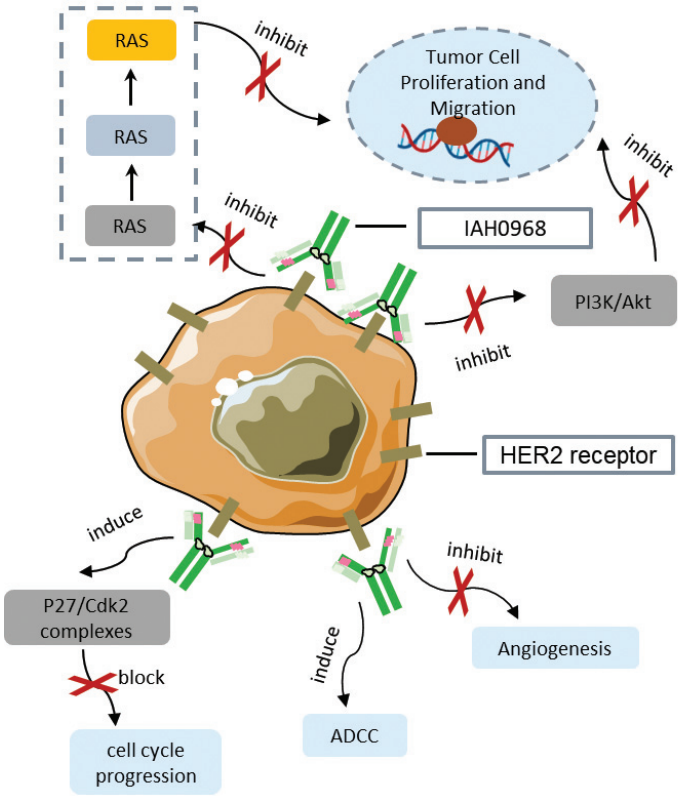


Note: The blue antibody on the right is the antibody with the core-fucose removed, and the purple is normal antibody with core-fucose unmodified.

Source: Ferrara et al., PNAS

HER2 is a validated molecular target for cancer therapy. Over-expression of HER2 has been observed in many cancer types including BTC and CRC. Researches demonstrated that HER2 plays a major role in promoting cell proliferation and suppress apoptosis. Amplification of the HER2 and overexpression of its product may drive excessive or uncontrolled cell growth and tumorigenesis. Antibodies targeting HER2 induce HER2 endocytosis followed by receptor degradation, and as a result constitutively inhibit the activation of the HER2 signaling network and thus inhibits angiogenesis and induces ADCC.

IAH0968 is produced from our proprietary AEA™ Platform. The platform is an internally constructed cell line with mutated FUT8, which encodes α-1,6-fucosyltransferase. α-1,6-fucosyltransferase catalyzes the transfer of fucose from GDP-fucose to the asparagine-linked GlcNAc residue of complex N-glycans via α1-6 linkage. Through biological engineering of FUT8, the cell line will not be able to express α-1,6-fucosyltransferase, and thus proteins generated through the cell line do not carry any fucose. In such a way, we have successfully generated potentially the first complete fucose removal anti-HER2 antibody. Because fucose residue located in the Fc region is also removed, IAH0968 is expected to have enhanced ADCC effect against HER2+ tumor cells.



Source: Frost & Sullivan analysis

Below is a comparison between IAH0968 and other approved anti-HER2 antibodies:

Categories	IAH0968	trastuzumab	pertuzumab
Similarities			
MoA	Binding to the HER2 protein on the surface of tumor cells, blocking tumor cell growth, while simultaneously killing tumor cells through ADCC activity.		
Subtype Class	IgG1	IgG1	IgG1
***In Vivo* Tumor Cell Proliferation Inhibition Activities**	According to our preclinical studies in human breast cancer cell lines of SKBR3 and BT474, and human ovarian cancer cell line SKOV-3, IAH0968 and trastruzumab achieved similar tumor cell proliferation inhibition effect.		Weaker than trastuzumab[1]
Epitope	The binding epitope of IAH0968 and trastuzumab on HER2 is the same, which differs from that of pertuzumab.		
Differences			
Fucose Modification Ratio	0%	76%[2]	97.4%[3]
Fc Receptor Affinity: CD16a（V158）	25.9 nM	275 nM	Similar to trastuzumab[4]
Fc Receptor Affinity: CD16a（F158）	79.3 nM	1560 nM	NA
BT474 158V/V ADCC Activity	Strong (EC_{50}: 17.75ng/ml)	Weak (EC_{50}: 343.7ng/ml)	Similar to trastuzumab[5]
BT474 158F/F ADCC Activity	Yes (EC_{50}: 63.25ng/ml)	No	Similar to trastuzumab[5]
Tumor Growth Inhibition Rate at 5mg/kg	106%	51%	Similar to trastuzumab[5]
MTD in cynomolgus monkeys	>100mg/kg	>25mg/kg[6]	15-50mg/kg[7]

Abbreviations: NA = not available.

Notes:

1 Brockhoff et al., Cell Prolif. 2007, 40, 488-507;

2 Junttila et al., Cancer Res; 70(11) June 1, 2010;

3 Yao et al., BioMed Research International 2022;

4 Boesch et al., MABS 2017, VOL. 9, NO. 3, 455-465;

5 Scheuer et al., Cancer Res 2009; 69: (24);

6 Japan Pharmacology Reviews;

7 FDA Pharmacology Reviews, 2012.

Source: Company data

Market Opportunities and Competition

We are currently investigating IAH0968 for the treatment of BTC and CRC, and plan to further explore its potential in these indications.

BTC

BTC ranks as the second most prevalent type of hepatobiliary cancer globally and primarily encompass cholangiocarcinomas ("**CCAs**") and gallbladder carcinoma. According to Frost & Sullivan, the global market of BTC drugs increased from US$0.5 billion to US$0.7 billion with a CAGR of 10.7% from 2018 to 2022. The number is projected to reach US$1.5 billion in 2026 and US$2.5 billion in 2030 with a CAGR of 21.7% and 13.3% from 2022 to 2026 and from 2026 to 2030, respectively. The China market BTC drugs increased from US$0.2 billion to US$0.3 billion with a CAGR of 7.9% from 2018 to 2022. The number is projected to reach US$0.8 billion in 2026 and US$1.6 billion in 2030 with a CAGR of 28.2% and 17.9% from 2022 to 2026 and from 2026 to 2030, respectively.

In clinical practice, there is a lack of standardized treatment recommendations in the guidelines for HER2+ BTC, which accounts for approximately 20% of BTC patients. In the first-line treatment of BTC, there are no specific drugs recommended for HER2+ BTC, indicating a notable scarcity of treatment options for these patients. While HER2-targeted therapies, such as pertuzumab in combination with trastuzumab, have been recommended for second-line treatment of BTC, the development of drug resistance against HER2-targeted therapies and disease progression remain inevitable challenges.

Therefore, there is an urgent need for novel treatment options to enhance the current BTC treatment landscape. Enhanced engagement of the immune system through ADCC holds significant promise in improving the outcomes of HER2-targeted therapy and should be explored as a potential avenue for advancement. For further details, see "Industry Overview — Immuno-Oncology Drugs Overview — Major Indications for Immuno-Oncology Therapies — BTC" in this document.

CRC

Colorectal cancer ("**CRC**"), also known as bowel, colon, or rectal cancer, refers to cancerous growths that develop in the colon or rectum. According to the Frost & Sullivan, the global market of CRC drugs increased from US$16.2 billion to US$20.6 billion from 2018 to 2022, and is projected to reach US$30.9 billion in 2026 and US$43.7 billion in 2030. The China market of CRC drugs increased from US$1.5 billion to US$2.6 billion from 2018 to 2022, and is projected to reach US$5.0 billion in 2026 and US$7.8 billion in 2030.

Due to a lack of early cancer screening and diagnosis in China, a staggering 89% of clinically diagnosed CRC patients are already in the late stages of the disease. Currently, for late-stage CRC (metastatic disease), chemotherapy alone or in combination with targeted therapies such as bevacizumab and cetuximab (an anti-EGFR antibody) is recommended as the first-line treatment. PD-1/PD-L1 inhibitors, like Keytruda, have only been recommended for a small subset of patients with the MSI-H/dMMR subtype in the first- and second-line treatments.

However, over time, the therapeutic benefits of targeted therapies in combination with chemotherapy, such as bevacizumab and cetuximab, diminish. The median progression-free survival ("**mPFS**") for these treatments ranges from 8.9 to 10.6 months in the first-line and decreases to 4.1 to 7.5 months in the second-line treatment. Patients have limited effective options if the initial treatment with bevacizumab, cetuximab and chemotherapy fails due to drug resistance. Additionally, PD-1 inhibitors, while providing an alternative treatment option for some CRC patients, are only approved for a very small percentage (5%) of patients with MSI-H/dMMR and have not been approved for general use in CRC due to limited overall response rates of less than 10% in clinical trials. Consequently, novel immuno-oncology therapies improving the immune response against tumor cells are needed to address the medical needs in metastatic CRC treatment, especially by enhancing T cells and NK cells activities. For further details, see "Industry Overview — Immuno-Oncology Drugs Overview — Major Indications for Immuno-Oncology Therapies — CRC" in this document.

Competitive Landscape

According to Frost & Sullivan, there are three anti-HER2 mAbs in clinical development for cancer treatment globally. Among them, the most advanced product is in the Phase II/III clinical stage. In China, there are four products in clinical development, with the most advanced ones also in Phase II/III stage. IAH0968 stands out as the only and the most clinically advanced ADCC-enhanced anti-HER2 mAb modified through fucose removal in China and rest of the world, which is currently in the Phase II/III clinical stage.

Competitive Advantages

IAH0968 is potentially the world's first 100% fucose-removed HER2 antibody developed based on our AEA™ Platform. This antibody exhibits enhanced tumor-killing abilities and can potentially be used for the treatment of a wider range of HER2+ tumors.

Advantages in terms of molecular design

IAH0968 is manufactured based on the AEA™ Platform, our proprietary, internally developed FUT8-knock-out cell line, which produces antibodies with 0% core fucose. As a result, because no fucose on the Fc region of the antibody, the antibody will have enhanced ADCC. In contrast, current HER2-targeted therapies such as trastuzumab expressed in FUT8 wild-type cells, which can have more than 90% core fucose residue on the Fc region.

Favorable safety portfolio

Toxicological studies conducted in cynomolgus monkeys have demonstrated that the maximum tolerated dose for a single dose of IAH0968 is 618 mg/kg, and the no observed adverse effect level for repeated doses (doubled for the first dose) is 200/100 mg/kg. These values significantly surpass the converted dose of the validated data for IAH0968 in mice, highlighting the encouraging safety profile of the product candidate.

The favorable safety profile has been validated in both Phase I and Phase II clinical trials. Specifically, in 18 patients who received IAH0968 monotherapy up to 20mg/kg, all patients experienced treatment-related adverse events (TRAEs), with most being Grade 1-2. Only four subjects experienced Grade 3 adverse events (AEs). Additionally, the maximum tolerated dose (MTD) was not reached. A similar safety profile was observed for IAH0968 combination therapy. In 9 patients who received IAH0968 (up to 15mg/kg) in combination with CapeOX, we observed that most TRAEs were Grade 1-2. No dose-limiting toxicities (DLTs) occurred, and the MTD has not been reached.

Superior efficacy portfolio

In a preclinical study, we demonstrated that IAH0968 and trastuzumab exhibit similar binding activities to tumor cells expressing the HER2 antigen, indicating that 100% removal of fucose does not affect the target recognition of IAH0968. In this study, we co-incubated IAH0968 with tumor cells of varying HER2 expression levels (SKBR3, BT474, SKOV3, and A549) and used APC anti-human IgG Fc fluorescent antibody as the secondary antibody to investigate the binding activity of the drugs to the tumor cells. Data showed that the binding activity of IAH0968 to tumor cells is similar to that of trastuzumab.

	Cell Type	IAH0968	trastuzumab
Binding to the surface antigen HER2 on tumor cells. (EC_{50} (μg/ml))	SKBR3	2.315	1.893
	BT474	2.732	2.661
	SKOV3	1.465	1.370
	A549	No binding	No binding

Source: Company data

- IAH0968 exhibits 10-20 times higher affinity for FcγRIIIa compared to trastuzumab, resulting in 5-20 times greater killing activity for ADCC in HER2+ tumor cells. In a mouse subcutaneous tumor model, IAH0968 achieved a 100% tumor growth inhibition rate, surpassing the effectiveness of trastuzumab despite lower dosage.

- IAH0968's ADCC efficacy remains unaffected by FcγR polymorphisms in NK cells and shows significant effectiveness against the 158V/F and 158F/F polymorphisms, which are prevalent in 80% of the population. The Phase I clinical trial has demonstrated that IAH0968 remains effective in patients with trastuzumab-resistant breast and gastric cancers. Additionally, in endline patients with cholangiocarcinoma and colorectal cancer who experienced drug resistance to previous treatments, IAH0968 achieved an ORR of 40% and DCR of 80%.

- In a Phase II clinical trial, IAH0968 demonstrated encouraging preliminary antitumor activities in combination with CapeOX in subjects with HER2+ advanced or metastatic CRC and malignant solid tumors who failed or were resistant to multiple frontline therapies, achieving an ORR of 50% and a DCR of 75%.

Advantages in terms of production

- The production of IAH0968 is enabled by the FUT8-knock-out cell line, which showed exceptional host cell growth and expression characteristics. The cell line can achieve a maximum cell density of 3×10^7 cell/mL. It can maintain stable antibody expression for extended periods and achieving high levels of cell expression at approximately 4g/L. The resulting purification efficiency is also notably high, ensuring the commercial scalability of IAH0968 while maintaining consistent quality.

- The manufacturing process for IAH0968 will utilize 5,000L stainless steel bioreactor for commercial production, further reducing production costs and elevating its market competitiveness.

Summary of Clinical Trial Results

Phase II clinical trial in patients with HER2+ advanced/metastatic CRC

Trial Design. This is an open-label Phase II study of IAH0968 in patients with HER2+ metastatic CRC. This trial is conducting in China. Phase IIa of the study is to evaluate the safety and tolerability of IAH0968 in combination with CapeOX in HER2+ advanced or metastatic malignant solid tumors and to determine the MTD and/or the RP2D of the combination therapy. Phase IIb of this study is to evaluate the efficacy of IAH0968 in combination with CapeOX in HER2+ metastatic CRC by PFS according to RECIST 1.1.

The primary objective of the Phase IIa trial are safety and tolerability. The secondary objective includes PK, anti-drug antibody ("**ADA**"), ORR and PFS. The primary objective of the Phase IIb study is PFS. The secondary objective includes ORR, OS, one year survival rate, DCR, AEs, SAEs and ADA.

Trial Status. The Phase IIa clinical trial of IAH0968 for 1L HER2+ metastatic CRC has been completed in March 2024. We have initiated the Phase IIb study in January 2024.

Safety Profile. As of the data cut-off date (March 11, 2024), patient enrollment for IAH0968 combination therapy has been completed in the 10 mg/kg and 15 mg/kg dose groups. A total of nine subjects received IAH0968 in combination with CapeOX administration during the study, and safety observations were conducted. No DLTs occurred, and the MTD has not been reached.

All nine subjects (100.00%) experienced treatment-related adverse events ("**TRAEs**") during the study, the majority of which were Grade 1-2. The most common TRAE was hypoalbuminemia (9/9), up to Grade 2. Grade 3 TRAEs were experienced by eight subjects (8/9), including diarrhea (3), decreased neutrophil count (2), decreased platelet count (2), asthenia (1), decreased white blood cell count (1), anemia (1) and hypokalemia (1).

Efficacy Profile. As of the data cut-off date (March 11, 2024), eight subjects underwent efficacy assessment. Among them, one subject achieved complete response ("**CR**") on the best response evaluation, three subjects achieved partial response ("**PR**") on the best response evaluation, resulting in an ORR of 50% (4/8). In addition, two subjects achieved SD, leading to a DCR of 75% (6/8). These results demonstrated the preliminary clinical efficacy of IAH0968 in combination with CapeOX in subjects with HER2+ advanced or metastatic CRC and malignant solid tumors who failed or were resistant to multiple frontline therapies. The efficacy of IAH0968 combination therapy during the Phase IIa study is summarized in the table below:

Group	Indication	Previous Treatment	Efficacy
10 mg/kg	Colon cancer with metastases to the liver, abdominal cavity, and supraclavicular lymph nodes	Treated with oxaliplatin + capecitabine; trastuzumab; raltitrexed + pyrotinib; pertuzumab + trastuzumab + irinotecan + calcium folinate + fluorouracil; DP303c; regorafenib; fruquintinib + trastuzumab + sintilimab; disitamab vedotin); trastuzumab + regorafenib; cadonilimab + bevacizumab + trifluridine + tipiracil; all resistant	SD. Achieved SD at first efficacy evaluation after two cycles of IAH0968 treatment, and lasted for six cycles
10 mg/kg	Gastric cancer with lymph node metastasis	Treated with trastuzumab + oxaliplatin + capecitabine followed by capecitabine maintenance regimen; paclitaxel + camrelizumab + apatinib; disitamab vedotin; all resistant	SD, still under treatment for 12 cycles. Achieved SD at first efficacy evaluation after two cycles of IAH0968 treatment, and lasted for ten cycles
10 mg/kg	Breast cancer with right chest wall, sternum, axilla, left supraclavicular fossa lymph nodes and lung metastases	Treated with docetaxel + epirubicin + cyclophosphamide; docetaxel + hesperidin; Gaynor; hesperidin; tamoxifen; disitamab vedotin; pyrotinib + capecitabine; trastuzumab + pertuzumab + gemcitabine + cisplatin; pyrotinib + inetetamab+ paclitaxel; norethindrone + abciximab + inetetamab; all resistant	PR. Achieved PR at first efficacy evaluation after two cycles of IAH0968 treatment, and lasted for four cycles

Group	Indication	Previous Treatment	Efficacy
15 mg/kg	Colon cancer with liver metastasis	Treated with oxaliplatin + fluorouracil + calcium folinate, resistant	CR, still under treatment for ten cycles. Achieved PR at first efficacy evaluation after two cycles of IAH0968 treatment, and lasted for six cycles; achieve CR at the fourth efficacy evaluation, and lasted for two cycles
15 mg/kg	Colon cancer with liver, lung, and peritoneal lymph node metastasis	Treated with oxaliplatin + capecitabine, resistant	PR, still under treatment for ten cycles. Achieved PR at first efficacy evaluation after two cycles of IAH0968 treatment, and lasted for eight cycles
15 mg/kg	Breast cancer with recurrent skin metastasis of left chest wall, left internal mammary lymph node, right axillary lymph node and left chest wall	Treated with cyclophosphamide + epirubicin; anastrozole + letrozole; pyrotinib maleate tablets/placebo + trastuzumab + docetaxel; capecitabine; vinorelbine + herceptin + pertuzumab; TDM-1; TPK-1 + apatinib; trastuzumab + fulvestrant + Ibex; Abemaciclib; all resistant	PR. Achieved PR at first efficacy evaluation after two cycles of IAH0968 treatment, and lasted for four cycles

Note: Cut-off date: March 11, 2024. Efficacy evaluation according to RECIST 1.1.

Source: Company data

Conclusion. The results of the above studies indicated that IAH0968 in combination with CapeOX was safe and well tolerated. The results also demonstrated preliminary efficacy in patients with HER2+ advanced or metastatic CRC and malignant solid tumors who have failed standard therapies. The RP2D was determined to be 15 mg/kg. Phase IIb/III clinical studies can be commenced in accordance with the Company's proposed clinical development plan.

Phase II clinical trial in adult patients with advanced HER2+solid tumors who have failed standard treatment and treatment-naïve patients with advanced/metastatic HER2+ BTC

Trial Design. This is an open-label, randomized, double-blind Phase II study of IAH0968 in patients with HER2+ metastatic BTC. This trial is conducting in China. Phase IIa study of this trial is in adult patients with advanced HER2+ solid tumors who have failed standard treatment. The study is to determine the MTD, DLT and/or RP2D of intravenous IAH0968 in combination with GC regimen (gemcitabine + cisplatin) in adults with advanced HER2+ solid tumors who have failed standard therapy. Phase IIb study of this trial will be conducted in treatment-naïve patients with advanced/metastatic HER2+ BTC. It is designed to study the first-line use of IAH0968 at the RP2D, as determined in the Phase IIa study, in patients with advanced or metastatic HER2+ BTC without systemic therapy, to compare the efficacy of IAH0968 in combination with GC regimen by ORR with that of placebo in combination with GC regimen according to RECIST 1.1.

The primary objective of the Phase IIa trial is safety and tolerability. The secondary objects include PK, ADA, ORR and PFS. The primary objective of the Phase IIb trial is ORR. The secondary objective includes one-year survival rate, PFS, OS, CRR, DCR, AEs, SAEs and ADA.

Trial Status. We have dosed the first patient in August 2023.

Phase I clinical trial in patients with HER2+ advanced solid tumors

Trial Design. This trial was a Phase I, open-label study of IAH0968 in patients with HER2+ advanced solid tumors. This trial was conducted in China. A total of 18 patients were enrolled in this study. Each treatment cycle is defined as 3 weeks, in which IAH0968 will be administered intravenously (IV) on day 1 of each cycle. Tumor assessments will be performed every 6 weeks (i.e., prior to dosing for Cycles 3, 5, 7, etc.). Patients enrolled in this study who do not experience a DLT or other unacceptable toxicity that necessitates permanent discontinuation of investigational product, may continue treatment for up to disease progression, initiation of alternative anti-cancer therapy, lost to follow-up, withdrawal of informed consent, death, or end of study.

The study included two phases: dose escalation and dose extension. The dose escalation study followed the 3+3 scheme. One subject was included in the 6 mg/kg dose group, and then three to six patients with HER2+ advanced solid tumors that failed standard treatment were included in the fixed three dose groups (10 mg/kg, 15 mg/kg and 20 mg/kg). Once RP2D/MTD dose level has been determined, we recruited additional patients to confirm the RP2D/MTD in HER2+ patients who had failed standard therapy. Dosing began with dose level 0 (10 mg/kg Q3W) and proceed to escalated dose levels of 10 mg/kg Q3W, 15mg/kg Q3W, and 20 mg/kg Q3W, successively.

The primary objective of the Phase I trial was to determine the MTD, RP2D of IAH0968 and DLT, AE and SAE. The secondary objective included assessing PK portfolio, and immunogenicity of IAH0968.

Trial Status. The Phase I study of this trial was completed on March 10, 2023. As of cut-off date (June 12, 2023), we were conducting follow-up observations. However, these follow-up observations will not affect the findings and conclusions from the Phase I clinical trial as reported by the principal investigator ("**PI**") of the trial in the clinical research report, nor will they change the fact that the Phase I clinical trial has been completed.

Safety Profile. The safety analyses were summarized from 18 subjects enrolled in the Phase I of IAH0968. Among 18 subjects, all the patients experienced TRAEs, but most AEs were Grade 1-2. Only four subjects experienced ≥ Grade 3 AEs. Also, MTD was not reached.

TRAEs occurring in ≥10% of patients or ≥ Grade 3 TRAEs

	All patients (N=18)	
	All grades, n (%)	**≥Grade 3, n (%)**
Any TRAE	18(100)	4(22.22)
TRAE in ≥10% of patients by preferred term		
Anemia	13(72.22)	0
Hypoalbuminemia	9(50.00)	0
Hyperuricemia	9(50.00)	0
Infusion-related reactions	9(50.00)	1(5.56)
Hypertriglyceridemia	6(33.33)	0
Alanine aminotransferase increased	6(33.33)	0
Blood alkaline phosphatase increased	5(27.78)	0
White blood cell count decreased	4(22.22)	1(5.56)
Platelet count decreased	4(22.22)	0
Aspartate aminotransferase increased	4(22.22)	0
Hypocalcemia	3(16.67)	0
Hypokalemia	3(16.67)	1(5.56)
Hyperglycemia	3(16.67)	0
Hyponatremia	3(16.67)	0
Diarrhea	3(16.67)	0
Gamma-glutamyl transferase increased	2(11.11)	0
Hypercholesteremia	2(11.11)	0
Neutrophil count decreased	2(11.11)	1(5.56)
Nodal tachycardia	2(11.11)	0
Hyperphosphataemia	2(11.11)	0
Fever	2(11.11)	0
Supraventricular tachycardia	1(5.56)	1(5.56)
Arrhythmia	1(5.56)	1(5.56)
Electrocardiogram QT prolonged	1(5.56)	1(5.56)

Abbreviations: TRAE = treatment-related adverse event.

Note: Cut-off date: June 12, 2023. AEs graded according to NCI CTCAEv.5.0.

Source: Company data

Efficacy Profile. As of the data cut-off date (June 12, 2023), the efficacy analyses were summarized based on data collected from 18 subjects enrolled in Phase I clinical trial of IAH0968, with 15 of them being evaluable for efficacy. An evaluable subject was defined as one who had undergone at least one post-baseline tumor assessment. Among the 15 evaluable subjects, two of them showed a PR, while six subjects exhibited SD. The ORR was calculated to be 13.3%, and the DCR was 53.3%. When considering heavily pretreated metastatic CRC and BTC patients, the ORR increased to 40%, with a DCR of 80%. The table provided below presents a summary of the best responses with PR and SD observed in the 15 evaluable subjects who received IAH0968 during Phase I study.

Indication	Group	Patient	Previous Treatment	Efficacy
CRC, CCA	10 mg/kg	Colon cancer, peritoneal metastasis	Treated with oxaliplatin, capecitabine, trastuzumab, irinotecan, raltitrexed, all resistant	SD, still under treatment. Achieved SD in the first efficacy evaluation after 2 cycles of IAH0968 treatment, and lasted for more than 12 months
	15 mg/kg	Rectal cancer, lung metastasis, pelvic metastasis	Treated with EGFR monoclonal antibody, irinotecan, calcium folinate, fluorouracil, all resistant	PR, still under treatment. After 2 cycles of IAH0968 administration, the subject achieved partial response PR at the first efficacy evaluation. The duration of PR exceeded 12 months, and the tumor volume continued to shrink

Indication	Group	Patient	Previous Treatment	Efficacy
		CCA, liver metastases	Treated with Nab-paclitaxel, capecitabine, all resistance	PR. The subject achieved SD at the first efficacy evaluation after 2 cycles of IAH0968 administration, and then achieved PR at the fourth cycle evaluation. The DCR duration was 3 months, and the tumor volume continued to shrink
		Rectal cancer, liver, perianal metastasis	Treated with Radiotherapy, oxaliplatin, capecitabine, Herceptin, irinotecan, raltitrexed, pirotinib, all resistant	SD. The subject achieved SD in the first efficacy evaluation after 2 cycles of IAH0968, and lasted for 5 months
BC, GC	10 mg/kg	BC, liver, lung, lymph node metastases	Treated with Docetaxel, trastuzumab, pertuzumab, all resistant	SD, still under treatment. The subject achieved SD at the first efficacy evaluation after 2 cycles of IAH0968 administration, and lasted for more than 20 months, and the tumor volume continued to shrink
		GC, lung, lymph node metastasis	Treated with Oxaliplatin, capecitabine, trastuzumab, irinotecan, apatinib, SHR-1701, nab-paclitaxel, all resistant	SD. The subject achieved SD in the first efficacy evaluation after 2 cycles of IAH0968 and lasted for 5 months, and the tumor volume continued to shrink

Indication	Group	Patient	Previous Treatment	Efficacy
	20 mg/kg	GC, liver metastases	Treated with Trastuzumab, oxaliplatin, capecitabine, Tegafur, albumin-paclitaxel treatment, all resistant	SD. The subject achieved SD in the first efficacy evaluation after 2 cycles of IAH0968, and lasted for 4 months, and the tumor volume continued to shrink
		BC, lung metastases	Treated with Pyrotinib Tablets, Trastuzumab, Docetaxel, all resistant	SD. The subject achieved SD in the first efficacy evaluation after 2 cycles of IAH0968, and lasted for 4 months

Source: Company data

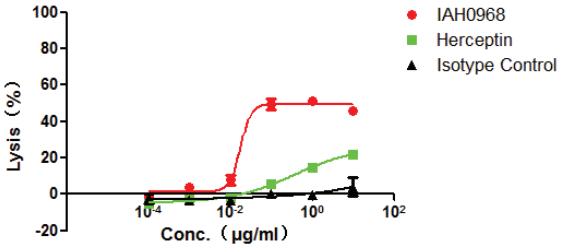
Conclusion. IAH0968, as a monotherapy, demonstrated a favorable safety profile and encouraging preliminary efficacy in individuals diagnosed with HER2+ advanced solid tumors and failed multiple prior therapies within a dose range of 6 mg/kg to 20 mg/kg.

Summary of Preclinical Data

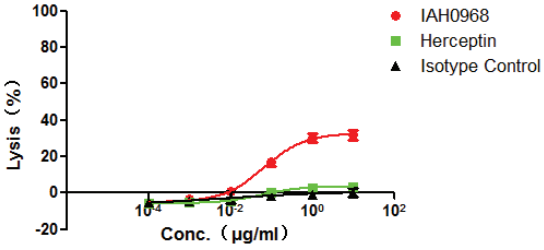
In vitro assays demonstrated that IAH0968 mediated stronger ADCC killing toxicity against HER2+ tumor cells SKBR3, BT474 and SKOV3 than trastuzumab. HER2 high expression breast cancer cell line BT474 was selected as target cells. FcγRIIIa-158V-F polymorphism is located in the extracellular membrane-proximal domain which is considered crucial for antibody binding. NK-92MI-CD16a overexpressing CD16a 158V/V (Fc high affinity receptor) or cells overexpressing 158F/F (Fc low affinity receptor) were effector cells. BT474 cells were collected and put into 96-well plates, and then NK-92MI-CD16a cells overexpressing CD16a 158V/V or CD16a 158F/F were added to each well. IAH0968 or trastuzumab (Herceptin) was diluted in series and added to the plate.

The results showed that IAH0968 could mediate ADCC activity against BT474 in the presence of effector cells NK-92MI-CD16a (158V/V) or NK-92MI-CD16a (158F/F). The ADCC activity was stronger than trastuzumab or Herceptin. Herceptin could not mediate the ADCC activity against BT474 in the presence of effector cells NK-92MI-CD16a (158F/F).

Tumor Cell Lysis by NK Cells Overexpressing CD16a 158V/V



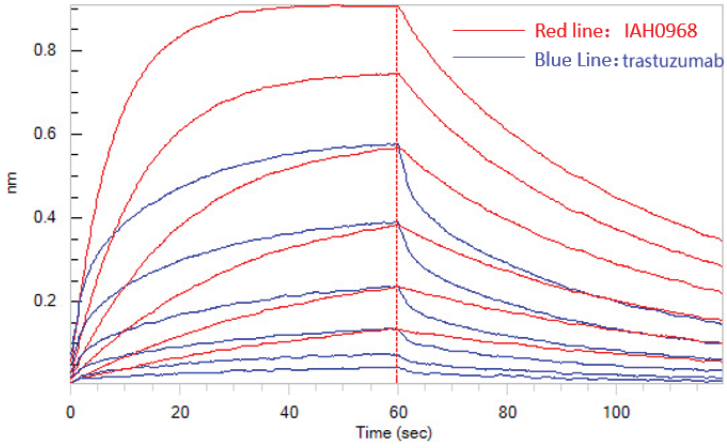
Tumor Cell Lysis by NK Cells Overexpressing CD16a 158F/F



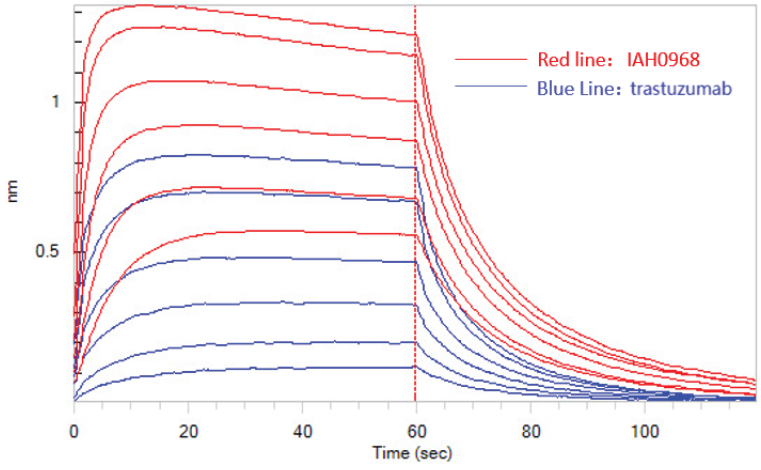
Source: Company data

The binding affinity of IAH0968 and trastuzumab to FcγRIIIa allotypes (158-V and 158-F) was measured. The result showed that IAH0968 increased the binding affinity up to 20-fold comparing to trastuzumab.

Affinity Assay Results of IAH0968 and Trastuzumab with Human CD16a (158-V)

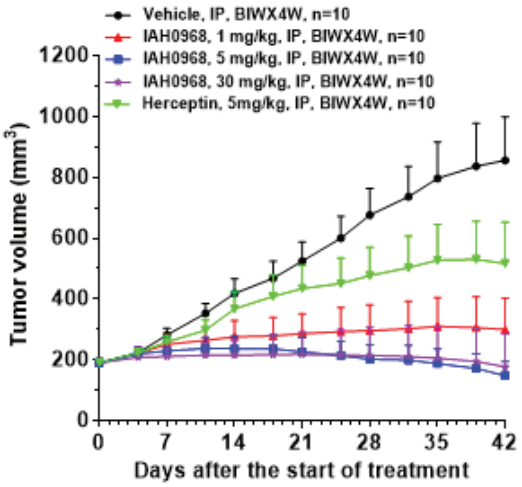


Affinity Assay Results of IAH0968 and Trastuzumab with Human CD16a (158-F)



Source: Company data

An *in vivo* pharmacodynamics study was conducted to evaluate the effects of IAH0968 on a transplanted tumor model using the human breast cancer cell line BT474. The data obtained from the study demonstrated that IAH0968 effectively inhibited tumor growth in mice with BT474 Balb/c subcutaneous transplantation tumors at all three dose levels, and a clear dose-dependent effect was observed. Particularly, at the 5 mg/kg dose and even lower doses (1 mg/kg), IAH0968 exhibited superior efficacy in suppressing tumor growth compared to the control group treated with trastuzumab.



Source: Company data

Safety pharmacology tests demonstrated that a single intravenous injection of IAH0968 at doses ranging from 30-120 mg/kg did not significantly affect the central nervous system function of Sprague Dawley rats. Similarly, intravenous administration of IAH0968 at doses ranging from 30-200 mg/kg had no drug-related effects on body temperature, respiratory parameters, electrocardiogram, and blood pressure in cynomolgus monkeys.

Furthermore, no drug-related toxicity was observed in cynomolgus monkeys (at a dose of 618 mg/kg) and rats (at a dose of 824 mg/kg) after a single administration of IAH0968. With repeated administration of various doses, no immunotoxicity, local irritation, or immunotoxicity was observed in cynomolgus monkeys. The no observed adverse effect level for repeated administration of IAH0968 was determined to be 200/100 mg/kg (twice the initial dose), which significantly exceeded the equivalent effective dose of IAH0968 in mice.

Clinical Development Plan

We are implementing a comprehensive clinical development plan that focuses on a wide range of cancer indications for our IAH0968.

Fast-to-Market Strategy

Our business development plan for IAH0968 includes a fast-to-market strategy of conducting Phase II clinical trials of IAH0968 for HER2+ advanced solid tumors where effective treatment options are scarce or limited, particularly BTC. Our rationale behind these strategic choices is to expedite the regulatory approval process and facilitate the commercial launch of IAH0968.

- 1L HER2+ BTC

According to Frost & Sullivan, there were approximately 63.5 thousand new cases of 1L HER2+ advanced BTC globally in 2022, and the number is projected to reach 84.2 thousand in 2030. In 2022, there were approximately 25.1 thousand new cases of 1L HER2+ advanced BTC in China, and the number is projected to reach 33.1 thousand in 2030. For late stage BTC, the five-year survival rate can be extremely low, at approximately 2%.

BTCs have a poor prognosis due to widespread metastasis and high recurrence rates. Surgery is the primary curative treatment option, but it is only suitable for a small fraction of patients (around 30%) based on the location of the primary tumor. Patients with advanced or unresectable disease rely on chemotherapy, targeted therapy, and immunotherapy. In clinical practice, there is lack of systematic treatment recommendation in the guideline for HER2+ BTC, which accounts for around 20% of BTC patients. In the first-line treatment of BTC, there is no specific drug recommended for HER2+ BTC, indicating a certain lack of treatment options for HER2+ BTC patients.

Our Phase I clinical trial indicated a PR with IAH0968 monotherapy in a heavily pretreated patient with BTC. Namely, a heavily pretreated CCA patient with liver metastases achieved SD at the first efficacy evaluation after two cycles of IAH0968 administration, and then achieved PR at the fourth cycle evaluation. The DCR duration was three months, and the tumor volume continued to shrink.

Given the unmet therapeutic need for HER2-targeted agents in BTC and the potential of IAH0968, we dosed the first patient of a Phase II trial in August 2023 to evaluate the combination of IAH0968 with gemcitabine plus cisplatin as first-line treatment for HER2+ advanced BTC. We plan to submit a BLA of IAH0968 for the treatment of 1L HER2+ advanced BTC to the NMPA in the second half of 2025.

Major Indication

In addition to its potential application in BTC, we are actively assessing the therapeutic efficacy of IAH0968 in the treatment of various other major HER2+ advanced solid tumors, especially CRC.

- 1L HER2+ CRC

CRC is the third most common cancer and the second leading cause of cancer-related deaths globally. According to Frost & Sullivan, there were approximately 50.5 thousand new cases of 1L HER2+ advanced CRC globally in 2022, and the number is projected to reach 64.6 thousand in 2030. In 2022, there were approximately 12.3 thousand new cases of 1L HER2+ advanced CRC in China, and the number is projected to reach 16.0 thousand in 2030. Despite advancements in metastatic CRC treatment, five-year survival rates remain low. For late stage CRC, the five-year survival rate can be approximately 16%. Chemotherapy is the primary treatment, and targeted therapies are limited. HER2 amplification occurs in around 5% of metastatic CRC cases, and clinical trials have demonstrated significant benefits of HER2 blockade in these patients.

On January 19, 2023, the FDA approved the combination of tucatinib and trastuzumab for adult patients with RAS wild-type, HER2+ unresectable or metastatic CRC that has progressed after previous fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy. However currently, there is no specific drug recommended as standard therapy or first-line treatment of HER2+ CRC. In our Phase I clinical trial, IAH0968 monotherapy showed one PR and two SD, resulting in a DCR of 75% among heavily pretreated CRC patients.

Considering the unmet need in CRC and the potential of IAH0968, we dosed the first patient of a Phase II trial in May 2023 to evaluate the combination of IAH0968 with CapeOX (Capecitabine-Oxaliplatin) as first-line treatment in HER2+ advanced CRC patients, and completed patient enrollment in October 2023. We completed the Phase IIa trial in March 2024, and initiated a Phase IIb/III trial in January 2024. We plan to complete the Phase IIb trial in the fourth quarter of 2024, and complete the Phase III trial in the first half of 2026.

Global Strategy

We have formulated a comprehensive global strategy for the clinical development of IAH0968. Leveraging the data collected from the Phase I and Phase II trials, we plan to submit an IND application for IAH0968 in the treatment of selected indications to the FDA in the fourth quarter of 2024. This crucial step will signify our commitment to advancing the development of IAH0968 and bringing a potential therapeutic option to patients worldwide.

Licenses, Rights and Obligations

IAH0968 was developed by us, and we maintain the global rights to develop and commercialize this drug candidate.

Material Communications with Competent Authorities

The material communications with the relevant competent authorities on all ongoing and completed clinical trials in respect of the Core Product IAH0968 are as follows:

- In October 2020, we received the IND approval from the NMPA for conducting Phase I and Phase II clinical trials of IAH0968 in patients with advanced HER2+ malignant solid tumors.

- In September 2022, we received the IND approval from the NMPA for conducting Phase II clinical trials for IAH0968 in combination with gemcitabine and cisplatin in inoperable HER2+ advanced or metastatic BTC as first-line therapy.

- In September 2022, we received the IND approval from the NMPA for conducting Phase II and Phase III clinical trials for IAH0968 in combination with CapeOX (capecitabine + oxaliplatin) in HER2+ metastatic CRC as first-line therapy.

- In September 2023, we conducted an interview with a senior examiner of the NMPA with the attendance of professional parties, which reconfirmed, amongst others, that the Phase I clinical trial of IAH0968 has been completed, and based on the safety and efficacy data from the Phase I clinical trial, that the NMPA had no objection for us to commence the above mentioned Phase II clinical trials of IAH0968.

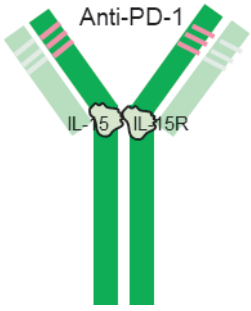
- In December 2023, we conducted a phone interview with the Director of Nanjing Inspection Branch, Jiangsu Provincial Medical Products Administration, which is a provincial branch regulated by the NMPA, with the participation of professional parties (the "**Regulatory Phone Interview**"). During the Regulatory Phone Interview, the Director confirmed that approval of drugs is managed by the approval number, which corresponds to the registration certificate of a drug, and the approval will encompass any different indications or combination therapy approved for marketing. In addition, if there are new indications or combination therapy for a marketed drug, the company can also make a supplemental application, but the company will not receive a new approval number for the same drug. Therefore, the monotherapy and combination therapy of the same drug for different indications, once approved by the NMPA, will be regulated under the same drug certificate in China.

We have not received any concerns or objections from the NMPA related to receiving IND approvals, conducting Phase II clinical trials, or executing any other clinical development plans as of the Latest Practicable Date.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET IAH0968 SUCCESSFULLY

Core Product: IAP0971 (PD-1/IL-15 antibody-cytokine fusion protein)

IAP0971 is a clinical stage, dual-moiety, anti-PD-1 antibody-IL-15/IL-15Rα heterodimer dual T cell/NK cell agonist. It is expected to target the PD-1/PD-L1 signaling pathway to relieve the immunosuppression in the tumor microenvironment ("**TME**"), and in the meantime deliver IL-15 to the tumor, and thus locally activates and enhances antitumor functions of CD8+ T cells and NK cells. The diagram below illustrates the structure of IAP0971:



Source: Frost & Sullivan Report

We implement a global registration strategy for IAP0971. IAP0971 received IND approvals for conducting Phase I and Phase II clinical trials in patients with advanced malignant tumors from both the NMPA and the FDA in January 2022 and December 2021, respectively. The Phase I clinical trial in patients with advanced malignant tumors in China was commenced in June 2022, and has been concluded in July 2023. In addition, we obtained the IND approvals of IAP0971 from the NMPA and the FDA in May 2023 and August 2023, respectively, to conduct Phase I and Phase II clinical trials using IAP0971 monotherapy or in combination with Bacillus Calmette-Guerin ("**BCG**") for high risk BCG-unresponsive NMIBC. We plan to commence a Phase II clinical trial for 2L NSCLC in the second quarter of 2024 and enter a pivotal Phase II clinical stage for BCG-unresponsive NMIBC in the fourth quarter of 2024.

Mechanism of Action

PD-1 immunotherapy is the front-line treatment for many cancer types but with unsatisfactory efficacy in immunosuppressed tumors

An important function of the immune system is its ability to differentiate normal cells from foreign objects (such as germs and cancer cells) so that the immune system will attack foreign objects only without harming normal cells. Part of how the immune system does this is by using "checkpoint" proteins on immune cells. The checkpoints act like switches that need to be turned on or off to start an immune response.

PD-1 is a checkpoint protein on T cells, NK cells, and other types of immune cells. It normally acts as a type of "off switch" that helps keep the T cells from attacking normal cells in the body. It turns off the immune system attacks when it attaches to PD-L1, a protein usually found on antigen presenting cells. When PD-1 interacts with PD-L1, it essentially signals the T cell to refrain from attacking the adjacent cell. But cancer cells sometimes also express PD-L1 on their cell surface in large amounts, which helps them evade attacks from the immune system. mAbs that target either PD-1 or PD-L1 can block this binding and boost the immune response against cancer cells.

There are several PD-1 inhibitors approved by the FDA, including Keytruda, Opdivo and Libtayo. Despite their considerable potential for treating certain cancers, drugs targeting PD-1 still present drawbacks including the substantial number of unresponsive patients and patients showing recurrences, represented by relatively low overall response rate. These drawbacks highlight the need for further improvement of anti-PD-1 therapy.

Cytokine monotherapy can be highly toxic to human body while immunocytokines potentially reduces the systemic toxicity of cytokines

Cytokines are small immunomodulating proteins produced by a broad range of cells, which play an important role in cell signaling to modulate the human immune system. They have long been considered a potential candidate for developing immunotherapy that could reverse the immunosuppressive TME. However, there are several major technical obstacles that greatly hinder its druggability, including short half-life due to its relatively low molecular weight and fast degradation (usually below 30kDa), narrow therapeutic window due to strong agonist effects, and systemic toxicity due to off-target delivery. Therefore, engineering cytokines to have improved therapeutic effects and safety has emerged to address these difficulties.

Immunocytokines demonstrate potential to overcome these challenges. They share a structure in form of an antibody-cytokine fusion protein, which consists of a cytokine moiety fused to a monoclonal antibody or to an antibody fragment. Therefore, they are capable of performing dual functions of preferentially localizing the cytokines on tumor lesions and activate antitumor immunity at the site of disease, and in the meantime increasing the half-life of cytokine through linkage to an antibody moiety. As such, this design can potentially increase the therapeutic window and reduce the systemic toxicity of cytokines.

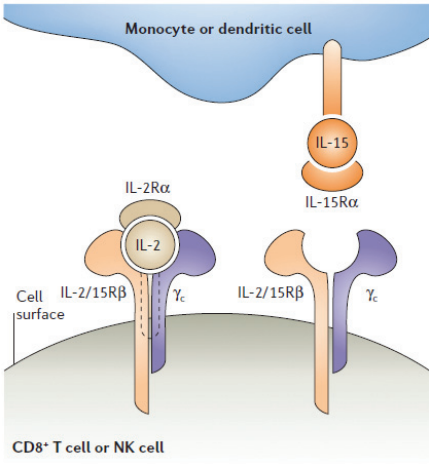
IAP0971, an IL-15-based immunocytokine may provide improved antitumor activity with lower safety risks

Cytokines include several subcategories, including interferons, interleukins and lymphokines. IL-15 is a type of interleukin. It plays a vital role in the regulation of lymphocytes, especially in form of IL-15/IL-15Rα complex. It promotes the proliferation of NK/T cells and inhibits activation-induced cell death of T cells, which can improve the T cell infiltration in tumor tissues and thus potentially address the issues of immune desertification and intrinsic resistance of immunotherapy. IL-15 binds to its receptor IL-15Rα, which

facilitates IL-15 trafficking through the cytoplasm and presentation of IL-15/IL-15Rα complexes on the cell surface. Then, it binds to a receptor complex composed of the IL-2/IL-15Rβ/γ subunits, which are highly expressed on CD8+ T cells and NK cells, to promote the proliferation of NK or T cells.

IL2, the initial cytokine employed in tumor immunotherapy, which has been developed and marketed as cytokine-based therapies like Ontak® and Proleukin®, exhibited promising outcomes in early clinical trials. However, its effectiveness and safety are closely tied to its high affinity receptor, IL2Rα. This receptor, which is predominantly found in Treg cells, competes with T cells for IL-2 binding. Consequently, IL2 exhibits limited efficacy at lower doses and can induce vascular leakage syndrome as a side effect at higher doses.

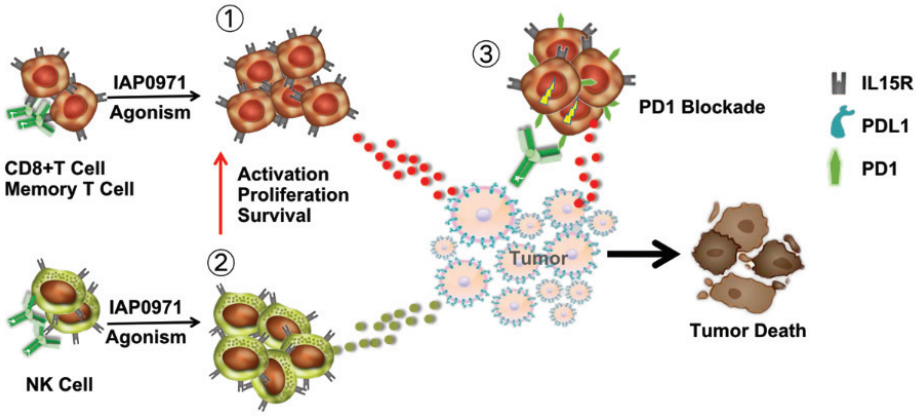
In comparison to IL-2, IL-15 or IL-15-based therapies have not been approved as standalone drugs for distinct clinical use. However, IL-15 possesses structural similarities to IL-2 while offering several unique advantages, making it a potential better candidate for developing cytokine-based therapies. In addition to stimulating immune responses through inducting the proliferation and survival of T cells and promoting the proliferation and differentiation of NK cells, unlike IL-2, it does not promote activation-induced cell death of T cells, and does not promote the maintenance of Tregs, which play the function of suppressing immune response, thereby maintaining homeostasis and self-tolerance. These advantages made IL-15 ranked the first for having the greatest potential for use in cancer immunotherapy by US National Cancer Institute in 2008.



Feature	IL-2	IL-15
Structure	15.5KD, 133AA,4-helix	14-15KD,114AA,4-helix
Producer	Activated T cells	DCs, Macrophages, and Stromal cells
Receptor	IL-2Rα,IL-2Rβ, IL-2Rγ on activated T and B cells	IL-15Rα,IL-2Rβ, IL-2Rγ; DC and Monocytes express IL-15Rα which presents IL-15 to IL-2Rβ, IL-2Rγ expressed on CD8+ T cells and NK cells
Function	Proliferation and differentiation of NK, T and B cells; Treg maintenance and promote AICD (activation-induced cell death) of T cells	Maintenance of CD8+ memory cells and NK cell development; Inhibit AICD of T cells

Source: Thomas Waldmann, Nature Review Immunology, and Company data

IAP0971 is an anti-PD-1 antibody-IL-15/IL-15Rα heterodimer dual T cell and NK cell agonist. It consists of an intact PD-1 antibody and a IL-15/IL-15Rα heterodimer, with the IL-15/IL-15Rα heterodimer being engineered to partially embed into the "hinge" region in the anti-PD-1 antibody. The partial embedded design is expect to balance the activity between PD-1 and IL-15 and to prevent degradation. The heterodimer of IL-15/IL-15Rα utilizes the natural pairing of IL-15 with IL-15Rα together with adopting a knobs-into-holes structure in the Fc region for better heterodimer formation. The anti-PD-1 antibody can thus protect IL-15 from hydrolysis by proteases, decrease the IL-15 activity by steric hindrance, and prolong the half-life of IL-15 without interfering with its target specificity. In addition to this special "protection" function, the anti-PD-1 antibody plays its role as an immune checkpoint inhibitor and blocks the PD-1/PD-L1 signaling pathway to enable T cells to recognize and kill tumors. Specifically targeted to tumor cells by the anti-PD-1 antibody, IL-15 is expected to stimulate CD+8 T cells and NK cells in the local TME without causing systemic cytotoxicity. As such, IAP0971 is expected to be a potent immune system stimulator that can activate both innate and adaptive immunity.



Source: Company data

Similarities and Differences of the Antibody Moiety of IAP0971 Compared to Marketed Anti-PD-1/PD-L1 Antibodies

IAP0971, as an antibody-cytokine fusion protein, comprises both an anti-PD-1 antibody moiety and an IL-15/IL-15Rα complex. In terms of mechanism of action, the anti-PD-1 antibody moiety of IAP0971 functions similarly to marketed anti-PD-1/PD-L1 antibodies by blocking the PD-1/PD-L1 signaling pathway to alleviate T cell immunosuppression. However, structurally, IAP0971 diverges as its heavy chains are distinct, forming a heterodimer through natural pairing, with each heavy chain accommodating either IL-15 or IL-15Rα to form a complex, and through knobs-into-holes mutations on the Fc region, unlike homodimeric monoclonal antibodies on the market. Functionally, IAP0971's anti-PD-1 antibody moiety collaborates with the IL-15/IL-15Rα complex in cis to not only relieve immune suppression but also expand and activate T cells and NK cells, contrasting with other anti-PD-1/PD-L1

antibodies that solely mitigate immune suppression without inducing immune cell expansion, potentially rendering them ineffective against "cold" tumors. For details of the similarities and differences of the antibody moiety of IAP0971 and marketed anti-PD-1/PD-L1 antibodies, see the table below:

A Comparison of the Antibody Moiety of IAP0971 with Marketed Anti-PD-1 and Anti-PD-L1 Antibodies

Categories	IAP0971	Marketed Anti-PD-1 Antibodies			Marketed Anti-PD-L1 Antibodies		
	Anti-PD-1 Antibody Moiety of IAP0971	pembrolizumab	nivolumab	cemiplimab	atezolizumab	avelumab	durvalumab
Similarities							
MoA of the Antibody or Antibody Moiety	Bind to PD-1 protein to block the PD-1/PD-L1 signaling pathway and restore the T cell function from immunosuppressive state.				Bind to PD-L1 protein to block the PD-1/PD-L1 signaling pathway and restore the T cell function from immunosuppressive state.		
Subtype Class	IgG4	IgG4	IgG4	IgG4	IgG1 with glycosylation mutation	IgG1	IgG1 with amino acid alterations
ADCC Effects	No	No	No	No	No	Strong	No
Differences							
Structure	Heterodimer: each of the two heavy chains contains either a IL-15 molecule or IL-15Rα molecule, which will naturally form a IL-15/IL-5Rα complex. The heavy chains also have "knobs-into-holes" amino acid changes.	Homodimer. No "knobs-into-holes" mutations.	Homodimer. No "knobs-into-holes" mutations.	Homodimer. No "knobs-into-holes" mutations.	Homodimer. No "knobs-into-holes" mutations.	Homodimer. No "knobs-into-holes" mutations.	Homodimer. No "knobs-into-holes" mutations.
Antitumor Mechanism	Except for the antitumor effect exerted through blocking the PD-1/PD-L1 pathway, anti-PD-1 antibody moiety is expected to have cis-synergistic effect with IL-15/IL-15Rα complex, expanding and activating T cells and NK cells.	No T cells and NK cells expansion function	No T cells and NK cells expansion function	No T cells and NK cells expansion function	No T cells and NK cells expansion function	No T cells and NK cells expansion function	No T cells and NK cells expansion function
***In Vivo* Efficacy Comparison**	In a head-to-head *in vivo* study in MC38-hPD-L1 C57BL/6 hPD1 mice model, IAP0971 demonstrated significantly improved antitumor effect.	No head-to-head comparison available					

Source: Company data

Market Opportunities and Competition

Based on the efficacy data obtained from the Phase I clinical trial, we believe in the potential of IAP0971 as a viable treatment option for non-small cell lung cancer ("**NSCLC**"). Consequently, we are actively progressing towards initiating Phase II clinical trials in patients with NSCLC. Moreover, we are also developing IAP0971 for the treatment of non-muscle-invasive bladder cancer ("**NMIBC**"), and obtained the IND approvals for this indication from the NMPA and the FDA in May 2023 and August 2023, respectively. In addition, we also plan to expand indications of IAP0971 from oncology to anti-viral infection field, especially for the treatment of HBV. Therefore, in the event that IAP0971 obtains marketing approval, it has the potential to create significant market opportunities in the aforementioned indications.

NMIBC

NMIBC refers to the papillary malignant tumor of the bladder that is limited to the bladder mucosa and lamina propria without muscle invasion. The global market of bladder cancer drugs was US$3.4 billion in 2018. The number is projected to reach US$9.0 billion in 2026 and US$13.9 billion in 2030. In China, the bladder cancer drugs market was US$0.2 billion in 2018, and is projected to grow to US$0.9 billion in 2026 and further to US$2.2 billion in 2030.

For postoperative transurethral resection of bladder tumor ("**TURBT**") in high-risk NMIBC patients, the first-line treatment in China and the U.S. is BCG intravesical instillation or radical cystectomy. Although BCG therapy can control tumor progression, the five-year recurrence rate is as high as 66%. In addition, BCG therapy has a high incidence of adverse reactions, with 62.8%-75.2% of patients developing local complications such as urinary frequency, urgency, hematuria, cystitis, and systemic complications such as fever and diarrhea.

Immunotherapy such as PD-1/PD-L1 inhibitors have been demonstrated with great efficacy in treating NMIBC patients who failed BCG therapy or relapsed, and Keytruda or pembrolizumab monotherapy is approved by the FDA for BCG-unresponsive, high-risk NMIBC. However, there is no such approved drug in China, and patients are at risk of radical cystectomy. Inevitably, for patients who cannot receive BCG therapy due to the shortage of BCG, or do not respond to or become relapsed/refractory ("**R/R**") of current therapies, treatment options are limited. This indicates a significant unmet need. For further details, see "Industry Overview – Immuno-Oncology Drugs Overview – Major Indications for Immuno-Oncology Therapies – NMIBC" in this document.

NSCLC

NSCLC is any type of epithelial lung cancer other than small cell lung cancer. According to Frost & Sullivan, the global market for NSCLC drugs has witnessed significant growth, expanding from US$44.7 billion in 2018 to US$72.9 billion in 2022. Projections indicate further substantial growth, with the market expected to reach US$120.4 billion in 2026 and US$168.2 billion in 2030. Similarly, the China market for NSCLC drugs experienced remarkable expansion, surging from US$3.9 billion in 2018 to US$8.0 billion in 2022. Forecasts suggest continued growth, with the market projected to reach US$17.1 billion in 2026 and US$23.8 billion in 2030.

According to Frost & Sullivan, the current treatments will not meet this tremendous need for NSCLC treatments. For NSCLC patients with EGFR mutations, drug resistance to targeted therapies needs to be addressed. For EGFR wild type NSCLC patients, current treatment options mainly include chemotherapy alone or in combination with antiangiogenic agents like bevacizumab, or PD-1/PD-L1 inhibitors such as pembrolizumab. Nevertheless overall, there is no recommended treatment for NSCLC patients who has failed the first-line treatment. Although PD-1/PD-L1 inhibitors have become the frontline treatment for the majority of EGFR wild type NSCLC patients, medical needs still exist due to low response rates. For further details, see "Industry Overview – Immuno-Oncology Drugs Overview – Major Indications for Immuno-Oncology Therapies – NSCLC" in this document.

HBV Infection

HBV is an infectious disease characterized by inflammation of the liver. The clinical symptoms include loss of appetite, liver pain, and weakness. Chronic HBV infection can lead to serious health issues, like cirrhosis or liver cancer. According to Frost & Sullivan, the number of people infected with HBV is gradually declining due to the vaccination plan. In 2022, the number of HBV infected patients reached 284.7 million globally, and it is expected to drop to 273.7 million in 2026. Similarly, in China, the number of people infected with HBV is also gradually declining. In 2022, the number of HBV infected patients in China reached 69.2 million, and it is expected to drop to 65.1 million in 2026. Nevertheless, since HBV infection still affect a large group of patients, treatment to control the progress of the disease is still in great needs.

According to Frost & Sullivan, the global market for HBV drugs increased from US$15.6 billion in 2018 to US$19.2 billion in 2022 with a CAGR of 5.3% from 2018 to 2022. The number is projected to reach US$26.8 billion in 2026 and US$45.9 billion in 2030 with a CAGR of 8.7% and 14.4% from 2022 to 2026 and from 2026 to 2030, respectively. There was an overall decrease in the China HBV drug market from US$1.9 billion in 2018 to US$1.6 billion in 2022 due to the significant decrease in the price of commonly used HBV drugs and the impact of the COVID-19 epidemic. However, in 2026, the number is projected to reach US$2.9 billion, representing a CAGR of 15.5% from 2022 to 2026. In 2030, the China HBV drug market is projected to reach US$7.4 billion, representing a CAGR of 27.0% from 2026 to 2030.

Competitive Landscape

According to Frost & Sullivan, currently, there is no IL-15-based immunotherapy indicated for the treatment of cancer approved for marketing worldwide. Globally, there are 14 products under clinical development. Among these products, IAP0971 and the other seven product candidates are IL-15 based immunocytokines. In China, there are seven products currently under clinical development, with the most clinically advanced products in Phase I/II stage. Only three products including IAP0971 are IL-15 based immunocytokines, and IAP0971 is the most clinically advanced immunocytokine in China.

Competitive Advantages

Advantage in terms of molecular design

IAP0971 represents a new generation of cytokine-based antibody therapeutics, being an immunocytokine with a structure of an anti-PD-1 antibody IL-15/IL-15Rα cytokine fusion protein developed through our AIC™ Platform. Unlike existing PD-1 antibodies and cytokine-based therapeutic areas, IAP0971 has several distinct advantages:

- **Cytokine selection**. IL-15 is a naturally occurring modulator of the human immune system. Unlike IL-2, IL-15's effective receptor is expressed exclusively on CD8+ T cells and NK cells, which have more direct immune cell activation and proliferative activity.

  IL-2 exerts its antitumor effects by binding to the IL-2/15Rβ and IL-2/15Rγ receptors shared with IL-15 on effector T cells and NK cells. Low doses of IL-2 are limited in efficacy due to its competitive binding to Treg. High doses of IL-2 have toxic side effects such as vascular leakage syndrome. Therefore, the clinical use of IL-2 was greatly limited due to these limitations.

  Compared to IL-2, IL-15 has a stronger antitumor effect. This is due to the fact that IL-15Rα is not expressed on Treg cells, and thus IL-15 cannot activate Treg cells or cause apoptosis of T cells. Moreover, IL-15, through the combination with its receptor IL-15Rα located on monocytes and DCs, can act on CD8+ T and NK cells. This makes IL-15 a preferred candidate for developing antitumor therapies. The latest clinical trial results support the therapeutic potential and druggability of IL-15 in NMIBC. Anktiva (N-803), an IL-15 superagonist, plus BCG was evaluated in a Phase II/III trial in BCG-unresponsive NMIBC. Data indicated that in a cohort of patients with carcinoma *in situ* for whom previous therapies had failed, the CR rate was 71% (95% CI, 59.6%-80.3%).

- **Structure and location of IL-15**. The IL-15/IL-15Rα complex is utilized to enhance the tissue distribution of IL-15 and form an anti-PD-1 antibody/IL-15 immunocytokine that preferentially targets T cells in the TME. In contrast, IL-15 alone primarily binds to dendritic cells expressing IL-15Rα, resulting in a receptor sink effect and greater activation of NK cells with high IL-2/15Rβγ expression. Therefore, by adopting IL-15/IL-15Rα complex, IAP0971 is expected to have an improved safety profile.

  An intact bivalent anti-PD-1 antibody fused with a IL-15/IL-15Rα by incorporating IL-15/IL-15Rα in the middle of the antibody to optimize the spatial block of the IL-15 heterodimer and reduce its biological activity. This balance of bioactivities of anti-PD-1 antibody and IL-15 heterodimer improves the therapeutic window of IAP0971. As demonstrated by the IAP0971 PBMC proliferation assay, the results showed that equimolar IL-15/IL-15Rα heterodimer alone and IAP0971 proliferated

CD8+ T and NK cells at similar rates, but IAP0971 exhibited a 5-10 fold reduction in proliferative capacity. This suggests that IAP0971 retains the function of IL-15/IL-15Rα with further reduced activity and an improved therapeutic window.

By placing the IL-15/IL-15Rα heterodimer on the two heavy chains of the anti-PD-1 antibody separately, IAP0971 can leverage the natural pairing of cytokine and cytokine receptor to avoid heavy chain mismatch of the antibody. Placing the IL-15/IL-15Rα heterodimer in the "hinge" region of the anti-PD-1 antibody improves its stability and reduces protease degradation. IAP0971 expression up to 4 g/L and stability data for 12 months demonstrate the advantages of this structure in terms of druggability.

- **Selection of antibody and *cis*-synergy between anti-PD-1 antibody and IL-15**. The anti-PD-1 antibody's activity is contingent upon IL-15 signaling. The anti-PD-1 antibody and IL-15 work in tandem to produce a *cis* synergistic effect on immune cells. This approach not only effectively alleviates immune suppression in the TME, but it also enhances lymphocyte activation and proliferation. IAP0971 is more effective than anti-PD-1 antibodies alone and can overcome primary and secondary drug resistance associated with anti-PD-1 antibodies.

  PD-1+ CD8+ T cells are abundant in the TME, making the anti-PD-1 antibody in IAP0971 particularly useful. It not only extends the half-life of IL-15 but also provides targeted delivery to improve the safety and efficacy of IL-15 while reducing side effects. PD-L1, on the other hand, is mainly present in tumor cells or DC and myeloid cells, whereas IL-15 functions on CD8+ T and NK cells. Therefore, only the fusion protein of anti-PD-1 antibody and IL-15 can act at the same location and on the same type of cells, producing a synergistic effect. In contrast, neither the combination therapy of anti-PD-1 antibodies and IL-15, nor the anti-PD-L1/IL-15 immunocytokines acts in the same location and on the same type of cells, which cannot achieve *cis*-synergy. Additionally, the anti-PD-1 antibody blocks PD-1/PD-L1 signaling, effectively relieving immunosuppression in the TME. Our preclinical studies showed that IAP0971 improves the therapeutic window by 40-fold compared to IL-15 fusion protein.

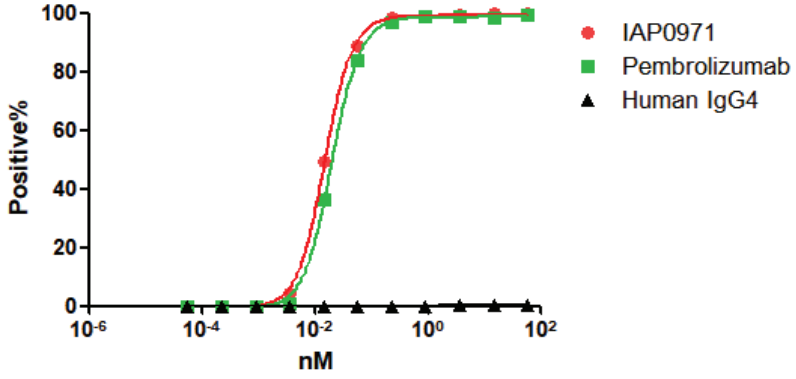
  In summary, the anti-PD-1 antibody moiety of IAP0971 is a humanized variant, the strategic choosing of which for constructing an IL-15 based immunocytokine is driven by several key considerations: Firstly, the combination of anti-PD-1 antibody and IL-15 yields a synergistic effect in *cis*, activating and expanding CD8+ T cells effectively. Secondly, as PD-1+ T cells are predominantly situated in the TME, anti-PD-1 antibodies exhibit heightened efficacy in targeting effector T cells within tumor lesions, thereby exerting a more potent antitumor effect. Thirdly, by incorporating anti-PD-1 antibodies, the issue of IL-15's short half-life can be addressed, leading to its prolonged activity.

- **Structure optimization**. IAP0971 employs the natural pairing of IL-15/IL-15Rα, which leads to more efficient dimerization and eliminates the formation of IL-15 homodimer and half antibody fragments. Additionally, a knobs-into-holes structure is introduced in the Fc region of the anti-PD-1 antibody, further reducing the mismatch of two different heavy chains. These structural designs result in improved productivity of IAP0971.

Our preclinical studies demonstrated the superior efficacy of IAP0971 over standalone anti-PD-1 antibodies, offering potential solutions to the challenges of drug resistance and inefficacy associated with the latter, with its functionalities extensively validated through numerous preclinical studies. These studies encompass assessments such as the efficiency of IAP0971 binding to PD-1 protein and PD-1 overexpressing cell lines *in vitro*, PD-1/PD-L1 blockade assays, PBMC stimulation assays, ADCC assays, and *in vivo* evaluations of antitumor efficacy.

In an *in vitro* preclinical study, binding of IAP0971 and pembrolizumab to PD-1-overexpressing CHO cell line was evaluated by flow cytometry. The results demonstrated that IAP0971 and pembrolizumab showed comparable binding affinity to PD-1.

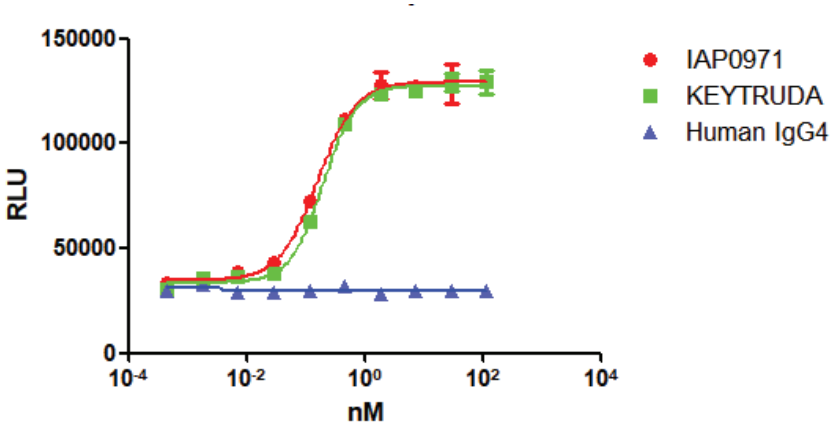
Binding of IAP0971 to CHO-PD-1



Source: Company data

In another *in vitro* preclinical study, Luciferase Reporter assay was used to detect the PD-1/PD-L1 blocking activity of IAP0971. The results showed that IAP0971 can efficiently block the binding of human PD-1 to human PD-L1 and transmit the activation signal of T cells. The blocking activity of IAP0971 was similar to that of pembrolizumab. These results indicated that IAP0971 can release the immune inhibition of PD-1/PD-L1 axis and activate immune effector cells for antitumor activities.

PD-1/PD-L1 Blockade Assay with Luciferase Report

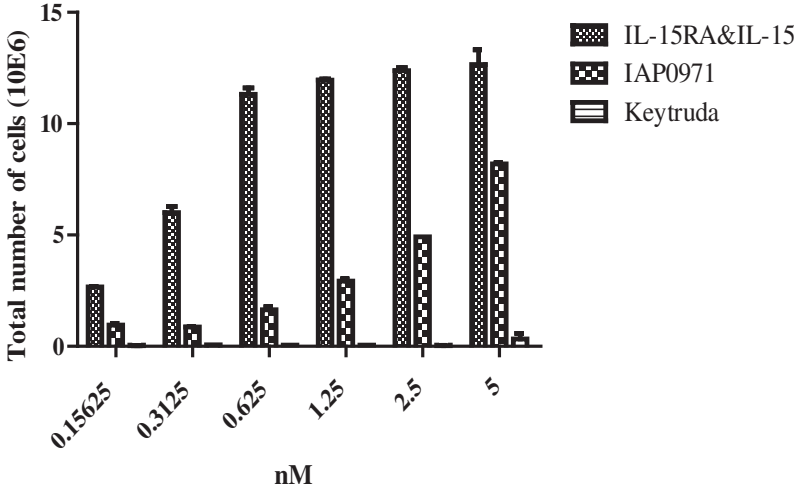


Sample	IAP0971	Pembrolizaumab (KEYRUDA)
EC_{50}(nM)	0.16	0.20

Source: Company data

Our preclinical study also showed that IAP0971 has the PBMC proliferation function. After pre-activation of PBMC with anti-CD3 antibody, stimulation of IAP0971 on PBMC proliferation was detected by the cell counting method. The results showed that IAP0971 and IL-15/IL-15Rα complex could stimulate PBMC proliferation in a concentration dependent manner, which was not observed for pembrolizumab, indicating that the stimulation of IAP0971 on PBMC proliferation depended on the IL-15/IL-15Rα complex in the molecule.

PBMC proliferation-Day12



Source: Company data

Furthermore, our preclinical study showed that IAP0971 was well tolerated and exhibited excellent TGI in MC38-hPD-L1 C57BL/6 hPD1 mice model, superior to the current bestselling anti-PD-1 antibody, Keytruda. For details, see "— Drug Candidates — Core Product: IAP0971 (PD-1/IL-15 antibody-cytokine fusion protein) — Summary of Preclinical Data" in this section.

Although not a head-to-head study, Phase I data also showed that IAP0971 potentially has superior safety and efficacy profiles to N-803, a recombinant IL-15 fusion protein fused with Fc region, indicated for advanced solid tumors when administered subcutaneously.

Phase I data comparison of N-803 and IAP0971

		N-803[1]	**IAP0971**
Registration on ClinicalTrials.gov		NCT01727076	NCT05396391
Indication		Advanced solid tumors	Advanced solid tumors
Route of administration		subcutaneous injection	subcutaneous injection
Dose range		6, 10, 15, 20μg/kg	0.5, 5, 20, 60, 120, 200μg/kg
Dosing frequency		weekly	biweekly
Number of patients		13	15
Safety	Injection site reaction/Infusion related reaction	85%	66.7%
	Hypoalbuminemia	46%	20%
	Anemia	38%	33.3%
	Fever	38%	33.3%
	Lymphocyte count decreased	31%	46.7%
PK		NA	37.08-49.16 hours
Efficacy	Clinical benefits	Single-agent clinical benefit for N-803 was not observed	The disease control rate (DCR) was 36.4%
	NK cell increase	2.3-7.9 fold	22.3-73.7 fold
	CD8 T cell increase	2.7-6.6 fold	9.1-92.3 fold
	CD4 T cell increase	1.6-3.0 fold	4.1-65.4 fold

Abbreviation: NA = not available.

Note:

1. Data for N-803 is from published paper: Clin Cancer Res; 24(22) November 15, 2018.

Source: Company data

As such, IAP0971 has been carefully designed to enhance its biological activity, expand its therapeutic window, optimize its druggability, and improve its production rate. The anti-PD-1 antibody in IAP0971 synergizes with IL-15 to relieve immune suppression in the TME and further activates and proliferates lymphocytes, resulting in a more effective treatment than anti-PD-1 antibodies alone. Additionally, subcutaneous administration of IAP0971 is better tolerated, has a longer half-life than IL-15/IL-15Rα complex Fc fusion protein (N-803), and addresses anti-PD-1 antibody resistance and futility. Overall, IAP0971 is a new therapy for cancer that potentially offers significant advantages over existing treatments.

Favorable safety profile

Based on the preclinical study in cynomolgus monkeys, the half-life of IAP097 spans from 10.5 to 15.7 hours, which is up to approximately two times longer than the half-life of the IL-15/IL-15Rα complex Fc fusion protein (i.e. N-803). In preclinical studies involving repeated subcutaneous dosing of IAP0971 at 1.2 mg/kg, it demonstrated excellent tolerability, surpassing N-803 by nearly 40-fold in dosage. Phase I dose escalation trials have revealed that subcutaneous administration of IAP0971, ranging from 0.5 to 200 μg/kg, was well tolerated by patients and achieved a clinical dose approximately ten times higher than that of N-803.

Superior preliminary efficacy profile

The resistance of anti-PD-1 antibody are mainly attributed to the depletion of immune cells in the TME, and the addition of IL-15 effectively enhances lymphocyte infiltration and numbers in this environment. *In vivo* efficacy data demonstrated that, at the same dose, IAP0971 is significantly more effective than anti-PD-1 antibodies in syngeneic mouse models and remains effective in PD-1-resistant metastatic melanoma models. In the Phase I clinical trial, four heavily pretreated patients including two NSCLC who failed and became resistant to all previous chemotherapy, targeted therapy, immunotherapy, and/or their combination, achieved SD.

Potentially improved efficacy than anti-PD-1 antibodies

The drugability of anti-PD1 antibodies has been thoroughly validated, effectively enhancing efficacy across a wide range of tumors by releasing the brakes on immune checkpoints. However, PD1-targeting antibody drugs still have some limitations, with their efficacy limited to only approximately 20% across various tumor types and facing issues of primary and acquired resistance. Primary resistance is primarily attributed to immune cell desertification in the TME, while acquired resistance is mainly due to immune cell exhaustion. IL-15, on the other hand, can effectively address these two issues. It can efficiently expand and activate CD8+ immune cells, thus addressing the primary resistance issue caused by immune cell desertification. In our preclinical study in the MC38-hPD-L1 C57BL/6 hPD1 mice model, IAP0971 achieved superior tumor inhibition rate (110.47% when treated with 0.5mg/kg of IAP0971 vs. 74% when treated with 0.5mg/kg of anti-PD-1 antibody) and complete tumor regression rate (90% when treated with 0.5mg/kg of IAP0971 vs. 50% when treated with 0.5mg/kg of anti-PD-1 antibody) in our preclinical study.

	IAP0971	An anti-PD-1 antibody
PD-1 binding activity	Similar	Similar
PD-1/PD-L1 blocking activity	Similar	Similar
ADCC activity	No	No
CD8+ T cell and NK cell stimulation activity	Yes	No
Tumor growth inhibition rate at 0.5mg/kg	110.47%	74%
Complete tumor regression rate	90%	50%

Source: Company data

Despite the potential competitive advantages based on the mechanism of action, drug design, preclinical studies, and preliminary clinical data, the successful development of IAP0971 remains highly uncertain, primarily due to the absence of approved IL-15 based immunocytokines. Additionally, whether the anticipated clinical benefits of using anti-PD-1 antibodies in the form of immunocytokines would materialize in targeted patients is still subject to further evaluation and validation in Phase II or later phases of clinical trials.

Summary of Clinical Trial Results

On January 29, 2022 and December 30, 2021, we obtained IND approvals from both the NMPA and the FDA for conducting Phase I and Phase II clinical trials in patients with advanced malignant tumors, respectively. We completed the Phase I clinical trial in July 2023. Based on the Phase I clinical results, upon communication with the principal investigator and without objection from the NMPA, we plan to initiate a Phase II clinical trial for IAP0971 for NSCLC in China in the second quarter of 2024. In addition, we received the IND approval for conducting Phase I and Phase II clinical trials of IAP0971 for NMIBC from the NMPA and the FDA in May 2023 and August 2023, respectively, and dosed the first patient in China in March 2024.

Phase II/III clinical trial of IAP0971 in PD-L1-positive naïve advanced or metastatic NSCLC

Trial Design. This study includes three phases: Phase IIa to evaluate the safety, tolerability and efficacy of IAP0971 for the treatment of subjects with advanced malignant tumors; Phase IIb to evaluate the efficacy of IAP0971 in subjects with driver gene-negative and PD-L1-positive (TPS ≥50%) with naïve advanced or metastatic NSCLC; Phase III to evaluate the efficacy of IAP0971 compared to pembrolizumab for the treatment of subjects with driver gene-negative and PD-L1-positive (TPS ≥50%) naïve advanced or metastatic NSCLC.

Phase IIa of this study is a dose-escalation experiment. We plan to set the starting dose at 400 μg/kg IAP0971, administered every three weeks. The maximum escalating dose is estimated to be at approximately 3000 μg/kg. After the DLT observation is completed in the 3000 μg/kg dose group, we will decide in collaboration with the PI the next step clinical trial design based on whether the MTD is reached considering the collected preliminary safety data.

Phase IIb of this study is a single-arm, open label, multicenter study. 20 to 30 treatment-naïve, driver gene-negative and PD-L1-positive (TPS ≥50%) subjects with advanced or metastatic NSCLC will be enrolled at the RP2D dose determined in Phase IIa. Each treatment cycle will be three weeks until withdrawal or termination.

Phase III of this study is a randomized, parallel-controlled, open label, multicenter study. Driver gene-negative and PD-L1-positive (TPS ≥50%) subjects with advanced or metastatic NSCLC will be enrolled to receive IAP0971 at the RP2D dose established in Phase IIa. Each treatment cycle will be three weeks until withdrawal or termination.

The primary endpoint of Phase IIa of this study is safety. The primary endpoint of Phase IIb/III is PFS. Secondary endpoints of Phase IIa include pharmacokinetic ("**PK**") portfolio, immunogenicity, biomarkers and preliminary efficacy. Secondary endpoints of Phase IIb/III include ORR, disease control rate ("**DCR**"), OS, adverse events ("**AE**") and serious adverse events ("**SAE**"), and ADA.

Trial Status. We plan to initiate the Phase II clinical trial in the second quarter of 2024.

Phase I clinical trial in patients with advanced malignant tumors

Trial Design. This trial was a Phase I, open-label study designed to characterize the safety, tolerability, and preliminary effectiveness of IAP0971 in patients with advanced malignant tumors. This trial was conducted in China according to a protocol approved by both the NMPA and the FDA. This study includes two phases: the dose escalation, followed by the dose extension with reference to the MTD dose achieved from the dose escalation study.

As of the cut-off date (June 29, 2023), a total of 18 patients have been enrolled. The dose escalation study was initiated with 0.5μg/kg, 5μg/kg and 20μg/kg, and switched to 3+3 scheme starting from 60μg/kg, and then 120μg/kg and 200μg/kg every-other-week ("**Q2W**") subcutaneously. The primary objective of Phase I trial was to determine the MTD, DLT, and the incidence and frequency of AEs and SAEs. The secondary objectives included assessing PK portfolio, and immunogenicity of IAP0971.

Trial Status. We completed the Phase I clinical trial of IAP0971 in July 2023.

Safety Profile. As of the cut-off date (June 29, 2023), TRAEs were observed in 12 out of 15 assessable patients, accounting for a rate of 80.0%. The majority of these adverse events were classified as Grade 1-2, indicating mild to moderate severity. Grade 3-4 TRAEs were reported in seven patients, representing 46.7% of the cohort. These included lymphocytopenia (seven patients), fever (one patient), hyperbilirubinemia (one patient), intestinal infection (one patient), and amylase increased (one patient). For all the lymphocytopenia patients, they recovered after a period of observation without any medicine treatment. Furthermore, no DLTs were observed, and the MTD was not reached.

TRAEs occurring in ≥10% of patients or ≥ Grade 3 TRAEs

	All patients (N=15)	
	All grades, n (%)	≥Grade 3, n (%)
Any TRAE	12(80)	7(46.7)
TRAE in ≥10% of patients by preferred term and ≥ Grade 3 TRAEs		
Infusion related reaction	10(66.7)	0
Lymphocytopenia	7(46.7)	7(46.7)
Leukocytopenia	5(33.3)	0
Anaemia	5(33.3)	0
Fever	5(33.3)	1(6.6)
Thrombocytopenia	4(26.6)	0
Elevated AST	3(20)	0
Elevated ALT	3(20)	0
Hypoalbuminemia	3(20)	0
CRS	2(13.3)	0
Neutropenia	2(13.3)	0
Hyperbilirubinemia	2(13.3)	1(6.6)
Elevated γ-GT	2(13.3)	0
Cough	2(13.3)	0
Elevated amylase	1(6.6)	1(6.6)
Intestinal infection	1(6.6)	1(6.6)

Abbreviations: TRAE = treatment-related adverse event; CRS = cytokine release syndrome.

Note: Data cut-off: June 29, 2023; AEs graded according to NCI CTCAEv.5.0.

Source: Company data

Efficacy Profile. As of June 29, 2023, a total of 15 subjects were assessed in the study, of which eleven subjects were considered evaluable for efficacy analysis. Evaluable subjects were defined as those who had undergone at least one tumor assessment after baseline. Preliminary efficacy findings demonstrated that out of the eleven evaluable subjects, four heavily pretreated patients who failed and became resistant to all previous chemotherapies/immunotherapies (one with colorectal cancer ("**CRC**"), one with cervical cancer, and two with NSCLC) achieved stable disease. This resulted in a DCR of 36.4%.

The table below provides a detailed overview of the previous treatment profiles for patients who achieved a best response of SD.

Group	Patient	Previous Treatment	Efficacy
20μg/kg	CRC with combined lung metastases, bone metastases and pleural effusion	Resistant to oxaliplatin and capecitabine in the front-line treatment, followed by irinotecan + raltitrexed + bevacizumab + cetuximab	Achieved SD in the first evaluation after two cycles of IAP0971 administration
120μg/kg	Cervical cancer with combined pelvic metastases	Resistant to radiotherapy combined with nedaplatin chemotherapy, paclitaxel liposome combined with carboplatin chemotherapy, paclitaxel liposome combined with sintilizumab monoclonal antibody therapy, docetaxel combined with sintilizumab, docetaxel combined with cisplatin chemotherapy, oral apatinib combined with capecitabine treatment, and tireprizu combined with anlotinib and tegio capsules	Achieved SD in the first evaluation after two cycles of IAP0971 administration
120μg/kg	NSCLC with lung, adrenal gland and other (retroperitoneal/ right abdominal sulcus) metastases	Resistant to pemetrexed + lobaplatin + endostar chemotherapy; pemetrexed + nedaplatin + endostar chemotherapy; paclitaxel liposome + gemcitabine + endostar chemotherapy; camrelizumab + paclitaxel liposome + gemcitabine; camrelizumab + docetaxel + gemcitabine; camrelizumab + albumin paclitaxel; camrelizumab + gemcitabine; camrelizumab combined with erlotinib; sintilizumab + irinotecan + cisplatin + bevacizumab; sintilizumab + irinotecan + bevacizumab + carboplatin; the combination of sintilizumab + bevacizumab and vinorelbine	Achieved SD in the first evaluation after two cycles of IAP0971 administration

Group	Patient	Previous Treatment	Efficacy
200μg/kg	Adenocarcinoma of right lung with lung and other (pleura, pleural effusion) metastases	Resistant to intrathoracic infusion of bevacizumab; pemetrexed combined with cisplatin and bevacizumab; gefitinib combined with bevacizumab, and then changed to albumin-paclitaxel combined with nedaplatin chemotherapy; erlotinib and then osimertinib	Achieved SD at first efficacy evaluation after two cycles of IAP0971 administration

Abbreviations: CRC = colorectal cancer; NSCLC = non-small cell lung cancer; SD = stable disease.

Note:

Data cut off on June 29, 2023.

Source: Company data

Conclusion. Based on the data from this clinical trial, IAP0971 has demonstrated a favorable profile in terms of both safety and preliminary efficacy in heavily pretreated patients with advanced malignant tumors. Our safety data also shows IAP0971 can be given safely in subjects up to 200ug/kg Q2W subcutaneously.

Phase I clinical trial in NMIBC patients who have failed BCG treatment, and are considered unsuitable for radical cystectomy, or choose not to undergo the procedure

Trial Design. This is a single-arm, open label, multicenter Phase I clinical trial to evaluate the safety and efficacy of IAP0971 monotherapy or in combination with BCG therapy. This clinical trial will be conducted in China according to the protocol approved by both the NMPA and the FDA. Phase Ia of this study to evaluate IAP0971 as a monotherapy adopts the classic "3+3" dose-escalation design, with three to six assessable NMIBC patients who are non-responsive to or relapsed on BCG treatment included in each group. Phase Ib of this study adopts a similar design to evaluate IAP0971 in combination with BCG therapy. Administration method in both stages is intravesical instillation.

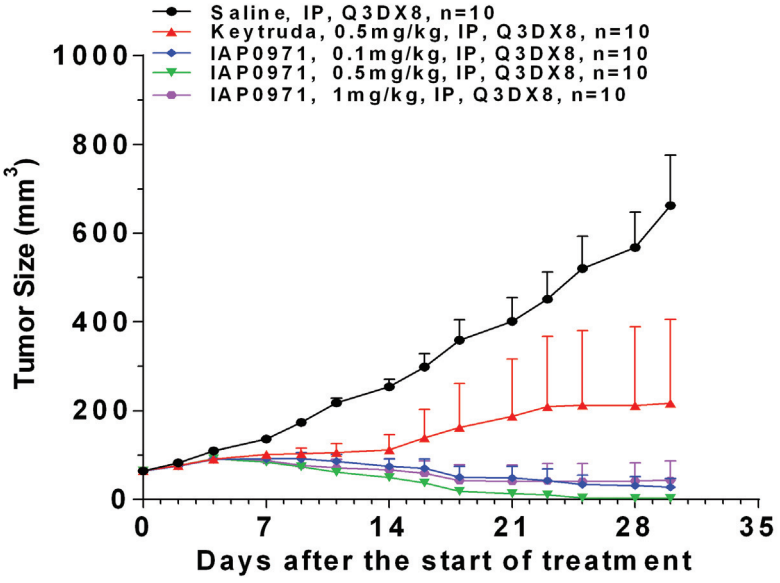
Primary endpoints of this study are the occurrence of AEs and DLT. Secondary endpoints include CR rate, DoR, disease free survival, PFS, time to cystectomy, and radical cystectomy rate.

Trial Status. We obtained the IND approval from the NMPA and the FDA in May 2023 and August 2023, respectively, with the first patient being dosed in China in March 2024.

Summary of preclinical study

In pharmacokinetic analysis, IAP0971 showed a half-life of 15.7 hours, which is approximately 15-fold longer than that of recombinant IL-15, and approximately 2-fold longer than that of an IL-15-Fc fusion protein. In addition, IAP0971 was also well tolerated up to 1.0 mg/kg when subcutaneously administered in the mouse model. In the repeated-dose toxicity study in cynomolgus monkeys, IAP0971 showed a favorable safety profile even at 1.2 mg/kg, around 40-fold higher than an IL-15-Fc fusion protein.

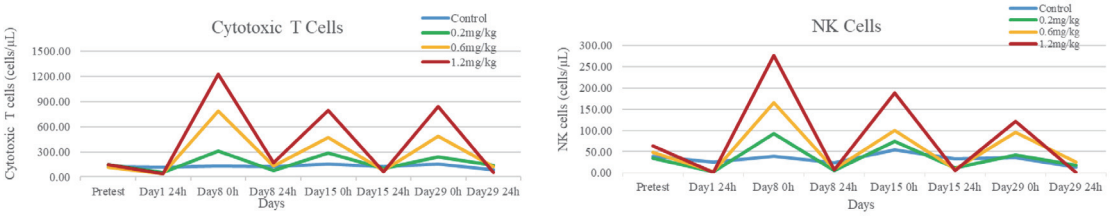
Our preclinical study showed that IAP0971 was well tolerated and exhibited excellent TGI in MC38-hPD-L1 C57BL/6 hPD1 mice model. IAP0971 was shown to be more effective in inhibiting tumor growth than Keytruda in the murine model. When intraperitoneally injected with 0.1mg/kg, 0.5mg/kg and 1mg/kg of IAP0971 every three days ("**Q3D**"), MC38-hPD-L1 C57BL/6 hPD1 mice showed significantly improved TGI comparing to 0.5 mg/kg Keytruda alone intraperitoneally injected Q3D. Data showed that at 0.1 mg/kg, 0.5 mg/kg and 1 mg/kg, IAP0971 demonstrated remarkable TGI rates of 106.13%, 110.47%, and 103.56%, respectively. Specifically, in the 0.1 mg/kg group, eight animals treated with IAP0971 achieved complete tumor regression, in the 0.5 mg/kg group, nine animals experienced complete response after treatment with IAP0971, and in the 1 mg/kg group, nine animals achieved complete tumor regression. The IAP0971 0.5 mg/kg group displayed superior tumor inhibition compared to the Keytruda 0.5 mg/kg group (110.47% when treated with 0.5mg/kg of IAP0971 vs. 75% when treated with 0.5mg/kg of Keytruda) and complete tumor regression rate (90% when treated with 0.5mg/kg of IAP0971 vs. 50% when treated with 0.5mg/kg of Keytruda).



Source: Company data

In another preclinical study conducted in cynomolgus monkeys, we specifically investigated the impact of IAP0971 on the proliferative activity of immune cells. The collected data revealed the effectiveness of IAP0971 in promoting the proliferation of CD8+ T lymphocytes and NK cells at various doses. Elevated levels of lymphocytes were sustained even seven days after the initial dose.

Proliferation of Cytotoxic T Cells and NK Cells after IAP0971 Dosing



Source: Company data

Conclusion. Based on the preclinical studies, IAP0971 demonstrates not only the biological activity of targeting a single pathway but also the advantageous dual-target synergistic effect. It not only activates T-cells but also stimulates NK-cell activation, enabling effective tumor cell growth inhibition.

Clinical Development Plan

We are executing a comprehensive clinical trial development plan in China and the U.S. targeting an array of cancer indications for our IAP0971. Our clinical development plan for IAP0971 involves first targeting an indication of significant unmet medical needs so that to quickly launch it on the China market, and then further expanding its potential application to major indications and other treatment areas to fully explore its potential.

Fast-to-Market Strategy

- 2L/3L BCG-unresponsive high risk NMIBC

According to Frost & Sullivan, globally, there were approximately 118.9 thousand new cases of 2L BCG-unresponsive high risk NMIBC in 2022, and the number is projected to reach 155.5 thousand in 2030. The number of new cases of 3L BCG-unresponsive high risk NMIBC was 64.2 thousand in 2022, and is anticipated to grow to 84.0 thousand in 2030. In China, there were approximately 25.7 thousand new cases of 2L BCG-unresponsive high risk NMIBC in 2022, and the number is projected to reach 34.1 thousand in 2030. The number of new cases of 3L BCG-unresponsive high risk NMIBC was 13.9 thousand in 2022, and is anticipated to grow to 18.4 thousand in 2030. The five-year survival rate of BCG-unresponsive high risk NMIBC is 72%.

Intravesical instillations with BCG have served as an established adjuvant therapy for NMIBC. Currently, the administration of intravesical BCG instillations subsequent to transurethral resection of the bladder tumor represents a crucial component of standard care for patients diagnosed with high-risk NMIBC. Although BCG is more effective than chemotherapy in patients with high-risk NMIBC, non-responsiveness to BCG treatment is observed in over 40% of this patient population, and 15% of them will progress to a muscle-invasive disease.

Immunotherapy has long been recognized as a viable approach in the management of NMIBC. According to Frost & Sullivan, anti-PD-1 antibody is considered a promising therapy for the treatment of 2L/3L BCG-unresponsive high risk NMIBC, with the complete response rate ("**CRR**") being approximately 41%. In January 2020, Keytruda monotherapy was approved by the FDA for BCG-unresponsive carcinoma *in situ* ("**CIS**") patients with high-risk NMIBC. In addition, N-803, an IL-15/IL-15Rα complex fused to an IgG1 Fc, in combination with intravesical BCG was examined and also achieved encouraging clinical results as a potential treatment for BCG-unresponsive NMIBC. Although the FDA did not approve the BLA of N-803 according to its complete response letter on May 9, 2023, the deficiencies are not safety or efficacy in nature but relate to third-party contract manufacturing organizations and CMC issues. In addition, in October 2023, the FDA accepted the resubmitted BLA of N-803 and set a new Prescription Drug User Fee Act date for April next year.

Given that Keytruda was approved by the FDA and N-803 combined with BCG has demonstrated its potential in treating BCG-unresponsive high risk NMIBC patients, and based on the fact that IAP0971 combines the targets from both drugs and accordingly is expected to have the full potential of these two drugs, we plan to conduct a Phase I trial in 2L/3L BCG-unresponsive NMIBC in China. We have obtained the IND approval for conducting Phase I and Phase II clinical trials from the NMPA and the FDA in May 2023 and August 2023, respectively, enrolled the first patient of the Phase I clinical study in China in March 2024, and expect to start a pivotal Phase II trial in the fourth quarter of 2024.

Major Indications

- 1L/2L Advanced NSCLC

We are currently assessing the potential of IAP0971 as a monotherapy for highly prevalent cancer types. In recent years, anti-PD-1 antibodies have become the standard of care for various tumor types. It can be expected that there will be urgent medical needs for effective treatments targeting PD-1/PD-L1 R/R tumors. Given the demonstrated efficacy of PD-1 and IL-15 combination therapy following PD-1 immunotherapy across different tumor types, we anticipate that IAP0971, as a PD-1/IL-15 immunocytokine, holds clinical potential for treating cancer types with significant unmet medical needs, particularly PD-1/PD-L1 R/R tumors.

According to Frost & Sullivan, globally, there were approximately 1,329.6 thousand new cases of 1L advanced NSCLC in 2022, and the number is projected to reach 1,709.3 thousand in 2030. The number of new cases of 2L advanced NSCLC was 930.7 thousand in 2022, and is anticipated to grow to 1,196.5 thousand in 2030. In China, there were approximately 561.7

thousand new cases of 1L advanced NSCLC in 2022, and the number is projected to reach 733.6 thousand in 2030. The number of new cases of 2L advanced NSCLC was 393.2 thousand in 2022, and is anticipated to grow to 513.5 thousand in 2030. See "Industry Overview — Immuno-Oncology Drugs Overview — Major Indications for Immuno-Oncology Therapies — NSCLC" in this document for further information regarding the patient population for 1L advanced non-squamous NSCLC and 2L advanced squamous NSCLC. For advanced NSCLC, the five-year survival rate can be extremely low, at approximately 9%. Anti-PD-1 antibody is considered a promising therapy for the treatment of 1L/2L NSCLC. For 1L advanced NSCLC, the ORR is 27% in tumors with as low as 1% expressing PD-1, i.e. a tumor proportion score ("**TPS**") ≥1%. For 2L advanced NSCLC, the ORR is 18% in PD-1 positive tumors with TPS ≥1%.

In treating NSCLC, we plan to explore both monotherapy and combination therapy, and investigate IAP0971 through subcutaneous administration. In the context of monotherapy, our focus is on investigating the potential of IAP0971 as a treatment for 2L advanced NSCLC. We plan to conduct a Phase II clinical trial of IAP0971 for locally advanced unresectable or metastatic NSCLC patients as second-line treatment, and enroll the first NSCLC patient in the second quarter of 2024.

In addition, we plan to explore IAP0971 in combination with pemetrexed and platinum in 1L non-squamous NSCLC as first-line treatment. The efficacy and safety profile demonstrated in our Phase I clinical trial of IAP0971, along with encouraging outcomes in trials combining anti-PD-1/PD-L1 antibodies with chemotherapy, support our approach. We plan to submit an IND application and after receiving the approval, enroll the first patient in a Phase II clinical trial of IAP0971 in the third quarter of 2024.

Indication Expansion to Anti-Viral Infection

- Chronic HBV Infection

In addition to exploring IAP0971's potential in oncology, we plan to examine IAP0971 as an immunotherapy for the treatment of viral infectious diseases, especially hepatitis B, which is one of the most prevalent infectious diseases in China, according to the National Health Commission. According to Frost & Sullivan, there were approximately 8,978.3 thousand new cases of chronic HBV infection globally in 2022, and the number is projected to reach 21,503.2 thousand in 2030. In 2022, there were approximately 2,182.3 thousand new cases of chronic HBV infection in China, and the number is projected to reach 4,993.0 thousand in 2030. The five-year survival rate of chronic HBV infection is approximately 89%.

In chronic viral hepatitis, upregulation of PD-1 and CTLA-4 is associated with T-cell exhaustion and persistent viral infection, favoring the chronicity of viral disease but limiting immunopathogenesis. Therefore, ICIs, including anti-PD-1 inhibitor, can potentially improve T-cell function by blocking PD-1-mediated signaling, a pathway that is confirmed to play an important role in inducing T-cell exhaustion. According to Frost & Sullivan, currently, there is no approved PD-(L)1 inhibitors indicated for HBV. However, ASC22, a PD-L1 antibody, has

shown potential for curing CHB patients. Data from Phase IIa clinical trials showed a dose-dependent decline in hepatitis B surface antigen after a single dose of ASC22. In addition, an exploratory Phase I clinical trial of N-803 for HIV infection has shown that N-803 was associated with proliferation and/or activation of CD4+ and CD8+ T cells and natural killer cells. Therefore, IAP0971 can potentially alleviate the T-cell exhaustion through the activation of both innate and adaptive immunity in patients with chronic HBV infection. We plan to submit an IND application for a Phase I clinical trial for chronic HBV infection in the third quarter of 2024 to explore IAP0971's anti-viral infection potential.

Global Strategy

We are carrying out a global strategy in the clinical development of IAP0971. In the U.S., we have obtained an IND approval for investigating IAP0971 as a monotherapy in advanced malignant tumors in December 2021. Because the Phase I and Phase II clinical trial designs approved by the NMPA and the FDA are the same including the site (located in China) and PI of the clinical trial, we plan to leverage the clinical data from the Phase I trial in China, carefully decide our clinical development plan in the U.S., communicate with the FDA regarding the Phase II clinical trial design, and upon reaching an agreement with the FDA regarding the trial design, initiate Phase II clinical trials for selected tumor types in the U.S. according to the FDA approved clinical trial design either by ourselves or through international collaboration. Alternatively, depending on the specific clinical stage and therapeutic regimen we carefully decide upon in the future, we will submit a new IND application to the FDA when new IND approval is required. Considering the costs, we decided to proceed with clinical trials in China first. As of the Latest Practicable Date, we had not commenced the clinical trials in the U.S. and had not planed to commence the trials in the U.S. within the coming six months.

Although the FDA has issued the IND approval and accepted that Phase I and Phase II clinical trials of IAP0971 can be conducted in China, we cannot guarantee that the FDA will accept our clinical results generated in China to support future clinical trials in the U.S., and we may face difficulties and incur additional costs thereof. For details, see "Risk Factors — Risks Relating to Government Regulations — We Primarily Conduct Clinical Trials for Our Drug Candidates in China, While FDA or Comparable Foreign Regulatory Authorities May Not Accept Data From Such Trials" in this document.

Licenses, Rights and Obligations

IAP0971 was developed by us, and we maintain the global rights to develop and commercialize this drug candidate.

Material Communications With Competent Authorities

The material communications with the relevant competent authorities on all ongoing and completed clinical trials in respect of the Core Product IAP0971 are as follows:

- In December 2021, we received the IND approval from the FDA for conducting Phase I and Phase II clinical trials of IAP0971 in patients with advanced malignant tumors.

- In January 2022, we received the IND approval from the NMPA for conducting Phase I and Phase II clinical trials of IAP0971 in patients with advanced malignant tumors.

- In May 2023, we received the IND approval of IAP0971 from the NMPA to conduct Phase I and Phase II clinical trials using IAP0971 monotherapy or in combination with BCG for high risk BCG-unresponsive NMIBC.

- In August 2023, we received the IND approval of IAP0971 from the FDA to conduct Phase I and Phase II clinical trials using IAP0971 monotherapy or in combination with BCG for high risk BCG-unresponsive NMIBC.

- In September 2023, we conducted an interview with a senior examiner of the NMPA with the attendance of professional parties, which reconfirmed, amongst others, that the Phase I clinical trial of IAP0971 has been completed, and based on the safety and efficacy data from the Phase I clinical trial, that the NMPA had no objection for us to commence a planned Phase II clinical trial of IAP0971 as a monotherapy for locally advanced unresectable or metastatic NSCLC.

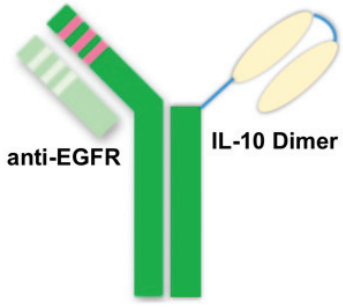
- In December 2023, we conducted a phone interview with the Director of Nanjing Inspection Branch, Jiangsu Provincial Medical Products Administration, which is a provincial branch regulated by the NMPA, with the participation of professional parties (the "**Regulatory Phone Interview**"). During the Regulatory Phone Interview, the Director confirmed that approval of drugs is managed by the approval number, which corresponds to the registration certificate of a drug, and the approval will encompass any different indications or combination therapy approved for marketing. In addition, if there are new indications or combination therapy for a marketed drug, the company can also make a supplemental application, but the company will not receive a new approval number for the same drug. Therefore, the monotherapy and combination therapy of the same drug for different indications, once approved by the NMPA, will be regulated under the same drug certificate in China.

We have not received any concerns or objections from the NMPA or the FDA related to receiving IND approvals, conducting the Phase II clinical trial, or executing our clinical development plans as of the Latest Practicable Date.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET IAP0971 SUCCESSFULLY

Core Product: IAE0972 (EGFR/IL-10 antibody-cytokine fusion protein)

IAE0972 is a clinical stage, dual-moiety, anti- EGFR antibody-IL-10 homodimer bifunctional fusion protein for immune cell activation. It is designed to bind to EGFR and trigger blockage of downstream signaling pathways that contribute to cell death suppression and promote cell proliferation, and deliver IL-10 to activate CD8+ T cells in the TME. The diagram below illustrates the structure of IAE0972:



Source: Company data

We implement a global registration strategy for IAE0972. We received IND approvals for conducting Phase I and Phase II clinical trials of IAE0972 for advanced solid tumors from the NMPA and the FDA in January 2022 and December 2021, respectively, and commenced the Phase I clinical trial in June 2022. In July 2023, we completed the Phase I clinical trial of IAE0972 in patients with advanced solid tumors in China. We have initiated a Phase II clinical trial of IAE0972 as monotherapy in China, and enrolled the first HNSCC patient and the first CRC patient in July 2023 and December 2023, respectively. In addition, we received the IND approval from the NMPA for conducting Phase II and Phase III clinical trials of IAE0972 in combination with lenvatinib in patients with locally advanced or metastatic HCC as first-line treatment in November 2023. We expect to commence a Phase II clinical trial for HCC in the second quarter of 2024.

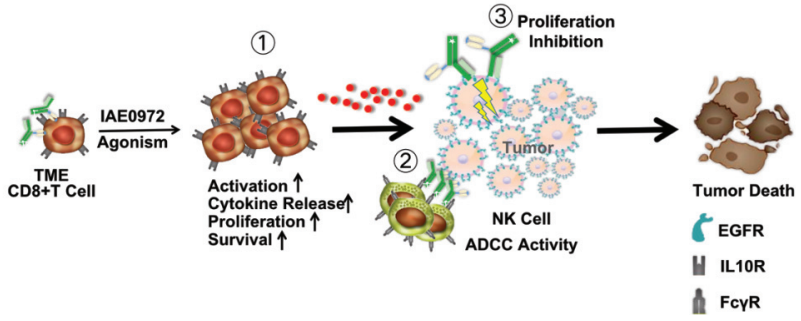
Mechanism of Action

IL-10 is one group of cytokines mainly produced by activated macrophages and certain T lymphocytes. It is a noncovalent homodimer in its natural form. IL-10 interacts with its receptor IL-10R, which is expressed on the surface of most hematopoietic cells, including T cells, B cells, and macrophages. Upon binding, IL-10 will be able to activate tumor-infiltrating memory-killing CD8+ T cells and even reactivate terminally exhausted T cells, and potentially NK cells and thereby convert the immunosuppressive TME into pro-inflammatory TME. In addition, IL-10 has strong antitumor activities and primarily acts on the TME, which reduces systemic cytotoxicity and is considered relatively safe among cytokines, producing immune cell activation and significant alterations in host physiology. It is because that naïve T cells in

peripheral have very low IL-10R expression, while antigen-specific tumor infiltrating and memory T cells in the TME have high IL-10R. Therefore, treatment strategies involving IL-10 may represent a potential solution for patients who suffer from primary or acquired drug resistance to immunotherapies, especially acquired drug resistance to immune checkpoint inhibitors caused by T cell exhaustion.

EGFR is a receptor tyrosine kinase involved in the proliferation and survival of cancer cells, and it is overexpressed in many cancer types including head and neck, breast, lung, colorectal, prostate, kidney, pancreas, ovary, brain and bladder cancer. The EGFR is activated via extracellular ligand binding, inducing phosphorylation of specific residues of the EGFR. This in turn will activate several downstream signaling pathways and finally promote or regulate cell proliferation, differentiation, invasion, angiogenesis and avoidance of apoptosis.

IAE0972 is an immunocytokine consisting of an anti-EGFR antibody fragment and an IL-10 homodimer. It adopts an asymmetric structure, which consists of a monovalent anti-EGFR antibody fragment and a homodimer of IL-10. Such a design is expected to reduce the binding activity of anti-EGFR antibody on EGFR-low expression normal cells while preserving the biological activity on EGFR-high expression tumor cells and thus reduce EGFR-related skin toxicities. The anti-EGFR antibody fragment targets EGFR and inhibits tumor growth through blockage of the EGFR signaling pathway. It also serves as a tumor-associated antigen for tumor-targeted delivery of IL-10 to EGFR-positive tumor cells. As such, IAE0972 activates the CD8+ T cells and potentially NK cells and direct them to the targeted local tumor lesion and reduces the skin toxicity commonly observed for IL-10-based treatment. By linking to the IL-10 homodimer, the antibody fragment portion also extends the half-life of IL-10 and therefore prolongs the therapeutic window of IAE0972.



Source: Company data

Similarities and Differences of the Antibody Moiety of IAE0972 Compared to Marketed Anti-EGFR Antibodies or Those in Clinical Trials

IAE0972, as an antibody-cytokine fusion protein, combines an anti-EGFR antibody with an IL-10 homodimer. Compared to the marketed anti-EGFR antibodies or those in clinical trials, IAE0972 shares a similar mechanism of action in which the anti-EGFR antibody targets and blocks the EGFR protein on tumor cells, thereby inhibiting their growth. However, IAE0972 differs in that its anti-EGFR antibody is monovalent, aimed at reducing the risk of skin toxicity. Structurally, it forms heterodimers using a "knobs-into-holes" structure, while current anti-EGFR antibodies, whether marketed or in clinical trials, are homodimers. Additionally, IL-10 within IAE0972 functions as an EGFR-specific T cell activator, enhancing its antitumor efficacy. These distinctions highlight the unique attributes of IAE0972, as outlined in the table below.

A Comparison of the Antibody Moiety of IAE0972 with Marketed Anti-EGFR Antibodies and Selected Ones in Clinical Trials

Categories	IAE0972	Marketed Anti-EGFR Antibodies or Selected Ones in Clinical Trials			
	Anti-EGFR Antibody Moiety of IAE0972	cetuximab	matuzumab	panitumumab	necitumumab
Similarities					
MoA of the Antibody or Antibody Moiety	Binds to the EGFR protein on the surface of tumor cells to block tumor cell growth signals; targets the tumor microenvironment				
Subtype Class	IgG1	IgG1	IgG1	IgG2	IgG1
Differences					
Antibodies' Valency	Monovalent to reduce the toxicity to skin	Bivalent	Bivalent	Bivalent	Bivalent
Structure	Heterodimer. The heavy chains have "knobs-into-holes" amino acid changes.	Homodimer. No "knobs-into-holes" mutations.	Homodimer. No "knobs-into-holes" mutations.	Homodimer. No "knobs-into-holes" mutations.	Homodimer. No "knobs-into-holes" mutations.
Antitumor Mechanism	Simultaneously binds to EGFR and IL-10 to activate T cells in the TME	No TME-specific T cell activation	No TME-specific T cell activation	No TME-specific T cell activation	No TME-specific T cell activation
In Vivo Effect	In a head-to-head in vivo study in the C57BL/6 mouse allograft tumor model, IAE0972 demonstrated significantly improved antitumor effect.	No head-to-head comparison available			

Market Opportunities and Competition

Based on the preliminary efficacy data obtained from our Phase I clinical trial, we plan to conduct a Phase II clinical trial of IAE0972 for CRC. Considering the mechanism of action and clinical data for EGFR targeted therapies from other researchers, we also plan to explore IAE0972's potential in the treatment of HNSCC, HCC and NSCLC.

HNSCC

Head and neck cancer is a group of cancers that arises in the mouth, nose, throat, larynx, sinuses, or salivary glands. Head and neck squamous cell carcinoma ("**HNSCC**") is the most common subtype that accounts for more than 90% of head and neck cancers. According to Frost & Sullivan, the global market of head and neck cancer drugs increased from US$2.9 billion to US$4.6 billion with a CAGR of 12.3% from 2018 to 2022, and is projected to reach US$6.4 billion in 2026 and US$8.7 billion in 2030. The China market of head and neck cancer drugs increased from US$0.3 billion to US$0.6 billion with a CAGR of 18.6% from 2018 to 2022, and is projected to reach US$1.2 billion in 2026 and US$1.8 billion in 2030 with a CAGR of 19.2% and 11.1% from 2022 to 2026 and from 2026 to 2030, respectively.

While PD-1-targeted immunotherapy has been established as the preferred first-line treatment for metastatic HNSCC, surpassing the efficacy of chemotherapy combined with cetuximab, a notable proportion of patients do not experience benefits from this approach. For example, Keytruda, when administered in conjunction with chemotherapy, demonstrates a modest ORR of only 36% in patients exhibiting positive PD-L1 expression (Combined Positive Score, CPS $\geq$ 1). Additionally, if patients fail to respond to first-line therapy, there is a paucity of effective follow-up treatment options. Specifically, although PD-1 inhibitors are recommended as second-line treatment, their efficacy in managing HNSCC patients with disease progression remains unsatisfactory, yielding an ORR ranging from 13.3% to 16%. Consequently, there is an urgent demand for novel treatment alternatives that can enhance the response rate of PD-1-targeted immunotherapy and achieve more efficacious eradication of tumors. For further details, see "Industry Overview — Immuno-Oncology Drugs Overview — Major Indications for Immuno-Oncology Therapies — HNSCC" in this document.

CRC

See "— Drug Candidates — Core Product: IAE0972 (EGFR/IL-10 antibody-cytokine fusion protein) — Market Opportunities and Competition — CRC" in this section for information related to market opportunities.

HCC

Liver cancer is the growth and spread of unhealthy cells in the liver. Hepatocellular carcinoma ("**HCC**") is the most common type of primary liver cancer (~90%), and is the most common cause of death in people with cirrhosis. According to Frost & Sullivan, the global market for HCC drugs increased from US$1.7 billion in 2018 to US$3.1 billion in 2022,

representing a CAGR of 16.5% during this period. Projections suggest this figure will reach US$6.6 billion in 2026 and US$11.2 billion in 2030, with anticipated CAGRs of 21.0% from 2022 to 2026 and 14.0% from 2026 to 2030, respectively. Similarly, the Chinese market for HCC drugs rose from US$0.7 billion in 2018 to US$1.5 billion in 2022, demonstrating a CAGR of 21.7% from 2018 to 2022. It is forecasted to reach US$3.7 billion in 2026 and US$6.2 billion in 2030, with projected CAGRs of 24.4% from 2022 to 2026 and 14.2% from 2026 to 2030, respectively.

Therapeutic options for HCC are generally determined based on disease staging. For late-stage HCC, systemic therapies are primarily recommended for first- and second-line treatments, two major classes of which are small molecule targeted drugs, such as NEXAVAR® (sorafenib), LENVIMA® (lenvatinib) and immune checkpoint inhibitors (e.g., PD-1/PD-L1 inhibitors). The corresponding combination therapies of targeted drugs or immune checkpoint inhibitors are also commonly used in first- and second-line treatments.

Due to the limited clinical outcomes associated with small molecule targeted drugs, PD-1/PD-L1 inhibitors have been introduced in the first- and second-line settings to improve treatment outcomes for HCC patients in recent years. However, current immuno-oncology therapy regimens still fail to yield material progression-free and overall survival benefits. For example, although the combination of a PD-1/PD-L1 inhibitor and anti-VEGF therapy, such as atezolizumab or sintilimab plus bevacizumab, has demonstrated certain efficacy (an overall mPFS of around 4 months), there is still room for improvement, indicating a need for more effective strategies.

NSCLC

See "— Drug Candidates — Core Product: IAP0971 (PD-1/IL-15 antibody-cytokine fusion protein) — Market Opportunities and Competition — NSCLC" in this section for information related to market opportunities.

Competitive Landscape

Currently, there are no approved IL-10 based immunotherapies indicated for the treatment of cancer according to Frost & Sullivan. Both globally and in China, three IL-10 based immunotherapies are currently under clinical development with two of them from us, i.e. IAE0972 and IBB0979. As of the Latest Practicable Date, our IAE0972 was in Phase II clinical stage and IBB0979 was in Phase I/II clinical stage, and they were the most clinically advanced IL-10 based immunocytokine in China.

Competitive Advantages

IAE0972 is another immunocytokine developed from our AIC™ Platform. It is the first anti-EGFR antibody/IL-10 immunocytokine that received IND approvals from both the NMPA and FDA. Through the distinct mechanism of simultaneously binding to EGFR and receptor of IL-10, IAE0972 activates antigen-specific CD8+ T cells in the TME, leading to a revival of tumor-killing activity in exhausted T cells.

Advantages in terms of molecular design

IAE0972 effectively targets both EGFR and the IL-10 receptor, facilitating the activation of CD8+ T cells within the TME. The anti-EGFR antibody component of IAE0972 specifically directs IL-10 to tumor tissues, mitigating the systemic toxicity of IL-10. This targeted approach enables a significantly higher safe dosage of IAE0972, approximately 300 times greater than the clinical dose of PEGylated IL-10. By binding to IL-10R on EGFR-specific CD8+ T cells, IL-10 promotes their expansion and activation, leading to the efficient elimination of EGFR-high expressing tumor cells and overcoming drug resistance commonly associated with EGFR mAbs.

- **Asymmetric structure design**. The monovalent design of IAE0972's anti-EGFR antibody component not only targets IL-10 specifically to tumor tissues but also reduces the skin toxicity associated with the anti-EGFR antibody. As a result, it significantly expands the therapeutic window of the drug.

  To address heavy chain mismatches, IAE0972 adopts an asymmetric heterodimeric structure in its Fc region, employing a knobs-into-holes structural design. This unique design not only enhances the stability of the drug but also ensures its efficacy.

- **Cytokine structure design**. The latest research indicates that IL-10 serves as a specific activator for antigen-activated CD8+ tumor-infiltrating lymphocytes in the TME. Due to the minimal expression of IL-10R in naïve T cells in peripheral blood, this specific activation is confined to the TME, necessitating the fusion of antibodies targeting tumor-related antigens with IL-10 to target IL-10 specifically to the TME. The IL-10 payload of IAE0972 naturally adopts a homodimeric structure, which provides enhanced immune cell activation activity and favorable CMC druggability. This characteristic makes it an ideal candidate for drug development purposes.

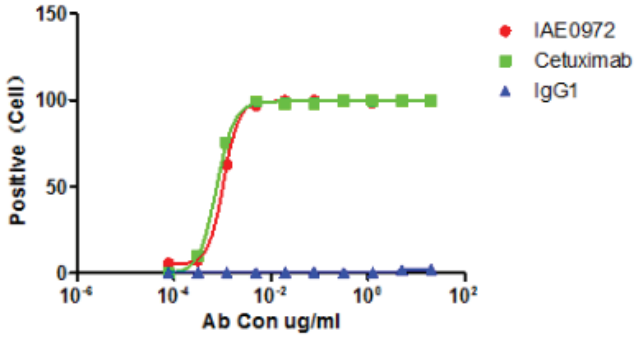
- **Synergistic Effect between anti-EGFR antibody and IL-10.** The EGFR protein is highly expressed in various tumor cells. Selecting anti-EGFR antibodies and fusing them with IL-10 can enrich IL-10 in TME of various tumors through anti-EGFR antibodies, potentially expanding the indications of this drug candidate. The anti-EGFR antibody moiety of IAE0972 is a chimeric antibody. It binds to antigen-specific CD8+ T lymphocytes expressing IL-10 receptors, promoting their proliferation and activation, thereby enhancing the safety and efficacy profile of the

drug. The role of the anti-EGFR antibody moiety of IAE0972 includes: 1) Enriching cytokines in the TME using anti-EGFR antibodies; 2) IAE0972 can simultaneously bind specifically to tumor cells and T cells to inhibit EGFR overexpression.

We have validated functionalities of IAE0972 through multiple preclinical studies of binding to EGFR overexpressing tumor cell line, dual target binding assay, *in vitro* CD8+ T cell activation assay, *in vitro* ADCC assay, and *in vivo* antitumor efficacy assay.

In a preclinical study, we verified that the anti-EGFR antibody in IAE0972 exhibits the same tumor-targeting effect as the marketed antibody, cetuximab. In the study, IAE0972 and the EGFR-positive tumor cells A549 were co-incubated, and the binding ability of IAE0972 to A549 was detected using PE-F(ab')2 Goat anti-human IgG Fcγ antibody as the secondary antibody, with cetuximab serving as a positive control. Data demonstrated that the binding ability of IAE0972 to A549 is equivalent to that of cetuximab.

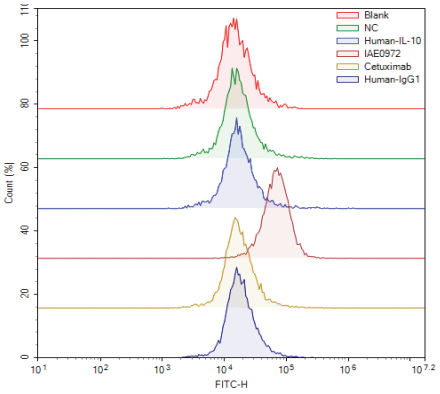
Binding of IAE0972 to A549



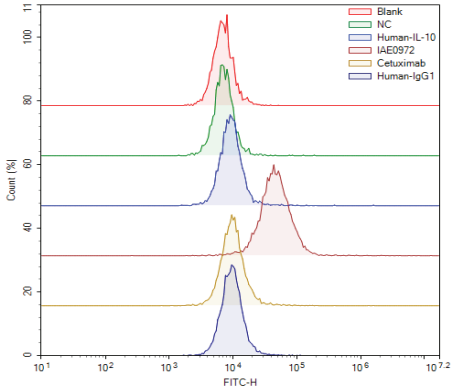
Source: Company data

In another preclinical study, we found that IAE0972 can simultaneously bind to EGFR and IL-10R receptors, whereas cetuximab cannot. Specifically, after incubating IAE0972 with IL-10RA protein, flow cytometry was used to detect the binding of IL-10 homodimer complex of IAE0972 to EGFR-positive MDA-MB-231 cells. Similarly, after binding IAE0972 to EGFR protein, flow cytometry was used to assess its binding to IL-10-Reporter-HEK-293 cells. Data demonstrated that IAE0972 can bind to both EGFR and IL-10R simultaneously, whereas the control cetuximab does not bind to IL-10R.

MDA-MB-231 cells



IL-10-Reporter-HEK-293 cells



Source: Company data

Further preclinical study results demonstrated that IAE0972 exhibited equimolar binding capacity to the IL-10R, similar to IL-10, and can selectively activate IL-10/IL-10R signaling. Moreover, IAE0972 also showed an excellent tumor inhibition effect in the C57BL/6 mouse allograft tumor model, superior to cetuximab. For details, see "— Drug Candidates — Core Product: IAE0972 (EGFR/IL-10 antibody-cytokine fusion protein) — Summary of Preclinical Data" in this section.

Favorable preclinical and clinical data

The IL-10 payload in IAE0972 enhances the killing effect of immune cells on EGFR-positive tumor cells. The inhibition rate of tumor growth in mice treated with IAE0972 reaches an impressive 83%, which is significantly better than that of an anti-EGFR mAb (20%). Moreover, the tolerated dose in cynomolgus monkeys reached 6mg/kg with no skin toxicity observed, surpassing that of the anti-EGFR mAb.

The potential toxic effects of IAE0972 were adequately exposed in multiple dosing trials, and the drug-related changes in cynomolgus monkeys in a repeat-dose toxicity study. We have focused on skin toxicity of the anti-EGFR antibody moiety and hematological toxicity of the IL-10 homodimer. The trial data showed that no drug-related skin toxicity was observed with IAE0972 at 6 mg/kg repeated dosing and 10 mg/kg single dosing, whereas literature data showed that cetuximab already exhibited mild skin toxicity at equivalent doses. This safety profile is in line with our structural design expectation that the anti-EGFR antibody of IAE0972 is monovalent, further reducing its skin toxicity and improving its safety of administration, while ensuring the targeting of the antibody.

When compared to an IL-10 cytokine product, IAE0972 demonstrates superior structural stability, enhanced targeting capabilities, extended half-life, and a significantly broader therapeutic window. In cynomolgus monkeys, IAE0972 exhibited a tolerated dose of 6mg/kg,

which is remarkably higher than the 15-20μg/kg dosage of the IL-10 cytokine product in clinical trials recorded in literatures. Consequently, the therapeutic window of IL-10 in IAE0972 has been expanded by 300-fold.

We evaluated IAE0972 in a Phase I clinical trial in patients with locally advanced or metastatic malignant tumors. In this trial, safety of IAE0972 was evaluated in pre-specified doses: 0.001 mg/kg, 0.01 mg/kg, 0.1 mg/kg, 0.3 mg/kg, 1.0 mg/kg and 2.5 mg/kg in cohorts of one to six patients each. As of the Latest Practicable Date, the Phase I clinical trial of IAE0972 have been completed in the 2.5mg/kg group, and favorable patient tolerability has been observed in all previous dose groups.

Potentially improved safety and efficacy than current anti-EGFR antibodies

EGFR is overexpressed in various tumors and correlates with the prognosis of malignant tumors, such as HNSCC, CRC and NSCLC. mAbs primarily target the extracellular domain of proteins, which are less likely to mutate, and thus the antitumor effect of the mAbs may less likely be affected by drug resistance due to intracellular amino acid mutations. However, their effectiveness and safety still pose challenges. The main antitumor mechanisms of the current anti-EGFR mAb, such as cetuximab, include blocking cell growth and inducing ADCC-mediated tumor cell killing, with skin toxicity observed at high doses. By reducing bivalent EGFR antibody into monovalent and fusing the antibody with IL-10, IAE0972 can effectively enrich IL-10 in the TME through anti-EGFR antibodies, further activating antigen-specific CD8+ T lymphocytes and significantly enhancing the safety and efficacy profile of this drug.

	IAE0972	**An anti-EGFR antibody**
Binding activity	similar	similar
***In vitro* tumor cell proliferation inhibition**	similar	similar
Dual EGFR/IL10R target binding activity	Yes	No
CD8+ T cell stimulation activity	Yes	No
Skin toxicity	Low	High
Tumor growth inhibition rate at 5mg/kg	83%	20%

Source: Company data

High and stable production rate

The company's asymmetric immunocytokine cell line technology has enabled the expression of IAE0972 to reach 2.9g/L, with a one-step affinity chromatography purity of about 85%. The final yield is about 50%, indicating excellent commercial scalability.

Despite the potential competitive advantages based on the mechanism of action, drug design, preclinical studies, and preliminary clinical data, the successful development of IAE0972 remains highly uncertain, primarily due to the absence of approved IL-10 based immunocytokines. Additionally, whether the anticipated clinical benefits of using anti-EGFR antibodies in the form of immunocytokines would materialize in targeted patients is still subject to further evaluation and validation in Phase II or later phases of clinical trials.

Summary of Clinical Trial Results

We have completed the Phase I clinical trial of IAE0972 in patients with advanced malignant tumors in China in July 2023. Based on the clinical results from the Phase I trial, upon communication with the principal investigator, we have initiated a Phase II clinical trial of IAE0972 as monotherapy in China, and enrolled the first HNSCC patient and the first CRC patient in July 2023 and December 2023, respectively. As of the Latest Practicable Date, we have not received objection for entering a Phase II clinical trial from the NMPA.

Phase II clinical trial in patients with relapsed or metastatic HNSCC and metastatic CRC who have failed standard treatments

Trial Design. This study is a single arm, open label, multi-centered Phase II clinical study to evaluate the safety and efficacy of intravenous infusion of IAE0972 as a monotherapy in subjects with relapsed or metastatic HNSCC and metastatic CRC who have failed standard treatments. The study will be divided into two cohorts: cohort A will include subjects with recurrent or metastatic HNSCC who have failed standard treatments; cohort B will include subjects with metastatic CRC who have failed standard treatment. Subjects in the study will continue to receive intravenous infusion of IAE0972 until the occurrence of disease progression, initiation of new antitumor therapy, judgement by the investigator that continued participation is not appropriate, loss to follow-up, voluntary withdrawal, death, or study termination/suspension. Subjects will be assessed for tumors every six weeks (±7 days) during the study. AEs will be assessed in the study through clinical observation, vital signs monitoring, and laboratory tests of the subjects.

The primary endpoint of this study is ORR. Secondary endpoints include PFS, DCR, DoR, 6-month progression-free survival rate, 12-month progression-free survival rate and 12-month survival rate, AEs and SAEs, and major PK parameters and immunogenicity.

Trial Status. We have initiated this trial and enrolled the first HNSCC patient and the first CRC patient in July 2023 and December 2023, respectively.

Phase II clinical trial in patients with advanced HCC or advanced solid tumors by us

Trial Design. This is a Phase II, open-label, multicenter clinical study of IAE0972 in combination with lenvatinib in patients with advanced HCC or advanced solid tumors. The study will be conducted in two phases: IIa and IIb. Phase IIa will use the classic "3+3" design for dose escalation. Each group will include three to six subjects with locally advanced/metastatic solid tumors who have failed standard treatment, or have no standard treatment options, or for whom standard treatment is not applicable at this stage. The starting dose of IAE0972 will be 2.5mg/kg QW administered intravenously, and lenvatinib will be administered orally with either 12mg or 8mg, depending on the subject's weight. Escalation dose will be determined based on the safety and efficacy data obtained in this study. Each treatment cycle is defined as 3 weeks. Phase IIb will be commenced after obtaining RP2D from the Phase IIa study. We expect to enroll unsystematically treated subjects with locally advanced/metastatic HCC who are not candidates for surgical and/or localized therapy, or who have experienced disease progression after undergoing surgical and/or localized therapy. The subjects will continue to receive IAE0972 in combination with lenvatinib until the occurrence of any endpoint event.

The primary objective of the Phase IIa study includes safety, tolerability, DLT and/or RP2D. The secondary objective includes PK, immunogenicity and preliminary efficacy. The primary objective of the Phase IIb study includes preliminary efficacy. The secondary objective includes safety, tolerability and immunogenicity.

Trial Status. We obtained the IND approval from the NMPA to conduct this clinical trial in November 2023.

Phase I clinical trial in patients with advanced or metastatic solid tumors

Trial Design. This trial was a Phase I, open-label study of IAE0972 in patients with selected advanced or metastatic solid tumors. This trial was conducted in China according to a protocol approved by both the NMPA and the FDA. The Phase I stage of the clinical trial aims to characterize the safety, tolerability, PK, immunogenicity, and preliminary antitumor activity of IAE0972 in previously treated patients with advanced solid tumors. Each treatment cycle spanned 4 weeks, during which IAE0972 was administered intravenously (IV) on Days 1, 8, 15 and 22. Tumor assessments was performed every 8 weeks, just prior to dosing for Cycles 3, 5, 7 and so on. Patients who did not experience a DLT or any other unacceptable toxicity that necessitated permanent discontinuation of the investigational product were eligible to continue treatment. Treatment discontinuation could occur upon documented disease progression, initiation of alternative anti-cancer therapy, loss to follow-up, withdrawal of informed consent, death, or at the end of the study.

The DLT evaluation period, specifically, encompasses the 28 days following the IV administration of the first dose of IAE0972 (Cycle 1). IAE0972 was evaluated across pre-specified dose levels: 0.001 mg/kg, 0.01 mg/kg, 0.1 mg/kg, 0.3 mg/kg, 1.0 mg/kg and 2.5

mg/kg with each cohort consisting of 1 to 6 patients. Additionally, lower, intermediate, or higher dose levels could be explored. Subsequent to the last dose of IAE0972, each patient's overall survival ("**OS**") will be monitored, with assessments conducted at 12-week intervals.

The primary objectives include safety and tolerability. The secondary objectives include PK portfolio, and immunogenicity of IAE0972.

Trial Status. We completed this Phase I clinical trial of IAE0972 in July 2023.

Safety Profile. As of the cut-off date (June 29, 2023), a safety evaluation was conducted on a total of 14 subjects enrolled in the dose escalation phase of IAE0972. Most of the patients experienced Grade 1 or 2 TRAEs, only one (7.1%) experienced Grade 3 TRAE, which was apocleisis. No Grade 4-5 TRAEs occurred. No DLT occurred and MTD was not reached.

TRAEs occurring in ≥10% of patients or ≥ Grade 3 TRAEs

	All patients (N=14)	
	All grades, n (%)	**≥Grade 3, n (%)**
Any TRAE	14(100.0)	1(7.1)
TRAE in ≥10% of patients and ≥ Grade 3 TRAEs by preferred term		
Anaemia	6(42.9)	0
IL increased	6(42.9)	0
Fatigue	3(21.4)	0
Bilirubin increased	3(21.4)	0
Apocleisis	3(21.4)	1(7.1)
Hypoalbuminemia	2(14.3)	0
Hypoproteinemia	2(14.3)	0
Nausea	2(14.3)	0
Vomiting	2(14.3)	0

Abbreviations: TRAE = treatment-related adverse event.

Note: Data cut-off: June 29, 2023; AEs graded according to NCI CTCAEv.5.0.

Source: Company data

Efficacy Profile. The efficacy analysis presented below encompasses data from the dose escalation phase of IAE0972, involving a total of 14 enrolled subjects, of which nine were evaluable until the data cut-off date. An evaluable subject was defined as a subject who had undergone at least one tumor assessment after baseline. Among the nine evaluable subjects, four heavily pretreated patients who failed and became resistant to all previous chemotherapies/immunotherapies (two patients with rectal cancer, one with GC, and one with glioblastoma) exhibited SD, with the tumor volume of a GC patient in Cohort 4 reduced by 20%. The DCR was calculated to be 44.4%.

Group	Patient	Previous Treatment	Efficacy
0.01mg/kg	Rectal cancer combined with lung metastasis	Resistant to standard mFOLFOX6 regimen and CapeOX regimen, followed by irinotecan + raltitrexed + bevacizumab; furoquinitinib, regorafenib-targeted drugs	Achieved SD at first efficacy evaluation after 2 cycles of IAE0972
0.1mg/kg	Glioblastoma combined with metastasis to pleura, bone and pleural effusion	Resistant to radiation therapy with temozolomide, followed by bevacizumab + temozolomide	Achieved SD at first efficacy evaluation after 2 cycles of IAE0972
0.3mg/kg	Gastric cancer combined with liver metastasis	Resistant to Nivolumab in combination with tegeo + oxaliplatin, later changed to selective tumor arterial continuous perfusion with paclitaxel in combination with raltitrexed (later changed to oxaliplatin) combined with Nivolumab immunotherapy; oral apatinib when discharged, during which systemic chemotherapy with cisplatin was administered, but disease progressed; given docetaxel in combination with nedaplatin chemotherapy	Achieved SD at first efficacy evaluation after 2 cycles of IAE0972 with tumor shrank by 20%
1.0mg/kg	Rectal cancer combined with lung metastasis and lymph node metastasis	Recurrence after first time resection; disease progressed with lung, lymph node metastasis after second time resection	Achieved SD at first efficacy evaluation after 2 cycles of IAE0972

Abbreviations: SCLC = small cell lung cancer; PR = partial response; SD = stable disease; PD = progressive disease; NA = not available.

Note:

Data cut off on June 29, 2023.

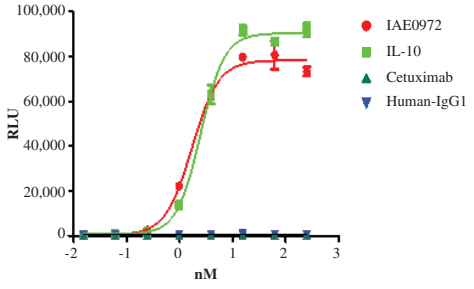
Source: Company data

Conclusion. The preliminary efficacy results showed encouraging antitumor activities when IAE0972 was administered as a monotherapy, even in heavily pretreated tumor types. Furthermore, our safety data indicated that IAE0972 can be safely administered to subjects at doses up to 2.5 mg/kg on a weekly basis.

Summary of Preclinical Data

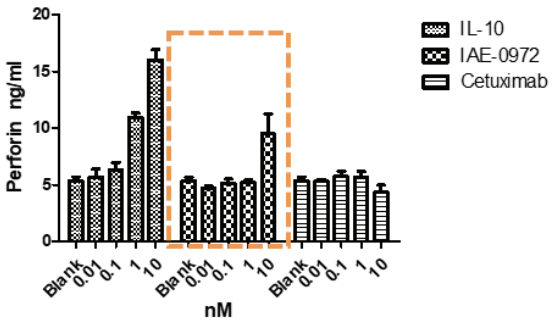
The preclinical study results demonstrate that IAE0972 exhibits equimolar binding capacity to the IL-10R, similar to IL-10, and can selectively activate IL-10/IL-10R signaling. *In vitro* studies using peripheral blood mononuclear cells demonstrated that IL-10 significantly stimulated the secretion of perforin by CD8+ T cells in a concentration-dependent manner. Perforin is a pore forming cytolytic protein found in the granules of cytotoxic T lymphocytes and NK cells, which plays a key role in granzyme-mediated programmed cell death, and in defense against tumor cells. At high concentrations, the IAE0972 antibody also significantly stimulated perforin secretion by CD8+ T cells, while cetuximab failed to induce such secretion.

IAE0972 activates IL-10 Reporter HEK-293 cell luciferase expression



	IAE0972	IL-10
EC_{50}	1.719	2.502

perforin cytokine secretion of CD8+T Cell

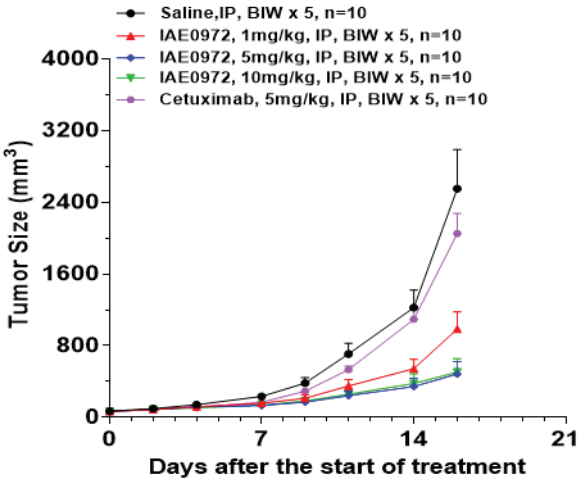


Source: Company data

In vivo data of the preclinical study showed that IAE0972 was well tolerated up to 6 mg/kg in cynomolgus monkeys, which is 300 times the safe dosage of IL-10 cytokine therapy. Also, no obvious EGFR-related skin toxicity, no significant organ changes for spleen, thymus, adrenal gland, axillary lymph nodes, and thyroid gland, as well as no significant changes for levels of IL-2, tumor necrosis factor-alpha ("**TNFα**") and Interferon-gamma ("**IFNγ**") were observed in the cynomolgus monkey repeated-dose toxicity studies.

IAE0972 also showed an excellent tumor inhibition effect in the C57BL/6 mouse allograft tumor model. Specifically, it showed a TGI rate of 83%, which is significantly higher than cetuximab. The *in vivo* data obtained from the study revealed significant tumor inhibition by IAE0972 at doses of 1mg/kg, 5mg/kg and 10mg/kg, resulting in TGI rates of 63.05%, 83.26% and 82.46%, respectively. The TGI effect of the 5mg/kg dose of IAE0972 was comparable to

that of the 10mg/kg dose. In comparison to the control group, the cetuximab 5mg/kg group did not exhibit a significant TGI effect, whereas the IAE0972 1mg/kg group demonstrated a significantly superior TGI effect when compared to cetuximab, despite using a much lower dose.



Source: Company data

Clinical Development Plan

We are currently implementing a comprehensive clinical trial development plan in China and the U.S. targeting a wide range of cancer indications for our product candidate IAE0972.

Fast-to-Market Strategy

We have strategically chosen to conduct Phase II clinical trials of IAE0972 in the treatment of two cancer indications, namely HNSCC and CRC, which have few or no effective treatment options for heavily pretreated patients. We believe that these strategic choices will accelerate the regulatory approval process and facilitate the commercial launch of IAE0972.

- 2L HNSCC

According to Frost & Sullivan, there were approximately 292.2 thousand new cases of 2L advanced HNSCC globally in 2022, and the number is projected to reach 358.6 thousand in 2030. In 2022, there were approximately 44.7 thousand new cases of 2L advanced HNSCC in China, and the number is projected to reach 53.0 thousand in 2030. The five-year survival rate of advanced HNSCC is approximately 40%. EGFR overexpression has been consistently observed in the majority of HNSCC cases, contributing to resistance against cytotoxic agents and radiotherapy, which ultimately leads to a poor prognosis. As a result, EGFR targeted therapy holds considerable promise as a second-line treatment option.

While immune checkpoint inhibitors have taken the forefront as first-line treatment options in major jurisdictions such as the U.S., EGFR inhibitor, particularly cetuximab, continue to hold significance as a viable second-line option for patients who have experienced progression on immune checkpoint inhibitors. Nonetheless, since chemotherapy continues to be an important first-line treatment option, most patients receive a combination of immune checkpoint inhibitors and chemotherapy. This highlights the existing medical needs for the development of treatments for patients who have either failed to respond or cannot tolerate immune checkpoint inhibitors in combination with chemotherapy. As of the Latest Practicable Date, despite the positive efficacy demonstrated by anti-EGFR antibodies, none of them have received regulatory approval from authorities such as the NMPA or the FDA for second-line treatment after the failure of immune checkpoint inhibitors in combination with chemotherapy.

Given the outlook for EGFR inhibitors, we plan to initiate a Phase II trial aimed at assessing the efficacy of IAE0972 as a monotherapy for patients diagnosed with advanced HNSCC who have undergone frontline treatment includes immunotherapy. We have initiated a Phase II clinical trial of IAE0972 as monotherapy in China, and enrolled the first HNSCC patient in July 2023.

- 3L CRC

CRC ranks as the third most frequently diagnosed cancer worldwide and the second leading cause of cancer-related mortality, as reported by the World Health Organization GLOBOCAN database. According to Frost & Sullivan, there were approximately 353.3 thousand new cases of 3L advanced CRC globally in 2022, and the number is projected to reach 452.2 thousand in 2030. In 2022, there were approximately 86.0 thousand new cases of 3L advanced CRC in China, and the number is projected to reach 111.8 thousand in 2030. The five-year survival rate of advanced CRC can be as low as 16%. The gravity of this disease and the limited therapeutic options available highlight the urgent need for new treatments to address the significant unmet medical needs of CRC patients, particularly those with metastatic CRC who have experienced disease progression after three or more prior lines of therapy, including EGFR antibody-based treatments.

Anti-EGFR monoclonal antibodies, such as cetuximab or panitumumab, are increasingly utilized in the first- or second-line treatment of RAS wild-type metastatic CRC patients. However, as patients progress beyond the second-line therapies, some individuals may no longer be suitable for additional chemotherapy due to poor performance status or personal preferences. Nevertheless, a considerable portion of patients still qualify for further anti-EGFR therapy despite the limited availability of standard treatment options. The potential role of rechallenge with anti-EGFR therapy, especially for patients who have previously shown a positive response, is often considered. Rechallenging with anti-EGFR therapy in former responders exhibiting wild-type RAS in circulating tumor DNA assay after an interval of more than eight months represents a promising treatment approach.

While EGFR antibodies have demonstrated encouraging efficacy signals in general, no EGFR antibody has yet obtained marketing approval from regulatory authorities such as the NMPA or the FDA specifically for CRC rechallenge. IAE0972, an EGFR/IL10 immunocytokine, is expected to exhibit improved response rates in patients with RAS wild-type CRC beyond the second line treatment. To assess its efficacy as a monotherapy in patients with advanced CRC as third-line or later treatment, we have initiated a Phase II clinical trial of IAE0972 as monotherapy in China, and enrolled the first CRC patient in December 2023.

Major Indications

We are currently exploring the possibility of broadening the indications of IAE0972 to encompass a wider range of patient populations, such as those diagnosed with 2L squamous NSCLC and 1L HCC.

- 2L squamous NSCLC

Lung cancer ranks highest in terms of incidence among all cancer types in China, with NSCLC comprising approximately 85% of the lung cancer cases, according to Frost & Sullivan. There were approximately 328.5 thousand new cases of 2L advanced squamous NSCLC globally in 2022, and the number is projected to reach 422.3 thousand in 2030. In China, there were approximately 138.8 thousand new cases of 2L advanced squamous NSCLC in 2022, and the number is projected to reach 181.2 thousand in 2030. The five-year survival rate of advanced NSCLC is extremely low, at approximately 9%.

Clinical data has indicated that the combination chemotherapy involving necitumumab, an anti-EGFR antibody, exhibits antitumor effects for lung cancer patients. As such, the FDA approved necitumumab under the brand name Portrazza for use with gemcitabine and cisplatin in previously untreated metastatic squamous NSCLC. Our IAE0972, which is an immunocytokine that targets EGFR carrying IL-10 payloads, holds potential for even greater efficacy compared to necitumumab, while maintaining a manageable safety profile.

The first-line treatment for NSCLC involves a combination of chemotherapy and PD-1 immunotherapy. Unfortunately, primary and acquired drug resistance to PD-1 treatment can eventually lead to disease progression, leaving NSCLC patients with limited options. Currently, as of the Latest Practicable Date, no targeted therapy or immunotherapy has obtained regulatory approval from authorities for second-line treatment after immune checkpoint inhibitors in combination with chemotherapy have failed to treat NSCLC. Due to its potential of simultaneously simulating both innate and adaptive immunity in patients who suffer from primary or acquired drug resistance to immunotherapies, especially acquired drug resistance to immune checkpoint inhibitors caused by T cell exhaustion, our IAE0972 can potentially address these medical needs.

In China, our upcoming plans involve initiating a Phase II clinical trial for IAE0972 in combination with docetaxel in squamous NSCLC patients as second-line treatment. We plan to submit an IND application and after receiving the approval, enroll the first patient in the trial in the third quarter of 2024. Subsequently, in the second half of 2026, we intend to commence a Phase III trial for IAE0972. These initiatives signify our commitment to advancing the development and assessment of IAE0972 as a treatment option for lung cancer patients in China.

- 1L HCC

HCC ranks the second deadliest cancer and the fourth most prevalent malignant tumor in China, according to Frost & Sullivan. Overexpression of EGFR has been observed in around 40%-70% of conventional HCCs in most scientific research studies. According to Frost & Sullivan, there were approximately 716.1 thousand new cases of 1L advanced HCC globally in 2022, and the number is projected to reach 897.2 thousand in 2030. In 2022, there were approximately 331.9 thousand new cases of 1L advanced HCC in China, and the number is projected to reach 409.5 thousand in 2030. For late stage HCC, the five-year survival rate can be extremely low, at approximately 4%.

For late-stage HCC, systemic therapies are primarily recommended for first-line treatments, two major classes of which are small molecule targeted drugs, such as NEXAVAR® (sorafenib), LENVIMA® (lenvatinib), and immune checkpoint inhibitors, such as PD-1/PD-L1 inhibitors. Sorafenib has become the standard of care for patients with advanced HCC and also for those progressing after loco-regional therapies. It is an inhibitor with reported activity against Raf-1, B-Raf, VEGFR2, PDGFR, c-Kit receptors, targeting the EGFR-Ras-MAPKK pathway.

By targeting EGFR while carrying IL-10 payloads, IAE0972 may offer higher efficacy and a better safety profile compared to the current first-line treatments. Our plans entail conducting Phase II and Phase III clinical trials to evaluate the efficacy of IAE0972 in combination with chemotherapy, in comparison to lenvatinib, as first-line treatment for advanced HCC in China. In November 2023, we received the IND approval from the NMPA for conducting Phase II and Phase III clinical trials of IAE0972 in combination with lenvatinib in patients with locally advanced or metastatic HCC as first-line treatment. The enrollment of the first patient in a Phase II trial is scheduled in the second quarter of 2024. Following that, we anticipate conducting a Phase III trial to delve further into the potential of IAE0972 in HCC.

Global Strategy

We are carrying out a global strategy in the clinical development of IAE0972. In the U.S., we have obtained an IND approval for investigating IAE0972 as a monotherapy in Phase I and Phase II clinical trials in advanced malignant tumors in December 2021. Because the Phase I and Phase II clinical trial designs approved by the NMPA and the FDA are the same including the site (located in China) and PI of the clinical trials, we plan to leverage clinical data

collected in the Phase I trial in China, carefully decide our clinical development plan in the U.S., communicate with the FDA regarding the Phase II clinical trial design, and upon reaching an agreement with the FDA regarding the trial design, initiate Phase II clinical trials in the U.S. according to the FDA approved clinical trial design either by ourselves or through international collaboration. We may conduct clinical trials by ourselves, or through third party CROs or international collaborators. Alternatively, depending on the specific clinical stage and therapeutic regimen we carefully decide upon in the future, we will submit a new IND application to the FDA when new IND approval is required. Considering the costs, we decided to proceed with clinical trials in China first. As of the Latest Practicable Date, we had not commenced the clinical trials in the U.S. and had not planed to commence the trials in the U.S. within the coming six months.

Although the FDA has issued the IND approval and accepted that Phase I and Phase II clinical trials of IAE0972 can be conducted in China, we cannot guarantee that the FDA will accept our clinical results generated in China to support future clinical trials in the U.S., and we may face difficulties and incur additional costs thereof. For details, see "Risk Factors — Risks Relating to Government Regulations — We Primarily Conduct Clinical Trials for Our Drug Candidates in China, While FDA or Comparable Foreign Regulatory Authorities May Not Accept Data From Such Trials" in this document.

Licenses, Rights and Obligations

IAE0972 was developed by us, and we maintain the global rights to develop and commercialize this drug candidate.

Material Communications with Competent Authorities

The material communications with the relevant competent authorities on all ongoing and completed clinical trials in respect of the Core Product IAE0972 are as follows:

- In December 2021, we received the IND approval for conducting Phase I and Phase II clinical trials of IAE0972 for advanced solid tumors from the FDA.

- In January 2022, we received the IND approval for conducting Phase I and Phase II clinical trials of IAE0972 for advanced solid tumors from the NMPA.

- In September 2023, we conducted an interview with a senior examiner of the NMPA with the attendance of professional parties, which reconfirmed, amongst others, that the Phase I clinical trial of IAE0972 has been completed, and based on the safety and efficacy data from the Phase I clinical trial, that the NMPA had no objection for us to commence the planned Phase II clinical trials of IAE0972 as a monotherapy for 2L HNSCC and 3L CRC.

- In November 2023, we received the IND approval for conducting Phase II and Phase III clinical trials of IAE0972 in combination with lenvatinib for locally advanced or metastatic HCC from the NMPA.

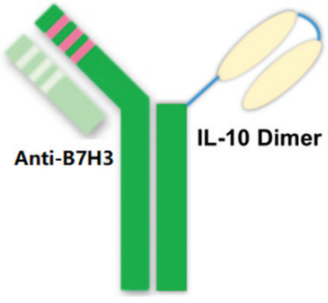
- In December 2023, we conducted a phone interview with the Director of Nanjing Inspection Branch, Jiangsu Provincial Medical Products Administration, which is a provincial branch regulated by the NMPA, with the participation of professional parties (the "**Regulatory Phone Interview**"). During the Regulatory Phone Interview, the Director confirmed that approval of drugs is managed by the approval number, which corresponds to the registration certificate of a drug, and the approval will encompass any different indications or combination therapy approved for marketing. In addition, if there are new indications or combination therapy for a marketed drug, the company can also make a supplemental application, but the company will not receive a new approval number for the same drug. Therefore, the monotherapy and combination therapy of the same drug for different indications, once approved by the NMPA, will be regulated under the same drug certificate in China.

We have not received any concerns or objections from the NMPA or the FDA related to receiving IND approvals, conducting Phase II clinical trials, or executing any other clinical development plans as of the Latest Practicable Date.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET IAE0972 SUCCESSFULLY

Clinical-Stage Product IBB0979 (B7H3/IL-10 antibody-cytokine fusion protein)

IBB0979 is a clinical stage, dual-moiety, anti- B7 homolog 3 protein ("**B7H3**") antibody-IL-10 homodimer bifunctional fusion protein for immune cell activation. It is designed to bind to B7H3 and trigger blockage of downstream signaling pathways that participate in TME shaping and development, and deliver IL-10 to activate CD8+ T cells in the TME. The diagram below illustrates the structure of IBB0979:



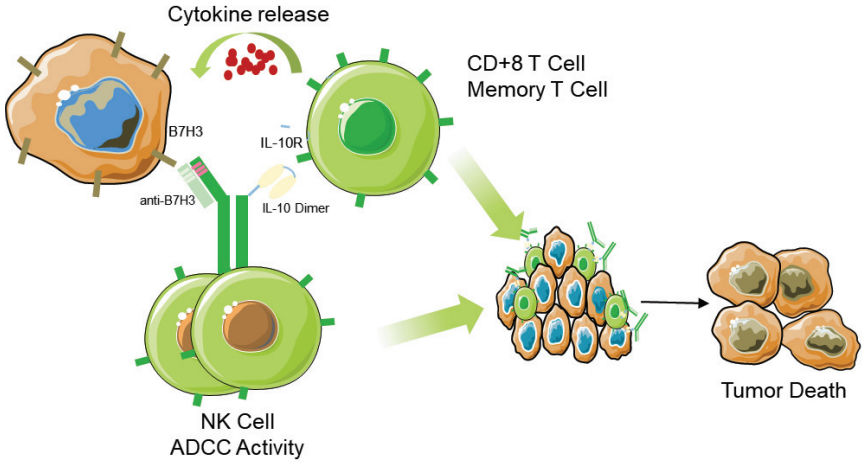
Source: Company data

We have obtained IND approvals from the NMPA and FDA for conducting Phase I and Phase II clinical trials of IBB0979 in locally advanced or metastatic solid tumors on November 2, 2022 and October 27, 2022, respectively. As of the Latest Practicable Date, we were investigating IBB0979 in a Phase I clinical trial to evaluate the safety, tolerability and preliminary efficacy of IBB0979 in patients with locally advanced or metastatic solid tumors in China. We expect to complete the Phase I clinical study in the fourth quarter of 2024 and enter the Phase II stage in the first quarter of 2025.

Mechanism of Action

B7H3, also known as CD276, a newly identified immune checkpoint protein member of the B7 family, is a popular target for cancer immunotherapy because it is overexpressed in tumor tissues and participating in TME shaping and development while showing limited expression in normal tissues due to its post-transcriptional regulation by microRNAs. It is overexpressed in many cancer types and is often associated with both negative prognosis and poor clinical outcome in patients. Researches revealed that in malignant tissues, B7H3 plays an important role in inhibiting tumor antigen-specific immune responses.

IBB0979 consists of an anti-B7H3 antibody fragment and a IL-10 homodimer. By targeting B7H3, the anti-B7H3 antibody fragment blocks the immunosuppressive signaling pathways in TME and enrich the IL-10 at the targeted tumor lesion. IL-10 will activate B7H3 specific CD8+ T cells to fight against the tumor.



Source: Frost & Sullivan Report

Market Opportunities and Competition

We believe IBB0979 has potential for the treatment of SCLC and mCRPC and plan to proceed the product into Phase II clinical trials.

SCLC

Lung cancer can be broadly categorized into two types: small cell lung cancer ("**SCLC**") and NSCLC. SCLC is a malignant tumor with high heterogeneity and invasiveness, accounting for 15% of lung cancer. In China, the number of SCLC cases is projected to increase to 166.5 thousand in 2026 with a CAGR of 3.2% from 2022 to 2026, and 185.7 thousand by 2030, with a CAGR of 2.8% from 2026 to 2030. The number of new SCLC cases worldwide increased from 314.1 thousand to 349.6 thousand from 2018 to 2022, with a CAGR of 2.7%. It is anticipated that by 2026 and 2030, the number of worldwide SCLC cases will reach 389.9 thousand and 432.7 thousand, respectively. The current drug treatment paradigm for SCLC in China involves applying EP/EC for LS SCLC and EP/EC/IP/IC for ES SCLC as the first-line treatment, with tyrosine kinase inhibitors ("**TKIs**") drugs being recommended as the 3rd-line treatment only in China.

Due to the asymptomatic nature and rapid progression of the disease, most SCLC patients are diagnosed in the extensive-stage (ES, which refers to the late-stage of SCLC with distant metastases), resulting in poor prognosis. The specific medical treatments such as chemotherapy alone or in combination with PD-1/PD-L1 inhibitors (such as atezolizumab, durvalumab and serplulimab), are recommended in the ES-SCLC.

Although the combination of chemotherapy with PD-L1 inhibitors (atezolizumab, durvalumab) has been approved for treating ES-SCLC, its clinical benefit is limited, with only a median overall survival improvement of two months compared to chemotherapy alone (12.3-13.0 months vs 10.3 months). Furthermore, serplulimab (a PD-1 inhibitor) combined with chemotherapy is currently restricted to treating MSI-H SCLC, indicating few options for immunotherapy in ES-SCLC. Consequently, many patients are unable to benefit from current treatments, and with relapse and drug resistance being common, the treatment options for R/R SCLC are limited to chemotherapy, with a median OS of only 4 to 5 months. Therefore, there is an urgent need for more effective treatments to improve survival outcomes for both primary and subsequent lines of treatment in ES-SCLC.

mCRPC

Prostate cancer is an epithelial malignant tumor that typically appears in the prostate gland and is the most common form of malignant tumor in the male genitourinary system. It primarily affects individuals over 65 years of age, and its progression is slow, with the early stages being mostly asymptomatic. However, once it migrates or metastasizes, the condition can become more severe, debilitating, and bearing a heavy disease burden for the patient.

In China alone, new cases of prostate cancer numbered 127.9 thousand in 2022, and is expected to increase to 147.8 thousand in 2026 and further to 170.6 thousand by 2030, representing a CAGR of 3.7% between 2026 and 2030. Globally, prostate cancer is one of the most prevalent cancer types, with an estimated 1,497.2 thousand new cases in 2022, expected to increase to 1,688.6 thousand in 2026 and 1,892.3 thousand in 2030.

In the case of mCRPC, endocrine drug therapy (such as mocetinostat) and chemotherapy are mainly recommended for first-line treatment. Immunotherapy options like PD-1 inhibitors, such as pembrolizumab, are approved for mCRPC patients with MSI-H/dMMR tumors. However, there is a significant unmet clinical need for effective therapies with improved efficacy, capable of benefitting more patients, in the mCRPC segment. Urgent strategies are therefore required.

Competitive Landscape

According to Frost & Sullivan, there are currently no approved B7H3-targeted immunotherapies indicated for the treatment of cancer. Globally, there are 16 products in various stages of clinical development, with the most advanced candidates undergoing Phase III clinical trials. In China, ten products targeting B7H3 are currently under clinical development, with the most advanced product in Phase II. Globally, among all product candidates targeting B7H3, IBB0979 stands out as the only immunocytokine currently undergoing investigation in clinical trials.

Competitive Advantages

IBB0979 is a B7H3/IL-10 immunocytokine developed based on our AIC™ Platform. It shares the same synergistic mechanism and structural design as IAE0972. The dual targeting offered by IBB0979 holds tremendous potential for expanding our indication footprint in solid tumors.

Advantages in terms of molecular design

IBB0979 adopts a mechanism of combining tumor-associated antigens and immune checkpoints, which represents a new approach in cancer treatment.

- B7H3 is abnormally highly expressed in various cancers while being expressed at low levels in normal human tissues. Available data from immunohistochemistry assays demonstrate that B7H3 is highly expressed in tumor cells and blood vessels in breast, brain, rectal colon, kidney, lung and pancreatic cancers but expressed at lower levels in normal tissues and blood vessels, making it an ideal target for developing cancer treatment.

- As a member of the B7-CD28 family of immunomodulatory proteins, B7H3 plays a crucial role in tumor development and immune escape. Its high expression in tumor tissues is often associated with tumor growth, reduced infiltrating lymphocytes in the tumor area, and T cell and NK cell-mediated antitumor immunosuppression. B7H3 has been demonstrated to be associated with tumorigenesis and progression of various types of cancer, including melanoma, glioma, lung cancer, pancreatic cancer, ovarian cancer, breast cancer, gastric cancer, and colon cancer, and is linked with poor prognosis in these tumors.

- While several drugs are currently being developed to target B7H3, none have yet received marketing approval. The range of drug types under development includes mAbs, dual antibodies, antibody-drug conjugates ("**ADCs**") and chimeric antigen receptor T-cell ("**CAR-T**") therapies. Among them, DS-7300A, a B7H3 ADC, is the most extensively studied drug and has shown promising preliminary efficacy, with ten confirmed partial remissions and five pending confirmed partial remissions.

The asymmetric heterodimer structure design of IBB0979 effectively address heavy chain mismatch and druggability issues.

- IBB0979 features a monovalent design at the antibody end, whereas IL-10 exhibits a naturally occurring homodimeric structure, providing natural immune cell activating activity.

- Additionally, IBB0979 incorporates a knobs-into-holes configuration that effectively addresses the heavy chain mismatch, thereby enhancing its druggability in terms of CMC considerations.

- IBB0979, developed through our asymmetric immunocytokine cell line technology, achieves an expression amount of 4g/L. With one-step affinity chromatography, it reaches approximately 86% purity and offers a final yield of around 60%, highlighting its strong commercial scalability.

Advantages in terms of safety and efficacy based on preclinical studies

- IBB0979 demonstrated complete tumor remission across a range of tumor models, achieving doses of 0.3-1 mg/kg. In cynomolgus monkeys, it exhibited a tolerated dose of 6mg/kg, significantly widening the safety and efficacy window compared to other B7H3-targeting drugs.

- IBB0979 exhibits structural stability, superior targeting capabilities, and a longer half-life when compared to an IL-10 cytokine product. Cynomolgus monkeys tolerated IBB0979 at a dose of 6 mg/kg, which is significantly higher than the 10-20 μg/kg tolerated by IL-10 cytokines alone. This represents at least a remarkable 300-fold increase in the therapeutic window.

Summary of Clinical Trial Results

Phase I clinical trial in patients with advanced solid tumors

Trial Design. This is a Phase I clinical trial designed to characterize the safety, tolerability, and preliminary effectiveness of IBB0979 in patients with locally advanced or metastatic solid malignant tumors. This trial is conducted with IND approvals from both the NMPA and FDA. The trial is currently being conducted in China. The study consists of a Dose Escalation Phase (Phase Ia) to determine the MTD of escalating doses of IBB0979, and a Dose

Expansion Phase (Phase Ib) to further define safety and initial effectiveness of IBB0979 at the dose established in Phase Ia. Each phase of the study includes: the screening period (28 days after the subject signs the informed consent form and before the first administration of the study drug), the treatment period (the first administration of the study drug until any endpoint event occurs), and the follow-up period. For the dose escalation phase, there are eight dosing cohorts, with dose levels ranging from 0.01 mg/kg QW to 10.0 mg/kg QW by intravenous injection.

Trial Status. We have initiated patient enrollment in July 2023 in China, and plan to complete the Phase I study in the fourth quarter of 2024.

Clinical Development Plan

We are executing a comprehensive clinical trial development plan in China and the U.S. targeting an array of cancer indications for our IBB0979.

Fast-to-Market Strategy

- 2L ES SCLC

ES-SCLC is an extremely aggressive form of cancer, and despite initially high response rates to first-line therapy, disease progression often occurs within a mere six months. Furthermore, there are very limited treatment options available for relapsed SCLC, highlighting a critical and urgent medical need for more effective therapies that can provide lasting benefits beyond the second line of treatment.

One promising avenue of research involves B7H3, a protein that is overexpressed in various cancers, including SCLC, and has been associated with a poor prognosis. DS-7300, an ADC consisting of a humanized anti-B7H3 antibody and deruxtecan, has shown great potential in an ongoing Phase I/II study involving 19 SCLC patients. Preliminary results showed encouraging ORR and DoR. These findings provide promising evidence of DS-7300's clinical activity.

Building upon this success, IBB0979, an immunocytokine targeting B7H3 and IL-10, is expected to further enhance the ORR while potentially offering improved safety. To evaluate the effectiveness of IBB0979 as a standalone treatment for patients with advanced-stage (≥2L) ES-SCLC, we plan to initiate a Phase II trial in China. The enrollment of the first patient is anticipated in the first quarter of 2025.

Major Indication

We are evaluating IBB0979 for the treatment of some of the most prevalent cancer types, such as mCRPC, considering that the combination therapy of B7H3 monoclonal antibody such as enoblituzumab (MGA271), and ADCs targeting B7H3 such as MGC018 and DS-7300, have demonstrated promising preliminary efficacy.

- 1L mCRPC

Prostate cancer ranks as the second most frequently diagnosed cancer and the sixth leading cause of cancer-related deaths among men worldwide. Despite the initial efficacy of androgen deprivation therapy in advanced prostate cancer, almost all patients eventually develop resistance, leading to biochemical and clinical evidence of treatment failure. This state is referred to as castration-resistant prostate cancer ("**CRPC**"). Over the past decade, researchers have identified various categories of treatments for CRPC, including chemotherapy, novel hormonal agents, and immune- and targeted therapies.

B7H3, a protein highly expressed in many prostate cancers, plays a role in modulating antitumor immune responses and is associated with a poor prognosis. MGC018 from, MacroGenics is a mAb targeting B7H3, currently undergoing Phase II investigation for mCRPC and ES-SCLC. Furthermore, DS7300a and MGC018, anti-B7H3 ADCs, have demonstrated promising outcomes in Phase I trials involving mCRPC subjects. Targeting B7H3 has emerged as an innovative therapeutic approach in the management of mCRPC.

IBB0979, an immunocytokine combining B7H3 and IL-10, holds potential as a treatment option to further enhance outcomes in mCRPC. We plan to enroll the first patient in the Phase II study of IBB0979 in combination with enzalutamide in China in the first quarter of 2025.

Global Strategy

We are carrying out a global strategy in the clinical development of IBB0979. In the U.S., we have obtained an IND approval for IBB0979 for conducting Phase I and Phase II clinical trials in solid tumors in October 2022. Because the clinical trial designs approved by the NMPA and the FDA are the same, we expect to leverage the Phase I clinical data collected in China to proceed with clinical development in the U.S. We will proceed clinical development in the U.S. either by ourselves or through collaboration with third parties. As of the Latest Practicable Date, we had not commenced the clinical trials in the U.S. and had not planned to commence the trials in the U.S. within the coming six months.

Licenses, Rights and Obligations

IBB0979 was developed by us, and we maintain the global rights to develop and commercialize this drug candidate.

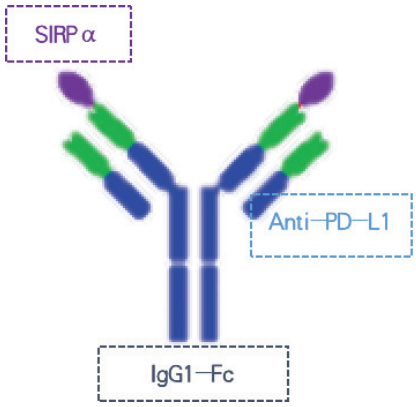
Material Communications With Competent Authorities

We have not received any concerns or objections from the NMPA and FDA related to our clinical development plans as of the Latest Practicable Date.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET IBB0979 SUCCESSFULLY

Clinical-Stage Product IBC0966 (PD-L1/SIRPα antibody fusion protein)

IBC0966 is a clinical stage, anti- PD-L1 antibody-SIRPα bifunctional fusion protein that simultaneously stimulates both innate and adaptive immunity to achieve strong synergistic effects and induce long-lasting tumor-specific immune responses. It is designed to bind to PD-L1 and trigger blockage of the PD-1/PD-L1 signaling pathway to enable T cells to recognize and kill targeted cancer cells, and in the meantime deliver SIRPα to the targeted TME to interact with CD47 to block the "don't eat me" signal of macrophages for tumor cell killing. The diagram below illustrates the structure of IBC0966:



Source: Company data

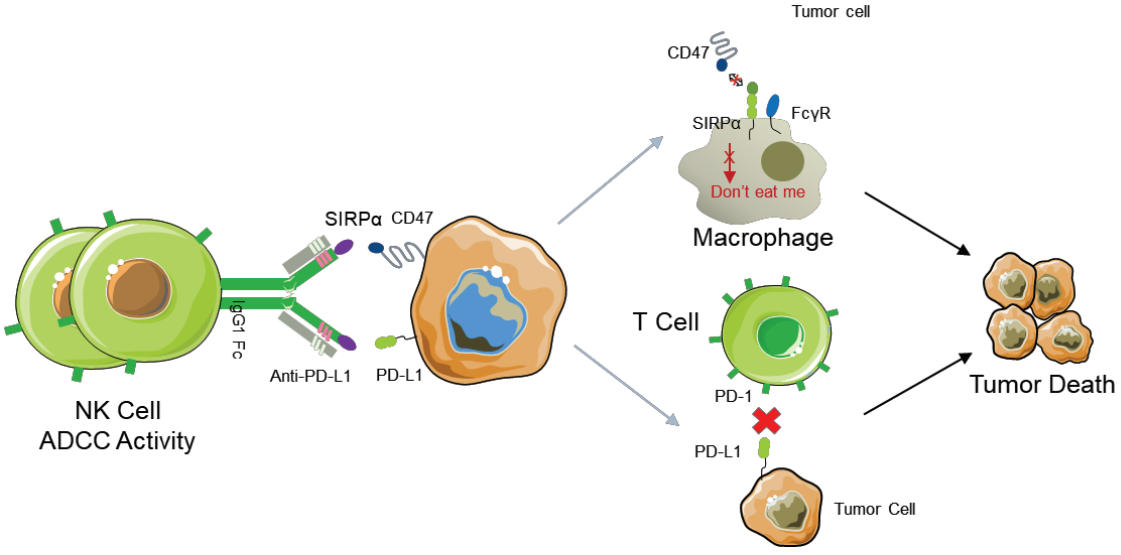
On March 17, 2021, we obtained the IND approval from the NMPA for conducting Phase I and Phase II clinical trials of IBC0966. We completed the Phase I study of IBC0966 as a monotherapy for advanced malignant tumors in December 2023, and expect to enter the Phase II clinical stage in the second quarter of 2024.

Mechanism of Action

SIRPα is a regulatory membrane protein that belongs to SIRP family. It interacts with CD47, which is usually over-expressed on tumor cells and trigger a signaling pathway called "don't eat me". This interaction negatively regulates the function of innate immune cells. Specifically, SIRPα diffuses laterally on the macrophage membrane and accumulates a phagocytic synapse to bind CD47 and signal "self", which inhibits the cytoskeleton-intensive process of phagocytosis by the macrophage. Therefore, blockade SIRPα from binding to CD47 will activate macrophage-mediated destruction against tumor cells that highly express CD47, and also present tumor antigens to activate the adaptive immune system.

The PD-1/PD-L1 pathway represents an adaptive immune resistance mechanism exerted by tumor cells in response to endogenous immune antitumor activity. PD-1 is expressed by all T cells during activation, which often shows high and sustained expression levels during persistent antigen encounter. Its ligand PD-L1 shows broad expression on tumor cells. Their engagement signals to prevent the immune system from attacking the tumor cells. Inhibitor that blocks the PD-1/PD-L1 pathway can prevent the cancer from evading the immune system attacks.

IBC0966 is a bifunctional antibody that targets both PD-L1 and CD47. It adopts a symmetrical mAb-Trap 2+2 molecular structure, and thus can avoid the potential mismatches between the light and heavy chains, which can improve the expression and purification yields and thus is suitable for industrial mass production. The SIRPα moiety of IBC0966 does not bind to human erythrocytes at all, which allows us to adopt an IgG1 structure that has enhanced antitumor activities through ADCC and ADCP activities. IBC0966's low systemic haematotoxicity also contributes to the anti-PD-L1 moiety, which binds to PD-1 with 45 times affinity of SIRPα to its target CD47. Through this design, IBC0966 is able to block "don't eat me" signal and PD-1/PD-L1 pathway, and thus simultaneously stimulates innate and adaptive immunity and exerts enhanced antitumor activities against tumor cells.



Source: Frost & Sullivan analysis

Market Opportunities

We plan to conduct a Phase II clinical trial of IBC0966 for NHL.

NHL

Lymphomas are a type of hematologic cancer that affects the lymphocytes, the cells of the immune system. There are two primary categories of lymphomas: Hodgkin's lymphomas and NHL. Non-Hodgkin lymphomas account for approximately 90% of all lymphoma cases and encompass various subtypes.

According to Frost & Sullivan, the global new cases of NHL reached approximately 569.4 thousand in 2022. It is estimated to rise to approximately 624.2 thousand in 2026 and 682.0 thousand in 2030. Incidence of NHL in China reached approximately 97.6 thousand in 2022. It is estimated to rise to approximately 107.3 thousand in 2026 and 117.0 thousand in 2030.

NHL treatment options, such as radiation therapy, chemotherapy, stem cell transplantation, and biologics, can lose their effectiveness due to drug resistance, resulting in R/R NHL that poses significant challenges with limited treatment options. In the case of R/R B-cell NHL, CD20-targeted therapy is typically recommended, but this option has limited efficacy and is susceptible to drug resistance and infusion-related reactions. While novel immunotherapies, such as PD-1/PD-L1 inhibitors, and targeted therapies, such as brentuximab, have been developed for R/R T-cell NHL, chemotherapy remains the primary treatment option, and there is a high demand for more specific treatment options. Similarly, the PD-1 inhibitor (sintilimab) has been tested for R/R NKTCL, but its complete response rate of 7.1% indicates limited efficacy. Therefore, there is an urgent need to introduce novel treatment options to address the medical needs of R/R NHL. For example, targeting SIRPα with novel options could potentially serve as a solution for T-cell NHL, addressing the unsatisfactory current treatment outcomes by enhancing innate immunity and promoting T cell response through activated macrophages.

Competitive Advantages

IBC0966 is the world's first PD-L1/SIRPα dual-target mAb-Trap molecule approved to enter clinical stage. It can achieve a differential binding of two targets and avoid binding to red blood cells and thus has an improved safety profile comparing to other CD47-targeting therapies. It targets two signaling pathways with synergistic mechanisms of action to activate both innate and adaptive immunity. Based on the excellent safety, efficacy and quality controllability, IBC0966 is currently in the Phase I clinical trial and has already demonstrated its initial safety and efficacy. IBC0966 has the potential to become a safer and more effective molecule in clinical practice, solving the current problem of drug resistance and ineffectiveness in solid tumors and hematological tumors.

In terms of molecular design, IBC0966 adopts a symmetrical mAb-Trap dual-target molecular structure, avoiding mismatches between light and heavy chains, with high expression and purification yields, and suitable for industrial mass production. In addition, the structure of SIRPα has undergone biological engineering to mutate certain amino acids to further optimize the quality of the product and the molecular stability.

IBC0966 showed high binding affinity for PD-L1 and thus improved the safety profile. IBC0966 does not bind to human red blood cells and thus does not cause erythrocyte agglutination or T cell apoptosis. Studies showed that there is a 45-fold difference in affinity between the PD-L1-binding end and the CD47-binding end, enabling the anti-PDL1 antibody moiety to further target the IBC0966 molecule to the TME and reducing the hematotoxicity of systemic cytotoxicity and providing a good safety profile. Preclinical data showed that cynomolgus monkeys tolerated IBC0966 well with a maximum tolerated dose of 50 mg/kg for a single dose and 5 mg/kg for repeated doses.

Furthermore, IBC0966 blocks CD47 and PD-L1-PD-1 signaling, which activates macrophages and CD8+ T cells, leading to the activation of tumor-specific T cells. It employs a more potent IgG1 isotype that acts as an ADCC and ADCP to mediate the killing of CD47/PD-L1-positive tumor cells and prevent tumor escape due to single target shedding. The death of tumor cells releases a large amount of tumor-associated antigens, which are presented to the adaptive immune system by antigen-presenting cells, changing the tumor microenvironment from "cold" tumors to "hot" tumors and activating the immune system to kill tumor cells more effectively. IBC0966 has shown a 91% tumor growth inhibition rate *in vivo*, which is significantly better than anti-PD-L1 mAb and its combination therapy.

Summary of Clinical Trial Results

Phase I clinical trial in patients with advanced malignant tumors

Trial Design. This was a Phase I open label study designed to evaluate the safety, tolerability, PK, immunogenicity, and preliminary efficacy of IBC0966 in patients with advanced malignant tumors who have failed standard treatment. The study included two phases: dose-escalation phase (Ia) and dose-expansion phase (Ib). Each treatment cycle was defined as four weeks. The DLT evaluation period was defined as 28 days following intravenous administration of the first dose of IBC0966 (Cycle 1). During the DLT evaluation period, IBC0966 was administered intravenously once weekly ("**QW**") for 0.025 mg/kg, 0.05 mg/kg and 0.1 mg/kg, 0.2 mg/kg, 0.4 mg/kg and Q2W for 0.8 mg/kg, 1.6 mg/kg and 3.2 mg/kg. Tumor assessments were performed every eight weeks (i.e., prior to dosing for Cycles 3, 5, 7, etc.). Patients enrolled in this study who did not experience a DLT or other unacceptable toxicity that necessitates permanent discontinuation of investigational product, may continue treatment for up to disease progression, initiation of alternative anti-cancer therapy, lost to follow-up, withdrawal of informed consent, death, or end of study.

The primary objective of Ia/Ib study of this trial was safety and RP2D. The secondary objective included assessing PK portfolio, immunogenicity, and preliminary efficacy. The secondary objective included PFS, OS, DCR, safety and immunogenicity.

Trial Status. We completed the Phase I study in December 2023.

Safety Profile. Among the 21 subjects enrolled in the Phase I study, all subjects experienced AEs with most of them were in Grade 1-2. Out of the 21 subjects, only 12 subjects experienced Grade 3-4 AEs, which were primarily related to decreased platelet count (9/12). The others experienced fatigue (1/12), abdominal bloating (1/12), pneumonia (1/12), decreased lymphocyte count (1/12), and hypokalemia (1/12).

Efficacy Profile. As of the cut-off date (September 5, 2023), 15 subjects were evaluable for the efficacy analysis. Evaluable subject was defined as a subject with at least one post-baseline tumor assessment. Of 15 evaluable subjects, one subject with lung cancer achieved PR and six subjects (one with breast cancer, one with Hodgkin's lymphoma, one with melanoma, one with ovarian cancer, and two with lung cancer) achieved SD. The DCR was 46.7%.

The table below shows the detailed profile of previous treatment for the patients achieving best response of PR and SD.

Group	Patient	Previous Treatment	Efficacy
0.05 mg/kg	Non-Hodgkin's lymphoma	Resistant to Vindesine Sulfate combined with Epirubicin and Asparaginase and Prednisone + Methotrexate+Methotrexate and 6-thioguanine + Vincristine combined with Daunorubicin and Prednisone and L-asparaginase (VDPL)+ Cytoxan combined with cytosine arabinoside and 6-thioguanine (CTA)+ Methotrexate and 6-thioguanine+fufang banmao capsule	Achieved SD in the first evaluation after two cycles of IBC0966 administration
0.4 mg/kg	Hodgkin's lymphoma	Resistant to Epirubicin combined with Bleomycin and Dacarbazine (ABVD)+ Tislelizumab + Sintilimab	Achieved SD in the first evaluation after two cycles of IBC0966 administration
1.6 mg/kg	Melanoma	Resistant to Docetaxel and carboplatin+ Docetaxel and cis-platinum+ Docetaxel+ Docetaxel and cis-platinum+ Toripalimab	Achieved SD after two cycles of IBC0966 administration
1.6 mg/kg	Ovarian cancer	Resistant to Docetaxel and carboplatin+ Docetaxel and cis-platinum+ Docetaxel+ Etoposide and cyclophosphamide+ Gemcitabine and cisplatin +Olaparib+ Niraparib+ Bevacizumab and paclitaxel+ bevacizumab and doxorubicin+ Bevacizumab and nab-paclitaxel+ Bevacizumab+ Bevacizumab and Niraparib+ Niraparib	Achieved SD after two cycles of IBC0966 administration
1.6mg/kg	Lung cancer	Resistant to Nedaplatin and nab-paclitaxel and Camrelizumab+ BC3402	Achieved SD after one cycle of IBC0966 administration
3.2mg/kg	Lung cancer	Resistant to pemetrexed and carboplatin combination therapy, crizotinib, and products in clinical trials	Achieved PR after two cycles of IBC0966 administration

Group	Patient	Previous Treatment	Efficacy
3.2mg/kg	Ovarian cancer	Resistant to paclitaxel and carboplatin combination therapy, radiotherapy for secondary and metastatic tumors, olaparib, fluzoparib, and bevacizumab and tirilizumab combination therapy	Achieved SD after two cycles of IBC0966 administration

Conclusion. IBC0966 exhibited a favorable safety profile in subjects with advanced or metastatic tumors and the preliminary efficacy results demonstrated encouraging antitumor activities for IBC0966 monotherapy in heavily pretreated patients.

Clinical Development Plan

We will strategically conduct Phase II clinical trials for conditional approval of IBC0966 for the treatment of R/R non-Hodgkin lymphoma ("**NHL**"). We believe that these strategic choices will accelerate the regulatory approval process and commercial launch of IBC0966.

- R/R NHL

R/R NHL continues to pose a significant clinical challenge. While autologous stem cell transplantation may cure some patients, the ORR to subsequent lines of treatment are suboptimal, and patients often face limited options. Although CAR-T therapy may offer long-term benefits to some patients, its impact remains limited by factors such as toxicity, cost, access, and relapse. Although checkpoint inhibitor has shown impressive activity in R/R Hodgkin lymphoma, the outcomes have been disappointing in NHL. The median ORR is approximately 20%, and complete or durable responses are infrequent, except for primary mediastinal B cell lymphoma.

In a Phase II study of anti-CD47 Magrolimab, patients with R/R NHL, including diffuse large B-cell lymphoma ("**DLBCL**") or follicular lymphoma, were administered magrolimab (anti-CD47 antibody) in conjunction with rituximab (anti-CD20 antibody) to assess safety and efficacy. Of the total patients, encouraging objective response and complete response rates were observed among patients with DLBCL and among those with follicular lymphoma. Therefore, the combination of magrolimab with rituximab therapy appeared to be safe and induced durable complete responses in patients.

IBC0966, a bifunctional antibody fusion protein blocking both CD47/SIRPα and PD-1/PD-L1 signaling pathways, is expected to provide improved clinical benefits. Our plan is to launch a Phase II trial in the second quarter of 2024 and evaluate the efficacy and safety of IBC0966 combination therapy for R/R NHL.

Licenses, Rights and Obligations

We acquired exclusive rights from ImmuneOnco Biopharmaceuticals (Shanghai) Inc. to develop, manufacture and commercialize IBC0966 in Greater China including mainland China, Hong Kong, Macau and Taiwan, and as well as 7.5% of interests in the overseas rights of IBC0966. For detailed information, see "— Collaboration Arrangement — Collaboration Agreement With ImmuneOnco in Relation to the Development of IBC0966" in this section.

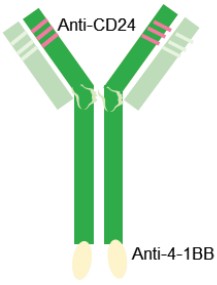
Material Communications with Competent Authorities

We have not received any concerns or objections from the NMPA related to our clinical development plans as of the Latest Practicable Date.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET IBC0966 SUCCESSFULLY

Clinical-Stage Product IBD0333 (4-1BB/CD24 BsAb)

IBD0333 is a clinical stage, 4-1BB and CD24 bsAb that simultaneously stimulates both innate and adaptive immunity to achieve strong synergistic effects with reduced hepatotoxicity. It is designed to bind to 4-1BB, a robust immune cell activator expressed by CD8+ T cells as well as DC cells, monocytes, B cells, mast cells, NK cells and neutrophils, and CD24, a target that plays a key role in tumor evasion in CD24-Siglec-10 axis and thus is highly expressed in many cancer types. The diagram below illustrates the structure of IBD0333:



Source: Frost & Sullivan analysis

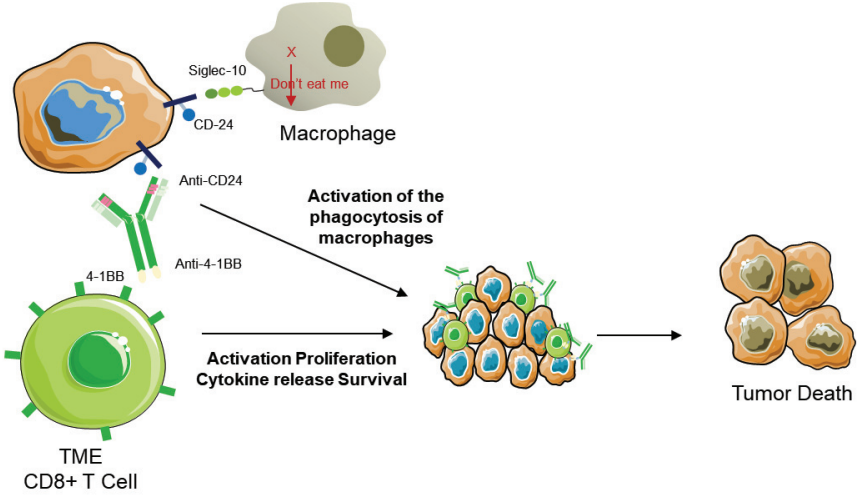
We have obtained IND approvals from the FDA on June 2, 2023 and from the NMPA on July 10, 2023. We initiated a Phase I clinical trial in March 2024 to evaluate its safety, tolerability, pharmacokinetic characteristics, and preliminary efficacy in patients with locally advanced/metastatic solid tumors in China. We expect to complete the Phase I study in the third quarter of 2025.

Mechanism of Action

4-1BB is a co-stimulatory molecule on immune cells. It is expressed on activated CD8+ T cells and forms a hexametric complex with the natural ligand 4-1BBL to stimulate T cell proliferation and activation. 4-1BB is also expressed on NK cells and enhances the ADCC effect of NK cells, promoting the proliferation of activated NK cells, eventually resulting in tumor cell apoptosis. In addition, 4-1BB is also highly expressed on DC cells, monocytes, B cells, mast cells, and neutrophils, which can trigger an activation signal in all these cell types. However, 4-1BB monoclonal antibody is hepatotoxic and requires TAA targeting to activate immune cells in the immune microenvironment more safely.

CD24 is a highly glycosylated protein with a small protein core that is linked to the plasma membrane via a glycosyl-phosphatidylinositol anchor. CD24 is primarily expressed by immune cells but is often overexpressed in human tumors. In cancer, CD24 is a regulator of cell migration, invasion and proliferation. Its expression is associated with poor prognosis and it is used as cancer stemness marker. CD24 can promote immune escape by interacting with the inhibitory receptor Siglec-10 on tumor-associated macrophages.

IBD0333 is a 4-1BB/CD24 bsAb. It adopts a symmetric structure of linking anti-CD24 moiety to the Fab region and anti-4-1BB moiety to the Fc region of both heavy chains of an IgG4 antibody backbone. The anti-CD24 moiety identifies CD24 expressed on the targeted tumor, and enrich anti-4-1BB terminus into the TME. As such, IBD0333 can specifically activate immune system in the tumor tissue and reduce systemic toxicity of 4-1BB.



Source: Frost & Sullivan Report

Competitive Advantages

Currently, there are no drugs targeting the 4-1BB pathway on the market, but there are multiple drugs under clinical development, including mAbs, bsAbs and CAR-T immunotherapy targeting 4-1BB. Among them, Urelumab (BMS-663513) and Utomilumab (PF-05082566) are two 4-1BB agonist mAbs that have made relatively fast progress. However, both drugs have certain limitations. Namely, Urelumab was observed to have dose-limiting hepatotoxicity and efficacy can be very limited at the safe dose. Utomilumab exhibited better safety and tolerability at higher doses than Urelumab, yet its efficacy was limited compared to Urelumab with only 3.8% overall ORR in solid tumor patients.

In addition to specifically enriching IBD0333 into the TME to reduce hepatoxicity, IBD0333 has additional unique structural designs that could potentially enable it to achieve superior safety and efficacy profile:

1. **Unique anti-4-1BB antibody design**. The 4-1BB signaling pathway is activated through binding to the 4-1BB and forming the 4-1BB trimer. The anti-4-1BB antibody in IBD0333 is an agonist antibody that targets a unique epitope so that when in absence of TAA, the anti-4-1BB antibody cannot stimulate the formation of the 4-1BB trimer. This design will reduce toxicity of 4-1BB in normal somatic cells, especially liver cells.

2. **Dual role of CD24**. When binding to CD24 overexpressed tumor cells, the anti-CD24 antibody of IBD0333 can specifically enrich anti-4-1BB antibody to the targeted site to induce a cross-linking effect between the anti-4-1BB antibodies. The cross-linking effect will enable anti-4-1BB antibodies to recognize 4-1BB and form the 4-1BB trimer to activate the T cells and other immune cells to kill tumor cells.

   CD24, expressed on the tumor cells, through its interaction with Siglec-10, expressed on macrophages, triggers a "don't eat me" signal that facilitate immune escape of tumor cells. By targeting CD24, the anti-CD24 antibody of IBD0333 blocks the signaling pathway of CD24/Siglec-10, and enable macrophage to recognize and kill tumor cells.

3. **The selection of IgG4 antibody backbone**. IBD0333 is a bsAb based on an IgG4. In general, IgG4 binds to its receptors with lower affinity (except for FcγRI), and is a poor inducer of Fc-mediated effector functions. Although existence of the anti-4-1BB antibody can block the Fc region's interaction with its receptors to some extent, Fc region of the antibody can still bind to its target to systemically activate immune cells that carries its receptors. By adopting IgG4 as its backbone antibody, IBD0333 further reduce the safety risk of 4-1BB.

Leveraging the synergistic effect between anti-CD24 moiety and anti-4-1BB moiety, IBD0333 is designed to specifically trigger the activation of immune cells, especially CD8+ T cells in the TME of the targeted tumor tissue, which can potentially lead to improved safety and efficacy portfolio.

Summary of Clinical Trial Results

Phase I clinical trial in patients with locally advanced/metastatic solid tumors or non-Hodgkin's lymphoma

Trial Design. This study is an open label, dose-escalation and extension Phase I clinical study to evaluate the safety, tolerability, PK profile, immunogenicity and preliminary efficacy of intravenous infusion of IBD0333 in subjects with locally advanced/metastatic solid tumors or non-Hodgkin's lymphoma, which is divided into two phases of dose-escalation and dose-expansion. Dose escalation is studied using an accelerated titration combined with a "3+3" design, starting with a starting dose of 0.05 mg/kg. The dose expansion is proposed to enroll six subjects with locally advanced/metastatic solid tumors or non-Hodgkin's lymphoma who have failed standard treatment or for whom no standard treatment is available or not applicable.

Primary endpoints of this study are DLT, MTD, RP2D and AEs. Secondary endpoints include PK profile, ADA assessment, ORR, DoR, PFS and OS.

Trial Status. We have obtained IND approvals from the FDA on June 2, 2023 and from the NMPA on July 10, 2023. We initiated the Phase I clinical trial in China in March 2024. As of the Latest Practicable Date, we had not commenced the clinical trials in the U.S. and had not planned to commence the trials in the U.S. within the coming six months.

Clinical Development Plan

We are executing a fast-to-market clinical development strategy in China and the U.S. targeting an array of cancer indications for our IBD0333. We plan to conduct Phase II clinical trials of IBD0333 for the treatment of cancer indications with few or no effective treatment options for heavily pretreated patients, including ovarian cancer ("**OC**"). We believe that this strategic choice will help accelerate IBD0333's regulatory approval process and commercial launch.

- *≥2L OC*

OC has a low cure rate and ranks fifth in terms of mortality rate among cancers affecting women. Approximately 75% of newly diagnosed patients are found to have advanced-stage disease, which partly explains the high mortality rate of this cancer. Even with aggressive treatment combining chemotherapy and debulking surgery, the five-year survival rate for advanced-stage disease is less than 30%.

Immunotherapy has emerged as a promising new option since immune checkpoint inhibitors (ICIs) have shown remarkable success in several cancers. However, unlike other immune-reactive cancers, OC has exhibited a response rate of only 10%-20% to immunotherapy in various clinical trials using anti-PD-1/PD-L1, and anti-CTLA-4 treatments. These poor results underscore the need for novel immunotherapeutic strategies.

Research on the 4-1BB+ T cell subset in ovarian cancer patients has revealed that this cell subset is distributed in three different locations: the TME, ascites, and peripheral blood. 4-1BB+ T cells are found to be in low level in peripheral blood, but they are predominantly found in ascites and even more so within the tumor. In addition, one patient with OC achieved a PR in a Phase I clinical trial of GEN1046 (PD-L1/4-1BB). Furthermore, a study showed a significant increase in the rate of apoptosis in the A2780 and HO-8910 PM OC cell lines after treatment with a monoclonal antibody targeting CD24.

We initiated the Phase I trial of IBD0333 for the treatment of advanced malignant solid tumor in China in March 2024, and expect to complete this trial in the third quarter of 2025. Based on the scientific finding and clinical data mentioned above, we intend to start a Phase II trial in the third quarter of 2025 to evaluate IBD0333 as a monotherapy in OC patients.

Licenses, Rights and Obligations

IBD0333 was developed by us, and we maintain the global rights to develop and commercialize this drug candidate.

Material Communications With Competent Authorities

We have not received any concerns or objections from the NMPA and FDA related to our clinical development plans as of the Latest Practicable Date.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET IBD0333 SUCCESSFULLY.

IND-Enabling Stage Pipeline Products

In addition to our clinical-stage drug candidates, we are developing a number of IND-enabling drug candidates that we believe have high commercial viability. As of the Latest Practicable Date, we are evaluating three of our IND-filed/IND-enabling candidates' pharmacokinetic and toxicokinetic in a variety of preclinical studies using *in vitro* and *in vivo* laboratory animal testing techniques, and these candidates have shown encouraging preliminary results in our preclinical studies.

IAN0982: IAN0982 is an internally developed multi-specific innate effector activator based on our AIM™ Platform. We are developing IAN0982 as a monotherapy or in combination with other therapeutics including chemotherapy and immunotherapy for the treatment of advanced solid tumors. Our IND application for IAN0982 is expected to be submitted to the NMPA and the FDA in the second quarter of 2024. We maintain the global rights to develop and commercialize IAN0982.

ISH0988: ISH0988 is an internally developed anti-inflammatory and tissue-protective bifunctional fusion protein based on our AIC™ Platform. We are developing ISH0988 as a monotherapy for the treatment of inflammatory bowel disease ("**IBD**"). Our IND application for ISH0988 is expected to be submitted to the NMPA and the FDA in the second quarter of 2024. We maintain the global rights to develop and commercialize ISH0988.

ISH0613: ISH0613 is an internally developed bifunctional antibody fusion protein that simultaneously inhibits B cell activation and IFNα secretion based on our AIC™ Platform. We are developing ISH0613 as a monotherapy for the treatment of SLE. Our IND application for ISH0613 is expected to be submitted to the NMPA and the FDA in the second quarter of 2024. We maintain the global rights to develop and commercialize ISH0613.

COLLABORATION ARRANGEMENT

In 2019, leveraging our platform capabilities and pipeline progress, we planned to further delve into our research and development domain, particularly focusing on simultaneous activation of both the innate and adaptive immune systems. Our initial investigations into the synergistic potential of dual-targeting PD-L1 and CD47 showed promising avenues for exploration. Recognizing that ImmuneOnco Biopharmaceuticals (Shanghai) Inc. ("**ImmuneOnco**") had achieved certain advancements in the differentiated study on SIRP, the ligand of CD47, we were particularly drawn to their drug candidate, namely IBC0966. This PD-L1/SIRPa bifunctional fusion protein matched our envisioned molecular design. With an eye on achieving a more definitive drug profile and capitalizing on the potential synergistic benefits of IBC0966 in tandem with our other pipeline drugs, we initiated a collaboration with ImmuneOnco.

Collaboration Agreement With ImmuneOnco in Relation to the Development of IBC0966

In October 2019, we entered into a collaboration agreement (the "**IBC0966 Agreement**") with ImmuneOnco with respect to the technology transfer, development, manufacture and commercialization of IBC0966. ImmuneOnco is a biotechnology company primarily engaged in the development of immuno-oncology therapies and it is an Independent Third Party to us. For details of IBC0966, see "— Drug Candidates — Clinical-Stage Product IBC0966 (PD-L1/SIRPα antibody fusion protein)" in this section.

Pursuant to the IBC0966 Agreement, ImmuneOnco transferred to us (i) all of its rights and interests, including but not limited to development, manufacture, regulatory filings, and commercialization, in relation to IBC0966 in mainland China, Hong Kong, Macau and Taiwan (the "**Territory**"); (ii) all related patents, if applicable, registered in the Territory; (iii) all technical data and analytical methods relating to the development of IBC0966. Accordingly, ImmuneOnco has transferred to us its invention patent in mainland China in relation to IBC0966 (patent number: CN111278865B), which invention patent covered all the key characteristics of IBC0966, and we have completed the administrative registration of the transfer. The application of this patent was filed on October 24, 2018 and the patent will expire on October 24, 2038.

We are entitled to all rights and interests of IBC0966 in the Territory and continue the development of IBC0966 including, among others, the preclinical and clinical researches, registrational applications, manufacture and commercialization of IBC0966 in the Territory at our costs, while ImmuneOnco retains the rights to develop, register and commercialize IBC0966 outside of the Territory. We do not share any R&D expenses with ImmuneOnco. We will assist ImmuneOnco in submitting IND and NDA applications to regulatory authorities in relation to IBC0966 outside of the Territory. Specifically, we will provide our clinical trial materials in relation to IBC0966 in the Territory, and application materials in relation to chemical, manufacturing and control as well as pre-clinical studies to ImmuneOnco. In return for the aforementioned efforts and assistance that we will make for ImmuneOnco's IND and NDA applications in relation to IBC0966 outside the Territory, as commercially agreed by both parties, we will be entitled to 7.5% of the interests of IBC0966 outside the Territory. In addition, should ImmuneOnco transfer or license its rights of IBC0966 outside of the Territory to a third party, we are entitled to 7.5% of the resulting proceeds garnered by ImmuneOnco.

In exchange of our rights, we are obligated to pay RMB20.0 million assignment fee by installments. As of the Latest Practicable Date, the rights and interests of IBC0966 as well as the related documents and materials had been duly transferred to us and we had paid ImmuneOnco an assignment fee of RMB10.0 million. The remaining RMB10.0 million will be payable upon our obtainment of the marketing approval of IBC0966 from the NMPA. In addition, ImmuneOnco is entitled to low single-digit percentage royalties based on the annual net sales of IBC0966 in the Territory until the earlier of the tenth year after the initial launch of IBC0966 or the expiration of the patents of IBC0966 molecule sequences. As of the Latest Practicable Date, we did not make or owe any royalties to ImmuneOnco.

The IBC0966 Agreement shall remain effective from execution until termination of the agreement. Either party may terminate the IBC0966 Agreement if the other party is in breach of its obligations under this agreement, and fails to take rectification measures after the non-breaching party gives a 30 days' written notice. The IBC0966 Agreement can also be terminated upon mutual consent if IBC0966 fails to obtain IND approval or reach the clinical endpoint due to reasons related to druggability. In addition, in the occurrence of certain safety issues resulting in the failure of IBC0966, we are entitled to a 50% payment return and ImmuneOnco is entitled to restitutions of the transferred rights and interests of IBC0966 upon the termination of the IBC0966 Agreement. The termination of this Agreement shall not release either party from any obligations or liabilities that have arisen under this agreement prior to such termination, nor shall it prevent either party from asserting any rights and remedies that it may have under this agreement or at law.

Apart from the rights and obligations under the IBC0966 Agreement, we procured a limited amount of raw materials (namely, cell culture medium) from ImmuneOnco. Other than the foregoing, there is no past or present relationships or dealings (including family, business, employment, trust, financing or otherwise) between our Group and ImmuneOnco, their respective substantial shareholders, directors or senior management, or any of their respective associates.

RESEARCH AND DEVELOPMENT

We consistently devote resources to research and development to pave for long-term growth. We believe the diversification and expansion of our product pipeline through both in-house research and development and through external collaboration are critical to our long-term competitiveness and success. Our research and development expenses in 2022 and 2023 amounted to RMB53.2 million and RMB43.0 million, respectively.

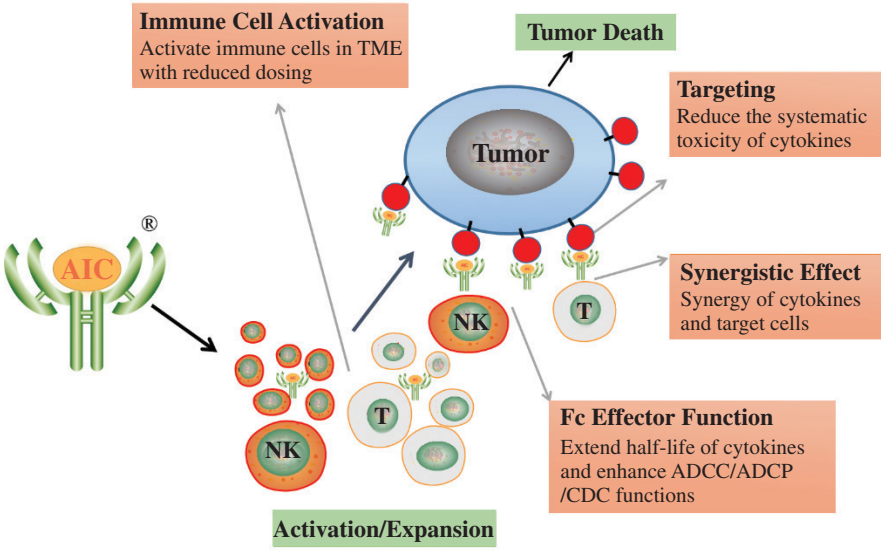
Our fully-integrated biological therapeutic platform encompasses all the key biologic drug development functionalities, and enables us to identify and address potential clinical and manufacturing issues early in the development process so we can direct our efforts towards biologics with the best potential to become clinically active, cost-effective and commercially viable drugs. Our platform spans from the early phase of identifying demand, developing core technologies, managing clinical trials and product registrations, to the manufacturing and marketing of products. We believe that our integrated capabilities give us the agility to formulate our innovation, registration, commercialization and product optimization strategies that can navigate us through rapidly changing market needs, enable us to improve pipeline viability and expedite product development cycle at lower cost.

R&D Platforms

We have built fully-integrated platforms to enable our in-depth R&D in the areas of immunology and oncology. Our core platforms include AIC™ Platform, AEA™ Platform and AIM™ Platform. Our platforms are integrated seamlessly to support key drug development functionalities, including antibody screening, functional evaluation, *in vivo* preclinical studies and biomarker identification. We have the expertise and capability to independently complete the entire drug development process from drug discovery to preclinical research to clinical development and to NDA/BLA application.

Armed ImmunoCytokine Platform, AIC™

Our AIC™ Platform is prominently positioned in the field of immunocytokine development from multiple aspects, including cytokine selection and optimization, antibody selection and engineering, structural design and engineering and production through customized cell line. It is a comprehensive research engine that includes not only a pool of intact IgG antibodies and cytokines, but also functional antibody fragments and other types of immune system modulators. It is able to generate products ranging from immunocytokines to bifunctional fusion proteins. The products designed from the AIC™ Platform may not only include immunostimulants that directly activate both innate and adaptive immunity, but also immunosuppressors that reduce an overactive immune system. Therefore, AIC™ Platform enables us to enrich our pipeline with candidates for treatment of cancer and viral infection, and also candidates for the treatment of autoimmune diseases and emergency care against cytokine storm. Our clinical programs IAP0971, IAE0972 and IBB0979 for cancer immunotherapy, and preclinical programs ISH0988 and ISH0613 for autoimmune diseases were developed based on the AIC™ Platform.



Source: Company data

Our AIC™ Platform successfully addresses technical difficulties for developing immunocytokines. These difficulties range from antibody and cytokine selection and optimization, to final drug production.

- Antibody/cytokine selection. Due to different spatial structure, different types of cytokines behave largely different when fused with antibodies targeting different antigens.

- Structural design. Dose ratio and activity between the selected antibody and cytokine is needed to be balanced to achieve the desired mechanism of actions ("**MoA**") and synergistic effects.

- Manufacturing capabilities. It is challenging for developing and manufacturing immunocytokine molecules, because they are structurally complicated, especially considering the degradation vulnerability of cytokines.

Core competencies of AIC™ Platform include MoA-based antibody-cytokine selection, biology-oriented structural design and protein engineering, and production through customized cell line.

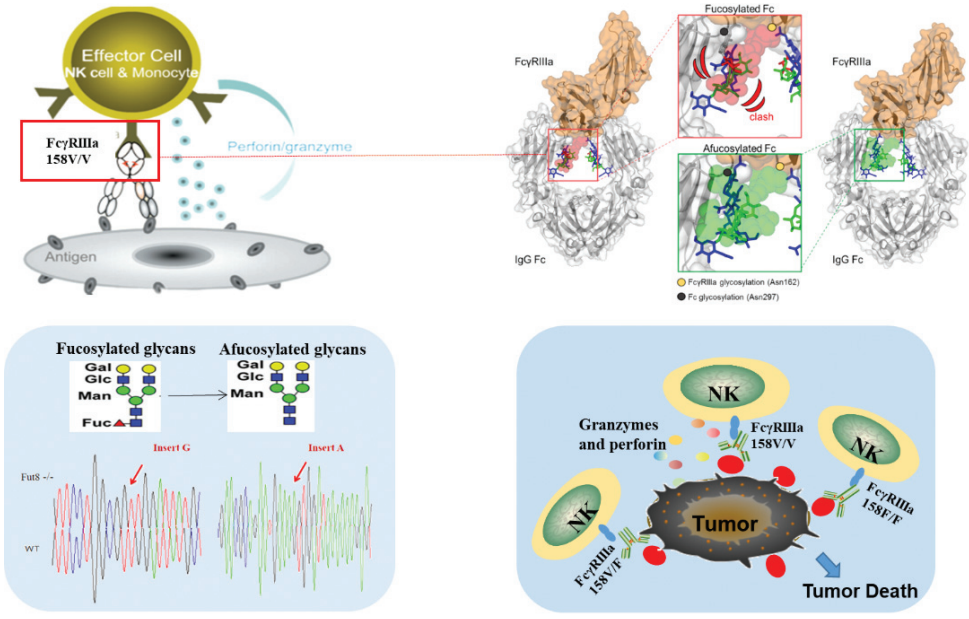
- MoA-based antibody-cytokine selection is the cornerstone to achieve desired synergistic effects between antibody and cytokine. For example, selection of anti-PD-1 antibody and IL-15 cytokine for developing IAP0971 is grounded on their shared action site on the same T/NK cells, leading to great *cis*-synergy. The combination of anti-EGFR antibody and IL-10 is selected based on the potential engager effects it can produce. Specifically, IAE0972 can engage CD8+ T cells through IL-10 while simultaneously targeting tumor cells through the EGFR antibody moiety.

- Structural design and protein engineering module enables us to structurally design and modify our products to achieve improved safety and efficacy profile while reducing manufacturing cost and enhancing product quality manageability. Structural modifications that we are capable to perform through AIC™ Platform include antibody and cytokine engineering, deglycosylation, linker/spacer design and optimization, and tertiary structure alteration. Especially, developed through the AIC™ Platform, IAP0971 employs the natural pairing of IL-15/IL-15Rα, which leads to more efficient dimerization and eliminates the formation of IL-15 homodimer and half antibody fragments. Additionally, a knobs-into-holes structure is introduced in the Fc region of the anti-PD-1 antibody, reducing the mismatch of two different heavy chains. These structural designs result in improved productivity of IAP0971. Furthermore, IAP0971 is also modified by engineering the IL-15/IL-15Rα heterodimers partially embedded into the "hinge" region in the anti-PD-1 antibody. We were the first to design and develop this structure. It can increase the stability of cytokine by "hiding" a substantial portion of cytokine within antibody to protect it from hydrolysis by proteases, as well as balances the activity of cytokine versus antibody by introducing steric hindrance to the cytokine, and in the meantime retains the specificity and affinity of cytokine to bind to its receptor and allows it to mediate immune responses.

- Production through customized cell line is another important function performed by our AIC™ Platform. The cell lines we constructed for producing immunocytokines and other bifunctional fusion proteins are obtained after undergoing multiple rounds of metabolic and growth optimization and are of high expression capacity and excellent purification yield. Coupled with unique cytokine-specific codon optimization, stably expressed vehicles with optimized expression cassettes and our high-throughput screening system, it is able to reach an expression level of 4g/L and one-step affinity chromatography purity of 86%, which is at the top level among rivals both at home and abroad, according to Frost & Sullivan.

ADCC Enhanced Antibody Platform, AEA™

Our AEA™ Platform is a biologically engineered Chinese hamster ovary ("**CHO**") cell line with the FUT8 knocked-out to generate antibodies with enhanced ADCC and improved antitumor activities. Through this bioengineering modification, the CHO cell line will not be able to catalyze the transfer of fucose residue from its donor to its target, and thus is not able to produce any antibody that carries fucose. Because absence of core fucose on the Fc region has been shown to increase the Fc region's binding affinity to its receptor FcγRIIIa present on immune effector cells, fucose-negative antibodies are expected to have enhanced ADCC activities through better activating immune effector cells. Accordingly, AEA™ Platform is expected to produce antibodies with 0% of fucose, which rapidly, stably, and thoroughly enhances the ADCC of antibodies and simplifies the quality control of the products. Therefore, AEA™ Platform can enable us to engineer any antibody or antibody portion (containing a Fc region) of biologics into ADCC enhanced products for enhanced immune effector cells activities.

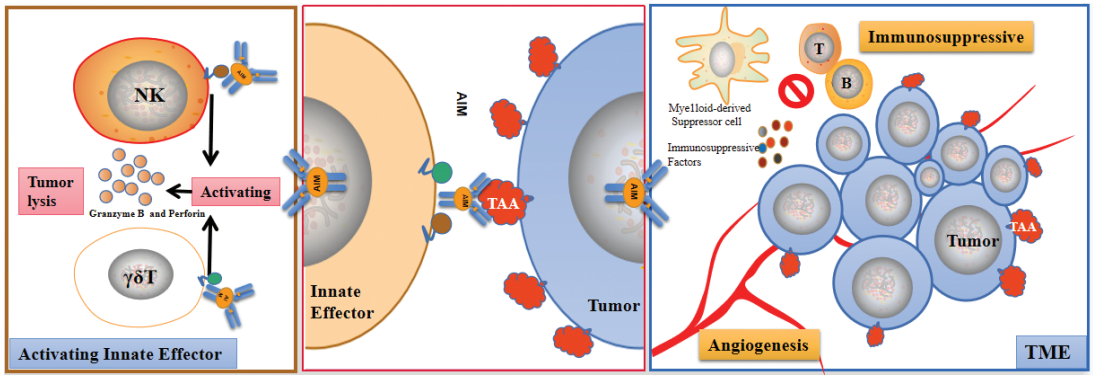


Source: Top left: Kubota et al, Cancer Sci (2009); top right: Yu et al, BioDrugs (2017); bottom left and bottom right: Company data

The feasibility and advantages of AEA™ Platform have been demonstrated by IAH0968, the potential first complete fucose-removal anti-HER2-antibody in clinical stage developed through this platform. We have verified through glycoprotein detection and glycosylation quantification that IAH0968 does not contain any fucose. In addition, *in vitro* and *in vivo* tests showed that the affinity between IAH0968 and its Fc receptor was 10-20 times higher than unmodified or the other ADCC enhanced anti-HER2 antibodies, resulting in greater enhanced ADCC activity and antitumor efficacy.

Armed Innate-effector Multispecific Platform, AIM™

Our AIM™ Platform focuses on designing multi-functional biological products by engaging the innate immune system for cancer immunotherapy. It selects tumor associated antigen antibodies for cancer targeting, receptors agonist antibodies for innate effector activation, and cytokines and other TME factors for immune modulation to design multi-specific antibody fusion proteins, and evaluates them in terms of expression, target binding, *in vitro* and *in vivo* biological activities, as well as druggability. Currently, we have developed several categories of proprietary AIM™ Platform that allow us to explore the combination of innate immunity stimulators with different types and numbers of targets, which provide us with abundant flexibility and diversity of various types of TME modulations for different clinical indications. In other words, AIM™ Platform can design and generate a huge pool of potential product candidates through combinations of different innate immunity stimulators, which will enable us to continuously develop new pipeline products.



Source: Company data

By targeting innate immunity stimulators instead of adaptive immunity stimulators, which is considered more cytotoxic and easily restrained by immune escape of tumors and the immunosuppressive TME, products developed from our AIM™ Platform are expected to achieve desired clinical safety and efficacy profiles. Our preclinical product IAN0982 was developed based on the AIM™ Platform.

R&D Team

Our core R&D team consists of eight members, each with industry experience ranging from over four to 16 years. The expertise of our team members spans the entire spectrum of biopharmaceutical development, encompassing drug discovery, preclinical pharmaceutical research, molecular structural design, drug testing and purification, formulation development, clinical researches, regulatory submissions and platform construction. As of the Latest Practicable Date, we had 43 members in our R&D team. In particular, 29 members focused on Core Products, around 82.8% of whom held master or doctoral degrees in relevant fields.

Our R&D team is led by our executive Director, chief executive officer and chief scientific officer, Dr. YIN Liusong, who had over 16 years of experience in antibody and cytokine development and pipeline management. Dr. Yin published more than 16 research papers in journals indexed in SCI, which were cited by others for more than 500 times. Dr. Yin received his Doctor's degree in biomedical sciences from UMass Chan Medical School. The executive Director and vice president overseeing our R&D is Ms. JIANG Xiaoling. Ms. Jiang had over 15 years' experience in R&D of pharmaceuticals including biosimilar drugs and antibody drugs, and led the development of about 20 innovative biologics and six biosimilars. Ms. Jiang received her master degree in Biochemistry and Molecular Biology from Nanjing University. Members of our experienced in-house R&D team come from a variety of medical backgrounds and has diverse and in-depth knowledge that is critical to strengthening our R&D capabilities.

In addition to Dr. Yin and Ms. Jiang, our core R&D team also consists of six managers with different expertise in drug development. Our pharmaceutical research manager, Mr. WU Chongbing, joined us in 2018 and had over 12 years of experience in protein engineering,

structural design, expression purification, and CMC research. He is responsible for the management of pharmaceutical research of our programs to ensure smooth and on time IND applications. Mr. Wu has contributed to the establishment of several technology platforms, formulation and purification process development, and structural design of antibodies and fusion proteins, and was named as inventor in over 30 patents. Our project evaluation and management manager, Ms. ZHOU Chong, also joined us in 2018 and had over five years of experience in cell line engineering and modification. She is mainly focusing on and responsible for antibody engineering, including cell line construction, antibody glycosylation engineering modification, and multi-specific antibody design. The core members of our R&D team also include our quality and analytic manager Ms. ZHOU Ying, our cell-line and upstream process development manager Ms. ZHU Yanan, our downstream and formulation development manager Mr. GU Haitao, and our *in vitro* pharmacology manager Ms. HUANG Zhenzhen. Leveraging comprehensive expertise of our core R&D team, we have successfully initiated and advanced our Core Products.

Since the inception of our business in 2018, we have been dedicated to the development and construction of R&D platforms facilitating the discovery and development of our pipeline portfolios. Before Dr. Yin and Ms. Jiang joining our Company, the design and establishment of the AIC™ and AIM™ Platforms were primarily led by Mr. Wu, who has completed the preliminary establishment of these two platforms. Leveraging the preliminary model of the AIC™ Platform, Mr. Wu also launched R&D projects for IAP0971 and IAE0972 and led the respective initial molecular structural design. The design and preliminary establishment of the AEA™ Platform were led by Ms. ZHOU Chong, who designed the FUT8 knockout strategy of the AEA™ Platform and verified and constructed cell lines with complete knockout of FUT8. In addition, she launched the R&D project for IAH0968 based on the AEA™ Platform.

Since Dr. Yin joined our Group in November 2020, he has further refined the system for cytokine selection of the AIC™ Platform based on his profound expertise and understanding of mechanisms of action of antibody and cytokines through structural design and activity validation of various immunocytokines. He has also refined the target selection mechanism of the AIM™ Platform to improve the potential efficacy of the generated product candidate leveraging his knowledge of mechanisms of synergistic effects of natural immune cell activators and tumor-associated antigens. Furthermore, he advanced the preclinical research of IAP0971 and IAE0972 by optimizing their respective structural designs, which led to the progression of their clinical process. Specifically, in relation to IAP0971, he proposed that forming a pre-complex of IL-15 with IL-15Rα can effectively avoid the silencing of IL-15 by its receptor in DC cells, placing IL-15/IL-15Rα complex in the middle of the antibody facilitates the regulation of cytokine activity. In relation to IAE0972, he proposed the monovalent design of the EGFR antibody to potentially reduce the skin toxicity of EGFR, and maintaining the natural activity of IL-10 by forming an IL-10 homodimer. Furthermore, he also determines the clinical development strategy of the Core Products based on the mechanism of action of the drug and the competitive landscape of the existing indications, as well as manages and monitors the progress of clinical advancement.

Since Ms. Jiang joined our Group in February 2020, she further refined the AEA™ Platform. Specifically, she led the screening of host cells of the AEA™ Platform to ensure that the growth and metabolism of AEA™ Platform host cells are normal, and verified each cell line through small-scale process studies. She also led the validation of multiple antibody drugs produced by AEA™ Platform host cells to ensure that the expression of the host cells was not affected by biological engineering, and verified the ADCC activity of the antibodies to determine the final cell line of the AEA™ Platform. In addition, Ms. Jiang led the preclinical pharmaceutical research of IAP0971 and IAE0972. She determined the preclinical research protocol in cynomolgus monkeys, and the clinical research protocol for investigating *in vivo* effectiveness and *in vitro* verification of mechanisms of action. Furthermore, she managed the IND applications for IAH0968, IAP0971 and IAE0972.

Drug Discovery and Preclinical Development

Leveraging our proprietary R&D platforms, AIC™, AEA™ and AIM™, we are able to conduct preclinical R&D activities including drug activity screening, studies of cellular functions of drugs, drug biochemical studies and biomolecule detection. The protein structures of our target candidates include single-pass transmembrane proteins, multi-pass transmembrane proteins, structure proteins with dependent molecular partners, and complex glycosylated proteins. Our R&D pathways span protein, whole-cell and Virus-like Particles immunization. We are also fully capable to perform common molecular and cellular biology experimental studies, such as cell activity detection, enzyme-linked immunosorbent assay test, molecular cloning, flow cytometry, and *in vitro* and *in vivo* assays.

- ***Candidate sequence discovery and screening.*** Our new targets are generally screened from candidate sequences via our discovery platforms. We established two discovery platforms – a mouse hybridoma platform for the production of full-length antibodies and a camelid antibody phage display screening platform for the production of nanobodies, enabling the construction of multi-target antibodies.

- ***Infrastructure in support of discovery platforms.*** Our discovery platforms are equipped with comprehensive infrastructure, including a hybridoma cell culture room for culture and fusion of myeloma and hybridoma cells; a physicochemical laboratory for screening of protein and cell binding; and a cell culture room for culture of tumor cells and function cells for *in vitro* activity evaluation.

- ***Evaluating functions and biological activities of candidate sequences.*** We will further evaluate the functions and biological activities of the selected antibody candidates. Early in the phase of candidate discovery and screening, we have established customized methods to evaluate the target binding affinity, competitive inhibition activities and biological functions of the candidate antibodies, by means of which we determine the candidate sequences with *in vitro* functionality.

- ***Evaluating in vivo efficacy and metabolism of rodents.*** We further evaluate the *in vivo* efficacy of molecules via the tumor or autoimmune disease models on laboratory rodents. Based on the results of efficacy test, we pick two to three molecules with clinical potential for further research on *in vivo* metabolism in rodents.

- ***Humanization and protein engineering.*** We pick the optimal germline from various forms of antibodies and transplant the complementarity-determining region of the non-humanized antibody to the humanized framework, followed by a restoration mutation to ensure the antibody affinity. Then we enhance druggability of the target antibodies by the post-translational modification in proteins.

With our preclinical research capability and leveraging our R&D platforms, we can efficiently complete target determination, screening optimization and IND application so as to continuously enrich our pipeline portfolio. We have the experience and ability to independently complete the entire drug development process from drug discovery to preclinical research to clinical development and to NDA/BLA application.

Clinical Development

Clinical Trial Design and Implementation

Our medical and clinical development team coordinates our trial design and execution, and manages the procedures of our clinical trials with the assistance of CROs, including implementation, drug supply, collection and analysis of trial data, and preparation of trial reports. Our trial advancements are driven by our clinical development experience, well-designed trial protocols, multi-center trial strategy in close collaboration with PIs, and efficient trial execution. We employ a clinical-demand-oriented approach to our R&D efforts. We strategically design the clinical trials of our drug candidates, critically select the registration pathways, diligently conduct our clinical trials to ensure speed of execution and data quality, and maintain constructive dialogues with the regulatory authorities to achieve optimal clinical efficacy, and accelerate the approval process of our drug candidates.

Our team is also responsible for the selection of trial sites. We select trial sites based on multiple factors. We regularly communicate with collaborating hospitals and principal investigators that can support our clinical trials of different indications at different stages. We believe that the size and the geographic diversity of these institutions provide us with a significant advantage in implementing large-scale clinical trials and also enable us to conduct multiple clinical trials concurrently.

Collaboration With CROs and Contract Service Providers

We take the lead in preclinical research, and design the clinical trials and protocols by ourselves. In line with the practice in the pharmaceutical industry, we engage CROs and third-party contract service providers to conduct and support our preclinical studies and clinical trials. They primarily assist in our research and development efforts by performing a

range of supportive tasks, such as toxicological testing, drug metabolism and pharmacokinetics ("**DMPK**") studies, early exploration of pipeline potential and site oversight, thereby enhancing the efficiency and effectiveness of our research initiatives. We closely supervise the activities of these third-party collaborators. We monitor their work progress to ensure they perform their duties to a standard in line with our protocols and industry benchmark to safeguard the integrity of the data collected from the trials and studies.

We engage the CROs and other contract service providers and research centers in our clinical trials on a project-by-project basis. We have taken several initiatives to make sure that these institutions perform their duties in a manner that complies with our protocols and applicable laws and to protect the integrity of clinical data. We provide these institutions with the final clinical trial protocols and a series of trainings to ensure their familiarity with the trials. They conduct the clinical trials based on our protocols, and we designate internal personnel to supervise the implementation phase. The following table sets forth the detailed information of the key contract service providers engaged by us during the Track Record Period:

Identity	**Background**	**Primary Involvement**	**Our purchase amount during the Track Record Period** *(RMB'000)*
CRO A	a pharmaceutical preclinical integrated R&D service CRO located in Shanghai, which mainly engaged in preclinical pharmacokinetics and safety evaluation research	Toxicological testing and DMPK evaluation	13,822
CRO B	a company based in Shanghai, which principally engaged in technology development, technology consulting, and clinical trial data management and statistical analysis services	Clinical data management	2,175
CRO C	a biotechnology company based in Suzhou, which mainly engaged in CRO services	Contract research services and testing	1,038

Identity	Background	Primary Involvement	Our purchase amount during the Track Record Period *(RMB'000)*
CRO D	a CRO company based in Nanjing, which mainly engaged in research and technology development relating to pharmaceutical and biological products	Sample testing	1,711
CRO E	a pharmaceutical company based in Guangzhou, which mainly engaged in CRO and CDMO services	Cell banking and testing, virus clearance validation	2,538
			21,284

Below is a summary of the key terms of an agreement we typically enter into with our CROs or contract service providers:

- ***Services.*** Our cooperating partner provides the research and development and technical services required by us, including but not limited to the implementation and management of a preclinical or clinical research project, preclinical safety evaluation, PK/PD research and clinical sample testing, as specified in the agreement.

- ***Term.*** Our cooperating partner is required to perform its services and complete the preclinical or clinical research project within the prescribed time limit set out in each agreement, or until the agreement is terminated by mutual agreement, by prior written notices from either party, or due to a material breach as stipulated in the agreement.

- ***Payments.*** We are required to make payments to our cooperating partner in accordance with the payment schedule agreed by the parties.

- ***Intellectual property rights.*** We own all intellectual property rights arising from the preclinical or clinical research project.

- ***Confidentiality.*** Our cooperating partner is obligated to keep confidential all the data, information or contents we distributed to our cooperating partner related to the project specified in the agreement, and such obligation may survive the termination of the agreement.

- ***Risk allocation.*** The risk allocation between the parties and indemnification are subject to further negotiation between the parties.

We determine the service fee with our contract service providers based on the expected or actual work performed by them as well as the estimated or actual cost incurred by project basis. During the Track Record Period, none of our CROs or other contract service providers, including their directors, shareholders and senior management, had any past or present relationship with us or our subsidiaries, shareholders, directors or senior management, or any of their close associates.

We believe working with CROs and contract service providers shortens the time required for drug development by generating the requisite data reliably and efficiently.

CMC AND MANUFACTURING

Chemistry, Manufacture & Controls ("CMC") Team

Our CMC team provides strong support throughout the drug development process. Our CMC team is led by Mr. JIANG Dongcheng, the vice president and head of production, who had 10 years of experience in GMP manufacturing. Our CMC team is mainly responsible for cell line development, upstream and downstream process development, formulation development, GMP-compliant manufacturing and quality management.

Manufacturing Facilities

We have established our own global GMP-compliant manufacturing facilities in Nanjing, PRC, which meet both clinical and commercial production demands for quantity, quality and dosage form of our drug candidates. We currently have four active drug substance production lines up to a total capacity of 1,600L, including three 200L and one 1,000L disposable bioreactors. We have successfully completed over 30 production batches of immunocytokines, mAbs, bsAbs and fusion proteins, which fulfilled the needs for preclinical studies, pilot production of antibody drugs and early phase clinical trials. In addition, we have completed the installation of a production line for 5,000L bioreactor capacity, and completed the qualification in November 2023. When putting into operation, it will enable us to manufacture our drug candidates for Phase III clinical trials and commercialization in-house. Our drug product facilities include one commercial-scale liquid injection filing production line and one commercial scale lyophlized powder production line, which enables us to prepare biological products into various dosage forms. Leveraging the vast experience of our industry veterans in manufacture of pharmaceutical products, we strategically front-loaded our production capacity

infrastructure in a relatively cost-efficient manner. As compared with production outsourcing, our robust independent production capability guarantees a stable and sufficient supply of drug candidates with more manageable production costs and guaranteed quality.

The table below sets for the production details of our pipeline products as of the Latest Practicable Date:

Pipeline product	Dosage form	Total volume produced as of the Latest Practicable Date	Number of batches produced for clinical use	Number of batches produced for non-clinical use	Success rate of product release
IAH0968	lyophilized powder	1,200L	3	3	100%
IAP0971	lyophilized powder	600L	1	2	100%
IAE0972	lyophilized powder	800L	2	2	100%
IBB0979	lyophilized powder	400L	1	1	100%
IBC0966	lyophilized powder	800L	2	2	100%
IBD0333	lyophilized powder	400L	1	1	100%

Leveraging our manufacturing capacities, we occasionally provided contract manufacturing services, primarily including cell line development process development, GMP/cGMP production, sample detection and stability study. We monitor and measure our CMC process and ensure sufficient manufacturing capacity in support of clinical trials. During the Track Record Period, we provided contract manufacturing services to one biotechnology company based in Hefei, Anhui Province, for production of monoclonal antibody drug in compliance with GMP/cGMP standards. The contract manufacturing services agreement set forth the exact scope of services with detailed specifications, standards, requirements and timeline for each type of services. The service fees were determined mainly based on the amount and type of services we provide and the cost of raw materials and consumables. For details, see "Financial Information — Description of Major Components of Our Results of Operations – Other Income" in this document. We expect to devote our productive forces to our own drug candidates and products as our clinical trials progress and after our commencement of commercialization. This biotechnology company is an Independent Third Party. None of our Directors, their close associates or any shareholder who, to the knowledge of our Directors, owned more than 5% of our issued share capital as of the Latest Practicable Date, had any interest in this biotechnology company during the Track Record Period.

CMC

CMC Activities and Capabilities

CMC refers to activities to properly define methods for manufacturing processes, product characteristics and testing, product storage and release to clinical usage in order to ensure that a pharmaceutical product is safe, effective and consistent between batches. Because of the complexity of therapeutic antibody, CMC is essential for antibody drug development from cell line development to process development to formulation.

Our CMC platform, which includes our proprietary manufacturing processes and related analytics, contributes to the potency and the safety profile of our product candidates. We endeavor to build our CMC expertise and create proprietary end-to-end manufacturing process with the capability to produce high quality, generally well-tolerated and potent product candidates. We believe that the combination of processes, analytics, know-how and understanding of biological immunotherapies that forms our CMC capability is competitive in the industry. Our proprietary process is made possible through a set of key in-house capabilities, ranging from process development to analytical capabilities, manufacturing, quality control and quality assurance. The modularity of our platforms and product characterization enable us to effectively leverage the knowledge we gained from our existing programs to optimize the development of new programs.

Cell Line Development

Our manufacturing process commences with cell-line development. In this stage, leveraging our R&D platforms, we utilize advanced biological engineering techniques to create cell lines, such as CHO and FUT8-knockout cell lines, that are capable of producing the desired therapeutic proteins. Theses cell lines, once established, served as the foundation for our production process.

Process Development

The process development can be generally divided into the upstream and downstream process development. Built on our advanced platform technologies, our process development capability ensures the biologics delivery for our preclinical studies and clinical trials:

- *Upstream process development*. The upstream process development, including, among others, cell thawing, cell proliferation, media optimization and focuses on generating products with a high product titer, high productivity and high quality.

- *Downstream process development*. The downstream process development improves the purity of biologics and assures safety through various chromatographic and non-chromatographic technologies to improve the efficiency of purification.

Formulation Development

Diving into researches on stability of antibody proteins, the osmotic regulation process, the protein structure and surface tension and other aspects in the process of drug formulation, we have established expertise in the development of drug formulations and conducted over ten formulation studies for different antibody proteins. Meanwhile, we have established production lines spanning lyophilization, vial filling and prefilled syringe. Through the formulation screening and optimization, our liquid filing capacity is up to 150 vials/minute while our lyophilization product filling capacity can reach 40,000 vials/batch.

We determine the optimal dosage form based on the mechanism of action and anticipated clinical use of various drug candidates. The table below sets forth a general timeline for the determination and development of dosage forms:

Development Phase	Key Steps	Approximately Time Consumed
Drug candidate characterization	Preliminary selection between the dosage forms of liquid injection and lyophilized powders	Four weeks
Cell line construction	Preliminary screening of formulation and preparation technique	Eight weeks
Laboratory development	Verification of prescription and development of formulation process	Eight weeks
Pilot scale production	Confirmation of prescription and formulation process	Four weeks
Early clinical research	Further development of the formulation in terms of dosage form, concentration, prescription, and specifications	One to two years
Pivotal clinical research	Finalization of the formulation's dosage form, concentration, and prescription	Two to three years

GMP-Compliant Manufacturing

We have our own global GMP-compliant manufacturing facilities and strictly implemented the requirements under the GMP/cGMP standards, Chinese and U.S. pharmacopoeias and other relevant regulations and guidelines in our product manufacturing process. We have completed the installation of a production line for 5,000L bioreactor capacity, and completed the qualification in November 2023. When putting into operation, it will enable us to manufacture our drug candidates for Phase III clinical trials and commercialization in-house. Our manufacturing capabilities play a critical role in our drug research and development and pave the way for our future commercialization.

Quality Management

Quality control ("**QC**") and quality assurance ("**QA**") are crucial to us. We endeavor to ensure the quality of our operation through a comprehensive quality management system in accordance with the regulations of the NMPA and the FDA and other applicable regulations, including GMP/cGMP and the standards of the Chinese and American Pharmacopoeias.

We have established QC and QA procedures for monitoring operations to ensure that they meet relevant regulatory and internal quality requirements. We implement QC measures for the development and production process, mainly including control and inspection of raw materials, management of each step of the development and production procedures, inspection of samples, establishment of internationalized product release standards, and risks evaluation during the product development and manufacturing.

Quality Control: Our QC team is mainly responsible for quality inspection of GMP-compliant manufacturing, analytical method validation, product quality standard establishment, product release testing, and stability assessment. Our QC team also inspects raw materials, intermediate products, raw liquids, finished products, and decides whether to release such materials for manufacturing. Process validation is generally conducted after the initiation of the pivotal clinical stage, and the key steps primarily include (i) the finalization of process validation plan that takes approximately one month; (ii) the preparation of materials for validation that takes approximately one month, and (iii) the validation process for three batches of drug substance and drug product that takes approximately four months. The analytical method validation for the BLA applications is typically conducted with the first batch of drug substance from the process validation and the whole process usually takes around two to four months.

Quality Assurance: Our QA team is mainly responsible for managing experimental documents, overseeing manufacturing site and final products for clinical usage, compliance assessment, and the inspection and audit of our outsourced vendors. We implement strict procedures for receiving and releasing of the raw materials used in the production, intermediate products, raw liquids and buffers, and finished products.

We have established a series of internal procedures and protocols including standard operating procedures for quality management of manufacturing process, product release and stability study. We also have standard operating procedures in place to ensure that the finished production meets the process requirements by relevant regulatory authorities. Such procedures ensure the high quality of our products used for clinical trials. In general, the Center for Food and Drug Inspection of NMPA will conduct the on-site GMP compliance inspection at the time when we submit BLA applications for our product candidates, or it may choose to conduct spot checks after the launch of products. We anticipate to receive the GMP compliance inspection when we submit BLA applications for our product candidates. As of the Latest Practicable Date, no deficiencies had been found in relation to our manufacturing process.

Inventory Management

Our inventories consist of raw materials and consumables for production of drug substance. As of December 31, 2022 and 2023, we had inventories of RMB0.9 million and RMB0.8 million, respectively. We generally maintain an inventory level for raw materials to support our preclinical and clinical demands based on the research and development plans for our drug discovery and pipeline product candidates. To ensure the quality of our inventory and prevent inventory loss due to improper storage, we conduct periodic inspections of our warehouses, ensuring that our inventories are stocked in appropriate conditions and are able to meet the needs of our operations.

Regulatory Affairs

Our regulatory affairs team is responsible for the registration filings and management of intellectual properties for our product candidates. To ensure the compliance with the application and registration requirements in relation to clinical trials and commercialization, our regulatory affairs team is responsible for assembling application dossiers for IND and NDA/BLA, addressing inquiries from relevant authorities, conducting CMC and cGMP compliance assessments for product candidates to ensure their compliance with relevant regulations. We possess both knowledge and experience with regard to regulatory filings in China and the U.S.

COMMERCIALIZATION

We currently have no drug approved or in commercial stage yet. However, we have been building up our commercial planning and portfolio management capability since our pipeline drug candidates entered into clinical trials. When the drug candidates are in late-stage development and getting closer to NDA or BLA filing, we intend to form our in-house marketing and sales team by recruiting senior-level sales and marketing personnel who are experienced in treatment fields we focus on. Our marketing and sales team will be responsible for market strategy, product positioning, market access, market penetration, promotion activities, and patient support. They will help oncologists, immunologist and other relevant industry experts understand the MoA, clinical data and differentiation of our products. We will promote medical science liaisons including KOL engagement, medical education, medical conference management, investigator-initiated study support, and promote product differentiation. We may also seek strategic collaboration opportunities for the commercialization of our drug candidates in China. In particular, we may selectively license-out, establish joint ventures or through other forms of partnerships collaborate with leading biopharmaceutical companies for executing late-stage clinical trials and/or marketing our drug candidates.

Pricing

When our Core Products and our other product candidates progress to commercialization, we mainly will determine their prices based on a number of factors, including our costs of production, prices of competing drugs (if applicable), differences in features between our drugs and competing drugs, health economics, market trends and changes in the levels of supply and demand. Considering that some cancer patients, especially late-stage cancer patients, may be reluctant to pay for highly-priced drugs to treat terminal or deadly diseases, in addition to aforementioned main factors, we may also consider treatment needs and payment preference of late-stage cancer patients when determine the prices. We plan to make a detailed pricing strategy when such drug candidates progress toward commercialization.

As of the Latest Practicable Date, there was no pricing guidance or centralized procurement requirement set by the PRC government on our product candidates. In order to gain market share against existing and future branded and generic competitors, we will seek inclusion of our Core Products and other product candidates into the NRDL and other reimbursement programs through active negotiations with the relevant authorities such inclusion. However, inclusion into the NRDL is evaluated and determined by the relevant government authorities and we may face significant competition for successful inclusion.

SUPPLIERS AND RAW MATERIALS

Suppliers

During the Track Record Period, our purchases mainly include contract services in support of our preclinical and clinical research, premise leases and equipment procurement, and application fees relating to the regulatory filings and clinical trial applications. In terms of our purchases of CRO services and other contract research services, we are generally required to make payments upon achieving certain milestones as stipulated in the related agreements.

The following table sets forth details of our five largest suppliers in 2023:

Five largest suppliers	Commencement of business relationship	Background	Major purchases	Credit terms	Purchase amount	Percentage of total purchase
					(RMB'000)	*(%)*
Supplier A	2021	a pharmaceutical preclinical integrated R&D service CRO located in Shanghai, which mainly engaged in preclinical pharmacokinetics and safety evaluation research	Contract research services and testing	Instalment payments to be made upon completion of milestones, as applicable	2,729	12.0
Supplier B	2022	a pharmaceutical company based in Guangzhou, which mainly engaged in CRO and CDMO services	Contract research services and testing	Instalment payments to be made upon completion of milestones, as applicable	2,538	11.2
Nanjing Bode	2018	a company based in Nanjing, which principally engaged in R&D, manufacturing and sales of small molecule active pharmaceutical ingredients	Premise lease	payment before next lease term	2,433	10.7
Supplier C	2022	a clinical trial site based in Jinan, providing clinical trials related services	Clinical trials	Instalment payments to be made upon completion of milestones, as applicable	1,964	8.6
Supplier D	2011	a company based in Shanghai, which principally engaged in clinical stage CRO services	Contract research services	Instalment payments to be made upon completion of milestones, as applicable	1,674	7.4
Total					**11,338**	**49.9**

The following table sets forth details of our five largest suppliers in 2022:

Five largest suppliers	Commencement of business relationship	Background	Major purchases	Credit terms	Purchase amount	Percentage of total purchase
					(RMB'000)	*(%)*
Supplier A	2021	a pharmaceutical preclinical integrated R&D service CRO located in Shanghai, which mainly engaged in preclinical pharmacokinetics and safety evaluation research	Contract research services and testing	Instalment payments to be made upon completion of milestones, as applicable	11,093	35.2
Nanjing Bode	2018	a company based in Nanjing, which principally engaged in R&D, manufacturing and sales of small molecule active pharmaceutical ingredients	Premise lease	payment before next lease term	2,224	7.1
Supplier E	2020	a medical and food engineering company based in Shanghai, which mainly engaged in research, development, manufacture and sales of medical equipment	Equipment purchase	Instalment payments within 12 months after acceptance of goods	1,679	5.3
Supplier F	2021	a biotechnology company based in Suzhou, which mainly engaged in testing services	Contract research services and testing	Instalment payments to be made upon completion of milestones, as applicable	1,038	3.3
NMPA	2020	the National Medical Products Administration responsible for registration of medical devices for the Chinese market	Clinical trials application	15 days after acceptance of application	1,008	3.2
Total					**17,042**	**54.1**

In 2022 and 2023, the aggregate purchase attributable to our five largest suppliers in each year accounted for 54.1% and 49.9% of our total purchases, respectively. The purchase attributable to our single largest supplier in each year accounted for 35.2% and 12.0% of our total purchases, respectively. We believe that adequate alternative sources for such supplies exist and we will establish necessary relationships with alternative sources based on supply continuity risk assessment.

To the best of our knowledge, all of our five largest suppliers in each year during the Track Record Period were Independent Third Parties, except for Nanjing Bode Biological Pharmaceutical Co., Ltd. (南京博德生物製藥有限公司) ("**Nanjing Bode**") which was a related party to us during the Track Record Period but has become an Independent Third Party since July 2023. For further details, see "Relationship with Our Controlling Shareholders — Clear Delineation of Business — Nanjing Bode" in this document.

During the Track Record Period, we leased premises and purchased equipment from Nanjing Bode, which was on an arm's length basis and in the ordinary course of our business operation. During the initial stage of production line setup, we opted to lease premise and purchase equipment from Nanjing Bode as it had leasable properties and ready-to-use machinery equipment with proven quality that met our specific manufacturing needs. Such arrangement facilitated a swift and efficient deployment of our manufacturing facilities. We believe that there is no concentration risk relating to our transactions with Nanjing Bode as (i) there are plenty of alternative locations with valid titles for us to choose from and we do not foresee difficulties or administration burden to relocate if needed; and (ii) the purchase of machinery and equipment was non-recurring in nature. We did not purchase any other machinery and equipment from Nanjing Bode during the Track Record Period and up to the Latest Practicable Date.

During the Track Record Period, we purchased a large portion of the contract research services and testing services from certain CROs. We select our CRO collaborators and third-party service providers based on various factors, including but not limited to their quality standard, regulatory compliance, technical expertise, production capacity, geographic proximity, track record and reputation in the industry, and reliability in meeting delivery timelines. For details of our collaboration, see "— Research and Development — Clinical Development — Collaboration with CROs and Contract Service Providers" in this section. We consider it important to maintain good business relationships with CROs and our other suppliers and where possible, diversify our supplier base so as to avoid any disruptions in service supply. Our Directors confirm that during the Track Record Period and as at the Latest Practicable Date: (i) we did not experience any material difficulties in obtaining clinical services in a timely manner; (ii) we did not have any material disputes with our major suppliers; (iii) as confirmed by F&S, there are many qualified service providers which are experienced in the area we focused on; and (iv) as our clinical trials needs expanded with the development of our product candidates as more of them entered into clinical trials and for indications expansion, we plan to collaborate with more service providers to support us.

Raw Materials

During the Track Record Period, we have procured raw materials and consumables for the production of our drug candidates and our contract manufacturing services. During the Track Record Period, we did not experience any significant fluctuations in raw material prices or delays that had a material impact on our results of operations or financial position. The raw materials for our drug candidates to be used in clinical trials as well as materials for our laboratory use are generally readily available in the market through multiple suppliers.

INTELLECTUAL PROPERTY

Intellectual property, including patents, trade secrets, trademarks and copyrights, is critical to our business. Our success depends in part on our ability to obtain and maintain intellectual property protection for our drug candidates, novel discoveries, product development technologies, inventions and know-how. Our success also depends in part on our ability to defend and enforce our patents including patents that we have or may issue from our patent applications, preserve the confidentiality of our trade secrets and operate without infringing the valid and enforceable patents and other proprietary rights of other parties.

We have adopted a strategy to develop a global portfolio of patents to protect our drug candidates and product development technologies. As of the Latest Practicable Date, we owned 14 issued patents and 124 patent applications, including 54 patent applications in China, nine patent applications in the U.S., and 61 patent applications under the Patent Cooperation Treaty ("**PCT**"), relating to certain of our drug candidates and product development technologies.

As of the Latest Practicable Date, (i) for our Core Product IAH0968, we had three material patents granted in China, and three material patent applications in China, and two material patent applications under PCT; (ii) for our Core Product IAP0971, we had one material patent granted in China, five material patent applications in China, and one material patent application in the U.S.; and (iii) for our Core Product IAE0972, we had five material patent applications in China and one material patent application under PCT. The following table summarizes the details of the material patents by our Company in connection with our Core Products:

Core Products	Patent/Patent application No.	Protection Scope	Jurisdiction	Status	Date of Application	Date of Grant	Date of Expiration	Commercial Rights	Applicant	Inventors
IAH0968	202110589738.6	A CHO cell culture method	PRC	Granted	2021/05/28	2023/10/24	2041/05/28	proprietary rights	SunHo (China) BioPharmaceutical	ZHU Yanan, JIANG Xiaoling, CHEN Jun, DING Liangliang

Core Products	Patent/Patent application No.	Protection Scope	Jurisdiction	Status	Date of Application	Date of Grant	Date of Expiration	Commercial Rights	Applicant	Inventors
IAH0968	202110520687.1	A CHO cell culture method	PRC	Granted	2021/5/13	2024/1/12	2041/5/13	proprietary rights	SunHo (China) BioPharmaceutical	JIANG Xiaoling, ZHU Yanan, WANG Xiuyuan[3]
IAH0968	202011532430.X	Fucose removed anti-HER2 antibody freeze-dried powder injection and preparation method thereof	PRC	Granted	2020/12/23	2024/1/2	2040/12/23	proprietary rights	SunHo (China) BioPharmaceutical	JIANG Xiaoling, WU Chongbing
IAP0971	202010534034.4	A multifunctional antibody, its preparation and application thereof	PRC	Granted	2020/06/12	2023/03/21	2040/06/12	proprietary rights	SunHo (China) BioPharmaceutical	JIANG Xiaoling[2], JIANG Dongcheng, WU Chongbing

The following table summarizes the details of the material filed patent applications by our Company in connection with our Core Products:

Core Products	Patent/Patent application No.	Protection Scope	Jurisdiction	Status	Date of Application	Commercial Rights	Applicant	Inventors[1]
IAH0968	202310193170.5	Use of an anti-HER2 antibody in the preparation of drugs for the treatment of cancer	PRC	Pending	2023/03/03	proprietary rights	SunHo (China) BioPharmaceutical	YIN Liusong, JIANG Xiaoling, XU Tie
	202310193224.8	Use of an anti-HER2 antibody in the preparation of drugs for the treatment of cancer	PRC	Pending	2023/03/03	proprietary rights	SunHo (China) BioPharmaceutical	YIN Liusong, JIANG Xiaoling, XU Tie
	202011244613.1	A method of knocking out the FUT8 gene	PRC	Pending	2020/11/10	proprietary rights	SunHo (China) BioPharmaceutical	JIANG Xiaoling, ZHOU Chong, WU Chongbing
	PCT/CN2024/079489	The usage of an anti-HER2 antibody in the preparation of cancer therapeutic drugs	PRC	Pending	2024/03/01	Proprietary rights	SunHo (China) BioPharmaceutical	YIN Liusong, JIANG Xiaoling, XU Tie

Core Products	Patent/Patent application No.	Protection Scope	Jurisdiction	Status	Date of Application	Commercial Rights	Applicant	Inventors[1]
	PCT/CN2024/079492	The usage of an anti-HER2 antibody in the preparation of cancer therapeutic drugs	PRC	Pending	2024/03/01	Proprietary rights	SunHo (China) BioPharmaceutical	YIN Liusong, JIANG Xiaoling, XU Tie
IAP0971	US17/633,477	A multifunctional antibody, its preparation and application thereof	U.S.	Pending	2020/07/09	proprietary rights	SunHo (China) BioPharmaceutical	JIANG Xiaoling[2], JIANG Dongcheng, WU Chongbing
	202310171538.8	A multifunctional antibody, its preparation and application thereof	PRC	Pending	2020/06/12	proprietary rights	SunHo (China) BioPharmaceutical	JIANG Xiaoling[2], JIANG Dongcheng, WU Chongbing
	202110010966.3	A target PD-1 multi-functional antibody combination	PRC	Pending	2021/01/06	proprietary rights	SunHo (China) BioPharmaceutical	JIANG Xiaoling, WU Chongbing, ZHU Cailin, DU Wuchen[3]
	202110010974.8	A multi-functional antibody combination	PRC	Pending	2021/01/06	proprietary rights	SunHo (China) BioPharmaceutical	JIANG Xiaoling, WU Chongbing, ZHU Cailin, DU Wuchen[3]
	202110329842.1	A fusion protein sample fast analysis method	PRC	Pending	2021/03/29	proprietary rights	SunHo (China) BioPharmaceutical	JIANG Xiaoling, ZHOU Ying, WU Huimin, LIU Mengting[3]
	202211293585.1	A fusion protein purification method	PRC	Pending	2022/10/21	proprietary rights	SunHo (China) BioPharmaceutical	JIANG Xiaoling, WU Chongbing, GU Haitao

Core Products	Patent/Patent application No.	Protection Scope	Jurisdiction	Status	Date of Application	Commercial Rights	Applicant	Inventors[1]
IAE0972	202110141918.8	A stable anti-EGFR antibody mixture	PRC	Pending	2021/02/02	proprietary rights	SunHo (China) BioPharmaceutical	JIANG Xiaoling, WU Chongbing, ZHU Cailin, DU Wuchen[3]
	202110497420.5	Anti-EGFR fusion protein or combination of its antigen-binding fragments and application thereof	PRC	Pending	2021/05/08	proprietary rights	SunHo (China) BioPharmaceutical	JIANG Xiaoling, WU Chongbing, ZHOU Ying, DU Wuchen[3]
	202110264314.2	A fusion protein fast analysis method	PRC	Pending	2021/03/11	proprietary rights	SunHo (China) BioPharmaceutical	JIANG Xiaoling, WU Chongbing, ZHOU Ying, WU Huimin, LIU Mengting[3]
	202210424493.6	An asymmetric fusion protein purification method	PRC	Pending	2022/04/21	proprietary rights	SunHo (China) BioPharmaceutical	JIANG Xiaoling, YIN Liusong, WU Chongbing, GU Haitao
	202211220978.X	A fusion protein purification method	PRC	Pending	2022/10/08	proprietary rights	SunHo (China) BioPharmaceutical	JIANG Xiaoling, YIN Liusong, GU Haitao
	PCT/CN2023/123701	A heterodimeric fusion protein and application thereof	PCT	Pending	2023/10/10	proprietary rights	SunHo (China) BioPharmaceutical	JIANG Xiaoling, YIN Liusong, WU Chongbing

Notes:

(1) All inventors of our material patents and patent applications are our current or previous R&D personnels.

(2) With JIANG Xiaoling's knowledge in the field of biotechnology, biochemistry, cell line construction and biosimilar drugs through her academic studies and past working experience, JIANG Xiaoling participated in discussions with, among others, WU Chongbing for the R&D project for IAP0971 at its initial phase and provided suggestions on IAP0971's certain features such as expression and purification outside her working hours during the time when her employment was with Nanjing Yoko Pharma Co., Ltd. (南京優科製藥有限公司) (a wholly-owned subsidiary of Nanjing Yoko). To recognize her contribution to and participation in the R&D project for IAP0971, JIANG Xiaoling was also named as one of the inventors in respect of a patent application of our Group numbered 201910776848.6 (the "**Patent Application**") which subsequently became a priority right for another patent of our Group numbered 202010534034.4 and two other patent applications of our Group numbered 202310171538.8 and US17/633,477, respectively. As confirmed by Nanjing Yoko, Ms. Jiang did not make use of any resources and technology of Nanjing Yoko in connection with her such participation and the Patent Application is not a service invention (職務發明創造) in which Nanjing Yoko has had any interest. Further, as advised by the Company's legal advisers as to intellectual property laws, Jingtian & Gongcheng and Venture Partner, LLC, the risk of disputes arising from the ownership of the Patent Application is relatively remote.

(3) Our previous employees.

As of the Latest Practicable Date, we had three material patent applications in the U.S., three material patent applications in China for AIM™ Platform, four material patent applications in China, and one material patent application under PCT for AIC™ Platform, and one material patent application in China for AEA™ Platform. The following table summarizes the details of the material filed patent applications by our Company in connection with our R&D platforms:

Platform/ product candidates	Patent/Patent application No.	Protection Scope	Jurisdiction	Status	Date of Application	Commercial Rights	Applicant	Inventors[1]
AIM™	US18/569,320	A multi-specific antigen-binding protein and use thereof	U.S.	Pending	2022/06/13	proprietary rights	SunHo (China) BioPharmaceutical	ZHOU Chong, YIN Liusong, JIANG Xiaoling
	US18/293,500	A multi-specific antigen-binding protein and use thereof	U.S.	Pending	2022/07/27	Proprietary rights	SunHo (China) BioPharmaceutical	ZHOU Chong, YIN Liusong, JIANG Xiaoling
	US18/293,515	A multi-specific antigen-binding protein and use thereof	U.S.	Pending	2022/07/27	Proprietary rights	SunHo (China) BioPharmaceutical	ZHOU Chong, YIN Liusong, JIANG Xiaoling
	202280052098.8	A multi-specific antigen-binding protein and its application	PRC	Pending	2022/06/13	proprietary rights	SunHo (China) BioPharmaceutical	ZHOU Chong, YIN Liusong, JIANG Xiaoling
	202280052163.7	A multi-specific antigen-binding protein and its application	PRC	Pending	2022/07/27	proprietary rights	SunHo (China) BioPharmaceutical	ZHOU Chong, YIN Liusong, JIANG Xiaoling
	202280052131.7	A multi-specific antigen-binding protein and its application	PRC	Pending	2022/07/27	proprietary rights	SunHo (China) BioPharmaceutical	ZHOU Chong, YIN Liusong, JIANG Xiaoling

Platform/ product candidates	Patent/Patent application No.	Protection Scope	Jurisdiction	Status	Date of Application	Commercial Rights	Applicant	Inventors[1]
AIC™	202110972207.50	A multifunctional fusion protein and application thereof	PRC	Pending	2021/08/24	proprietary rights	SunHo (China) BioPharmaceutical	ZHOU Chong, WU Chongbing, YIN Liusong, JIANG Xiaoling, WANG Yizhen[2]
	202110971791.20	A multifunctional fusion protein and application thereof	PRC	Pending	2021/08/24	proprietary rights	SunHo (China) BioPharmaceutical	ZHOU Chong, WU Chongbing, YIN Liusong, JIANG Xiaoling, WANG Yizhen[2]
	202210801304.20	A dimeric fusion protein and applications thereof	PRC	Pending	2022/07/08	proprietary rights	SunHo (China) BioPharmaceutical	ZHOU Chong, YIN Liusong, JIANG Xiaoling
	202210853460.30	A dimeric fusion protein and applications thereof	PRC	Pending	2022/07/08	proprietary rights	SunHo (China) BioPharmaceutical	WU Chongbing, YIN Liusong, JIANG Xiaoling
	PCT/CN2023/105535	A heterodimeric fusion protein and its application	PCT	Pending	2023/07/3	proprietary rights	SunHo (China) BioPharmaceutical	ZHOU Chong, YIN Liusong, JIANG Xiaoling
AEA™	202110752316.60	A method for knocking out the FUT8 and the antibodies obtained thereof	PRC	Pending	2021/07/02	proprietary rights	SunHo (China) BioPharmaceutical	ZHOU Chong, YIN Liusong, JIANG Xiaoling

Notes:

(1) All inventors of our material patents and patent applications are our current or previous R&D personnels.

(2) Our previous employees.

Our IAH0968 is featured by completely defucosylated anti-HER2 antibody and indication, which have been covered by patent No. CN202110589738.6 and patent applications No. CN 202310193170.5, CN 202310193224.8.

Our IAP0971 is featured with two main components. Each component consists of a paired heavy and light chain. These pairs are designed to bind to the PD-1 antigen, a key target of the immunotherapy. Additionally, one heavy chain in our product comprises a cytokine IL-15 moiety and an immunoglobulin Fc part, while the other comprises a cytokine IL-15 receptor and an immunoglobulin Fc part. These elements are designed to interact with each other, enhancing the product's functionality. The features of IAP0971 have been covered by patent No. CN 112409484B and patent applications No. CN 202310171538.8 and US 17/633,477.

Our IAE0972 is featured by a composition of a first heavy chain, a light chain, and a second heavy chain. The first heavy chain features an Fc region fused with IL10. In contrast, the second heavy chain collaborates with the light chain to create a targeted portion specifically binding to EGFR. Together, these chains synergize to form the heterodimer fusion protein. The features of IAE0972 have been covered by patent application No. PCT/CN2023/123701.

In view of the above, we come to the conclusion that our current patents and patent applications have covered all the key features or characteristics of the Core Products.

We do not foresee difficulties in obtaining the relevant approvals of patent applications that cover the key features or characteristics of our Core Products based on a comprehensive review of the following facts. Our patent and patent applications covered our drug candidates that were internally discovered and developed by us. Up to the Latest Practicable Date, none of our patent applications had been rejected by the PRC and U.S. Patent Offices. We performed competitor landscape search for the inventions defined in our patent applications to determine whether our inventions are covered by any prior art and whether they are novel and potentially inventive, and the search results indicate high probability for obtaining patents for our Core Products. Our Industry Consultant, Frost & Sullivan, is also of the view that the competitor landscape search is commonly used and reliable means to estimate the probability of obtaining a patent in the pharmaceutical industry. In addition, we would like to highlight the inherent advantages associated with biological drugs, like our Core Products, in obtaining patent protection. Given the complexity and specificity of the structure and sequence of each biological drugs including our Core Products, it inherently possesses a distinctiveness that typically simplifies the patent approval process. Unlike small molecule drugs, which may face challenges due to the existence of numerous similar compounds, the unique sequence and structure of a biological drug makes it easily distinguishable, reducing the likelihood of overlaps with existing patents. Based on the inherent characteristics of our Core Products, we believe there is no foreseeable difficulties or legal impediments for us to obtain approvals for material patent applications, which is also in line with the general trends observed in the patenting of biologics. Even if our Group fails to obtain relevant patents, this would simply mean that the technology intended to be covered by such patent applications is not protected by patent rights, and we believe the loss of patent protection will not hinder us from developing and commercializing the drug candidates by using such technology, as well as our know-how and trade secrets in developing the drug candidates. Therefore, there is no material implication on our Group's business, financial position or results of operations. However, we cannot provide any assurance that patents will be issued with respect to any pending patent applications or any such patent applications that may be filed in the future. See also "Risk Factors — Risks Relating to Our Intellectual Property Rights" in this document for the impact on our business, financial position or results of operations if we eventually fail to obtain the relevant patents.

Our legal advisers as to intellectual property law, Jingtian & Gongcheng and Venture Partner, LLC, having checked and reviewed the legal status of the material patent applications, in the public online databases of the CNIPA, and World Intellectual Property Organization, and some other public patent databases as well as information provided by us regarding the pending patent applications, advised that they were not aware of foreseeable difficulties or legal impediments for us to obtain the relevant approvals for material patent applications, except that these patent applications remain subject to the examination opinions (if any) from the applicable patent examination authorities during the ordinary pendency and examination of such patent applications.

As further advised by legal advisers as to intellectual property law, given that obtaining relevant patents is not a prerequisite for our future R&D or commercial activities, the loss of patent protection (if any) will not hinder us from developing and commercializing the drug candidates by using the related technology, know-how and trade secrets in developing the drug candidate.

In addition, based on the results of the competitor landscape search, we have not identified any foreseeable risk of infringement by our Core Products against other major market player's patents or patent applications. During the Track Record Period and up to the Latest Practicable Date, we had not received any IP rights infringement complaints and our product candidates had not been subjected to any claim, litigation or investigation for any IP issue. Furthermore, our legal advisers as to intellectual property law have conducted the freedom-to-operate searches and analysis and did not identify any substantial risk of infringement by any current key technologies or features of our Core Products against any active patents in China and the U.S.

The term of individual patents may vary based on the countries in which they are obtained. In most countries in which we file patent applications, including China and the U.S., the term of an issued patent is generally 20 years from the filing date of the earliest non-provisional patent application on which the patent is based in the applicable country. In the U.S., a patent's term may be lengthened in some cases by a patent term adjustment, which extends the term of a patent to account for administrative delays by the United States Patent and Trademark Office ("**USPTO**"), in excess of a patent applicant's own delays during the prosecution process, or may be shortened if a patent is terminally disclaimed over a commonly-owned patent having an earlier expiration date.

In addition, with respect to any issued patents in the U.S., China and certain other foreign jurisdictions, we may be entitled to obtain an extension of the patent's term provided we meet the applicable requirements for obtaining such patent term extensions. For example, in the U.S., 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, referred to as the Hatch-Waxman Amendments. The exact duration of the extension depends on the time we spend in clinical trials, as well as getting a BLA 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 product approval, a patent may be extended only once, and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. Furthermore, a reference biological product is granted 12 years of data exclusivity from the time of first licensure of the product, and the FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product. Furthermore, in China, the PRC Patent Law introduces patent extensions to patents of new drugs that launched in the PRC, which may enable the owner of the patent for an innovative new drug that has been granted the marketing authorization in China to submit applications for a patent term extension of up to a maximum length of five years, in order to compensate the time required for the regulatory approval for

the commercialization of such innovative new drug; provided that, the patent term of such innovative new drug shall not exceed a total of 14 years. In certain other foreign jurisdictions, similar extensions as compensation for regulatory delays are also available.

The actual protection afforded by a patent varies on a claim-by-claim and country-by-country basis and depends upon many factors, including the type of the 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 issue with respect to any of our pending patent applications or any such patent applications that may be filed in the future, nor can we provide any assurance that any of our issued patents or any such patents that may be issued in the future will be commercially useful in protecting our drug candidates and methods of manufacturing the same.

We may rely, in some circumstances, on trade secrets and/or confidential information to protect our technology. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with consultants, scientific advisors and contractors, and invention assignment agreements with our employees. We have entered into confidentiality agreements and non-competition agreements with our senior management and key members of our R&D team and other employees who have access to trade secrets or confidential information about our business.

These agreements may not provide sufficient protection of our trade secrets and/or confidential information. These agreements may also be breached, resulting in the misappropriation of our trade secrets and/or confidential information, and we may not have an adequate remedy for any such breach. In addition, our trade secrets and/or confidential information may become known or be independently developed by a third party, or misused by any collaborator to whom we disclose such information. Despite any measures taken to protect our intellectual property, unauthorized parties may attempt to or successfully copy aspects of our products or to obtain or use information that we regard as proprietary without our consent. As a result, we may be unable to sufficiently protect our trade secrets and proprietary information.

We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. Despite any measures taken to protect our data and intellectual property, unauthorized parties may attempt to or successfully gain access to and use information that we regard as proprietary. For more details, see "Risk Factors — Risks Relating to Our Intellectual Property Rights" in this document.

We also own a number of registered trademarks and pending trademark applications. We have registered trademarks for our corporate logo in China and are seeking trademark protection for our corporate logo in the jurisdictions where available and appropriate.

During the Track Record Period and up to the Latest Practicable Date, (i) we were not involved in any legal, arbitral or administrative proceedings in respect of, and we had not received notice of any claims of infringement, misappropriation or other violations of third-party intellectual property; and (ii) we were not involved in any proceedings in respect of any intellectual property rights that may be threatened or pending and that may have an influence on the research and development for any of our drug candidates in which we may be a claimant or a respondent.

COMPETITION

The markets for biopharmaceutical industry, in particular, antibody products and fusion proteins, are evolving and highly competitive. While we believe that our research and development capabilities enable us to establish a favorable position in the industry, we encounter competition from international and domestic biopharmaceutical companies, specialty pharmaceutical and biotechnology companies of various sizes, academic institutions and research institutions.

We believe our principal competitive advantages are integration of proprietary R&D platforms, identification of promising targets, mechanisms and pathways for drug development, molecule screening and design, efficacy and safety of drug candidates, and manufacturing efficiency. We expect the competition will become more intensive in the future as additional players enter into these segments. Any drug candidates that we successfully develop and commercialize will compete with existing drugs or any new drugs that may become available in the future. For more information on the competitive landscape of our drug candidates, see "Industry Overview" in this document and "— Drug Candidates" in this section.

INSURANCE

We maintain insurance policies that we consider to be in line with market practice and adequate for our business. We maintain property insurance covering physical damage to, or loss of, our equipment; employer's liability insurance covering death or work injury of employees; and clinical trial insurance covering us against liability in the event of injury to any trial subject caused by serious adverse events in our clinical trial. For details, see "Risk Factors — Risks Relating to our Operations — We have limited insurance coverage, and any claims beyond our insurance coverage may result in our incurring substantial costs and a diversion of resources" in this document.

We consider that the coverage from the insurance policies maintained by us is adequate for our present operations and is in line with the industry norm. During the Track Record Period, we had not made or been the subject of any material insurance claims.

EMPLOYEES

As of the Latest Practicable Date, we had 118 employees in total in China. The following table sets forth the number of our employees categorized by function as of the Latest Practicable Date.

Function	Number	Percentage of total
R&D	40	33.9%
CMC and Regulatory Affairs	57	48.3%
General and Administration	21	17.8%
Total	118	100.0%

We enter into individual employment contracts with our employees covering salaries, bonuses, employee benefits, workplace safety, confidentiality obligations, work product assignment clause and grounds for termination. We also enter into separate confidentiality and non-competition agreements with our senior management and certain key members of our R&D team and other employees who have access to trade secrets or confidential information about our business.

To maintain our workforce's quality, knowledge, and skill levels, we also provide regular and specialized trainings tailored to the needs of our employees in different departments. We regularly organize training sessions conducted by senior employees or third-party consultants covering various aspects of our business operations including overall management, project execution and technical know-how. We also provide training programs to our employees from time to time to ensure their awareness and compliance with our policies and procedures in various aspects.

We are committed to making sure that working conditions throughout our business network are safe and that employees are treated with care and respect. Our employees' remuneration comprises salaries, bonuses, house provident funds, social insurance premium, and other welfare payments. Furthermore, we provide various incentives and benefits, including bonuses and share-based compensation, to our employees, particularly our key employees. We have made contributions to our employees' social insurance premium (including pension plans, medical insurance, work-related injury insurance, unemployment insurance and maternity insurance) and housing provident funds pursuant to applicable laws and regulations. Certain of our practices is not in full compliance with relevant statutory social insurance premium and housing provident fund obligations applicable to us under the PRC laws. See "Risk Factors — Risks Relating to Our Operations — Any failure to comply with the PRC regulations regarding contribution of social insurance premium or housing provident funds may subject us to fines and other legal or administrative measures" for more information. As of the Latest Practicable Date, we had not received any order of correction or any fines or

penalties from the competent authority as a result of any such failure. We have obtained certain confirmation letters issued by the relevant competent social insurance and housing provident fund authorities confirming that there is no record of any member of our Group that hires employees being imposed administrative penalties by the relevant authorities for violation of the relevant laws and regulations. As advised by our PRC Legal Adviser, the likelihood that we will be required to settle all historical social insurance premiums and housing provident funds and be subject to material administrative penalties due to our failure to make full contributions of social insurance premium and housing provident funds for some of our employees during the Track Record Period is relatively low, provided that there are no material adverse changes in the current regulatory policies and environment and no material employee complaints occur.

As of the Latest Practicable Date, our employees were represented by a labor union. We believe that we maintain a good working relationship with our employees. During the Track Record Period, we did not have any strikes, protests or other material labor conflicts that may materially affect our business and image.

LAND AND PROPERTIES

As of the Latest Practicable Date, we had entered into a state-owned construction land use rights grant contract with Planning and Natural Resources Bureau (規劃和自然資源局) in Nanjing for a parcel of land with a total site area of approximately 26,524.8 sq.m. We were in the process of obtaining the land use right certificate for such land. As of the Latest Practicable Date, we leased two properties with an aggregate GFA of approximately 8,070.6 sq.m., which were primarily used for offices, R&D and manufacturing. We believe our current facilities are sufficient to meet our near-term needs, and additional space can be obtained on commercially reasonable terms. We do not anticipate undue difficulty in renewing our leases upon their expiration.

The following table sets forth the details of our leased property as of the Latest Practicable Date:

Location	Type of Property	GFA	Lease Term
		(sq.m.)	
Nanjing	Office/R&D center/ Manufacturing Plant	8,000	April 1, 2023 – March 31, 2028
Huzhou	Office	70.6	October 15, 2023 – October 14, 2026

As of the Latest Practicable Date, our lease in Huzhou had not been filed with competent governmental authority. For details of risks relating to our leased properties, see the section headed "Risk Factors — Risks Relating to Our Operations — We do not own the real property for our current major operation sites and are subject to risks associated with leasing space" in this document.

We do not have any property interest with a carrying amount of 15% or more of our consolidated total assets as of December 31, 2023. Therefore, according to Chapter 5 of the Listing Rules and [**REDACTED**] of the Companies (Exemption of Companies and Prospectuses from Compliance with Provisions) Notice (Chapter 32L of the Laws of Hong Kong), this document is exempted from compliance with the requirements of section 342(1)(b) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance in relation to paragraph 34(2) of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance which requires a valuation report with respect to all of our interests in land or buildings.

AWARDS AND RECOGNITIONS

We have received various awards and recognitions for our projects and entities. The following table sets forth the selected awards and projects as of the Latest Practicable Date:

Year of Grant	Project/Entity	Award/Recognition	Issuing Authority
2023	SunHo (China) BioPharmaceutical	Top 50 in China's Biologics R&D Strength Ranking in 2023	2023 Conference on the High-quality Development of the Health Industry
2021	IAH0968	Provincial Key Research and Development Plan (Social Development) Project (Project Announcement No. 168)	Jiangsu Provincial Department of Science and Technology
2021	IAP0971	Nanjing Life and Health Technology Special Project – Breakthrough in Clinical Frontier Technology	Nanjing Municipal Science and Technology Bureau

OCCUPATIONAL HEALTH, SAFETY AND ENVIRONMENTAL MATTERS

Overall

We are committed to operating our business in a manner that protects the environment and providing our employees with a healthy and safe workplace.

We will comply with the environmental, social and governance ("**ESG**") reporting requirements after [**REDACTED**] and the responsibility to publish ESG report on an annual basis in accordance with Appendix C2 to the Listing Rules. We will focus on each of the areas as specified in Appendix C2 to the Listing Rules to analyze and disclose important ESG matters, risk management and the accomplishment of performance objectives, particularly those environmental and social issues that could have a material impact on the sustainability of our operations and that are of interest to our Shareholders. Specifically, we have implemented the following measures with respect to hazardous waste discharge: (i) requiring

proper handling and disposal of hazardous waste; (ii) setting up hazardous waste storage sits in accordance with relevant standards and establish standardized hazardous waste management system; and (iii) engaging qualifies third-party suppliers for waste disposal. In addition, we will adopt the following measures to mitigate environmental impact from our business, strategy and financial performance in the near, medium and long term, as summarized below:

Area	Key Measures
Energy and resource conservation	• Introduces new environmental equipment and gradually phases out energy-intensive facilities • Update technologies for energy conservation and environmental protection • Improve energy recycling
Sewage and solid waste management	• Recycle the packaging materials • Improve sewage treatment mode
Greenhouse gas management	• Increase the use of clean energy • Use energy efficient equipment
Exhaust gas management	• Adopt exhaust gas treatment system and install active carbon filters

We have implemented company-wide environmental, health and safety ("**EHS**") manuals, policies and standard operating procedures. In particular, our EHS protection measures include (i) strict compliance with the GMP qualification requirements and relevant pollutant emissions standards and pollutants management policies during our production process to reduce pollutant emissions of exhaust gas, sewage and hazardous solid waste; (ii) implementation of safety guidelines with respect to employee health and safety, environmental protection and operational and manufacturing safety in laboratories and manufacturing facilities, and closely monitor internal compliance with these guidelines; (iii) storage of hazardous substances in special warehouse and contract with qualified third parties for the disposal of hazardous materials and waste; (iv) conducting periodic environmental evaluations on exhaust gas detection and emissions, hazardous waste disposals, noise emissions, and waste water detection and emissions to make sure all operations are in compliance with the applicable laws and regulations; and (v) resource conservation policies to reduce the levels of resource consumption.

As we are currently at an early stage of laboratory operations and partially rely on CROs for testings, clinical trials and other activities, the current nature of our business does not expose us to a substantial risk of environmental, health or work safety matters, and we do not expect the potential risks of such matters will have a material adverse impact on our business operation and financial performance.

Environmental Protection

The pollutants produced during our production process mainly include filtered fermentation broth, purified buffer solution, disposable cell culture bags, deep filter membrane bags and used solid waste. The filtered fermentation broth and purified buffer solution themselves do not contain any toxic substances and could be discharged safely into the sewage treatment plant for processing. Depending on mature sewage treatment technology, we have made sewage treatment a routine part of our production process. The solid waste is disposed of by qualified third-party waste recycling institutions. The local environmental protection department regularly inspects our production activities and waste emissions and no material administrative penalties imposed on us had been found that may have a material adverse effect on our business operations during the Track Record Period and up to the Latest Practicable Date.

We endeavor to reduce negative impact on the environment through our commitment to energy saving and sustainable development. We actively promote the idea of a paperless workplace, and we encourage double-sided printing of documents in our office. With our future business expansion, we focus on the balance between business growth and the need of ESG to achieve sustainable development. The relevant material metrics for our resource consumption will be reviewed regularly to ensure that they remain appropriate to the needs of our Group. While we appreciate that the identification and prioritization of ESG-related issues is a dynamic and on-going process, we will build the following targets as our initial focuses:

- To reduce the level of power and water consumption density;
- To advocate green office and make full use of natural lighting, and provide energy-efficient solutions for air conditioning;
- To strictly abide by the laboratory "three waste" treatment implementation standards;
- To provide ESG-related training for our staff members, with at least two working days per person per year.

In the upcoming future, our relevant expenses regarding environmental, social, and climate-related issues are estimated to increase, along with our overall business development, however, the proportion of such expenses against our total revenue is estimated to trend downwards.

During the Track Record Period and up to the Latest Practicable Date, we had not received any fines or penalties associated with the breach of any environmental laws or regulations. To the best knowledge and belief of our Directors, we are not subject to material environmental liability risk and will not incur material compliance costs in the future.

Resource Consumption and Pollutant Disposals

We monitor the following metrics to assess and manage the environmental and climate-related risks arising from our business and manufacturing operations:

- *Electricity consumption*. We have monitored our electricity consumption levels and implement measures. In 2022 and 2023, our electricity consumption levels were 1.0 million kWh and 1.4 million kWh, respectively.

- *Water consumption*. We have monitored our water consumption levels and implement measures to promote water conservation during the Track Record Period. In 2022 and 2023, our water consumption levels were 7.0 thousand tons, and 18.0 thousand tons, respectively.

- *Hazardous waste discharge*. We have a safety administrator who monitors and manage our hazardous waste storage and disposal. We have also contracted with qualified third-party waste disposal company for the disposal of hazardous material and waste. As of the Latest Practicable Date, a total of 0.1 tons of hazardous waste was stored in our warehouse and was overseen by our safety administrator. Considering our storage capacity and cost efficiency, we will transfer hazardous waste to the waste disposal company once we accumulated considerately large amount of waste.

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. We will make continuous efforts in working towards the target of reducing our electricity and water consumption and hazardous wastes discharge per thousand dollars of R&D expense by 5% in 2024.

Greenhouse Gases Emissions

We aim to reduce our greenhouse gases ("**GHG**") emissions and contribute to the transition to a low-carbon economy. We adhere to the "3R" approach to environmental conservation, i.e. reduction of waste, reuse of resources and recycling of used materials, to the extent possible in our business operation. The GHG emissions of various scopes are respectively generated from the fuel consumption of vehicles of our Group (Scope 1), power consumption (Scope 2), water consumption, waste discharge, paper consumption and GHG

emission resulting from the business travel of our employees (Scope 3) during business operation. Our Group's GHG emission results principally from Scope 2 energy indirect GHG emission which is power consumption to support our operations, and Scope 3 other indirect emissions.

We will implement measures in mitigating the GHG emissions, including (i) providing trainings and educate our employees on the concept of energy efficiency; (ii) posting water-saving or power-saving signs in eye-catching areas to cultivate our employees' awareness of environment protection; (iii) promoting paperless environment, encourage the usage of electronic copies instead of hard copies, the use of double-sided printing, and the use of single-sided printed paper when there is no confidential information on it; (iv) requiring employee to turn off all electrical appliances when they are not in use; and (v) implementing policies regarding waste management.

Climate-related Risks

The environmental and climate-related risks we are exposed to can be divided into two broad categories: physical and transition risks. We define physical risks as risks related to the physical impacts of climate change, consisting of (i) acute physical risks, such as increased severity of typhoon or floods; and (ii) chronic physical risks that are affected by long-term changes in climate patterns, such as changes in average annual rainfall or temperature. We define transition risks as the transition from dependence on fossil fuels to a low-carbon economy, which may involve changes in policy, laws, technology markets, as well as social culture, such as possible carbon taxes, compliance disclosures, and increased use of new energy sources across businesses and households.

We have made disaster preparedness plans for the extreme events and will closely monitor our business operation to reduce the possible impacts of physical and transition risks. We incorporate environmental risk analysis into the risk assessment process and risk preference setting. If risks and opportunities are deemed material, we incorporate them into our strategic and financial planning processes and take appropriate mitigation measures. Due to the nature of our business, we are not prone to material impacts of chronic physical risks or transition risks.

Our business, operations and financial condition had not been materially affected by any climate-related events during the Track Record Period and up to the Latest Practicable Date.

Employee Health and Safety

We also emphasize providing a safe working environment for our employees and clinical trial participants. We incorporate work safety guidelines on safe practices, accident prevention and accident reporting as core aspects of our employee training and induction processes, and we ensure that clinical trial participants properly acknowledge their understanding of safety matters at the time of enrollment and on an ongoing basis as necessary. In addition, we have adopted and maintained a series of rules, standard operating procedures and measures to

maintain a healthy and safe environment for our employees, including those required under the GMP standards. Furthermore, we conduct safety inspections of our laboratories and manufacturing facilities on a regular basis. Last but not least, we established an occupational health and monitoring management system, for the protection of the health and rights of our employees, prevention of occupational diseases, and proper placement and compensation for employees diagnosed with occupational diseases.

During the Track Record Period and up to the Latest Practicable Date, we had not been and were not involved in any material non-compliance incidents regarding the environmental and occupational health and safety laws and regulations that have led to fines or penalties that could, individually or in the aggregate, have a material adverse effect on our business, financial condition, and results of operations, and we did not have any workplace accident.

Workforce Welfare and Diversity

Within our organization, we are committed to creating an open and inclusive workplace that promotes equality. We hire employees based on their merits and it is our corporate policy to offer equal opportunities to them regardless of gender, age, race, religion or any other social or personal characteristics. As of the Latest Practicable Date, we had 118 employees, among whom more than 60% were female. In addition, more than 40% of our employees aged over 30 and more than 5% aged over 50. Our employees boast a diverse range of experiences and professional backgrounds, encompassing areas such as biomedicine, biochemistry, pharmaceutical engineering, food quality and engineering, immunology, genetics, financial management, human resources, intellectual property, and international trade, among others. We adhere to a fair and transparent employee management system and strive to enhance gender and age diversity of our workforce.

We established human resources management policies that systematically outline the recruitment processes, promotion procedures, dismissal/resignation processes, performance evaluation approaches, retention strategies, salary and benefits procedures, employee training, etc. In particular, we stick to our corporate governance philosophy of "valuing, attracting, nurturing, and employing talents appropriately." Our implement a merit-based hiring approach so make sure our recruitment is based on the principles of openness, fairness, and equity.

Supply Chain Management

Our suppliers primarily include raw material suppliers and contract services providers. Our considerations in supply chains include technical quality, cost effectiveness, delivery efficiency and reliability. Accordingly, we define risks related to supply chains consisting of shortage of raw materials, workforce health and safety incidents, proper disposal of hazardous waste, and internal control for corruption and bribery.

To identify and cope with any potential risks, we established procurement management policies that clearly define the overall review and regular evaluation processes for suppliers, based on which we made a qualified supplier list and update the list from time to time. Additionally, we established management policies in relation to procurement of technical contract services that specifies the responsibilities for the service providers, including CROs, testing organizations, clinical trial centers, etc. The policies also outline due diligence procedures, selection criteria, approval process, performance management and payment settlement. Furthermore, we tend to opt for scaled suppliers that are public companies as we believe such partners are subject to stricter compliance standards and capable of offering more environmentally-friendly products and services. We have also implemented strict anti-corruption and anti-bribery policies to prevent collusion and corruption.

Governance on EHS Matters

We have a dedicated group level EHS team under the supervision of our senior management responsible for overseeing our compliance with EHS related regulations and policies, and monitoring our implementation of related internal measures, such as: (i) adopting appropriate safety measures at our facilities and implementing best practice procedures; (ii) conducting regular safety awareness training to our employees; (iii) inspecting our facilities regularly to identify and eliminate any potential safety hazards; (iv) adopting appropriate procedures regarding the disposal of any hazardous waste such as Waste Management Procedure, which aims to effectively manage the waste generated during our normal course of business, standardize the classification of the waste into solid waste and hazardous waste according to the relevant laws and regulations and dispose them accordingly to reduce environmental pollution; (v) maintaining a system of recording and handling accidents in our facilities; and (vi) cooperating with regulatory authorities for the regular environmental compliance monitoring. Our EHS team may assess or engage independent third party(ies) to evaluate the ESG risks and review our existing strategies, targets and internal controls at least once a year. Necessary improvement will then be implemented to mitigate the risks.

Our EHS department to implement the national and our own safety production and environmental protection guidelines, and follow up with the instructions or notice from local authorities with regard to fire protection, safety supervision and environmental protection in a timely manner, as well as formulate our Company's safety production policies and operating procedures. The management personnel at all levels and all of our employees will implement the work responsibility system according to EHS related regulations and policies, and related internal measures.

Social Responsibility

In respect of social responsibilities, it is our corporate policy to offer equal opportunities to our employees regardless of gender, age, race, religion or any other social or personal characteristics. We strive to operate our facilities in a manner that protects the environment and the health and safety of our employees and communities.

PERMITS, LICENSES AND OTHER APPROVALS

Our PRC Legal Adviser has advised that, as of the Latest Practicable Date, we have obtained all licenses, permits, approvals and certificates from the relevant PRC government authorities that are material to our operations in the PRC. The table below sets forth the relevant details of the material license we hold for our operations in China.

License	License No.	Date of Expiration	Issuing Authority
Drug Manufacturing License (藥品生產許可證)	SU20180566 (蘇20180566)	December 20, 2025	Jiangsu Medical Products Administration

LEGAL PROCEEDINGS AND COMPLIANCE

We may from time to time be involved in contractual disputes or legal proceedings arising out of the ordinary course of business or pursuant to governmental or regulatory enforcement actions. During the Track Record Period and up to the Latest Practicable Date, neither we nor any of our Directors were involved in or subject to any litigation, arbitration, administrative proceedings, claims, damages or losses which would have a material adverse effect on our business, financial position or results of operations as a whole. As of the Latest Practicable Date, we were not aware of any pending or threatened material litigation, arbitration or administrative proceedings against us or any of our Directors, which individually or as a whole would have a material adverse effect on our business, financial position or results of operations.

During the Track Record Period and up to the Latest Practicable Date, we had complied, in all material respects, with relevant PRC laws and regulations in the jurisdictions we operate in, and no material administrative penalties were imposed on us.

RISK MANAGEMENT AND INTERNAL CONTROL

Risk Management

We are exposed to various risks in our business operation and we recognize that risk management is critical to our success. For details, see "Risk Factors — Risks Relating to Our Operations" in this document. Additionally, we are faced with credit risk, liquidity risk and market risks including currency risks credit and interest rate risk, all of which are inherent in the ordinary course of our business. See "Financial Information — Market Risk Disclosure" in this document for detailed discussion. We have adopted a series of risk management policies which set out a risk management framework to identify, assess, evaluate and monitor key risks associated with our strategic objectives on an ongoing basis. Risks identified by management

will be analyzed on the basis of likelihood and impact, and will be properly followed up and mitigated and rectified by our Company and reported to our Directors. Our audit committee, and ultimately our Directors supervise the implementation of our risk management policies.

To monitor the ongoing implementation of risk management policies and corporate governance measures after [**REDACTED**], we have adopted or will 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;

- adopt various policies to ensure compliance with the Listing Rules, including but not limited to aspects related to risk management, connected transactions and information disclosure; and

- attend training sessions in respect of the relevant requirements of the Listing Rules and duties of directors of companies [**REDACTED**] in Hong Kong.

Intellectual Property Risk Management

We have designed and adopted strict internal procedures to ensure the compliance of our business operations with the relevant rules and regulations, as well as the protection of our intellectual property rights.

In accordance with these procedures, our legal counsel performs the basic function of reviewing and updating the form of contracts we enter into with our customers and suppliers. Our legal counsel as well as business operation teams examine the contract terms and reviews all relevant documents for our business operations, including licenses and permits obtained by the counterparties or us to perform contractual obligations and all the necessary underlying due diligence materials, before we enter into any contract or business arrangements.

Our regulatory affairs team reviews our products and services, including upgrades to existing products, for regulatory compliance before they are made available to the general public. Our regulatory affairs team is responsible for obtaining any requisite governmental pre-approvals or consent, including preparing and submitting all necessary documents for filing with relevant government authorities within the prescribed regulatory timelines and ensuring all necessary application, renewals or filings for trademark, copyright and patent registration have been timely made to the competent authorities.

Internal Control

Our Board is responsible for establishing our internal control system and reviewing its effectiveness. We have engaged an independent internal control consultant (the "**Internal Control Consultant**") to perform certain agreed-upon procedures (the "**Internal Control Review**") in connection with the internal control in certain aspects, including entity-level

controls, financial reporting and disclosure controls, human resources and payroll management, general controls of IT system and other procedures of our operations. The Internal Control Consultant performed the Internal Control Review and identified internal control deficiencies and provided recommendation accordingly. We have adopted the corresponding remediation actions to improve the effectiveness of internal control system. The Internal Control Consultant performed a follow-up review with regard to those actions taken by us and there are no further material findings identified in the process of the follow-up review. As of the Latest Practicable Date, there were no material outstanding issues relating to our Company's internal control.

During the Track Record Period, we reviewed and enhanced our internal control system on a regular basis. Below is a summary of the internal control policies, measures and procedures we have implemented or plan to implement:

- We have adopted various measures and procedures regarding each aspect of our business operation, such as related risk management, protection of intellectual property, environmental protection and occupational health and safety. We provide periodic training about these measures and procedures to our employees as part of our employee training program. We monitor the implementation of our internal control policies, reports the weakness identified to our management and audit committee and follows up on the rectification actions.

- Our Directors (who are responsible for monitoring the corporate governance of our Group) with help from our legal advisers, will also periodically review our compliance status with all relevant laws and regulations after [**REDACTED**].

- We [have established] an audit committee which, among others, (i) makes recommendations to our Board of Directors on the appointment and removal of external auditors; and (ii) reviews the financial statements and internal control system of our Company.

- We have engaged Somerley Capital as our compliance adviser to provide advice to our Directors and management team until we distribute our annual report of financial results for the first full financial year after [**REDACTED**] regarding matters relating to the Listing Rules. We must consult with and if necessary, seek advice from our compliance adviser where we propose to use the [**REDACTED**] of the [**REDACTED**] in a manner different from our plan that sets forth in "Future Plans and Use of [**REDACTED**]" in this document after [**REDACTED**]. Our compliance adviser will also provide support and advice regarding requirements of relevant regulatory authorities in a timely fashion.

- We plan to provide various and continuing trainings to update our Directors, senior management, and relevant employees on the latest PRC laws and regulations from time to time with a view to proactively identify any concerns and issues relating to any potential non-compliance.

- We intend to maintain strict anti-corruption and anti-bribery policies and we believe we will therefore be less affected by the increasingly stringent measures taken by the PRC government to correct corruptive practices in the pharmaceutical industry.

We plan to provide our Directors, senior management, and relevant employees with continuous training programs and updates regarding the relevant applicable laws and regulations regularly and update our internal control policies in due course.

Data Privacy Protection

We have established procedures to protect the confidentiality of trial participants' data. We demand that all parties involved in clinical trials, both external and internal, adhere to confidentiality obligations. We require our personnel to collect and safeguard personal information in their possession. Our CROs and other partners are obligated to safeguard the confidentiality of such information pursuant to our contracts with them. Compliance with GCP and relevant rules ensures that only approved personnel can access clinical trial data. Data utilization is strictly confined to the use consented to by the patients, which is in line with the Informed Consent Form ("**ICF**"). We ensure to obtain further consent from patients for any data usage that extends beyond the ICF's scope.

Any data transfer related to our product development initiatives and regulatory communications must adhere to relevant local data protection and privacy laws. Accordingly, we have implemented a series of control measures and structures. These measures include ensuring the legality of the cross-border data transfers, securing necessary regulatory approvals, and making appropriate filings with competent authorities according to applicable laws and regulations (particularly in the case of any transfer between China and the U.S.). This is particularly important for data transfers between China and the U.S. Despite the evolving nature of these laws and our potential clinical trials, we have not encountered significant issues with data transfers so far. We believe our practices related to transferring clinical trial data between China and the U.S. conform to industry standards.

As confirmed by our PRC Legal Adviser, we were not subject to any material claims, lawsuits, penalties or administrative actions which had a material and adverse effect on our business, financial condition or results of operations in accordance with applicable PRC laws and regulations with respect to data privacy and protection.

The following discussion and analysis should be read in conjunction with the consolidated financial information together with the accompanying notes in the Accountants' Report included in Appendix I to this document. Our historical financial information and the consolidated financial statements of our Group have been prepared in accordance with the IFRSs, which may differ in certain material aspects from generally accepted accounting principles in other jurisdictions. You should read the whole Appendix I and not rely merely on the information contained in this section. Unless the context otherwise requires, historical financial information in this section is described on a consolidated basis.

The discussion and analysis set forth in this section contains forward-looking statements that involve risks and uncertainties. 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 we believe are appropriate under the circumstances. Our actual results may differ significantly from those projected. Factors that could cause or contribute to such differences include, without limitation, those discussed in the sections headed "Risk Factors" and "Business" and elsewhere in this document. Discrepancies between totals and sums of amounts listed in this section in any table or elsewhere in this document may be due to rounding.

OVERVIEW

Founded in 2018, we are a clinical stage biopharmaceutical company that focuses on the discovery, development and commercialization of biologics for the treatment of cancers and autoimmune diseases. We have three Core Products, IAH0968, IAP0971 and IAE0972, all of which are developed in-house. IAH0968 is an antibody-dependent cell-mediated cytotoxicity ("**ADCC**") enhanced monoclonal antibody ("**mAb**"), and we have initiated Phase II clinical trials for biliary tract carcinoma ("**BTC**") and colorectal cancer ("**CRC**"). IAP0971 and IAE0972 are both immunocytokines and we have completed Phase I clinical trials for advanced solid tumors including non-small cell lung cancer ("**NSCLC**") and CRC. As of the Latest Practicable Date, we had nine pipeline products, in addition to our Core Products, three of which were in the clinical stage, also focusing on the treatment of cancer.

We currently have no products approved for commercial sales and have not generated any revenue from product sales. We have not been profitable and have incurred operating losses during the Track Record Period. In 2022 and 2023, we had loss and total comprehensive expense of RMB52.0 million and RMB132.7 million, respectively.

We expect to incur an increasing amount of operating expenses for the next several years as we further our preclinical research, continue the clinical development of, seek regulatory approval for, manufacture and launch our product candidates, and recruit more talents necessary for our business operation. Subsequent to the [**REDACTED**], we expect to incur costs associated with operating as a [**REDACTED**] company. We expect that our financial performance will fluctuate from year to year, taking into account the development status of our product candidates, regulatory approval timeline and commercialization of our product candidates.

MAJOR FACTORS AFFECTING OUR RESULTS OF OPERATIONS

Our results of operations have been, and are expected to continue to be, affected by a number of factors, many of which are outside of our control, including the following.

Development and Commercialization of Our Product Candidates

Our business and results of operations are dependent on our ability to successfully obtain necessary regulatory approvals and commercialize our product candidates. As of the Latest Practicable Date, we have identified and developed a pipeline of nine product candidates at different development stages, including six of them at clinical stage and three of them at preclinical stage. In September 2022, we received the IND approval from the NMPA for conducting Phase II clinical trials for IAH0968 in combination with gemcitabine and cisplatin in inoperable HER2+ advanced or metastatic BTC as first-line therapy; and the IND approval from the NMPA for conducting Phase II and Phase III clinical trials for IAH0968 in combination with CapeOX (capecitabine + oxaliplatin) in HER2+ metastatic CRC as first-line therapy. We dosed the first CRC patient in May 2023 and completed patient enrollment for Phase IIa clinical trial in October 2023. We also dosed the first patient of Phase II clinical trial for BTC in August 2023. In addition, we have completed the Phase I clinical trials of IAP0971 and IAE0972 in July 2023. We have initiated a Phase II clinical trial of IAE0972 as monotherapy and enrolled the first HNSCC patient and the first CRC patient in July 2023 and December 2023, respectively, in China, and expect to commence Phase II clinical trials of IAP0971 in the second quarter of 2024. For more details, see "Business" in this document.

Although all of our product candidates currently have not been approved for commercialization, and we have not generated any revenue from sales of our product candidates, we expect to commercialize one or more of our product candidates over the coming years. Our commercialization strategies, including establishing our own commercialization and distribution team, seeking collaboration with leading biopharmaceutical companies with relevant experience in the filed of global drug commercialization, as well as enhancing our manufacturing capabilities, require significant marketing efforts and inputs. Upon commercialization of our drug candidates, our business and results of operations will be driven by the market acceptance and sales of our commercialized drugs and our manufacturing capabilities to meet commercial demands.

Our Cost Structure

Our results of operations are significantly affected by our cost structure, particularly research and development expenses.

Research and development activities are crucial to our business. During the Track Record Period, our research and development expenses consisted of (i) contract research expenses relating to our engagement of contract service providers; (ii) R&D staff costs; (iii) depreciation and amortization expenses in relation to our research and development machinery and equipment; (iv) material consumed in the course of our research and development activities; (v) our patents and IND applications fees; (vi) share-based compensation; and (vii) others, which primarily consisted of traveling and transportation expenses of our R&D personnel, utilities expenses and other miscellaneous expenses. In 2022 and 2023, our research and development expenses amounted to RMB53.2 million and RMB43.0 million, respectively.

We expect our cost structure to evolve as we continue to develop and expand our business. As the clinical trials of our drug candidates continue to progress and as we continue to enrich our pipeline products, we expect to incur additional costs in relation to preclinical studies and clinical trials, headcount expansion for our research and development team and production line expansion, among other things. Moreover, once our drug candidates receive marketing approvals and are commercialized, we are expected to dedicate our resources to sales and marketing. We may recruit sales and marketing personnel, conduct sales and marketing promotion activities, and cooperate with third-party marketing service providers. Additionally, we anticipate increasing legal, compliance, accounting, insurance and investor and public relations expenses associated with being a [**REDACTED**] company in Hong Kong.

Funding for Our Operations

During the Track Record Period, we funded our operations primarily through capital contributions by our shareholders and loans. Going forward, in the event of a successful commercialization of one or more of our drug candidates, we expect to fund our operations in part with revenue generated from sales of our products. However, with the continuing expansion of our business, we may require further funding through public or private offerings, debt financing, or other sources. Any fluctuation in the funding for our operations will impact our cash flow plan and our results of operations.

BASIS OF PREPARATION

The historical financial information has been prepared based on the accounting policies set out in Note 4 to the Accountants' Report set out in Appendix I to this document, which conform with the International Financial Reporting Standards, or IFRSs issued by the International Accounting Standards Board, or IASB. All IFRSs effective for the accounting period commencing from January 1, 2023, together with the relevant transitional provisions, have been adopted by our Group in the preparation of the historical financial information throughout the Track Record Period. The historical financial information has been prepared on the historical cost basis except for certain financial instruments which are measured at fair values at the end of each reporting period.

MATERIAL ACCOUNTING POLICIES AND SIGNIFICANT ACCOUNTING JUDGMENTS AND ESTIMATES

Material Accounting Policies

The historical financial information has been prepared in accordance with the following accounting policies which conform with IFRSs issued by the IASB. For the purpose of preparation of the historical financial information, information is considered material if such information is reasonably expected to influence decisions made by primary users. In addition, the historical financial information includes the applicable disclosures required by the Listing Rules and by the Companies (Winding Up and Miscellaneous Provisions) Ordinance.

The historical financial information has been prepared on the historical cost basis except for certain financial instruments which are measured at fair values at the end of each reporting period, as explained in the accounting policies set out below.

Historical cost is generally based on the fair value of the consideration given in exchange for goods and services.

Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date, regardless of whether that price is directly observable or estimated using another valuation technique. In estimating the fair value of an asset or a liability, our Group takes into account the characteristics of the asset or liability if market participants would take those characteristics into account when pricing the asset or liability at the measurement date. Fair value for measurement and/or disclosure purposes in the historical financial information is determined on such a basis, except for share-based payment transactions that are within the scope of IFRS 2 *Share-based Payment*, leasing transactions that are within the scope of IFRS 16 *Leases*, and measurements that have some similarities to fair value but are not fair value, such as net realizable value in IAS 2 *Inventories* or value in use in IAS 36 *Impairment of Assets*.

In addition, for financial reporting purposes, fair value measurements are categorized into Level 1, 2 or 3 based on the degree to which the inputs to the fair value measurements are observable and the significance of the inputs to the fair value measurement in its entirety, which are described as follows:

- Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities that the entity can access at the measurement date;

- Level 2 inputs are inputs, other than quoted prices included within Level 1, that are observable for the asset or liability, either directly or indirectly; and

- Level 3 inputs are unobservable inputs for the asset or liability.

Our most critical accounting policies are summarized below. See note 4 to the Accountants' Report set out in Appendix I to this document for a full description of our material accounting policies.

Financial Liabilities and Equity

Classification as Debt or Equity

Debt and equity instruments are classified as either financial liabilities or as equity in accordance with substance of the contractual arrangements and the definitions of a financial liability and an equity instrument.

Equity Instruments

An equity instrument is any contract that evidences a residual interest in the assets of an entity after deducting all of its liabilities. Equity instruments issued by a group are recognized at the proceeds received, net of direct issue costs.

Financial Liabilities

All financial liabilities we hold are subsequently measured at amortized cost using the effective interest method.

Financial Liabilities at Amortized Cost

Financial liabilities including trade and other payables, amount due to a related party and amounts due to a subsidiary are subsequently measured at amortized cost, using the effective interest method.

Intangible Assets

Intangible Assets Acquired Separately

Intangible assets with finite useful lives, which are acquired separately, are carried at costs less accumulated amortization and any accumulated impairment losses. Amortization for intangible assets with finite useful lives is recognized on a straight-line basis over their estimated useful lives when the assets are available for use. The estimated useful life and amortization method are reviewed at the end of each reporting period, with the effect of any changes in estimate being accounted for on a prospective basis.

Internally-Generated Intangible Assets — Research and Development Expenditure

Expenditure on research activities is recognized as an expense in the period in which it is incurred.

An internally-generated intangible asset arising from development activities is recognized if, and only if, all of the following have been demonstrated:

- the technical feasibility of completing the intangible asset so that it will be available for use or sale;
- the intention to complete the intangible asset and use or sell it;
- the ability to use or sell the intangible asset;
- how the intangible asset will generate probable future economic benefits;

- the availability of adequate technical, financial and other resources to complete the development and to use or sell the intangible asset; and

- the ability to measure reliably the expenditure attributable to the intangible asset during its development.

The amount initially recognized for internally-generated intangible asset is the sum of the expenditure incurred from the date when the intangible asset first meets the recognition criteria listed above. Where no internally-generated intangible asset can be recognized, development expenditure is recognized in profit or loss in the period in which it is incurred.

Subsequent to initial recognition, internally-generated intangible assets are reported at cost less accumulated amortization and accumulated impairment losses (if any), on the same basis as intangible assets that are acquired separately.

Impairment on Property and Equipment, Right-of-Use Assets and Intangible Assets

At the end of each reporting period, we review the carrying amounts of our property and equipment and right-of-use assets to determine whether there is any indication that these assets have suffered an impairment loss. If any such indication exists, the recoverable amount of the relevant asset is estimated in order to determine the extent of the impairment loss (if any). Intangible assets not yet available for use are tested for impairment at least annually, and whenever there is an indication that may be impaired.

The recoverable amount of property and equipment, intangible assets and right-of-use assets are estimated individually. When it is not possible to estimate the recoverable amount individually, we estimate the recoverable amount of the cash-generating unit to which the asset belongs.

In testing a cash-generating unit for impairment, corporate assets are allocated to the relevant cash-generating unit when a reasonable and consistent basis of allocation can be established, or otherwise they are allocated to the smallest group of cash-generating units for which a reasonable and consistent allocation basis can be established. The recoverable amount is determined for the cash-generating unit or group of cash-generating units to which the corporate asset belongs, and is compared with the carrying amount of the relevant cash-generating unit or group of cash-generating units.

Recoverable amount is the higher of fair value less costs of disposal and value in use. In assessing the recoverable amount, the estimated future cash flows are discounted to their present value using a discount rate that reflects current market assessments of the time value of money and the risks specific to the asset (or a cash-generating unit) for which the estimates of future cash flows have not been adjusted.

If the recoverable amount of an asset (or a cash-generating unit) is estimated to be less than its carrying amount, the carrying amount of the asset (or a cash-generating unit) is reduced to its recoverable amount. For corporate assets or portion of corporate assets which cannot be allocated on a reasonable and consistent basis to a cash-generating unit, we compare the carrying amount of a group of cash-generating units, including the carrying amounts of the corporate assets or portion of corporate assets allocated to that group of cash-generating units, with the recoverable amount of the group of cash-generating units. In allocating the impairment loss, the impairment loss is allocated first to reduce the carrying amount of any goodwill (if applicable) and then to the other assets on a pro-rata basis based on the carrying amount of each asset in the unit or the group of cash-generating units. The carrying amount of an asset is not reduced below the highest of its fair value less costs of disposal (if measurable), its value in use (if determinable) and zero. The amount of the impairment loss that would otherwise have been allocated to the asset is allocated pro rata to the other assets of the unit or the group of cash-generating units. An impairment loss is recognized immediately in profit or loss.

Where an impairment loss subsequently reverses, the carrying amount of the asset (or cash-generating unit) is increased to the revised estimate of its recoverable amount, but so that the increased carrying amount does not exceed the carrying amount that would have been determined had no impairment loss been recognized for the asset (or a cash-generating unit) in prior years. A reversal of an impairment loss is recognized immediately in profit or loss.

Share-Based Payments

Equity-Settled Share-Based Payment Transactions

Restricted Share Units ("**RSU**") Granted to Employees and Other Share Incentive Plan

Equity-settled share-based payments to employees and others providing similar services are measured at the fair value of the equity instruments at the grant date.

The fair value of the equity-settled share-based payments determined at the grant date without taking into consideration all non-market vesting conditions is expensed on a straight-line basis over the vesting period, based on our estimate of equity instruments that will eventually vest, with a corresponding increase in equity (share-based payment reserve). At the end of each reporting period, we revise our estimate of the number of equity instruments expected to vest based on assessment of all relevant non-market vesting conditions. The impact of the revision of the original estimates, if any, is recognized in profit or loss such that the cumulative expense reflects the revised estimate, with a corresponding adjustment to the share-based payment reserve. For shares that vest immediately at the date of grant, the fair value of the shares granted is expensed immediately to profit or loss.

When RSU are vested, the amount previously recognized in share-based payments reserve will be transferred to capital reserve.

Shares Granted to Non-Employees

Equity-settled share-based payments transactions with parties other than employees are measured at the fair value of the goods or services received, except where that fair value cannot be estimated reliably, in which case they are measured at the fair value of the equity instruments granted, measured at the date the entity obtains the goods or the counterparty renders the service. The fair values of the goods or services received are recognized as expenses (unless the goods or services qualify for recognition as assets).

Critical Accounting Judgements and Estimates

In the application of our accounting policies, which are described in Note 4 to the Accountants' Report set out in Appendix I to this document, our Directors are required to make judgments, estimates and assumptions about the carrying amounts of assets and liabilities that are not readily apparent from other sources. The estimates and underlying assumptions are based on historical experience and other factors that are considered to be relevant. Actual results may differ from these estimates.

The estimates and underlying assumptions are reviewed on an on-going basis. Revisions to accounting estimates are recognized in the period in which the estimate is revised if the revision affects only that period, or in the period of the revision and future periods if the revision affects both current and future periods.

The following are the critical judgments that our Directors have made in the process of applying our accounting policies and that have the most significant effect on the amounts recognized in the historical financial information, and key assumptions concerning the future, and other key sources of estimation uncertainty at the end of each of reporting periods, that may have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the coming twelve months.

Research and Development Expenses

Research and development expenses incurred on our drug product pipelines are capitalized and deferred only when we can demonstrate (i) the technical feasibility of completing the intangible asset so that it will be available for use or sale; (ii) our intention to complete and our ability to use or sell the asset; (iii) how the asset will generate future economic benefits; (iv) the availability of resources to complete the pipeline; and (v) the ability to measure reliably the expenditure during the development. Research and development expenses which do not meet these criteria are expensed when incurred. The management assesses the progress of each of the research and development projects and determine whether the criteria for capitalization are met. During the Track Record Period, all research and development costs are expensed when incurred.

Useful Lives of Property and Equipment

Our management determines the estimated useful lives and the depreciation method in determining the related depreciation charges for its property and equipment. This estimate is reference to the useful lives of property and equipment of similar nature and functions in the industry. Management will increase the depreciation charge where useful lives are expected to be shorter than expected, or will write off or write down obsolete assets that have been abandoned or sold.

OUR CONSOLIDATED STATEMENTS OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

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

	Year Ended December 31,	
	2022	**2023**
	RMB'000	*RMB'000*
Other income	13,795	21,005
Other expenses	(1,258)	(70)
Other gains and losses, net	97	(49,615)
Research and development expenses	(53,171)	(43,041)
Administrative expenses	(5,558)	(40,701)
[**REDACTED**]	[**REDACTED**]	[**REDACTED**]
Finance costs	(5,074)	(692)
Loss before tax	(51,988)	(132,701)
Income tax expense	–	–
Loss and total comprehensive expense for the year	(51,988)	(132,701)

DESCRIPTION OF MAJOR COMPONENTS OF OUR RESULTS OF OPERATIONS

Other Income

During the Track Record Period, other income consisted of (i) government grants by the PRC local government authorities mainly to support our research and development activities; (ii) interest income from financial institutions, which primarily represented the interest generating from our bank deposits; (iii) sales income from contract manufacturing services; and (iv) relocation incentive. The following table sets forth a breakdown of our other income for the years indicated.

	Year Ended December 31,	
	2022	**2023**
	RMB'000	*RMB'000*
Government grants	119	17,326
Interest income from financial institutions	15	3,471
Sales income from contract manufacturing services	1,731	208
Relocation incentive	11,930	–
Total	13,795	21,005

During the Track Record Period, we received subsidies for our research and development activities from local governmental authorities. In 2022 and 2023, we recorded government grants of RMB0.1 million and RMB17.3 million, respectively. In 2023, we were granted subsidies for our R&D progress, installment of machinery and equipment and operating activities. In particular, we received subsidies granted in accordance with the Policy Measures on Promoting the High-Quality Development of the Jiangsu Province's Biomedical Industry (《關於促進全省生物醫藥產業高質量發展的若干政策措施》) and Several Policy Measures on Promoting High-Quality Development of the Nanjing City's Biomedical Industry (《關於促進全市生物醫藥產業高質量發展的若干政策措施》) for our receipt of IND approvals from the NMPA for the clinical trials of IAH0968 and IBC0966. During the Track Record Period, we also received a relocation incentive from the local government authority. In 2022, we recorded a one-time incentive from Nanjing Economic Development Zone Management Committee for relocating our supporting facilities. As of the Latest Practicable Date, this relocation had been completed, and as confirmed by our Directors, it had no adverse impacts on our business operation.

During the Track Record Period, leveraging our GMP-compliant production capabilities, we entered into a contract manufacturing service agreement with a biotechnology company based in Hefei, Anhui Province. The biotechnology company was established in 2013, with registered capital of approximately RMB34.7 million, and primarily focuses on the research and development of biologically engineered antibody new drugs in the field of immune unresponsive and drug-resistant tumor diseases, with a pipeline of three product candidates at clinical stage. Pursuant to the contract manufacturing service agreement, we provided the biotechnology company with the contract manufacturing services including procurement, research, process development and production of a monoclonal antibody drug against a target that is different from the targets of any of our product candidates. According to Frost & Sullivan, such monoclonal antibody drug is unlikely to be a potential competing product to any of our product candidates. As of February 29, 2024, the contractual obligations under the contract manufacturing service agreement had been fully fulfilled.

Other Expenses

We did not record other expenses during the Track Record Period except for the expenses of RMB1.3 million in 2022 and RMB70.0 thousand in 2023, attributable to the contract manufacturing services we provided to a biotechnology company. The expenses incurred primarily included the raw materials, labor costs, depreciation and other production costs.

Other Gains and Losses, Net

During the Track Record Period, our net other gains and losses consisted of (i) realized gains on other financial assets measured at FVTPL, mainly representing gains on the wealth management products we purchased. During the Track Record Period, we purchased wealth management products comprising short-term or low-risk financial products from time to time. The expected rate of return ranged from 1.56% to 3.60% per annum; (ii) loss from fair value change of financial liabilities at FVTPL, mainly representing fair value losses of the preferred shares issued to Pre-[**REDACTED**] Investors; and (iii) net foreign exchanges losses or gains, mainly representing the losses or gains resulting from exchange rate fluctuation between USD and RMB.

We purchase wealth management products as a supplemental approach to improve utilization of our cash on hand on a short-term basis. We believe that making such investments is in the best interest of the Company, and we can make better use of our cash by utilizing principal guaranteed structured deposits, to enhance our income without interfering with our business operations or capital expenditures. The purchases of wealth management products are subject to the approval of our management team, and the purchases are carefully reviewed and assessed by the staff in our finance department with financial management or accounting background. Additionally, we have adopted various measures regarding risk management and our investment in wealth management products. These policies and measures include:

- our investment decisions are made on a case-by-case basis and after due and careful consideration of a number of factors, such as the duration of the investment and the expected returns;

- we only purchase low-risk wealth management products issued by qualified financial institutions, and in any given period, we invest in products provided by multiple issuers to mitigate concentration risks;

- our finance department, subject to the review and approval of our finance manager, is responsible for the overall execution of our short-term investments, including risk assessment; and

- after making an investment, we closely monitor its performance and fair value on a regular basis.

In the future, we may continue to purchase low-risk wealth management products with a short maturity period based on surplus cash situation to maximize our capital utilization efficiency. Our investments in wealth management products will be subject to the compliance with the requirements under Chapter 14 of the Listing Rules.

Research and Development Expenses

During the Track Record Period, our research and development expenses consisted of (i) contract research expenses in relation to the engagement of contract service providers. During the Track Record Period, fluctuations in our contract research expenses reflected the evolving preclinical and clinical study needs of our product candidates in line with the normal course of our research and development progress; (ii) staff costs incurred by our research and development personnel; (iii) depreciation and amortization expenses in relation to our research and development machinery and equipment; (iv) material consumed in the course of our research and development activities; (v) application fees for our patents and IND applications; (vi) share-based compensation; and (vii) other research and development expenses, mainly comprising traveling and transportation expenses of our research and development personnel, utilities incurred for our research and development activities and other miscellaneous expenses. The following table sets forth a breakdown of our research and development expenses for the years indicated.

	Year Ended December 31,	
	2022	**2023**
	RMB'000	*RMB'000*
Contract research expenses	19,273	11,263
Staff costs	16,089	15,231
Depreciation and amortization expenses	7,694	8,005
Materials consumed	4,317	3,239
Application fees	1,330	1,180
Share-based compensation	2,039	756
Others	2,429	3,367
Total	53,171	43,041

With respect to the research and development expenses incurred for the Core Products, we recorded RMB10.7 million and RMB17.4 million in 2022 and 2023, respectively, accounting for 20.1% and 40.4% of the total research and development expenses in the corresponding years. The following table sets forth a breakdown of our research and development expenses incurred on the Core Products and other product candidates for the years indicated.

	Year Ended December 31,			
	2022		2023	
	RMB'000	*%*	*RMB'000*	*%*
IAH0968	7,428	14.0	6,895	16.0
IAP0971	2,078	3.9	3,705	8.6
IAE0972	1,172	2.2	6,783	15.8
Core products	10,678	20.1	17,383	40.4
IBB0979	7,637	14.4	1,692	3.9
IBC0966	3,396	6.4	234	0.5
IBD0333	12,644	23.8	5,369	12.5
IAN0982	876	1.6	38	0.1
ISH0988	825	1.6	1,433	3.3
ISH0613	754	1.4	1,824	4.2
Other products candidates	26,132	49.2	10,590	24.6
Others[(1)]	16,361	30.7	15,068	35.0
Total	**53,171**	**100.0**	**43,041**	**100.0**

Note:

(1) Others include R&D expenses incurred for our other in-house-developed early-stage biologics.

We have invested significant R&D resources for our Core Products, which are all in-house developed, since the commencement of their preclinical researches in 2018, and hence made our Core Products most advanced in development stage among all the pipelines. Based on our management accounts, between 2018 and 2020, the aggregate R&D expenses incurred for our Core Products were higher than the aggregate R&D expenses incurred for other drug candidates then being developed by our Group, both in absolute amount and as percentages of our Group's total R&D expenses incurred for the same period.

The R&D expenses incurred for Core Products amounted to RMB10.7 million in 2022. The R&D expenses for Core Products in 2022 accounted for 20.1% of our total R&D expenses during the same year, lower than the R&D expenses of IBD0333, which accounted for 23.8% of our total R&D expenses, in 2022. This was primarily owing to the significant R&D expenses incurred for the preclinical studies of IBD0333 launched in August 2022.

In 2023, our R&D expenses incurred for Core Products amounted to RMB17.4 million, accounting for 40.4% of the total R&D expenses in the same year, representing an increase from RMB10.7 million in 2022. The increase was primarily in line with the patient enrollment progress of the Phase I clinical trials of IAP0971 and IAE0972. As for IAH0968, though we entered into two Phase II clinical trials of IAH0968 in May 2023 and August 2023, there was a slight decrease in the R&D expenses for IAH0968 from RMB7.4 million in 2022 to RMB6.9 million in 2023, primarily due to a two-month interim period between the completion of Phase I clinical trial and the launch of Phase II clinical trials for IAH0968. The R&D expenses for IBD0333 accounted for 12.5% in 2023, primarily due to the continuous preclinical studies of IBD0333, which was completed in January 2023 and required a significant R&D expenditure.

Administrative Expenses

During the Track Record Period, our administrative expenses consisted of (i) general office expenses mainly comprising office product expenses, conference expenses and traveling and transportation expenses of administrative personnel; (ii) employee benefits expenses mainly relating to salaries, bonus and other welfare for our administrative employees; (iii) depreciation and amortization expenses for assets which were used for administrative purpose; (iv) professional service fees, which were primarily for related consulting, auditing and asset valuation in relation to corporate administration and restructuring; (v) share-based compensation; and (vi) other administrative expenses mainly including tax and surcharges and other miscellaneous expenses.

Finance Costs

During the Track Record Period, our finance costs consisted of (i) interest expenses on our borrowing from a related party, for details of which, see "— Related Party Transactions" in this section and note 31 to the Accountants' Report in Appendix I to this document; and (ii) interest expenses on our lease liabilities. The following table sets forth a breakdown of our finance costs for the years indicated.

	Year Ended December 31,	
	2022	**2023**
	RMB'000	*RMB'000*
Interest expenses on borrowing from Nanjing Bode	5,055	491
Interest expenses on lease liabilities	19	201
Total	5,074	692

[**REDACTED**]

[**REDACTED**] represent expenses incurred for our proposed [**REDACTED**] and [**REDACTED**]. In 2022 and 2023, we recorded [**REDACTED**] of RMB[**REDACTED**] and RMB[**REDACTED**], respectively.

Income Tax Expense

We did not record any income tax expense during the Track Record Period.

We were incorporated in the Cayman Islands as an exempted company with limited liability under the Companies Act, and Sunho bio Investments, our subsidiary, was incorporated in the BVI. We and Sunho bio Investments are exempted from income tax pursuant to the current laws of the Cayman Islands and the BVI.

Pursuant to the Enterprise Income Tax Law and Implementation Regulations of the Law of the PRC, the applicable tax rate of our PRC subsidiaries was 25% during the Track Record Period.

No Hong Kong profits tax has been provided for as there was no assessable profit that was subject to Hong Kong Profits Tax during the Track Record Period.

Pursuant to Caishui 2018 circular No. 99, Caishui 2022 circular No. 28 and Caishui 2023 circular No. 7, Sunho (China) Biopharmaceutical enjoyed super deduction of 175% on qualified research and development expenditures for the nine months ended September 30, 2022. In addition, Sunho (China) Biopharmaceutical enjoyed super deduction of 200% on qualified research and development expenditures during the three months from October 1, 2022 to December 31, 2022 and the year ended December 31, 2023.

YEAR TO YEAR COMPARISON OF RESULTS OF OPERATIONS

Year Ended December 31, 2023 Compared With Year Ended December 31, 2022

Other Income

Our other income increased from RMB13.8 million in 2022 to RMB21.0 million in 2023, primarily due to (i) an increase in government grants of RMB17.2 million for our R&D progress and installment of machinery and equipment; and (ii) an increase in interest income from financial institutions of RMB3.5 million primarily due to the increase of our bank deposits. Such increase was partially offset by a decrease in relocation incentive of RMB11.9 million as we only recorded a one-time incentive from a local governmental authority in the first quarter of 2022.

Other Gains and Losses, Net

We recorded net other losses of RMB49.6 million in 2023, changed from net other gains of RMB97.0 thousand in 2022, primarily due to (i) an increase in loss from fair value change of financial liabilities at FVTPL primarily due to the fair value loss of the preferred shares of the Pre-[**REDACTED**] Investors; and (ii) an increase in net foreign exchange losses of RMB8.3 million resulting from the fluctuation of foreign exchange rates in 2023.

Research and Development Expenses

Our research and development expenses decreased from RMB53.2 million in 2022 to RMB43.0 million in 2023, primarily in line with the evolving progress of preclinical studies and clinical trial status of different product candidates during the respective periods.

Administrative Expenses

Our administrative expenses significantly increased from RMB5.6 million in 2022 to RMB40.7 million in 2023, primarily due to (i) an increase in share-based compensation of RMB29.3 million in relation to RSUs transferred to Mr. Zhang in May 2023. For details, see notes 13 and 30 to the Accountants' Report in Appendix I to this document; (ii) an increase in our other administrative expenses in relation to our general operations, such as fees paid for our purchase of office supplies and traveling fees; and (iii) an increase in professional service fees paid for auditing and legal services.

Finance Costs

Our finance costs significantly decreased from RMB5.1 million in 2022 to RMB0.7 million in 2023, primarily due to a decrease in interest expenses on borrowing from a related party, which was in line with a decrease in our borrowings due to Nanjing Bode. For more details, see "— Related Party Transactions" in this section and note 31 to the Accountants' Report in Appendix I to this document.

Loss for the Period

As a result of the foregoing, our loss for the period increased significantly from RMB52.0 million in 2022 to RMB132.7 million in 2023.

DISCUSSION OF CERTAIN SELECTED ITEMS FROM THE CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

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

	As of December 31,	
	2022	**2023**
	RMB'000	*RMB'000*
ASSETS		
Non-current assets		
Property and equipment	45,500	41,119
Right-of-use assets	551	9,587
Intangible asset	10,000	10,000
Prepayments for acquisition of equipment	178	103
Refundable fulfillment deposits	–	2,500
Total non-current assets	56,229	63,309
Current assets		
Inventories	881	818
Deposits, prepayments and other receivables	11,613	16,256
Amounts due from shareholders	317	–
Other financial assets	–	49,579
Time deposits	–	35,414
Cash and cash equivalents	1,821	125,074
Total current assets	14,632	227,141

	As of December 31,	
	2022	**2023**
	RMB'000	*RMB'000*
LIABILITIES		
Current liabilities		
Trade and other payables	8,779	73,960
Amounts due to a related party	57,375	–
Lease liabilities	–	2,178
Financial liabilities at FVTPL	–	311,525
Total current liabilities	66,154	387,663
Net current liabilities	(51,522)	(160,522)
Non-current liabilities		
Lease liabilities	–	6,896
Amounts due to a related party	6,206	–
Total non-current liabilities	6,206	6,896
Net liabilities	(1,499)	(104,109)
Capital and reserves		
Share capital	322	322
Treasury stock	(29)	(19)
Reserves	(1,792)	(104,412)
Total deficit	(1,499)	(104,109)

Property and Equipment

Our property and equipment primarily includes machinery and equipment for our drug substance production, furniture and office equipment, leasehold improvements, and construction in progress, primarily representing the construction of our production lines. Our property and equipment decreased from RMB45.5 million as of December 31, 2022 to RMB41.1 million as of December 31, 2023, as a result of depreciation charged throughout the year. The following table sets out our property and equipment as of the dates indicated.

	As of December 31,	
	2022	**2023**
	RMB'000	*RMB'000*
Machinery and equipment	41,818	39,400
Furniture and office equipment	478	390
Leasehold improvements	376	281
Construction in progress	2,828	1,048
Total	45,500	41,119

Right-of-Use Assets

Our right-of-use assets primarily arose from the lease of premises for our research and development activities and general operations. Our right-of-use assets increased from RMB0.6 million as of December 31, 2022 to RMB9.6 million as of December 31, 2023, primarily because we entered into a new five-year lease agreement in the first quarter of 2023 upon the expiration of the previous premise lease agreement. For details, see note 18 to the Accountants' Report in Appendix I to this document.

Intangible Asset

Our intangible asset arose from our acquisition of rights and interests in relation to our product candidate, IBC0966. For more details, see "Business — Collaboration Arrangement — Collaboration Agreement With ImmuneOnco in Relation to the Development of IBC0966" in this document. The acquisition of rights and interests associated with IBC0966 was recognized as intangible asset with fair value of RMB10.0 million based on the collaboration agreement. Our intangible asset remained stable at RMB10.0 million as of 2022 and 2023, as we will not recognize any amortization or impairment loss of this intangible asset prior to the commercialization of IBC0966.

Deposits, Prepayments and Other Receivables

Our deposits, prepayments and other receivables primarily consisted of (i) prepayments for research and development costs; (ii) prepayments for [**REDACTED**], which mainly represents prepayments for our legal consulting services; (iii) value added tax ("**VAT**") recoverable; (iv) deferred [**REDACTED**], which represents [**REDACTED**] that will be capitalized upon the completion of the [**REDACTED**]; (v) relocation incentive receivable from the local government authority; (vi) refundable performance guarantee deposits to acquire a land use right in Zhejiang Province. Such deposit will be refunded when the land use right is transferred to us; and (vii) others.

Our deposits, prepayments and other receivables increased from RMB11.6 million as of December 31, 2022 to RMB16.3 million as of December 31, 2023, mainly due to (i) an increase in deferred [**REDACTED**] resulting from additional cost recognized in respect of the [**REDACTED**]; (ii) an increase in prepayments for research and development costs as we continued to advance our research and development activities; and (iii) an increase in refundable fulfillment deposits. Such increases were partially offset by a decrease in relocation incentive. The following table sets out our deposits, prepayment and other receivables as of the dates indicated.

	As of December 31,	
	2022	**2023**
	RMB'000	*RMB'000*
Prepayments for research and development costs	6,733	8,303
Deferred [**REDACTED**]	[**REDACTED**]	[**REDACTED**]
Refundable fulfillment deposits	–	2,500
Prepayments for [**REDACTED**]	[**REDACTED**]	[**REDACTED**]
Value added tax recoverable	685	999
Relocation incentive	2,380	–
Others	623	1,288
Total	11,613	18,756

As of March 31, 2024, RMB3.1 million, or 16.8%, of our deposits, prepayments and other receivables as of December 31, 2023 had been subsequently settled.

Other Financial Assets

Our other financial assets increased from nil as of December 31, 2022 to RMB49.6 million as of December 31, 2023, as we made a principal protected short-term investment in December 2023 which carries interest at 5.65% per annum and was issued by an asset management company. For details, see note 24 to the Accountants' Report in Appendix I to this document.

Cash and Cash Equivalents

Our cash and cash equivalents significantly increased from RMB1.8 million as of December 31, 2022 to RMB125.1 million as of December 31, 2023, mainly as we received the Pre-[**REDACTED**] Investments in 2023. For an analysis on cash flows during the Track Record Period, see "— Liquidity and Capital Resources" in this section.

Trade and Other Payables

Our trade and other payables primarily consisted of (i) accrued research and development costs; (ii) accrued staff costs and benefits; (iii) payables for research and development costs; (iv) other payables, mainly including deferred relocation incentive, payable for equipment acquisition, [**REDACTED**] and [**REDACTED**], and others; and (v) other tax payables. Our trade and other payables significantly increased from RMB8.8 million as of December 31, 2022 to RMB74.0 million as of December 31, 2023, mainly as we reclassified RMB60.3 million in other payables to Nanjing Bode Biological Pharmaceutical Co., Ltd. (南京博德生物製藥有限公司) ("**Nanjing Bode**"). For more details of the transactions between Nanjing Bode and us, see "— Discussion of Certain Selected Items From the Consolidated Statements of Financial Position — Amounts Due to A Related Party" and "— Related Party Transactions" in this section. The following table sets out our trade and other payables as of the dates indicated.

	As of December 31,	
	2022	**2023**
	RMB'000	*RMB'000*
Accrued research and development costs	1,688	1,833
Accrued staff costs and benefits	2,908	2,561
Accrued [**REDACTED**] and [**REDACTED**]	[**REDACTED**]	[**REDACTED**]
Payables for research and development costs	3,562	1,305
Other payables:		
Payable for equipment	221	1,137
Other payables to Nanjing Bode	–	60,285
Others	153	578
Other tax payables	61	53
Total	8,779	73,960

Our trade and other payables resulting from our research and development activities were primarily due to our CRO collaborators and other contract service providers in support of our preclinical studies and clinical trials. As of December 31, 2022 and 2023, a majority of our payables for research and development activities aged over 90 days, primarily due to our internal policy of verifying the achievement of corresponding milestones. The relative payables will be settled after we confirm the milestone achievement and complete our internal payment approval process. The following table sets forth an aging analysis of our payables for research and development costs based on the invoice dates as of the dates indicated.

	As of December 31,	
	2022	**2023**
	RMB'000	*RMB'000*
0 – 30 days	–	140
31 – 60 days	73	–
61 – 90 days	19	–
Over 90 days	3,470	1,165
Total	3,562	1,305

As of March 31, 2024, RMB1.0 million, or 30.4%, of our trade payables as of December 31, 2023 had been subsequently settled.

Amounts Due to A Related Party

Our amounts due to a related party represented our payables to Nanjing Bode, which are non-trade in nature and consisted of (i) payables for loan principal in support of our daily business operations and relevant interest; and (ii) payables for premise lease, equipment acquisition and others. Our amounts due to a related party decreased from RMB63.6 million as of December 31, 2022 to nil as of December 31, 2023, primarily because (i) all outstanding loans from Nanjing Bode, amounting to RMB34.4 million, was repaid by us in December 2023; and (ii) Nanjing Bode has become an Independent Third Party since July 2023 and we reclassified the amounts due to Nanjing Bode of RMB60.3 million to trade and other payables as of December 31, 2023. For more details, see "Relationship with Our Controlling Shareholders — Clear Delineation of Business — Nanjing Bode" in this document and notes 23, 26 and 31 to the Accountants' Report in Appendix I to this document.

As confirmed by our Directors, all outstanding non-trade payables to Nanjing Bode, amounting to RMB60.3 million as of December 31, 2023, will be fully settled before [**REDACTED**], and we do not plan to have additional non-trade related party transactions in the future. For more details, see "— Trade and Other Payables" above in this section and note 23 to the Accountants' Report in Appendix I to this document.

LIQUIDITY AND CAPITAL RESOURCES

Overview

Our primary sources of liquidity consist of cash and cash equivalents, which we have historically generated primarily through capital contributions from our shareholders and debt financing. We expect that our cash needs in the near future will primarily relate to progressing the development of our drug candidates towards receiving regulatory approval and commencing commercialization, as well as expanding our drug candidate portfolio. Our management closely monitors uses of cash and cash balances and strives to maintain a healthy liquidity for our operations. Going forward, expect our liquidity requirements will be satisfied by a combination of net [**REDACTED**] from the [**REDACTED**], and other sources, if necessary. With the continuing expansion of our business, we may require further funding through public or private offerings, debt financings, or other sources. As of February 29, 2024, we had unutilized banking facilities of RMB110 million.

Cash Flows

The following table sets forth our consolidated statements of cash flows for the years indicated.

	Year Ended December 31,	
	2022	**2023**
	RMB'000	*RMB'000*
Cash used in operations before movements in working capital	(36,171)	(47,124)
Changes in working capital	1,585	6,471
Net cash flows used in operating activities	(34,586)	(40,653)
Net cash flows used in investing activities	(1,362)	(83,888)
Net cash flows generated from financing activities	27,104	255,497
Net (decrease)/increase in cash and cash equivalents	(8,844)	130,956
Cash and cash equivalents at the beginning of the year	10,665	1,821
Effect of foreign exchange rate changes	–	(7,703)
Cash and cash equivalents at the end of the year	1,821	125,074

Net Cash Flows Used in Operating Activities

In 2023, we used RMB47.1 million in operating activities. The difference with RMB132.7 million of loss before tax was mainly the result of adding back non-cash items such as (i) RMB41.3 million in loss from changes in fair value of financial liabilities at FVTPL; (ii) RMB30.1 million of share-based payment expenses; (iii) RMB8.3 million of net foreign exchange loss; and (iv) RMB6.4 million of depreciation of property and equipment. In addition, a total of RMB6.5 million of cash was released from our working capital as our trade and other payables increased by RMB9.3 million, partially offset by an increase of RMB2.9 million in deposits, prepayments and other receivables.

In 2022, we used RMB34.6 million in operating activities. The difference with RMB52.0 million of loss before tax was mainly the result of adding back non-cash items such as (i) RMB6.6 million of depreciation of property and equipment, (ii) RMB5.1 million of finance costs, representing interest from right-of-use assets and interest on borrowing from Nanjing Bode and (iii) RMB2.2 million of depreciation of right-of-use assets. In addition, a total of RMB1.6 million of cash was released from our working capital mainly as our deposits, prepayments and other receivables decreased by RMB2.7 million, partially offset by a decrease of RMB1.4 million in trade and other payables.

We expect our net operating cash outflows position to improve, mainly through (i) expediting the registration and commercialization of our Core Products; (ii) selectively seeking out-licensing opportunities for our product candidates; and (iii) further improving our operational efficiency to enhance our working capital position by reviewing regularly and updating our liquidity and funding policies to ensure that it is aligned with our business plan and financial position, and preparing cash flow and funding summaries on a regular basis to monitor our cash flow.

Net Cash Flows Used in Investing Activities

In 2023, our net cash flows used in investing activities was RMB83.9 million, primarily as a result of (i) our purchase of other financial assets of RMB49.7 million, and (ii) our placement of time deposits with maturity of more than three months of RMB35.9 million.

In 2022, our net cash flows used in investing activities was RMB1.4 million, primarily as a result of (i) purchase of financial assets at FVTPL of RMB17.5 million, and (ii) acquisition of property and equipment of RMB1.4 million, partially offset by redemption of financial assets at FVTPL of RMB17.6 million.

Net Cash Flows Generated From Financing Activities

In 2023, our net cash flows generated from financing activities was RMB255.5 million, primarily as a result of the proceeds from issuance of shares by our Company of RMB270.5 million.

In 2022, our net cash flows generated from financing activities was RMB27.1 million, primarily as a result of borrowings from Nanjing Bode of RMB42.7 million, partially offset by repayments to Nanjing Bode of RMB15.1 million.

Net Current Liabilities

	As of December 31,		As of February 29
	2022	2023	2024
	RMB'000	*RMB'000*	*RMB'000 (unaudited)*
Current assets			
Inventories	881	818	776
Deposits, prepayments and other receivables	11,613	16,256	24,779
Amounts due from shareholders	317	–	–
Other financial assets	–	49,579	51,856
Time deposits	–	35,414	35,518
Cash and cash equivalents	1,821	125,074	101,994
Total current assets	14,632	227,141	214,923
Current liabilities			
Trade and other payables	8,779	73,960	69,120
Bank borrowings	–	–	10,000
Amounts due to a related party	57,375	–	–
Lease liabilities	–	2,178	2,189
Financial liabilities at FVTPL	–	311,525	316,925
Total current liabilities	66,154	387,663	398,234
Net current liabilities	(51,522)	(160,522)	(183,311)

Our net current liabilities increased from RMB51.5 million as of December 31, 2022 to RMB160.5 million as of December 31, 2023, primarily attributable to (i) an increase in financial liabilities at FVTPL; and (ii) an increase in trade and other payables, partially offset by a decrease in amounts due to a related party. For details, see "— Discussion of Certain Selected Items From The Consolidated Statements of Financial Position — Amounts Due to A Related Party" and "— Related Party Transactions" in this section.

Our net current liabilities increased from RMB160.5 million as of December 31, 2023 to RMB183.3 million as of February 29, 2024, primarily attributable to (i) a decrease in cash and cash equivalents and (ii) an increase in bank borrowings, partially offset by an increase in deposits, prepayments and other receivables.

We expect to improve our net current liabilities and net liabilities positions in the future and turn into net assets position upon [**REDACTED**], taking into account the estimated net [**REDACTED**] from the [**REDACTED**], and that the carrying amount of the financial liabilities of the convertible redeemable preferred shares of RMB316.9 million as of February 29, 2024 will be derecognized and credit to equity as a result of the automatic conversion into ordinary Shares upon the [**REDACTED**].

Working Capital Confirmation

Our Directors are of the opinion that, taking into account the financial resources available to our Group, including cash and cash equivalents and the estimated net [**REDACTED**] from the [**REDACTED**], as well as cash burn rate, we have available sufficient working capital to cover at least 125% of the Group's costs, including general, administrative and operating costs (including any production costs), research and development costs for at least the next 12 months from the date of this document.

Our cash burn rate refers to the average monthly amount of net cash used in operating activities, capital expenditures, and other scheduled cash payment. Assuming an average cash burn rate going forward of 6.5 times the level in 2023, taking into account the scheduled payment of indebtedness, we estimate that our cash at bank and on hand, together with other financial assets and time deposits as of December 31, 2023 will be able to maintain our financial viability for 9 months, or, if we also take into account the estimated net [**REDACTED**] (based on the [**REDACTED**] of HK$[**REDACTED**] per Share, being the low-end of the indicative [**REDACTED**]), [**REDACTED**]. Our Directors and our management team will continue to monitor our working capital, cash flows, and our business development progress.

CASH OPERATING COSTS

The following table sets forth key information relating to our cash operating costs for the years indicated.

	Year Ended December 31,	
	2022	**2023**
	RMB'000	*RMB'000*
Costs relating to research and development of our Core Product		
Contract research expenses	3,428	5,625
Staff costs	2,563	4,544
Materials consumed	334	859
Application fees	507	555
Others	1,121	2,157
Costs relating to research and development of our other product candidates		
Contract research expenses	15,845	5,638
Staff costs	13,526	10,687
Materials consumed	3,983	2,380
Application fees	823	625
Others	1,308	1,210
Total research and development costs	43,438	34,280
Workforce employment cost[(1)]	2,260	2,868
Direct production cost[(2)]	–	–
Non-income taxes, royalties and other governmental charges	–	–
Contingency allowances	–	–
Product marketing[(3)]	–	–
Total	**45,698**	**37,148**

Notes:

(1) Workforce employment cost represents total non-research and development personnel costs mainly including salaries and benefits.

(2) We had not commenced commercial manufacturing as of the Latest Practicable Date.

(3) We had not commenced product sales as of the Latest Practicable Date.

INDEBTEDNESS

Our indebtedness mainly included financial liabilities at FVTPL, loans from Nanjing Bode, amounts due to Nanjing Bode and lease liabilities during the Track Record Period. Except as disclosed in the table below, we did not have any material mortgages, charges, debentures, loan capital, debt securities, loans, bank overdrafts or other similar indebtedness, finance lease or hire purchase commitments, liabilities under acceptances (other than normal trade bills), acceptance credits, which are either guaranteed, unguaranteed, secured or unsecured, or guarantees or other contingent liabilities as of February 29, 2024. After due and careful consideration, our Directors confirm that there had been no material change in our indebtedness since February 29, 2024 and up to the Latest Practicable Date. The following table sets forth a breakdown of our indebtedness as of the dates indicated.

	As of December 31,		As of February 29
	2022	2023	2024
	RMB'000	*RMB'000*	*RMB'000 (unaudited)*
Indebtedness:			
Financial liabilities at FVTPL	–	311,525	316,925
Loans from Nanjing Bode	11,025	–	–
Amounts due to Nanjing Bode	52,556	60,285	51,116
Lease liabilities	–	9,074	9,119
Bank borrowings	–	–	10,000
	63,581	380,884	387,160

Our Directors confirm that as of the Latest Practicable Date, there was no material covenant on any of our outstanding debt and there was no breach of any covenant during the Track Record Period and up to the Latest Practicable Date. Our Directors further confirm that our Group did not experience any difficulty in obtaining bank loans and other borrowings, default in payment of bank loans and other borrowings or breach of covenants during the Track Record Period and up to the Latest Practicable Date.

Financial Liabilities at FVTPL

As of December 31, 2023, we recorded financial liabilities at FVTPL of RMB311.5 million. This was a result of our receipt of an aggregated proceeds of RMB270.2 million from Pre-[**REDACTED**] Investments, whereby we designated the shares of Pre-[**REDACTED**] investments as financial liabilities at FVTPL and recognized subsequent fair value changes as of December 31, 2023. As of February 29, 2024, our financial liabilities at FVTPL increased to RMB316.9 million, primarily due to our recognition of subsequent fair value changes. For further information regarding our issuance of shares of Pre-[**REDACTED**] Investments, see note 28 to the Accountants' Report set out in Appendix I to this document.

Loans From Nanjing Bode

Our loans from Nanjing Bode represented payables for loan principal and interests due to Nanjing Bode which was a related party to us until July 2023. Since that time, it has become an Independent Third Party, further details of which are set out in the paragraph headed "Relationship with Our Controlling Shareholders — Clear Delineation of Business — Nanjing Bode" in this document. In December 2023, all of the loan principal and interests due to Nanjing Bode had been repaid by us in full.

Amounts Due to Nanjing Bode

Our amounts due to Nanjing Bode mainly represented payables for our leases and acquisition of equipment. For further information, see note 26 to the Accountants' Report set out in Appendix I to this document.

Lease Liabilities

Our lease liabilities amounted to nil, RMB9.1 million and RMB9.1 million as of December 31, 2022 and 2023 and February 29, 2024, respectively. At the commencement date of a lease, we recognize and measure the lease liability at the present value of lease payments that are unpaid at that date. In calculating the present value of lease payments, we use the incremental borrowing rate at the lease commencement date if the interest rate implicit in the lease is not readily determinable. The weighted average incremental borrowing rates applied to the lease liabilities was 3.00% per annum during the Track Record Period.

Bank borrowings

Our bank borrowings amounted to nil, nil and RMB10.0 million as of December 31, 2022 and 2023 and February 29, 2024, respectively. The bank borrowings as of February 29, 2024 include a loan in an amount of RMB10.0 million, which is denominated in RMB and is unsecured and unguaranteed and repayable in 12 months with an interest rate at 3.45% per annum.

CONTINGENT LIABILITIES

Except for the under provision of social insurance and housing provident fund contributions, we did not have any material contingent liabilities as of December 31, 2022, and 2023. For the related risk, see "Risk Factors — Risks Relating to Our Operations — Any failure to comply with the PRC regulations regarding contribution of social insurance premium or housing provident funds may subject us to fines and other legal or administrative measures" in this document. We confirm that as of the Latest Practicable Date, there had been no material changes or arrangements to our contingent liabilities.

RELATED PARTY TRANSACTIONS

During the Track Record Period, we had entered into certain related party transactions and leases. For details, see notes 23 and 31 to the Accountants' Report in Appendix I to this document. During the Track Record Period, our related party transactions mainly included (i) our purchase of machinery and equipment from Nanjing Bode which has ceased to be a related party and become an Independent Third Party since July 2023; (ii) interest expenses on borrowings from Nanjing Bode in support of our daily business operations; and (iii) a waiver of loan due to Nanjing Bode in 2022 which resulted in a corresponding increase in our capital reserve in 2022. In December 2023, all of the loan principal and interests due to Nanjing Bode had been repaid by us in full. In addition, we held lease liabilities to Nanjing Bode during the Track Record Period, resulting from a five-year lease agreement we entered into with Nanjing Bode for lease of premises for our business operation, pursuant to which we pay rents on an annual basis. The lease term will expire in March 2028. For further details relating to Nanjing Bode and our transactions with Nanjing Bode, see "Relationship with Our Controlling Shareholders — Clear Delineation of Business — Nanjing Bode" and "Business — Suppliers and Raw Materials — Suppliers" in this document.

Our amounts due from shareholders were non-trade in nature and repayable on demand. These amounts are primarily associated with the Reorganization and have been fully settled as of December 31, 2023.

Our Directors confirm that all material related party transactions during the Track Record Period were conducted on an arm's length basis, and would not distort our results of operations over the Track Record Period or make our historical results over the Track Record Period not reflective of our expectations for our future performance.

CAPITAL EXPENDITURE

In 2022 and 2023, our capital expenditures were RMB1.4 million and RMB1.0 million, respectively, which were acquisition of property and equipment. We regularly incur capital expenditures to purchase and maintain our property and equipment in order to enhance our research and development capabilities and expand our business operations, upgrade our facilities and increase our operating efficiency. The following table sets forth our capital expenditures for the years indicated.

	Year Ended December 31,	
	2022	**2023**
	RMB'000	*RMB'000*
Acquisition of property and equipment	(1,439)	(1,030)
Total	(1,439)	(1,030)

Our historical capital expenditures during the Track Record Period primarily included expenditures associated with the purchase of property and equipment, which mainly consists of machinery and equipment, furniture and office equipment, leasehold improvements and construction in progress. We may adjust our capital expenditures for any given period according to our development plans or in light of market conditions and other factors we believe to be appropriate.

COMMITMENTS

Capital Commitments

During the Track Record Period, our capital commitments contracted but not provided in the historical financial information primarily arose from the contracts we entered into with suppliers for the acquisition of equipment and the contract we entered into to acquire the land use right to support the construction of our production lines and the expansion of our business operations. We had the following commitments as of the dates indicated. For more information, see note 32 to the Accountants' Report in Appendix I to this document.

	Year Ended December 31,	
	2022	**2023**
	RMB'000	*RMB'000*
Contracted for but not provided in the historical financial information	1,015	18,610
Total	1,015	18,610

KEY FINANCIAL RATIO

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

	As of December 31,	
	2022	**2023**
Current ratio[(1)]	0.2	0.6

Note:

(1) Current ratio equals to current assets divided by current liabilities as of the same date.

Our current ratio increased from 0.2 as of December 31, 2022 to 0.6 as of December 31, 2023, primarily due to an increase in cash and cash equivalents, as we received the Pre-[**REDACTED**] Investments in 2023.

MARKET RISK DISCLOSURE

Our major financial assets and liabilities include amounts due from shareholders, cash and cash equivalents, trade and other payables, and amounts due to a related party. The risks associated with these financial assets and liabilities include market risks (currency risk and interest rate risk), credit risk and liquidity risk. Our management manages and monitors these exposures to ensure appropriate measures are implemented on a timely and effective manner. For more details, see note 34 to the Accountants' Report in Appendix I to this document.

Market Risks

Our activities expose ourself primarily to currency risk and interest rate risk. There has been no change in our exposure to these risks or the manner in which we manage and measure the risks.

Currency Risk

Certain financial assets and liabilities are denominated in foreign currency of respective group entities which are exposed to foreign currency risk. We currently do not have a foreign currency hedging policy. However, the management monitors foreign exchange exposure and will consider hedging significant foreign currency exposure should the need arise.

Interest Rate Risk

We are primarily exposed to fair value interest rate risk in relation to lease liabilities and loan from a related party. We currently do not have an interest rate hedging policy to mitigate interest rate risk; nevertheless, the management monitors interest rate exposure and will consider hedging significant interest rate risk should the need arise.

We consider that the exposure of cash flow interest rate risk arising from variable-rate bank balances is insignificant because the current market interest rates are relatively low and stable.

Credit Risks

Our maximum exposure to credit risk which will cause us a financial loss is arising from the amount of bank balances, other receivables and amounts due from shareholders disclosed in the consolidated statements of financial position. We do not hold any collateral or other credit enhancements to cover our credit risks associated with our financial assets.

Amounts Due From Shareholders

For amounts due from shareholders, we have applied 12m ECL to measure the loss allowance. In assessing the probability of defaults of amounts due from shareholders, the management has taken into account the financial position of the counterparties as well as forward looking information that is available without undue cost or effort. The management considered the ECL provision of amounts due from shareholders is insignificant.

Bank Balances

The credit risk on bank balances is limited because the counterparties are reputable financial institutions. We assessed 12m ECL for bank balances by reference to information relating to probability of default and loss given default of the respective credit rating grades published by external credit rating agencies. Based on the average loss rates, the 12m ECL on bank balances is considered to be insignificant and therefore no loss allowance was recognized.

Liquidity risk

In the management of the liquidity risk, we monitor and maintain a level of cash and cash equivalents deemed adequate by the management to finance our operations and mitigate the effects of fluctuations in cash flows.

OFF-BALANCE SHEET COMMITMENTS AND ARRANGEMENTS

During the Track Record Period and as of the Latest Practicable Date, we had not entered into any off-balance sheet transactions.

DIVIDENDS

No dividend has been declared or paid by entities comprising our Group. We currently expect to retain all future earnings for use in operation and expansion of our business, and do not have any dividend policy to declare or pay any dividends in the foreseeable future. Any declaration and payment by our Company as well as the amount of dividends will be subject to our constitutional documents and the Cayman Companies Act. The declaration and payment of any dividends in the future will be determined by our Board, in its discretion, and will depend on a number of factors, including our earnings, capital requirements, overall financial condition and contractual restrictions. Our Shareholders in a general meeting may approve any declaration of dividends, which must not exceed the amount recommended by our Board.Under the laws of the Cayman Islands, a Cayman Islands company may pay a dividend out of its profits or the credit standing to its share premium account, provided that immediately after the date on which the dividend is proposed to be paid, the company will be able to pay its debts as they fall due in the ordinary course of business. As advised by our legal adviser as to Cayman Islands laws, a position of accumulated losses does not necessarily restrict us from declaring and paying dividends to our Shareholders, as dividends may still be declared and paid out of our share premium account, provided that, immediately after payment of the dividend, we are able to pay our debts as they fall due in the ordinary course of business.

We may need dividends and other distributions on equity from our subsidiaries to satisfy our liquidity requirements, including those incorporated in the PRC. Current PRC regulations permit our PRC subsidiaries to pay dividends to us only out of their distributable profits. Distributable profits are our PRC subsidiaries' after-tax profits, less any recovery of accumulated losses and appropriations to statutory and other reserves that our PRC subsidiaries are required to make. In addition, our PRC subsidiaries are required to set aside at least 10% of their respective after-tax profits each year to fund statutory reserve until the total amount set aside reaches 50% of their respective registered capital. Where the aggregate balance of statutory reserve is insufficient to cover loss in the previous financial year, the current financial year's profits shall first be used to cover the loss before any statutory reserve is set aside. Our PRC subsidiaries may also allocate a portion of their after-tax profits to discretional reserve where our PRC subsidiaries have set aside statutory reserve from their after-tax profits, subject to a resolution of the shareholders. These reserves are not distributable as cash dividends. Furthermore, if our PRC subsidiaries incur debt on their own behalf, the instruments governing such debt may restrict their ability to pay dividends or make other payments to us.

DISTRIBUTABLE RESERVES

As of December 31, 2023, we did not have any distributable reserves.

IMPAIRMENT TESTING ON INTANGIBLE ASSETS NOT READY FOR USE

Intangible assets not yet ready for use ("**IPR&D**"), is tested impairment annually and whenever there is an indication for impairment, based on the recoverable amount of the cash-generating unit to which the intangible asset is related. The appropriate cash-generating unit is at the pipeline level.

Impairment review on the IPR&D of our Group has been conducted by our management by engaging an independent qualified professional valuer, Valuelink Asia (Beijing) Enterprise Management Consulting Co., Ltd. (藍策亞洲(北京)企業管理諮詢有限公司) ("**ValueLink**"), whose address is Room 511, Jiasheng Center, No. A19, Dongsanhuan Road, Chaoyang District, Beijing, the PRC, to estimate the recoverable amount of the cash-generating unit at the end of each year. For the purpose of impairment review, the recoverable amount of the cash-generating unit is determined based on value in use by using the discounted cash flow approach.

With the assistance of ValueLink, the management determined the recoverable amount of the above cash-generating unit based on the following approach and the key assumptions:

- The cash-generating unit will generate cash inflows starting from year 2027 based on the timing of clinical development and regulatory approval, commercial ramp up to reach expected peak revenue potential till year 2032, and up to the end of the exclusivity for the product; The management considers the length of the forecast period is appropriate because it generally takes longer for a biopharma company to generate positive cash flows, compared to companies in other industries, especially when the related products are under clinical trial. Hence, the management believes that a forecast period for the cash generating unit longer than five years is justifiable and consistent with industry practice;

- The expected market penetration rate was based on the expected selling conditions considering the features of marketing and technology development;

- The discount rate used is pre-tax and reflect specific risks relating to the relevant products that would be considered by market participants; and

- The expected success rate of commercialization by reference to practices of pharmaceutical industries, development of technologies and related regulations from administrations.

The key parameters used for recoverable amount calculations are as follows.

	As of December 31,	
	2022	**2023**
Expected annual growth rates till 2032	18%~516%	18%~516%
Expected market penetration rate	0.6%~11.7%	0.6%~11.7%
Pre-tax discount rate	21.76%	21.05%
Expected success rate of commercialization	13.0%	16.22%

The revenue growth rate for the forecast period and budgeted gross margin were determined by the management based on their expectation for market and product development.

Based on the result of the IPR&D impairment testing, the recoverable amount of the cash-generating unit exceeded its carrying amount as of December 31, 2022 and 2023. Thus, no impairment is noted.

Impairment Testing — Sensitivity Analysis

The Company performed sensitivity test by increasing 1% of discount rate or decreasing of 5% revenue growth rate, which are the key assumptions determine the recoverable amount of the intangible asset, with all other variables held constant. The impacts on the amount by which the intangible asset's recoverable amount above its carrying amount (headroom) are as below:

	As of December 31,	
	2022	**2023**
	RMB'000	*RMB'000*
Headroom	14,900	18,300
Impact by increasing discount rate	(3,800)	(4,700)
Impact by decreasing annual revenue growth rate	(5,900)	(9,000)

As of December 31, 2023, the management is not aware of any significant adverse changes on the respective cash-generating unit that indicates the carrying amount of the cash-generating unit exceeds its recoverable amount. As a result, no impairment assessment as of December 31, 2023 was performed.

If the pre-tax discount rate used as of December 31, 2022 and 2023 was changed to 27.4% and 25.6%, respectively, while other parameters remain constant, the recoverable amount of the cash-generating unit would equal its carrying amount. If the annual revenue growth rate used as of December 31, 2022 and 2023 was decreased by 10.1% and 8.0%, respectively, while other parameters remain constant, the recoverable amount of the cash-generating unit would equal its carrying amount. Any reasonably possible changes in key assumptions would not lead to impairment as of December 31, 2022 and 2023.

[**REDACTED**]

[**REDACTED**] to be borne by us are estimated to be approximately HK$[**REDACTED**] (assuming an [**REDACTED**] of HK$[**REDACTED**] per Share, being the mid-point of the indicative [**REDACTED**] range of HK$[**REDACTED**] to HK$[**REDACTED**] per Share), representing approximately [**REDACTED**]% of the estimated gross [**REDACTED**] from the [**REDACTED**]. The [**REDACTED**] consist of (i) [**REDACTED**] expenses, including [**REDACTED**], of approximately HK$[**REDACTED**] (representing approximately [**REDACTED**]% of the estimated gross [**REDACTED**] from the [**REDACTED**]), and (ii) [**REDACTED**] expenses of approximately HK$[**REDACTED**], comprising (a) fees and expenses of our legal advisors and reporting accountants of approximately HK$[**REDACTED**], and (b) other fees and expenses of approximately HK$[**REDACTED**]. During the Track Record Period, the [**REDACTED**] charged to our consolidated statements of profit or loss were RMB[**REDACTED**] (HK$[**REDACTED**]) and the [**REDACTED**], which was recognized as prepayments and are expected to be deducted from equity upon the [**REDACTED**], were RMB[**REDACTED**] (HK$[**REDACTED**]). After the Track Record Period, approximately HK$[**REDACTED**] is expected to be charged to our consolidated statements of profit or loss, and approximately HK$[**REDACTED**] is expected to be accounted for as a deduction from equity upon the [**REDACTED**]. We do not believe any of the above fees or expenses are material or are unusually high to our Group. The [**REDACTED**] above are the latest practicable estimate for reference only, and the actual amount may differ from this estimate.

UNAUDITED [REDACTED] STATEMENT OF ADJUSTED NET TANGIBLE ASSETS

[**REDACTED**]

[**REDACTED**]

IMPACT OF THE COVID-19

During the Track Record Period and up to the Latest Practicable Date, we had not experienced material disruptions in our operations as a result of the COVID-19 pandemic. Although our planned subject enrollment of Phase I clinical trials of IAP0971 and IAE0972 encountered temporary slow-down for around one month due to the reoccurrence of the pandemic in Shanghai in May 2022, we did not experience any delay of these clinical trials from the pandemic and theses clinical trials were completed within the original timetable. The overall impact of the COVID-19 pandemic on our clinical activities, drug development timeline, business and results of operations has been immaterial, and especially as the COVID-19 pandemic has come under control as of the Latest Practicable Date and our Directors are of the view that it is unlikely that COVID-19 pandemic will have material adverse impact on our business going forward.

NO MATERIAL ADVERSE CHANGE

Our Directors confirm that there has been no material adverse change in our business, financial condition and results of operations since December 31, 2023, being the latest balance sheet date of our consolidated financial statements in the Accountants' Report set out in Appendix I to this document, and up to the date of this document.

DISCLOSURE UNDER RULES 13.13 TO 13.19 OF THE LISTING RULES

We confirm that, as of the Latest Practicable Date, there were no circumstances that would give rise to disclosure required under Rules 13.13 to 13.19 of the Listing Rules.

OUR CONTROLLING SHAREHOLDERS

As of the Latest Practicable Date, Mr. Zhang is able to exercise approximately 81.62% voting rights in our Company through 88,000,000 Shares held by Sunho Wisdom, 6,000,000 Shares held by No5XJR and 6,000,000 Shares by Sunho Stellar. Sunho Wisdom is owned as to 99.9% by Sunho Fortune (as a nominee which is wholly owned by a trust established by Mr. Zhang as the settlor and beneficiary) and 0.1% by Innovalue Investments (a wholly-owned subsidiary of Mr. Zhang), respectively. Mr. Zhang is entitled to exercise approximately 73.19% voting rights in No5XJR through Innovalue Investments, details of which are set out in the section headed "History, Reorganization and Corporate Structure" in this document. Sunho Stellar is wholly owned by an independent professional trustee which shall exercise all voting rights attached to the Shares held by Sunho Stellar in accordance with the instructions of Mr. Zhang.

Immediately upon completion of the [**REDACTED**], Mr. Zhang will be able to exercise approximately [**REDACTED**]% voting rights in our Company. Therefore, Mr. Zhang, Sunho Fortune, Innovalue Investments, Sunho Wisdom, No5XJR and Sunho Stellar will be considered as a group of Controlling Shareholders under the Listing Rules.

Sunho Fortune, Innovalue Investments, Sunho Wisdom and No5XJR are investment holding companies with no substantive business activities. Sunho Stellar serves as the share incentive platform of our Company. For further details, see "History, Reorganization and Corporate Structure" in this document. For background and biographical details of Mr. Zhang, see "Directors and Senior Management" in this document.

CLEAR DELINEATION OF BUSINESS

We are a biopharmaceutical company committed to the discovery, development and commercialization of biologics that regulate immune microenvironment by directly modulating both the innate and adaptive immune systems. For details, see "Business" in this document.

Nanjing Yoko

As of the Latest Practicable Date, apart from the interest in our Group, Mr. Zhang was the chairman of the board of directors of, and through his controlled entities, was entitled to exercise approximately 50.37% voting rights in, Nanjing Yoko, a joint stock company established in the PRC in February 2002 and principally engaged in the R&D, manufacturing and sales of chemical drugs with different application areas and indications, including bacterial infections, analgesia, type II diabetes, respiratory infections and locally advanced or metastatic NSCLC with EGFR mutations. As of the Latest Practicable Date, save for Mr. Zhang, there was no overlap in the board of directors of our Group and Nanjing Yoko, and there had been no sharing of entities, businesses, personnel, premises, facilities and other resources between our Group and Nanjing Yoko. Further, as of the Latest Practicable Date, Mr. Zhang was a substantial shareholder and a director in certain companies which had not commenced any business activities.

There is a clear delineation of business between our Group and Nanjing Yoko based on the following grounds:

(a) Different Drug Products by Nature

Our Group is principally engaged in the discovery, development and commercialization of biologics, which are pharmaceutical products manufactured using biological methods and sources, and are designed to replicate the activity of natural substances.

Unlike our Group, Nanjing Yoko is principally engaged in the R&D, manufacturing and sales of chemical drugs, i.e. small molecule drugs which are pharmaceutical products derived from a production process based on chemical synthesis.

As set forth in the below table, biologics and chemical drugs are significantly distinctive from each other in terms of mechanisms of action, development and production technology, and treatment application and usage.

	Biologics	**Chemical drugs**
Mechanisms of Action	• Biologics are biologically derived from living organisms or cells. • Biologics have high specificity, which identify antigens on the surface of tumor cells and various receptors, precisely targeting at the cancer cells and reacting distinctively with targets. • Biologics can inhibit growth of cells after cells cycles and promote cell apoptosis, so as to kill the cancer cells through a combination of mechanisms involving action between antibody-dependent cell-mediated cytotoxicity (ADCC), complement dependent cytotoxicity (CDC), and antibodies and molecules.	• Chemical drugs are chemically derived. • Chemical drugs are used to treat a variety of diseases and conditions and can be quite diverse in their mechanisms of action. • Because of their small size and typical physicochemical properties, small molecules can be effective enzyme inhibitors and allosteric modifiers and can target extracellular proteins or intracellular receptors in the cytosol, nuclei, and central nervous system.

	Biologics	Chemical drugs
Development and production technology	• Biologics consist of complicated molecular structures and have high molecular weights. For biologics, structural characterization is more complicated than small molecules, but it is an essential part of the development and quality control process. Various antibody-based assays have been used to address the challenge of quantification of biologics. • Biologics involve complicated molecular biology and biological engineering technology, which includes antibody engineering technology, cell culture medium and technology for developing hybridoma producing macromolecular biologics. Production of chemical drugs does not involve such technologies. • Given that biologics are sensitive to and vulnerable to changes in the pH, temperature, and osmotic pressure of the environment, the R&D and manufacturing of biologics involve complicated biopharmaceutical technology, a high level of requirements in respect of production specifications, as well as time- and labor-consuming process. Biologics, being more complicated in nature, may take more than one month to manufacture. Based on the above, the production of biologics requires manufacturing facilities separate and distinct from those for chemical drugs.	• Chemical drugs generally have well-defined chemical structures, and a finished drug can usually be analyzed to determine all its various components through traditional laboratory methods. • Development and production of chemical drugs mainly involve technologies for deriving such drugs from chemicals including the technologies for producing (i) freeze-dried chemical powder; (ii) drug tablets, capsules and granules; and (iii) medical patches. Chemical drugs generally take less than a week to manufacture.

	Biologics	Chemical drugs
Treatment application and usage	• Biologics are highly specific, and would generally target patients with medical conditions which are suitable for treatment targeting a specific biomarker expressed on body cells. In particular, biologics are used for reinforcing the anti-cancer efficacy of chemical drugs in treatment known as combination therapies. While chemical drugs often have off-target effects, biologics offer a more targeted treatment option as they are designed to interact with the immune system in specific ways, and biologics bind with high specificity to their targets on intracellular components or cell surfaces.	• As the mechanism of actions of chemical drugs are diverse, chemical drugs would target patients with medical conditions which are suitable for a treatment generally on body cells or a certain type of body cells.

(b) Different Application Areas and Indications

Our Group focuses on biologics that regulate immune microenvironment by directly modulating both the innate and adaptive immune systems. Leveraging our in-depth understanding of immunology, we have developed various types of immunotherapies, including immunocytokines and antibodies, for treatment of cancers and autoimmune diseases.

On the other hand, save for two chemical drugs for treatment of NSCLC, all the chemical drugs of Nanjing Yoko are for treatment of such medical indications as bacterial infections, analgesia, type II diabetes and respiratory infections, which are completely different from the application areas of our product candidates.

In respect of the two chemical drugs of Nanjing Yoko for treatment of NSCLC, namely, Erlotinib and Geftinib (collectively, the "**NSCLC Chemical Drugs**"), although our Core Products, IAP0971 and IAE0972, are expected to have indications including, among others, NSCLC, there are clear distinctions between these products and our Core Products, considering that (i) the treatment options of NSCLC vary by molecular subtyping and (ii) the NSCLC Chemical Drugs and our Core Products target mutually exclusive patient groups with entirely different medical conditions with different mechanisms of action, and are not substitutes for each other:

	NSCLC Chemical Drugs	**IAP0971**	**IAE0972**
Different target patient groups	The NSCLC Chemical Drugs target NSCLC patients at stage IV with EGFR mutations (a subtype of NSCLC with a different form of EGFR gene from the wild type). EGFR mutations are one of the oncogenic drivers in NSCLC. Chemical drugs known as EGFR-tyrosine kinase inhibitors (such as the NSCLC Chemical Drugs) are primarily recommended throughout the treatment process.	IAP0971 targets patients with EGFR wild type NSCLC (a subtype of NSCLC with a natural EGFR gene (without mutation)) at stage IV and driver-gene negative NSCLC (a subtype of NSCLC without oncogenic drivers) at stage IV. Such medical conditions cannot co-exist within oncogene-driven NSCLC patients with EGFR mutations and therefore, EGFR-tyrosine kinase inhibitors, such as the NSCLC Chemical Drugs, are not applicable to patient groups with such medical conditions.	IAE0972 targets patients with EGFR wild type NSCLC (a subtype of NSCLC with a natural EGFR gene (without mutation)) at stage IV and driver-gene negative NSCLC (a subtype of NSCLC without oncogenic drivers) at stage IV. Such medical conditions cannot co-exist within oncogene-driven NSCLC patients with EGFR mutations and therefore, EGFR-tyrosine kinase inhibitors, such as the NSCLC Chemical Drugs, are not applicable to patient groups with such medical conditions.

	NSCLC Chemical Drugs	IAP0971	IAE0972
Different mechanisms of action	The NSCLC Chemical Drugs are targeted therapies, and are known as small molecule chemical EGFR-tyrosine kinase inhibitors. Instead of acting on the patient's immune system to attack cancer cells (which our Core Products, IAP0971 and IAE0972, do), the NSCLC Chemical Drugs target cancer cells with specific EGFR mutations or overexpression of EGFR, and bind to the intracellular catalytic domain of EGFR tyrosine kinase, thereby inhibiting EGFR autophosphorylation and downstream signaling.	IAP0971 is a type of large molecule biological immunotherapy. It is designed to adopt the structure of an intact bivalent anti-PD-1 antibody in combination with a monovalent IL-15. It is expected to target the PD-1/ PD-L1 signaling pathway to relieve the immunosuppression in the tumor microenvironment, and in the meantime, deliver IL-15 to the tumor, and thus locally activates and enhances antitumor functions of immune cells, leading to a significantly enhanced antitumor immunity.	IAE0972 is a type of large molecule biological immunotherapy. It is designed to adopt the structure of monovalent anti-EGFR antibody fused with homodimer of IL-10. It blocks the EGFR signaling pathway to kill EGFR-positive tumor cells and specifically delivers IL-10 to the targeted tumor site to activate the immune system by reinvigorating antigen specific CD8+ T cells and facilitating its proliferation, and inhibiting tumor growth.

Based on the above, we consider that there is a clear delineation of business between our Group and Nanjing Yoko and the business of Nanjing Yoko does not compete and is unlikely to compete, directly or indirectly, with the business of our Group. As such, as of the Latest Practicable Date, our Controlling Shareholders did not have any interest in a business, apart from the business of our Group, which competes or is likely to compete, directly or indirectly, with the business of our Group, and which requires disclosure under Rule 8.10 of the Listing Rules.

In view of the clear business delineation as set out above, our Company considers that (i) Nanjing Yoko has a different business focus from our Group and provides chemical drugs that are not and will not be otherwise offered by our Group, (ii) the business of Nanjing Yoko (i.e. the R&D, manufacturing and sales of chemical drugs with a diversified application areas and indications) is not in line with the strategic direction of the development of our Group, (iii) Nanjing Yoko is a commercial-stage pharmaceutical company with more than ten years' experience of successful commercialization of chemical drugs and is at a different development stage as compared to our Group as a clinical-stage biopharmaceutical company, (iv) the inclusion, and thereby operation, of Nanjing Yoko within our Group will require significant management and internal resources and may divert our management's attention and time from the operation and development of our core businesses, and (v) the exclusion of Nanjing Yoko from our Group will give a clear focus to our investors. As such, we believe that it is not in the best interest of our Group or our Shareholders to include Nanjing Yoko in our Group.

Nanjing Bode

Nanjing Bode Biological Pharmaceutical Co., Ltd. (南京博德生物製藥有限公司) ("**Nanjing Bode**") is a limited liability company established in the PRC in March 2003. In September 2014, Mr. Zhang acquired, through his holding vehicles, the entire equity interest in Nanjing Bode from Mr. ZHU Zhenfei (朱振飛) ("**Mr. Zhu**") and Nanjing Chenhe Pharmaceutical Technology Co., Ltd. (南京辰和醫藥科技有限公司), which in turn was held as to 40% by Mr. YUAN Jingsong (袁勁松) and 60% by Ms. LI Xinyuan (李欣園), respectively. Each of Mr. Zhu, Nanjing Chenhe Pharmaceutical Technology Co., Ltd., Mr. YUAN Jingsong and Ms. LI Xinyuan is an Independent Third Party. Mr. Zhang first became acquainted with Mr. Zhu at a business event in 2006 and Mr. Zhu has been an external legal consultant to our Group since the establishment of SunHo (China) BioPharmaceutical in April 2018. Further, Mr. Zhang became acquainted with Mr. YUAN Jingsong (a shareholder of Nanjing Chenhe Pharmaceutical Technology Co., Ltd.) through Mr. Zhu in 2014. Following the acquisition by Mr. Zhang, Nanjing Bode has been principally engaged in R&D, manufacturing and sales of small molecule active pharmaceutical ingredients, which are raw materials for production of chemical drugs and are not used in production of biologics. There is no past or present business relationship between Nanjing Bode and Nanjing Yoko.

During the Track Record Period, Nanjing Bode leased premises and sold certain equipment to us, which was on an arm's length basis and in the ordinary course of our business operation. For further details, see "Business — Suppliers and Raw Materials — Suppliers" in this document. In addition, during the Track Record Period, to support the daily operation and the R&D activities of our Group, Nanjing Bode also provided financial support to us in the form of loans mainly by utilizing the cash generated from its business operations, as it was generally difficult for us to obtain bank facilities on favorable terms as a clinical-stage private biopharmaceutical company with no external investor before the Pre-[**REDACTED**] Investments. Specifically, in July 2020, December 2020 and December 2021, respectively, Nanjing Bode entered into three loan agreements with us, pursuant to which Nanjing Bode agreed to make available revolving loan facilities at a maximum amount of RMB100.0 million each, with a term of three years at a fixed interest rate of 3% per annum. In 2022, after taking into account, among others, that (i) our Group was in need of a significant amount of funds to explore and advance the clinical development of our drug candidates, and (ii) the business of our Group, being the discovery, development and commercialization of biologics, was considered by Mr. Zhang to be with more potential in sustainable growth than that of Nanjing Bode, Mr. Zhang, who has been one of our Controlling Shareholders and was the then sole beneficial owner of Nanjing Bode, decided to further re-arrange his investment layout between Nanjing Bode and our Group, and to re-allocate his financial resources into our Group to maximize the efficiency of fund utilization within his various investments at that time and to improve our financial position to facilitate our development and equity financings from potential investors. As such, Nanjing Bode entered into an irrevocable and unconditional loan waiver agreement with us for a loan waiver in the amount of RMB180.0 million on December 30, 2022, which resulted in a corresponding increase in our capital reserve of RMB180.0 million in 2022. Following the waiver in respect of the loans, in December 2023, all of the loan principal and interests due to Nanjing Bode had been repaid by us in full.

In July 2023, Mr. Zhang transferred his entire indirect equity interest in Nanjing Bode to a holding vehicle indirectly wholly owned by an Independent Third Party, who is a university professor and first became acquainted with Mr. Zhang at an academic conference in 2020, at a consideration of RMB1.00, in order to better focus on his business ventures in our Group and Nanjing Yoko. The consideration of the transfer of equity interest in Nanjing Bode was determined after arm's length negotiations with reference to the negative net asset value of Nanjing Bode of approximately RMB(62,865,000) as at March 31, 2023, as appraised by an independent valuer in a valuation report. As a result, Nanjing Bode has ceased to be a related party to us and become an Independent Third Party since July 2023. Save for the transfer of the entire equity interest in Nanjing Bode, there is no past or present relationship, transaction, agreement or arrangement between the purchaser and our Company, our subsidiaries, Shareholders, Directors or senior management or any of their respective associates.

INDEPENDENCE FROM OUR CONTROLLING SHAREHOLDERS

Our Directors consider that we are capable of carrying on our business independently of our Controlling Shareholders and their close associates after [**REDACTED**], taking into consideration of the factors below.

Management Independence

Our Board comprises seven Directors, including three executive Directors, one non-executive Director and three independent non-executive Directors. We believe that our Board as a whole, together with our senior management, is able to perform the managerial role in our Group independently from our Controlling Shareholders for the following considerations:

(a) none of the business undertaken or carried on by Mr. Zhang or his close associates outside of our Group competes with our business and therefore, the dual roles assumed by Mr. Zhang in our Group and Nanjing Yoko will not affect the requisite degree of impartiality of Mr. Zhang in discharging his fiduciary duties owed to our Company;

(b) each of our Directors is aware of his/her fiduciary duties as a Director which require, among others, that he/she acts for the benefit of and in the best interests of our Company and not allow any conflict between his/her duties as a Director and his/her personal interests;

(c) our daily management and operation decisions are made by all our executive Directors and senior management, all of whom have substantial experience in the industry in which we are engaged and will be able to make business decisions that are in the best interest of our Group. For details of the industry experience of our senior management, see "Directors and Senior Management" in this document;

(d) we have appointed three independent non-executive Directors with a view to bringing independent judgment to the decision-making process of our Board;

(e) in the event that there is a potential conflict of interest arising out of any transaction to be entered into between our Group and a Director and/or his/her associate, he/she shall abstain from voting and shall not be counted towards the quorum for the voting; and

(f) we have adopted a series of corporate governance measures to manage conflicts of interest, if any, between our Group and our Controlling Shareholders which would support our independent management. For further details, see "— Corporate Governance Measures" in this section.

Operational Independence

We have full rights to make all decisions on, and to carry out, our own business operations independently. We have our own departments specializing in these respective areas which have been in operation and are expected to continue to operate independently from our Controlling Shareholders and their close associates. We hold licenses, intellectual property rights and qualifications necessary to carry on our principal business. We also have independent access to suppliers and have sufficient capital, facilities and employees to operate our business independently from our Controlling Shareholders and their close associates.

Based on the above, our Directors believe that we will be able to operate independently from our Controlling Shareholders and their close associates.

Financial Independence

We have an independent financial system. We make financial decisions according to our own business needs and neither our Controlling Shareholders nor their close associates intervene with our use of funds. We have established an independent finance department with a team of financial staff and an independent audit, accounting and financial management system.

In addition, we are capable of obtaining equity and debt financings from third parties without relying on any guarantee or security provided by our Controlling Shareholders or their close associates. In particular, we obtained the Pre-[**REDACTED**] Investments totalling RMB270.18 million from Efung Capital and Yuexiu Industrial Investment Fund in August 2023 and October 2023, a line of credit in the amount of RMB60 million granted by China CITIC Bank Corporation Limited (Nanjing Branch) in September 2023 with a drawdown period of one year, and a line of credit in the amount of RMB30 million from China Merchants Bank Co., Ltd. (Nanjing Branch) in January 2024 with a drawdown period of one year.

During the Track Record Period, we obtained loans from Nanjing Bode which was indirectly wholly owned by Mr. Zhang prior to July 2023. All of the loan principal and interests due to Nanjing Bode had been repaid by us in full in December 2023. For further details, see "— Clear Delineation of Business — Nanjing Bode" in this section.

As of the Latest Practicable Date, there was no loan, advance or guarantee provided by our Controlling Shareholders or their close associates, and our Company did not plan to have any additional non-trade related party transactions in the future.

Based on the above, our Directors believe that we are capable of carrying on our business independently of, and do not place undue reliance on our Controlling Shareholders and their close associates after [**REDACTED**].

NON-COMPETITION UNDERTAKING

Mr. Zhang [has provided] a non-competition undertaking (the "**Non-competition Undertaking**"), pursuant to which Mr. Zhang has unconditionally and irrevocably undertaken that he will not, and will use his best endeavors to procure his close associates (except any member of our Group) not to, whether directly or indirectly, as principal or agent either on his/their own account or in conjunction with or on behalf of any person, engage in any business that competes, or is likely to compete, directly or indirectly with our Group (the "**Restricted Business**").

In addition, under the Non-competition Undertaking, Mr. Zhang unconditionally and irrevocably granted us the option to acquire new business opportunities, options for acquisitions, and pre-emptive rights in respect of the Restricted Business.

Options for New Business Opportunities

Mr. Zhang has unconditionally and irrevocably undertaken in the Non-competition Undertaking that he will first offer any investment or other commercial business opportunities in the Restricted Business (a "**New Business Opportunity**") to us in the following manner when such New Business Opportunity becomes available to him:

(a) within 20 Business Days when any New Business Opportunity becomes available to him, he will refer the New Business Opportunity to us and will inform us in writing all information (including but not limited to details of the nature and investment or acquisition cost of such New Business Opportunity) which is necessary and reasonably required for us to consider (i) whether such New Business Opportunity will compete with our business and (ii) whether it is in the interest of our Group to engage in such New Business Opportunity (the "**Offer Notice**");

(b) our independent non-executive Directors will be responsible for reviewing, considering and deciding whether or not to take up any New Business Opportunity. Within seven Business Days of receipt of an Offer Notice, we will notify our independent non-executive Directors for their consideration. Our Company shall inform Mr. Zhang in writing within 20 Business Days after receipt of the Offer Notice about our decision on whether the New Business Opportunity will be pursued;

(c) Mr. Zhang will only be entitled to engage in the New Business Opportunity until the earlier of: (i) the receipt by Mr. Zhang of a written notice from us declining the New Business Opportunity, or (ii) our failure to respond within 20 Business Days of our receipt of the Offer Notice; and

(d) if there is any material change in the terms and conditions of the New Business Opportunity after the referral, Mr. Zhang shall refer the New Business Opportunity with the revised terms and conditions to us again in the manner as stated above.

Mr. Zhang has further unconditionally and irrevocably undertaken that he shall procure his close associates to first offer to us any New Business Opportunity offered to them in accordance with the same procedures as described above.

Options for Acquisition

In relation to any New Business Opportunity which has been offered to but has not been taken up by us, and has been retained by Mr. Zhang or any of his close associates, Mr. Zhang has granted us the option to purchase any equity interests, assets or other interests which form part of the new business, to the extent such arrangement is not in violation of any applicable laws and regulations, the articles of association, or any contractual arrangements with any third parties. The consideration and other terms for the acquisition of the new business will be determined after arm's length negotiation between Mr. Zhang or his close associate(s) (as the case may be) and us. Our independent non-executive Directors will be responsible for regularly reviewing, considering and deciding whether or not to exercise the options for acquisition.

Pre-emptive Rights

Mr. Zhang has unconditionally and irrevocably undertaken that if he intends to transfer, sell, lease, license or by any other means transfer or grant the right to any New Business Opportunity which has been offered to but has not been taken up by us, and has been retained by him (the "**Proposed Transaction**"), then we shall have the pre-emptive right to be offered the Proposed Transaction on the same terms as, and before or at the same time of, the offer of the Proposed Transaction to any third party, to the extent such arrangement is not in violation of any applicable laws and regulations, the articles of association, or any contractual arrangements with any third parties. Mr. Zhang shall notify us of the Proposed Transaction by written notice (the "**Selling Notice**"), to which the terms of the Proposed Transaction and all information reasonably required by us to make a decision on whether or not to exercise our pre-emptive right shall be attached.

Our independent non-executive Directors will be responsible for reviewing, considering and deciding whether or not to exercise our pre-emptive rights. Within seven Business Days of receipt of a Selling Notice, we will notify our independent non-executive Directors and furnish them with necessary information for their consideration. Our Company shall inform Mr. Zhang in writing within 20 Business Days after receipt of the Selling Notice about our decision on whether the Company will exercise the pre-emptive rights. If we decide to exercise our pre-emptive right, the terms will be determined between Mr. Zhang and us in accordance with applicable laws and regulations and principles of fairness and reasonableness.

Mr. Zhang will only be entitled to engage in the Proposed Transaction with any third party until the earlier of: (i) the receipt by Mr. Zhang of a written notice from us declining to exercise the pre-emptive right, or (ii) our failure to respond within 20 Business Days of our receipt of the Selling Notice.

Mr. Zhang has further unconditionally and irrevocably undertaken that he shall procure his close associates to first offer to us any Proposed Transaction in accordance with the same procedures as described above.

In order to monitor ongoing compliance with the Non-competition Undertaking, we intend to adopt the following measures:

(a) provision to our independent non-executive Directors of any Offer Notice or Selling Notice received within seven Business Days of receipt;

(b) disclosure in our annual reports of the confirmation by Mr. Zhang of compliance with the Non-competition Undertaking by him, including that all relevant notices and pre-emptive offers have been given to us for all relevant business opportunities; and

(c) disclosure in our annual reports of the findings of our independent non-executive Directors on each Offer Notice or Selling Notice received, and the basis of their decision(s) (where applicable).

The Non-competition Undertaking will terminate upon the earlier of:

(a) Mr. Zhang and his close associate(s) (except any member of our Group), directly or indirectly, ceasing to hold 30% or more voting rights in aggregate of our total share capital, ceasing to have control the composition of a majority of our Board, or ceasing to be Controlling Shareholders; and

(b) our Shares no longer being [**REDACTED**] on the [**REDACTED**] (save for [**REDACTED**]).

CORPORATE GOVERNANCE MEASURES

Our Directors recognize the importance of good corporate governance in protecting our Shareholders' interests. We have adopted the following measures to safeguard good corporate governance standards and to avoid potential conflict of interests between our Group and our Controlling Shareholders:

(a) under the Articles of Association, where a Shareholders' meeting is to be held for considering proposed transactions in which our Controlling Shareholders or any of their associates has a material interest, our Controlling Shareholders or their associates will not vote on the relevant resolutions and shall not be counted in the quorum for the voting;

(b) our Company has established internal control mechanisms to identify connected transactions. Upon [**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;

(c) our Board consists of a balanced composition of executive Directors and non-executive Directors (including independent non-executive Directors), with independent non-executive Directors representing not less than one-third of our Board to ensure that our Board is able to effectively exercise independent judgment in its decision-making process and provide independent advice to our Shareholders. Our independent non-executive Directors individually and collectively possess the requisite knowledge and experience to perform their duties. They will review whether there is any conflict of interests between our Group and our Controlling Shareholders and provide impartial and professional advice to protect the interests of our minority Shareholders;

(d) where our Directors reasonably request the advice of independent professionals, such as financial advisers, the appointment of such independent professionals will be made at our Company's expenses; and

(e) we have appointed Somerley Capital Limited as our compliance adviser to provide advice and guidance to us in respect of compliance with the applicable laws in Hong Kong and the Listing Rules, including various requirements relating to corporate governance.

Based on the above, our Directors believe that sufficient corporate governance measures have been put in place to manage conflicts of interest that may arise between our Group and our Controlling Shareholders and to protect our Shareholders' interests as a whole after [**REDACTED**].

AUTHORIZED AND ISSUED SHARE CAPITAL

The following is a description of the authorized and issued share capital of our Company in issue and to be issued as fully paid or credited as fully paid prior to and immediately following completion of the [**REDACTED**]:

Authorized Share Capital

Description of Shares	Number of Shares	Aggregate nominal value of Shares *(US$)*
ordinary shares with a par value of US$0.0005 each (assuming all Series A Preferred Shares have been converted into Shares on a one-to-one basis)	200,000,000	100,000

Issued Share Capital

Description of Shares	Number of Shares	Aggregate nominal value of Shares *(US$)*
Shares in issue as of the date of this document (assuming all Series A Preferred Shares have been converted into Shares on a one-to-one basis)	122,515,000	61,257.5
Shares to be [**REDACTED**] under the [**REDACTED**]	[**REDACTED**]	[**REDACTED**]
Total	[**REDACTED**]	[**REDACTED**]

The above tables assume that the [**REDACTED**] becomes unconditional and the Shares are [**REDACTED**] pursuant to the [**REDACTED**], and do not take into account any Shares which may be issued or repurchased by our Company pursuant to the general mandates granted to our Directors to issue or repurchase Shares as described below.

RANKING

The [**REDACTED**] are Shares in the share capital of our Company and rank equally with all Shares currently in issue or to be [**REDACTED**] (including the Shares to be converted from Series A Preferred Shares upon completion of the [**REDACTED**]) and, in particular, will rank equally for all dividends or other distributions declared, made or paid on the Shares in respect of a record date which falls after the date of this document.

CIRCUMSTANCES UNDER WHICH GENERAL MEETINGS ARE REQUIRED

Pursuant to the Cayman Companies Act and the terms of the Articles of Association, our Company may from time to time by ordinary resolution of Shareholders: (i) increase its share capital; (ii) consolidate and divide its share capital into shares of larger amount; (iii) subdivide its shares into shares of smaller amount; and (iv) cancel any Shares which have not been taken or agreed to be taken. In addition, our Company may, subject to the provisions of the Cayman Companies Act, reduce its share capital or capital redemption reserve by its Shareholders passing a special resolution. For further details, see "Appendix III — Summary of the Constitution of Our Company and Cayman Islands Company Law — 2. Articles of Association — 2.4 Alteration of capital" in this document.

RSU SCHEME

Our Company adopted the RSU Scheme. For further details, see "Appendix IV — Statutory and General Information — D. RSU Scheme" in this document.

GENERAL MANDATE TO ISSUE AND REPURCHASE SHARES

Subject to the [**REDACTED**] becoming unconditional, our Directors [have been granted] general unconditional mandates to issue and repurchase our Shares.

For further details of the general mandates, see "Appendix IV — Statutory and General Information — A. Further Information about Our Group — 4. Resolutions of Our Shareholders" and "Appendix IV — Statutory and General Information — A. Further Information about Our Group — 5. Repurchase of Our Own Securities" in this document.

So far as our Directors are aware, immediately following the completion of the [**REDACTED**], the following persons will have an interest or short position in the Shares or the underlying Shares which would fall to be disclosed to our Company and [**REDACTED**] under the provisions of [**REDACTED**] of the SFO or, will be, directly or indirectly, interested in 10% or more of the nominal value of any class of share capital carrying rights to vote in all circumstances at general meetings of our Company or any other member of our Group:

		As of the Latest Practicable Date[1]		Immediately following completion of the [REDACTED][2]	
Name of Shareholder	**Capacity/Nature of interest**	**Number of Shares held**	**Approximate percentage of interest** *(%)*	**Number of Shares held**	**Approximate percentage of interest** *(%)*
Sunho Wisdom	Beneficial owner	88,000,000	71.83	88,000,000	[REDACTED]
Sunho Fortune[3]	Interests in controlled corporations	88,000,000	71.83	88,000,000	[REDACTED]
Trident Trust Company (HK) Limited[3]	Trustee	88,000,000	71.83	88,000,000	[REDACTED]
Mr. Zhang[3]	Interests in controlled corporations	100,000,000	81.62	100,000,000	[REDACTED]
Huzhou Efung Ansheng Venture Capital Partnership (Limited Partnership) (湖州市倚鋒安盛創業投資合夥企業(有限合夥)) ("**Efung Ansheng**")	Beneficial owner	11,666,660	9.52	11,666,660	[REDACTED]
Shenzhen Efung Investment Management Enterprise (Limited Partnership) (深圳市倚鋒投資管理企業(有限合夥))[4]	Interests in controlled corporations	11,666,660	9.52	11,666,660	[REDACTED]
Shenzhen Efung Venture Capital Investment Co., Ltd. (深圳市倚鋒創業投資有限公司)[4]	Interests in controlled corporations	11,666,660	9.52	11,666,660	[REDACTED]
Shenzhen Efung Holdings Group Co., Ltd. (深圳市倚鋒控股集團有限公司) ("**Efung Holdings**")[4]	Interests in controlled corporations	17,500,000	14.28	17,500,000	[REDACTED]
Mr. ZHU Jinqiao (朱晉橋)[4]	Interests in controlled corporations	17,500,000	14.28	17,500,000	[REDACTED]
Guocheng (Zhejiang) Industrial Development Co., Ltd. (國成(浙江)實業發展有限公司)[4]	Interests in controlled corporations	17,500,000	14.28	17,500,000	[REDACTED]

Notes:

(1) Based on the assumption that all Series A Preferred Shares have been converted into Shares on a one-to-one basis.

(2) The calculation is based on the total number of [**REDACTED**] Shares in issue immediately following completion of the [**REDACTED**].

(3) Sunho Wisdom is owned as to 99.9% by Sunho Fortune (as a nominee which is wholly owned by a trust established by Mr. Zhang as the settlor and beneficiary) and 0.1% by Innovalue Investments (a wholly-owned subsidiary of Mr. Zhang), respectively. As such, under the SFO, Sunho Fortune is deemed to be interested in the Shares held by Sunho Wisdom. Further, Mr. Zhang is entitled to exercise approximately 73.19% voting rights in No5XJR through Innovalue Investments, details of which are set out in the section headed "History, Reorganization and Corporate Structure" in this document. Sunho Stellar is wholly owned by an independent professional trustee who shall exercise all voting rights attached to the Shares held by Sunho Stellar in accordance with the instructions of Mr. Zhang. As such, under the SFO, Mr. Zhang is deemed to be interested in the Shares held by Sunho Wisdom, No5XJR and Sunho Stellar.

(4) Efung Ansheng is a limited partnership established in the PRC and is managed by its general partner, Shenzhen Efung Investment Management Enterprise (Limited Partnership) (深圳市倚鋒投資管理企業(有限合夥)), whose general partner is Shenzhen Efung Venture Capital Investment Co., Ltd. (深圳市倚鋒創業投資有限公司) which is in turn held as to approximately 60% by Efung Holdings and approximately 40% by Mr. ZHU Jinqiao (朱晉橋). As such, each of Shenzhen Efung Investment Management Enterprise (Limited Partnership) and Shenzhen Efung Venture Capital Investment Co., Ltd. is deemed to be interested in the Shares held by Efung Ansheng. Huzhou Efung Anhe Venture Capital Partnership (Limited Partnership) (湖州市倚鋒安禾創業投資合夥企業(有限合夥)) ("**Efung Anhe**") is a limited partnership established in the PRC and is managed by its general partner, Hainan Efung Junma Private Equity Fund Management Co., Ltd. (海南倚鋒駿馬私募基金管理有限公司), which is held as to approximately 70% by Efung Holdings. Efung Holdings is held as to approximately 54% by Mr. ZHU Jinqiao (朱晉橋). Besides, Guocheng (Zhejiang) Industrial Development Co., Ltd. (國成(浙江)實業發展有限公司) holds approximately 99.99% partnership interest in Efung Ansheng as its limited partner and approximately 49.99% partnership interest in Efung Anhe as its limited partner. As such, each of Efung Holdings, Mr. ZHU Jinqiao and Guocheng (Zhejiang) Industrial Development Co., Ltd. is deemed to be interested in the Shares held by Efung Ansheng and Efung Anhe.

Save as disclosed herein, our Directors are not aware of any persons who will, immediately following completion of the [**REDACTED**], without taking into account the [**REDACTED**] that may be taken up under the [**REDACTED**], have any interests or short positions in the Shares or underlying Shares which would fall to be disclosed to our Company and [**REDACTED**] under the provisions of [**REDACTED**] of the SFO or, will be, directly or indirectly, interested in 10% or more of the nominal value of any class of share capital carrying rights to vote in all circumstances at general meetings of our Company or any other member of our Group.

BOARD OF DIRECTORS

Our Board consists of seven Directors, with three executive Directors, one non-executive Director and three independent non-executive Directors. Our Board serves a term of three years and is responsible and has general powers for the management and conduct of our business.

The table below sets out certain information of our Directors.

Name	Age	Position(s)	Date of appointment as Director	Date of founding/ joining our Group	Role and responsibilities	Relationship with other Directors or senior management
Mr. ZHANG Feng (張峰)	51	Chairman of our Board and executive Director	May 14, 2021	April 2, 2018	Responsible for supervising and providing overall management, operation and strategies of our Group	None
Dr. YIN Liusong (殷劉松)	37	Executive Director, chief executive officer and chief scientific officer	July 21, 2023	November 2, 2020	Responsible for daily operations and scientific affairs of our Group	None
Ms. JIANG Xiaoling (姜曉玲)	42	Executive Director and vice president	July 21, 2023	February 1, 2020	Responsible for management of our R&D department and product registration	None
Mr. FAN Rongkui (范融奎)	32	Non-executive Director	July 21, 2023	July 21, 2023	Responsible for providing guidance on investment strategies and governance to our Group	None

Name	Age	Position(s)	Date of appointment as Director	Date of founding/ joining our Group	Role and responsibilities	Relationship with other Directors or senior management
Mr. CHAN Heung Wing Anthony (陳向榮)	50	Independent non-executive Director	July 22, 2023 (effective from the [REDACTED])	[REDACTED]	Responsible for supervising and providing independent opinions to our Board	None
Ms. FENG Lan (馮嵐)	45	Independent non-executive Director	July 22, 2023 (effective from the [REDACTED])	[REDACTED]	Responsible for supervising and providing independent opinions to our Board	None
Mr. SHI Luwen (史錄文)	60	Independent non-executive Director	July 22, 2023 (effective from the [REDACTED])	[REDACTED]	Responsible for supervising and providing independent opinions to our Board	None

The following sets forth the biographies of our Directors:

Executive Directors

Mr. ZHANG Feng (張峰), aged 51, founded our Group on April 2, 2018. He was appointed as a Director on May 14, 2021 and was re-designated as an executive Director on July 22, 2023. He was further appointed as the chairman of our Board on July 22, 2023. He is responsible for supervising and providing overall management, operation and strategies of our Group. Mr. Zhang is also currently the chairman of the board of directors of SunHo (China) BioPharmaceutical and a director of Sunho bio Investments.

Mr. Zhang has more than 22 years of experience in the pharmaceutical industry. Prior to February 2002, Mr. Zhang worked at pharmaceutical companies, where he was primarily responsible for marketing and promotion of chemical drugs of those companies. Since February 2002, he has been the chairman of the board of directors of Nanjing Yoko where he has been primarily responsible for providing overall management, operation and investment strategies.

Mr. Zhang obtained his master's degree in business administration from the Nanjing University of Science and Technology (南京理工大學) in Jiangsu in July 2006. Besides, Mr. Zhang has successfully obtained marketing approvals for nearly 20 drugs and manufacturing certificates for over 30 drugs, and has been involved in the development of more than 50 clinical and preclinical products, 15 of which are Class 1 or Class 2 new drugs according to the drug classification standards issued by the NMPA. In addition to his leadership in the pharmaceutical industry, Mr. Zhang holds various positions in academic and industry organizations. For instance, he is a member of the sixth editorial board of Progress in Pharmaceutical Sciences (《藥學進展》), a committee member of the Antitumor Drug Committee of the Chinese Pharmaceutical Association (中國藥學會抗腫瘤藥物專業委員會), and the vice president of the Jiangsu Provincial Pharmacy Association (江蘇省醫藥行業協會).

Dr. YIN Liusong (殷劉松), aged 37, has joined our Group as the chief executive officer and chief scientific officer of SunHo (China) BioPharmaceutical since November 2020. He was appointed as a Director on July 21, 2023, and was re-designated as an executive Director and further appointed as the chief executive officer and chief scientific officer of our Company on July 22, 2023. He is responsible for daily operations and scientific affairs of our Group. Dr. Yin is also currently a director of SunHo (China) BioPharmaceutical, Sunho bio Investments, Sunho HK, Sunho Pharmaceutical Technology and Nanjing Sunho.

Dr. Yin has more than nine years of experience in the biopharmaceutical industry. From 2014 to 2015, he worked as a postdoctoral fellow at Pfizer (輝瑞公司), a pharmaceutical company, where he was involved in the research on immunogenicity of macromolecular drugs. From March 2015 to October 2020, he worked at and last served as an executive director of GenScript Biotech Corporation (金斯瑞生物科技股份有限公司), a company listed on the Stock Exchange (stock code: 1548) and principally engaged in the manufacturing and sale of life science research products and services, where he was primarily responsible for biopharmaceutical projects and discovery platforms.

Dr. Yin obtained his bachelor's degree in biological sciences from the University of Science and Technology of China (中國科學技術大學) in Anhui in July 2008. He further obtained his doctor's degree in biomedical sciences from UMass Chan Medical School (formerly known as UMass Medical School) in Massachusetts in April 2014.

Ms. JIANG Xiaoling (姜曉玲), aged 42, has joined our Group as a deputy general manager and the head of R&D at SunHo (China) BioPharmaceutical since February 2020. She was appointed as a Director on July 21, 2023, and was re-designated as an executive Director and further appointed as our vice president on July 22, 2023. She is responsible for management of our R&D department and product registration. Ms. Jiang is also currently a supervisor of SunHo (China) BioPharmaceutical, Sunho Pharmaceutical Technology and SunHo (Zhejiang) BioPharmaceutical.

Ms. Jiang has more than 16 years of experience in R&D of pharmaceuticals, including biosimilar drugs and antibody drugs. From December 2007 to October 2009, Ms. Jiang worked as a researcher at Dragon Boat Pharmaceutical Technology (Shanghai) Co., Ltd. (寶船生物醫藥科技(上海)有限公司), a company principally engaged in the R&D of biologics, where she was involved in protein expression-related drugs and cell line construction. From October 2009 to October 2011, she worked as a senior researcher at Nanjing GenScript Biotechnology Co., Ltd. (南京金斯瑞生物科技有限公司), a company principally engaged in providing outsourcing services for the R&D of antibody drugs, where she was primarily responsible for production of stable cell line construction and R&D of biosimilar drugs. From October 2011 to February 2020, she served as a project leader and project manager at Nanjing Yoko Pharma Co., Ltd. (南京優科製藥有限公司), a wholly-owned subsidiary of Nanjing Yoko, where she was primarily responsible for R&D of chemical drugs.

Ms. Jiang obtained her bachelor's degree in biotechnology from Shandong Agriculture University (山東農業大學) in Shandong in July 2005. She further obtained her master's degree in biochemistry and molecular biology from Nanjing University (南京大學) in Jiangsu in June 2008. She has been certified as an engineer by the Nanjing Professional Titles Working Leading Group (南京市職稱工作領導小組) since July 2011.

Non-executive Director

Mr. FAN Rongkui (范融奎), aged 32, was appointed as a Director on July 21, 2023, and was re-designated as a non-executive Director on July 22, 2023. He is responsible for providing guidance on investment strategies and governance to our Group.

Mr. Fan has more than seven years of experience in audits and investment. From October 2016 to August 2018, he worked at Deloitte Touche Tohmatsu Certified Public Accountants LLP (德勤華永會計師事務所(特殊普通合夥)), an accounting firm. From September 2018 to November 2020, he served as a senior investment manager at V-Capital Company Limited (一村資本有限公司), a company principally engaged in healthcare investment, where he was primarily responsible for project discovery, investment decisions and post-investment management. From November 2020 to March 2022, Mr. Fan served as an investment director at Shanghai Xingong Investment Management Co. Ltd. (上海信公投資管理有限公司), a company principally engaged in healthcare investment, where he was primarily responsible for project discovery, investment decisions and post-investment management. Since March 2022, he has served as an investment director at Shenzhen Efung Investment Management Enterprise (Limited Partnership) (深圳市倚鋒投資管理企業(有限合夥)), a company principally engaged in healthcare investment, where he has been primarily responsible for project discovery, investment decisions and post-investment management.

Mr. Fan obtained his bachelor's degree in accounting from the China University of Geosciences (中國地質大學) in Hubei in June 2014. He further obtained his master's degree in science with a major in accounting and finance from Durham University in the United Kingdom in January 2016. He has been certified as a certified public accountant by the Certified Public Accountant Examination Committee of the MOF (中華人民共和國財政部註冊會計師考試委員會) since December 2018.

Independent Non-executive Directors

Mr. CHAN Heung Wing Anthony (陳向榮), aged 50, was appointed as our independent non-executive Director on July 22, 2023, with effect from the [**REDACTED**]. He is responsible for supervising and providing independent opinions to our Board.

Mr. Chan has more than 25 years of experience in the legal industry. He has practised law for more than 23 years at various law firms since July 2000, and he is currently a partner of KEMP M.B. LLP.

Mr. Chan obtained his bachelor's degree in law and his bachelor's degree in commerce with a major in finance from the University of New South Wales in New South Wales in October 1997. He obtained his Postgraduate Certificate in Laws from the University of Hong Kong (香港大學) in Hong Kong in June 1998. He further obtained his master's degree in accounting from Central Queensland University in Queensland in March 2004. Mr. Chan was admitted as a solicitor in Hong Kong in July 2000. He has been a member of the American Institute of Certified Public Accountants since March 2006.

Ms. FENG Lan (馮嵐), aged 45, was appointed as our independent non-executive Director on July 22, 2023, with effect from the [**REDACTED**]. She is responsible for supervising and providing independent opinions to our Board.

Ms. Feng has more than 21 years of experience in the pharmaceutical industry. From July 2001 to July 2008, she worked as an associate editor at the Center for Information, the NMPA (國家藥品監督管理局信息中心), where she was primarily responsible for monitoring drug market advertisements as well as the thesaurus project of the Ministry of Science and Technology of the PRC (中華人民共和國科學技術部). From July 2009 to June 2012, she worked at and last served as the general manager of the Chinese Journal of New Drugs Co., Ltd. (《中國新藥雜誌》有限公司), a company principally engaged in reporting on global developments and achievements in the R&D of new drugs, where she was primarily responsible for editorial work, and the academic and marketing promotion of pharmaceutical companies. Since July 2012, Ms. Feng has worked at and is currently serving as a secretary-general of the China Pharmaceutical Innovation and Research Development Association (中國醫藥創新促進會), an association principally engaged in the promotion and improvement of China's pharmaceutical innovation ecosystem, where she has been primarily responsible for the overall operation and management of the association. Since September 2021, she has also served as an independent director of Tibet Aim Pharm. Inc. (西藏易明西雅醫藥科技股份有限公司), a company listed on the Shenzhen Stock Exchange (stock code: 002826) and principally engaged in the R&D of core products in the obstetrics field and treatment of chronic diseases such as diabetes and cardiovascular diseases in the elderly, where she has been primarily responsible for supervising and providing independent opinions to the company.

Ms. Feng obtained her bachelor's degree in medicine with a major in medical and pharmaceutical informatics from Jilin University (吉林大學) in Jilin in July 2001. She further obtained her executive master's degree in business administration from Peking University (北京大學) in Beijing in January 2014. She has been certified as an engineer by the National Institutes for Food and Drug Control (中國食品藥品檢定研究院) (formerly known as the National Institute for the Control of Pharmaceutical and Biological Products (中國藥品生物製品檢定所)) since November 2007.

Mr. SHI Luwen (史錄文), aged 60, was appointed as our independent non-executive Director on July 22, 2023, with effect from the [**REDACTED**]. He is responsible for supervising and providing independent opinions to our Board.

Mr. Shi has more than 23 years of experience in the pharmaceutical industry. Since April 2000, he has been working at and is currently a professor in pharmaceutical administration and clinical pharmacy at the School of Pharmaceutical Sciences of Peking University (北京大學藥學院). Since 2002, he has worked as a researcher and director at the International Research Center for Medical Administration of Peking University (北京大學醫藥管理國際研究中心), where he has been primarily involved in research. From December 2015 to December 2021, Mr. Shi served as an independent director of China Meheco Group Co., Ltd. (中國醫藥健康產業股份有限公司), a company listed on the Shanghai Stock Exchange (stock code: 600056) and principally engaged in the distribution of pharmaceutical and healthcare products in the PRC, where he was primarily responsible for supervising and providing independent opinions to the company. From May 2017 to July 2020, he served as a director of Zhejiang CONBA Pharmaceutical Co., Ltd (浙江康恩貝製藥股份有限公司), a company listed on the Shanghai Stock Exchange (stock code: 600572) and principally engaged in the R&D, manufacturing and distribution of medicines and chemical drugs in the PRC.

Besides, Mr. Shi has served as an independent non-executive director of Hospital Corporation of China Limited (弘和仁愛醫療集團有限公司) (a company listed on the Stock Exchange (stock code: 3869) and principally engaged in hospital operations and management) since December 2016, Dragon Laboratory Instruments Limited (大龍興創實驗儀器(北京)股份公司) (a company principally engaged in the manufacturing of laboratory instruments in the PRC) since June 2020, Beijing Centergate Technologies (Holding) Co., Ltd (北京中關村科技發展(控股)股份有限公司) (a company listed on the Shenzhen Stock Exchange (stock code: 000931) and principally engaged in pharmaceutical production and sales) since February 2022, Shandong Boan Biotechnology Co., Ltd. (山東博安生物技術股份有限公司) (a company listed on the Stock Exchange (stock code: 6955) and principally engaged in medical research and experimental development) since March 2022, and China National Medicines Corporation Ltd. (國藥集團藥業股份有限公司) (a company listed on the Shanghai Stock Exchange (stock code: 600511) and principally engaged in the sale and distribution of medical equipment) since April 2022, where he has been primarily responsible for supervising and providing independent opinions to the aforementioned companies.

Mr. Shi obtained his bachelor's degree in chemistry from Peking University (北京大學) in Beijing in July 1987. He further obtained his master's degree in health professions education from the University of Illinois in Illinois in July 1992. He obtained his independent director qualification from the Shanghai Stock Exchange in January 2016.

General

Our Directors have confirmed that:

(1) he/she has obtained the legal advice referred to under Rule 3.09D of the Listing Rules on July 22, 2023, and understood his/her obligations as a director of a [**REDACTED**];

(2) save as disclosed in the paragraph headed "Appendix IV — Statutory and General Information — C. Further Information about Our Directors — 2. Particulars of Directors' Service Contracts and Appointment Letters" in this document, none of our Directors has any existing or proposed service contract with our Group other than contracts expiring or determinable by the relevant member of our Group within one year without payment of compensation (other than statutory compensation);

(3) save as disclosed in the paragraph headed "Appendix IV — Statutory and General Information — C. Further Information about Our Directors — 1. Disclosure of Interests" in this document and above, each of our Directors has no interest in the Shares within the meaning of Part XV of the SFO as of the Latest Practicable Date;

(4) save as disclosed above, each of our Directors does not hold and has not held any other directorships in public companies the securities of which are listed on any securities market in Hong Kong or overseas in the three years prior to the Latest Practicable Date and as of the Latest Practicable Date;

(5) save as disclosed above, other than being a Director of our Group, a member of our Group's senior management and/or a selected participant of the RSU Scheme, he/she does not have any relationship with any other Directors, senior management or substantial shareholders of our Group as of the Latest Practicable Date; and

(6) none of our Directors completed his/her respective education programs as disclosed in this section by way of attendance of long distance learning or online courses.

Each of our independent non-executive Directors has confirmed:

(1) his/her independence after taking into consideration each of the factors referred to under Rules 3.13(1) to 3.13(8) of the Listing Rules;

(2) that he/she does not have any past or present financial or other interest in the business of our Company or our subsidiaries, or any connection with any core connected person of our Company; and

(3) that there are no other factors which may affect his/her independence at the time of his/her appointment as our independent non-executive Director.

Except as disclosed in this document, to the best of the knowledge, information and belief of our Directors having made all reasonable enquiries:

(1) there is no other matter with respect to the appointment of our Directors that needs to be brought to the attention to the Shareholders as of the Latest Practicable Date; and

(2) there is no other information relating to our Directors that is required to be disclosed pursuant to Rule 13.51(2) of the Listing Rules as of the Latest Practicable Date.

SENIOR MANAGEMENT

Our senior management is responsible for the day-to-day management and operation of our business. The table below sets out certain information in respect of the senior management of our Group.

Name	Age	Position(s)	Date of appointment as senior management	Date of founding/ joining our Group	Role and responsibilities	Relationship with Directors or other senior management
Mr. ZHANG Feng (張峰)	51	Chairman of our Board and executive Director	July 22, 2023	April 2, 2018	Responsible for supervising and providing overall management, operation and strategies of our Group	None
Dr. YIN Liusong (殷劉松)	37	Executive Director, chief executive officer and chief scientific officer	July 22, 2023	November 2, 2020	Responsible for daily operations and scientific affairs of our Group	None

Name	Age	Position(s)	Date of appointment as senior management	Date of founding/ joining our Group	Role and responsibilities	Relationship with Directors or other senior management
Ms. JIANG Xiaoling (姜曉玲)	42	Executive Director and vice president	July 22, 2023	February 1, 2020	Responsible for management of our R&D department and product registration	None
Ms. XU Chunqin (徐春芹)	44	Chief financial officer and joint company secretary	July 22, 2023	December 1, 2021	Responsible for overseeing financial management and corporate development of our Group	None
Mr. JIANG Dongcheng (姜東成)	41	Vice president	July 22, 2023	May 1, 2018	Responsible for overseeing process development and production of antibody drugs	None

The following sets forth the biographies of our senior management:

Mr. ZHANG Feng (張峰) is the chairman of our Board and our executive Director. For details, see "— Board of Directors — Executive Directors" in this section.

Dr. YIN Liusong (殷劉松) is our executive Director, chief executive officer and chief scientific officer. For details, see "— Board of Directors — Executive Directors" in this section.

Ms. JIANG Xiaoling (姜曉玲) is our executive Director and vice president. For details, see "— Board of Directors — Executive Directors" in this section.

Ms. XU Chunqin (徐春芹), aged 44, has joined our Group as a deputy general manager of SunHo (China) BioPharmaceutical since December 2021, and was appointed as our chief financial officer and joint company secretary on July 22, 2023. She is responsible for overseeing financial management and corporate development of our Group.

Ms. Xu has more than 23 years of experience in financial management. From May 2000 to September 2009, she worked as an assistant manager at Jiangsu Simcere Pharmaceutical Co., Ltd. (江蘇先聲藥業有限公司), a company principally engaged in sales, distribution and R&D of pharmaceutical products. From September 2009 to December 2021, she was a deputy general manager of Nanjing Yoko.

Ms. Xu graduated from a part-time financial management course at Nanjing University (南京大學) in Jiangsu in January 2011.

Mr. JIANG Dongcheng (姜東成), aged 41, has joined our Group as the head of production at SunHo (China) BioPharmaceutical since May 2018, and was appointed as our vice president on July 22, 2023. He is responsible for overseeing process development and production of antibody drugs.

Mr. Jiang has more than 14 years of experience in the pharmaceutical industry. From June 2009 to June 2011, Mr. Jiang worked at Nanjing Meibo Biomedical Co., Ltd. (南京美博生物科技有限公司), a company principally engaged in the R&D and provision of technical services relating to biological products and *in vitro* diagnostic reagents. From June 2011 to March 2018, Mr. Jiang worked as a biological researcher at Nanjing Yoko, where he was primarily responsible for the R&D of chemical drugs.

Mr. Jiang obtained his bachelor's degree in bioengineering from the Inner Mongolia University of Science & Technology (內蒙古科技大學) in the Inner Mongolia Autonomous Region in June 2006. He further obtained his master's degree in biomedical engineering from Chongqing University (重慶大學) in Chongqing in June 2009.

General

Save as disclosed above, each of our senior management members has confirmed that:

(1) he/she does not hold any other positions in our Group as of the Latest Practicable Date;

(2) other than being our Director, a member of our Group's senior management and/or a selected participant of the RSU Scheme, he/she does not have any relationship with any Directors, other members of senior management or substantial shareholders of our Group as of the Latest Practicable Date;

(3) save as disclosed above, he/she does not hold and has not held any other directorships in public companies the securities of which are listed on any securities market in Hong Kong or overseas in the three years prior to the Latest Practicable Date and as of the Latest Practicable Date; and

(4) he/she has not completed his/her respective education programs as disclosed in this section by way of attendance of long distance learning or online courses.

JOINT COMPANY SECRETARIES

Ms. XU Chunqin (徐春芹) is our chief financial officer and joint company secretary. For details, see "— Senior Management" in this section.

Ms. WONG Hoi Ting (黃凱婷) was appointed as a joint company secretary of our Company on July 22, 2023. She currently serves as an assistant manager in the listing services department of TMF Hong Kong Limited. She is responsible for providing corporate secretarial and compliance services to listed companies.

Ms. Wong has approximately ten years of experience in the corporate secretarial field. She obtained her bachelor's degree in social sciences from Lingnan University (嶺南大學) in Hong Kong in October 2009. She further obtained her master of science degree in professional accounting and corporate governance from City University of Hong Kong (香港城市大學) in Hong Kong in July 2014. Ms. Wong is an associate member of both The Hong Kong Chartered Governance Institute (formerly known as The Hong Kong Institute of Chartered Secretaries) in Hong Kong and The Chartered Governance Institute in the United Kingdom.

COMPLIANCE ADVISER

We have appointed Somerley Capital Limited as our compliance adviser pursuant to Rule 3A.19 of the Listing Rules. Pursuant to Rule 3A.23 of the Listing Rules, the compliance adviser will advise us on the following circumstances:

- before the publication of any announcements, circulars or financial reports required by regulatory authorities or applicable laws;
- where a transaction, which might be a notifiable or connected transaction under Chapters 14 and 14A of the Listing Rules, is contemplated, including share issues and share repurchases;
- where we propose to use the [**REDACTED**] of the [**REDACTED**] in a manner different from such 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 [**REDACTED**] makes an inquiry of us regarding unusual [**REDACTED**] and [**REDACTED**] or other issues under Rule 13.10 of the Listing Rules.

The terms of the appointment shall commence on the [**REDACTED**] and end on the date which we distribute our annual report of our financial results for the first full financial year commencing after the [**REDACTED**].

BOARD COMMITTEES

We [have established] the following committees on our Board: an audit committee, a remuneration committee and a nomination committee. The committees operate in accordance with the terms of reference established by our Board.

Audit Committee

Our Company [has established] the Audit Committee (effective from the [**REDACTED**]) with written terms of reference in compliance with Rule 3.21 of the Listing Rules and paragraph D.3 of part 2 of the Corporate Governance Code as set out in Appendix C1 to the Listing Rules (the "**Corporate Governance Code**"). The Audit Committee consists of Mr. CHAN Heung Wing Anthony (陳向榮), Ms. FENG Lan (馮嵐) and Mr. SHI Luwen (史錄文), with Mr. CHAN Heung Wing Anthony (陳向榮) serving as the chairperson. Mr. CHAN Heung Wing Anthony (陳向榮) holds the appropriate professional qualifications as required under Rules 3.10(2) and 3.21 of the Listing Rules. The primary duties of the Audit Committee are to assist our Board by providing an independent view of the effectiveness of the financial reporting process, internal control and risk management systems of our Group, overseeing the audit process, and performing other duties and responsibilities as assigned by our Board.

Remuneration Committee

Our Company [has established] the Remuneration Committee (effective from the [**REDACTED**]) with written terms of reference in compliance with Rule 3.25 of the Listing Rules and paragraph E.1 of part 2 of the Corporate Governance Code. The Remuneration Committee consists of Ms. FENG Lan (馮嵐), Mr. Zhang and Mr. SHI Luwen (史錄文), with Ms. FENG Lan (馮嵐) serving as the chairperson. The primary duties of the Remuneration Committee include, but are not limited to, the following: (i) making recommendations to our Board on our policy and structure for all remuneration of Directors and senior management and on the establishment of a formal and transparent procedure for developing policy on such remuneration; (ii) determining or making recommendations to our Board the specific remuneration packages of all Directors and senior management; and (iii) reviewing and approving performance-based remuneration by reference to corporate goals and objectives resolved by our Board from time to time.

Nomination Committee

Our Company [has established] the Nomination Committee (effective from the [**REDACTED**]) with written terms of reference in compliance with Rule 3.27A of the Listing Rules and paragraph B.3 of part 2 of the Corporate Governance Code. The Nomination Committee consists of Mr. Zhang, Ms. FENG Lan (馮嵐) and Mr. SHI Luwen (史錄文), with Mr. Zhang serving as the chairperson. The primary functions of the Nomination Committee include, but are not limited to, reviewing the structure, size and composition of our Board, assessing the independence of independent non-executive Directors and making recommendations to our Board on matters relating to the appointment of Directors.

CORPORATE GOVERNANCE

Board Diversity

We [have adopted] a board diversity policy (the "**Board Diversity Policy**") to enhance the effectiveness of our Board and to maintain a high standard of corporate governance. Pursuant to the Board Diversity Policy, in reviewing and assessing suitable candidates to serve as a Director, the Nomination Committee will consider a range of diversity perspectives with reference to our Company's business model and specific needs, including but not limited to gender, age, language, cultural and educational background, professional qualifications, skills, knowledge, industry and regional experience and/or length of service.

Our Directors have a balanced mix of knowledge and skills, including but not limited to overall business management, R&D, law, audits and project management. They obtained degrees in various majors including, biological sciences, biomedical sciences, biotechnology, accounting, chemistry, medicine and business administration. In addition, we have taken steps to promote and enhance gender diversity at all levels of our Group, and our Board currently comprises five male members and two female members. Furthermore, our Board has a relatively wide range of ages, ranging from 32 years old to 60 years old. Our Board is of the view that our Board satisfies the Board Diversity Policy. The Nomination Committee is responsible for reviewing the diversity of our Board, reviewing the Board Diversity Policy from time to time, developing and reviewing measurable objectives for implementing the Board Diversity Policy, and monitoring the progress on achieving these measurable objectives in order to ensure that the policy remains effective. Our Company will (i) disclose the biographical details of each Director and (ii) report on the implementation of the Board Diversity Policy (including whether we have achieved board diversity) in its annual corporate governance report. In particular, our Group will take opportunities to increase the proportion of female members of our Board when selecting and recommending suitable candidates for Board appointments to help enhance gender diversity in accordance with stakeholder expectations and recommended best practices. Our Group also intends to promote gender diversity when recruiting staff at the mid to senior level so that our Company will have a pipeline of female senior management and potential successors to our Board. We believe that such merit-based selection process with reference to our Board Diversity Policy and the nature of our business will be in the best interests of our Group and our Shareholders as a whole.

COMPETITION

Save as disclosed in the section headed "Relationship with Our Controlling Shareholders" in this document, each of our Directors confirms that as of the Latest Practicable Date, he or she did not have any interest in a business which competes or is likely to compete, directly or indirectly, with our business, and requires disclosure under Rule 8.10 of the Listing Rules.

KEY TERMS OF EMPLOYMENT CONTRACTS

We normally enter into (i) an employment contract and (ii) a confidentiality and non-competition agreement with our senior management members and other key personnel (other than Directors). Below sets forth the key terms of these contracts we enter into with our senior management and other key personnel.

Confidentiality

- *Confidentiality obligations*. The employee shall, during the course of employment with our Company and thereafter, keep in confidence trade secrets of our Group. Without our Group's written consent, the employee shall not disclose, inform, announce, issue, publish, teach, transfer or otherwise make available to any third party (including employees who are not privy to such confidential information) any trade secrets in any manner and shall not use such trade secrets apart from discharging his/her duties as an employee of our Group.

Ownership of intellectual work products

- *Acknowledgment*. The employee acknowledges and agrees that our Group shall own all intellectual property rights relating to inventions, works, computer software, technical secrets or other trade secrets, including those produced (i) during the course of discharging his/her duties as an employee of our Group; or (ii) mainly using the resources, technology, information or data of our Group during the course of his/her employment.

Non-competition

- *Non-competition obligations during employment term*. During the term of his/her employment with our Group, except with our Group's consent, the employee shall not hold any positions (including but not limited to partner, director, supervisor, manager, employee, agent and consultant) in any entity that manufactures products or provides services similar to our Group's products or services, or is engaged in business operation with our Group. The employee shall not, whether directly or indirectly, as a principal or agent, engage in any business that competes with our Group's business.

- *Non-competition obligations following termination of employment relationship*. Within two years after termination of the employment relationship between the employee and our Group, the employee shall not provide services to any other entity or individual that manufactures products or provides services similar to our Group's products or services, and shall not engage in any business similar to our Group.

- *Compensation paid during the term of non-competition*. Following the termination of employment and during the term of non-competition, the employee shall be compensated in accordance with the minimum wage standard adopted in the place where the employing entity is situated before the termination of employment.

Compensation for breach of covenants

- If any employee breaches any of his/her obligations under the confidentiality and non-competition agreement, our Group shall be entitled to terminate the employment relationship with the employee immediately without prior notice where such breach constitutes a serious breach of discipline or internal policy, and recover from the employee all losses incurred by our Group as a result of such breach by the employee.

COMPENSATION OF DIRECTORS AND MANAGEMENT

Our Directors receive compensation in the form of fees, salaries, discretionary bonuses and other benefits in kind, including our Company's contribution to the retirement benefit scheme on their behalves. Our Directors' remuneration is determined with reference to the relevant Director's experience and qualifications, level of responsibility, performance and the time devoted to our business, and the prevailing market conditions.

The aggregate amounts of remuneration which were paid to our Directors (including fees, salaries and other benefits, discretionary bonuses, retirement benefit scheme contributions and share-based payments) for the two financial years ended December 31, 2022 and 2023 were approximately RMB4.2 million and RMB32.0 million, respectively.

It is estimated that the aggregate amount of remuneration payable to our Directors (including fees, salaries and other benefits, discretionary bonuses, retirement benefit scheme contributions and share-based payments) for the financial year ending December 31, 2024 will be approximately RMB32.0 million under arrangements in force as of the date of this document.

For the two financial years ended December 31, 2022 and 2023, there were two and two Directors among the five highest paid individuals, respectively. The aggregate amounts of remuneration which were paid by our Group to the five highest paid individuals (excluding Directors) for the two financial years ended December 31, 2022 and 2023 were RMB1.0 million and RMB1.6 million, respectively.

During the Track Record Period, (i) no remuneration was paid to our Directors or the five highest paid individuals as an inducement to join, or upon joining our Group, (ii) no compensation was paid to, or receivable by, our Directors or past Directors or the five highest paid individuals for the loss of office as a director of any member of our Group or any other office in connection with the management of the affairs of any member of our Group, and (iii) none of our Directors waived or agreed to waive any emoluments.

Except as disclosed above, no other payment has been paid, or is payable, by our Group to our Directors or the five highest paid individuals of our Group during the Track Record Period.

For additional information on Directors' remuneration during the Track Record Period as well as information on the highest paid individuals, see note 13 of the Accountants' Report as set out in Appendix I to this document.

FUTURE PLANS AND PROSPECTS

See "Business — Our Strategies" in this document for a detailed description of our future plans.

USE OF [REDACTED]

We estimate that we will receive net [**REDACTED**] from the [**REDACTED**] of approximately HK$[**REDACTED**], after deducting [**REDACTED**] and other estimated expenses paid and payable by us in connection with the [**REDACTED**], assuming an [**REDACTED**] of HK$[**REDACTED**] per Share, being the mid-point of the indicative [**REDACTED**] of HK$[**REDACTED**] to HK$[**REDACTED**] per Share in this document.

We intend to use the net [**REDACTED**] from the [**REDACTED**] for the following purposes:

(1) [28.1]%, or approximately HK$[**REDACTED**], will be used for ongoing and planned clinical trials (mainly including costs for raw materials and consumables used in clinical trials, salary and benefits for relevant clinical teams, as well as costs relating to recruiting patients and hiring external consultants) of IAH0968 in China. Specifically, we expect that:

   (i) [9.9]%, or approximately HK$[**REDACTED**], will be used to fund ongoing and planned clinical trials of IAH0968 for the treatment of 1L advanced BTC. We dosed the first patient of a Phase II clinical trial in August 2023 with an expected patient pool of approximately 130 to 150 subjects in total to evaluate IAH0968 combination therapy as a first-line treatment for HER2+ advanced BTC. We expect to complete the Phase II trial by the third quarter of 2025. We plan to submit a BLA of IAH0968 for the treatment of 1L HER2+ advanced BTC to the NMPA in the second half of 2025. See "Business — Drug Candidates — Core Product: IAH0968 (ADCC enhanced anti-HER2 mAb) — Clinical Development Plan — Fast-to-Market Strategy — 1L HER2+ BTC" in this document; and

   (ii) [18.2]%, or approximately HK$[**REDACTED**], will be used to fund ongoing and planned clinical trials of IAH0968 for the treatment of 1L advanced CRC. We dosed the first patient of a Phase II clinical trial in May 2023 to evaluate the combination of IAH0968 with CapeOX (Capecitabine-Oxaliplatin) in HER2+ advanced CRC patients and completed the Phase IIa trial in March 2024. In addition, we initiated a Phase IIb/III trial in January 2024 with approximately 230 to 250 patients to be enrolled, and expect to complete the Phase IIb trial in the fourth quarter of 2024 and complete the Phase III trial by the first half of 2026. See "Business — Drug Candidates — Core Product: IAH0968 (ADCC enhanced anti-HER2 mAb) — Clinical Development Plan — Major Indication — 1L HER2+ CRC" in this document;

(2) [35.8]%, or approximately HK$[**REDACTED**], will be used for ongoing and planned clinical trials (mainly including costs for raw materials and consumables used in clinical trials, salary and benefits for relevant clinical teams, as well as costs relating to recruiting patients and hiring external consultants) of IAP0971 in China. Specifically, we expect that:

(i) [8.5]%, or approximately HK$[**REDACTED**], will be used to fund planned clinical trials of IAP0971 for the treatment of 2L/3L BCG-unresponsive NMIBC. We have obtained the IND approval for conducting Phase I and Phase II clinical trials in 2L/3L BCG-unresponsive NMIBC in China in May 2023. Following this, we initiated the Phase I trial in March 2024 with 15 patients to be enrolled. We also expect to commence a pivotal Phase II trial with approximately 90 to 110 patients to be enrolled in the fourth quarter of 2024, and complete such pivotal trial by the first half of 2026. See "Business — Drug Candidates — Core Product: IAP0971 (PD-1/IL-15 antibody-cytokine fusion protein) — Clinical Development Plan — Fast-to-Market Strategy — 2L/3L BCG-unresponsive high risk NMIBC" in this document;

(ii) [8.2]%, or approximately HK$[**REDACTED**], will be used to fund planned clinical trials of IAP0971 for the treatment of 1L advanced non-squamous NSCLC. We plan to initiate a Phase II clinical trial with approximately 40 to 50 patients to be enrolled for our exploration of IAP0971 in combination with pemetrexed and platinum in advanced non-squamous NSCLC in the third quarter of 2024, and complete the Phase II trial by the first half of 2026. In addition, we also expect to initiate a Phase III trial in the second half of 2026. We currently plan to enroll approximately 200 to 300 patients for the Phase III trial. See "Business — Drug Candidates — Core Product: IAP0971 (PD-1/IL-15 antibody-cytokine fusion protein) — Clinical Development Plan — Major Indications — 1L/2L Advanced NSCLC" in this document;

(iii) [10.0]%, or approximately HK$[**REDACTED**], will be used to fund planned clinical trials of IAP0971 for the treatment of 2L advanced NSCLC. We plan to initiate a Phase II clinical trial for IAP0971 in locally advanced unresectable or metastatic NSCLC patients in the second quarter of 2024, and complete such trial by the first half of 2026. We currently expect to enroll approximately 100 to 150 patients for the Phase II trial. See "Business — Drug Candidates — Core Product: IAP0971 (PD-1/IL-15 antibody-cytokine fusion protein) — Clinical Development Plan — Major Indications — 1L/2L Advanced NSCLC" in this document; and

(iv) [9.1]%, or approximately HK$[**REDACTED**], will be used to fund planned clinical trials of IAP0971 for the treatment of chronic HBV infections. We plan to submit an IND application and initiate a Phase I trial with 24 patients to be enrolled in the third quarter of 2024 and complete this trial by the second quarter of 2025. Following the completion of the Phase I trial, a Phase II trial is expected to be initiated in the third quarter of 2025 with approximately 25 to 35 patients to be enrolled, and the trial is expected to be completed by the second quarter of 2026. Moreover, we plan to initiate a Phase III trial with approximately 200 to 300 patients to be enrolled in the second half of 2026. See "Business — Drug Candidates — Core Product: IAP0971 (PD-1/IL-15 antibody-cytokine fusion protein) — Clinical Development Plan — Indication Expansion to Anti-Viral Infection — Chronic HBV Infection" in this document; and

(3) [36.1]%, or approximately HK$[**REDACTED**], will be used to fund ongoing and planned clinical trials (mainly including costs for raw materials and consumables used in clinical trials, salary and benefits for relevant clinical teams, as well as costs relating to recruiting patients and hiring external consultants) of IAE0972 in China. Specifically, we expect that:

(i) [7.9]%, or approximately HK$[**REDACTED**], will be used to fund planned clinical trials of IAE0972 for the treatment of 2L advanced HNSCC. We have initiated a Phase II clinical trial to assess the efficacy of IAE0972 as a monotherapy for patients who are diagnosed with advanced HNSCC and have undergone frontline treatment includes immunotherapy. The Phase II trial is expected to be completed by the first half of 2026 and approximately 100 to 120 patients are planned to be enrolled in the Phase II trial. See "Business — Drug Candidates — Core Product: IAE0972 (EGFR/IL-10 antibody-cytokine fusion protein) — Clinical Development Plan — Fast-to-Market Strategy — 2L HNSCC" in this document;

(ii) [7.9]%, or approximately HK$[**REDACTED**], will be used to fund planned clinical trials of IAE0972 for the treatment of 3L advanced CRC. We have initiated a Phase II clinical trial for IAE0972 as a monotherapy with approximately 100 to 120 patients to be enrolled, and complete the Phase II trial by the first half of 2026. See "Business — Drug Candidates — Core Product: IAE0972 (EGFR/IL-10 antibody-cytokine fusion protein) — Clinical Development Plan — Fast-to-Market Strategy — 3L CRC" in this document;

(iii) [7.4]%, or approximately HK$[**REDACTED**], will be used to fund planned clinical trials of IAE0972 for the treatment of 2L advanced squamous NSCLC. We plan to initiate a Phase II clinical trial of IAE0972 in combination with docetaxel in the third quarter of 2024 with approximately 40 to 50 patients to be enrolled, and complete the Phase II trial by the second quarter of 2026. Subsequently, in the third quarter of 2026, we intend to commence a Phase III

trial for IAE0972. See "Business — Drug Candidates — Core Product: IAE0972 (EGFR/IL-10 antibody-cytokine fusion protein) — Clinical Development Plan — Major Indications — 2L squamous NSCLC" in this document; and

(iv) [12.8]%, or approximately HK$[**REDACTED**], will be used to fund planned clinical trials of IAE0972 for the treatment of 1L advanced HCC. We plan to initiate a Phase II clinical trial with approximately 40 to 50 patients to be enrolled in the second quarter of 2024. Following the expected completion of the Phase II trial by the fourth quarter of 2025, we expect to commence a Phase III trial in the first quarter of 2026. See "Business — Drug Candidates — Core Product: IAE0972 (EGFR/IL-10 antibody-cytokine fusion protein) — Clinical Development Plan — Major Indications — 1L HCC" in this document.

The above allocation of the net [**REDACTED**] from 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 estimated [**REDACTED**]. If the [**REDACTED**] is set at HK$[**REDACTED**] per Share, being the high end of the indicative [**REDACTED**], the net [**REDACTED**] from the [**REDACTED**] will be approximately HK$[**REDACTED**]. If the [**REDACTED**] is set at HK$[**REDACTED**] per Share, being the low end of the indicative [**REDACTED**], the net [**REDACTED**] from the [**REDACTED**] will be approximately HK$[**REDACTED**].

To the extent that the net [**REDACTED**] are not immediately applied to the above purposes and to the extent permitted by the relevant law and regulations, so long as it is deemed to be in the best interests of our Group, we may hold such funds in short-term interest-bearing accounts at licensed commercial banks and/or other authorized financial institutions (as defined under the SFO or applicable laws and regulations in other jurisdictions). We will issue an appropriate announcement if there is any material change to the above proposed use of [**REDACTED**].

[**REDACTED**]

[**REDACTED**]

[**REDACTED**]

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The following is the text of a report set out on pages I-1 to I-[56], received from the Company's reporting accountants Deloitte Touche Tohmatsu, Certified Public Accountants, Hong Kong, for the purpose of incorporation in this document.

Deloitte. 德勤

ACCOUNTANTS' REPORT ON HISTORICAL FINANCIAL INFORMATION TO THE DIRECTORS OF SUNHO BIOLOGICS, INC. (盛禾生物控股有限公司) AND CHINA INTERNATIONAL CAPITAL CORPORATION HONG KONG SECURITIES LIMITED

Introduction

We report on the historical financial information of Sunho Biologics, Inc. (盛禾生物控股有限公司) (the "Company") and its subsidiaries (collectively referred to as the "Group") set out on pages I-[4] to I-[56], which comprises the consolidated statements of financial position of the Group as at December 31, 2022 and 2023, the statements of financial position of the Company as at December 31, 2022 and 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 of the Group for each of the two years ended December 31, 2023 (the "Track Record Period") and 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-[56] forms an integral part of this report, which has been prepared for inclusion in the document of the Company dated [Date] (the "Document") in connection with the initial [**REDACTED**] of shares of the Company on the [**REDACTED**] of [**REDACTED**].

Directors' responsibility for the Historical Financial Information

The directors of the Company are responsible for the preparation of the Historical Financial Information that gives a true and fair view in accordance with the basis of preparation set out in note 2 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 (the "HKICPA"). This standard requires that we comply with ethical standards and plan and perform our work to obtain reasonable assurance about whether the Historical Financial Information is free from material misstatement.

Our work involved performing procedures to obtain evidence about the amounts and disclosures in the Historical Financial Information. The procedures selected depend on the reporting accountants' judgment, including the assessment of risks of material misstatement of the Historical Financial Information, whether due to fraud or error. In making those risk assessments, the reporting accountants consider internal control relevant to the entity's preparation of Historical Financial Information that gives a true and fair view in accordance with the basis of preparation set out in note 2 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 of the Company, as well as evaluating the overall presentation of the Historical Financial Information.

We believe that the evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Opinion

In our opinion, the Historical Financial Information gives, for the purposes of the accountants' report, a true and fair view of the Group's and the Company's financial position as at December 31, 2022 and 2023, and of the Group's financial performance and cash flows for the Track Record Period in accordance with the basis of preparation set out in note 2 to the Historical Financial Information.

Report on matters under the Rules Governing the Listing of Securities on the Stock Exchange and the Companies (Winding Up and Miscellaneous Provisions) Ordinance

Adjustments

In preparing the Historical Financial Information, no adjustments to the Underlying Financial Statements as defined on page I-[4] have been made.

Dividends

We refer to note 15 to the Historical Financial Information which states that no dividend was declared or paid by the Company in respect of the Track Record Period.

[Deloitte Touche Tohmatsu]
Certified Public Accountants
Hong Kong
[Date]

HISTORICAL FINANCIAL INFORMATION OF THE GROUP

Preparation of Historical Financial Information

Set out below is the Historical Financial Information which forms an integral part of this accountants' report.

The consolidated financial statements of the Group for the Track Record Period, on which the Historical Financial Information is based, have been prepared in accordance with the accounting policies which conform with International Financial Reporting Standards ("IFRSs") issued by International Accounting Standards Board ("IASB") and were audited by us in accordance with Hong Kong Standards on Auditing issued by the HKICPA ("Underlying Financial Statements").

The Historical Financial Information is presented in Renminbi ("RMB") and all values are rounded to the nearest thousand (RMB'000) except when otherwise indicated.

CONSOLIDATED STATEMENTS OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

		Year ended December 31,	
	Notes	**2022**	**2023**
		RMB'000	*RMB'000*
Other income	*7A*	13,795	21,005
Other expenses	*7B*	(1,258)	(70)
Other gains and losses, net	*8*	97	(49,615)
Research and development expenses	*10*	(53,171)	(43,041)
Administrative expenses		(5,558)	(40,701)
[**REDACTED**]		[**REDACTED**]	[**REDACTED**]
Finance costs	*9*	(5,074)	(692)
Loss before tax	*11*	(51,988)	(132,701)
Income tax expense	*12*	–	–
Loss and total comprehensive expense for the year		(51,988)	(132,701)
Loss per share			
– Basic and diluted (RMB)	*14*	(0.57)	(1.43)

CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

	Notes	As at December 31, 2022 RMB'000	2023 RMB'000
Non-current assets			
Property and equipment	*16*	45,500	41,119
Right-of-use assets	*18*	551	9,587
Intangible asset	*17*	10,000	10,000
Prepayments for acquisition of equipment		178	103
Refundable fulfillment deposits	*21*	–	2,500
		56,229	63,309
Current assets			
Inventories	*22*	881	818
Deposits, prepayments and other receivables	*21*	11,613	16,256
Amounts due from shareholders	*23*	317	–
Other financial assets	*24*	–	49,579
Time deposits	*25*	–	35,414
Cash and cash equivalents	*25*	1,821	125,074
		14,632	227,141
Current liabilities			
Trade and other payables	*26*	8,779	73,960
Amounts due to a related party	*23*	57,375	–
Lease liabilities	*27*	–	2,178
Financial liabilities at fair value through profit or loss ("FVTPL")	*28*	–	311,525
		66,154	387,663
Net current liabilities		(51,522)	(160,522)
Total assets less current liabilities		4,707	(97,213)
Non-current liabilities			
Lease liabilities	*27*	–	6,896
Amounts due to a related party	*23*	6,206	–
		6,206	6,896
Net liabilities		(1,499)	(104,109)
Capital and reserves			
Share capital	*29A*	322	322
Treasury stock	*29A*	(29)	(19)
Reserves		(1,792)	(104,412)
Total deficit		(1,499)	(104,109)

STATEMENTS OF FINANCIAL POSITION OF THE COMPANY

	Notes	As at December 31, 2022	2023
		RMB'000	*RMB'000*
Non-current asset			
Investment in a subsidiary	*20*	10,339	192,037
		10,339	192,037
Current assets			
Deposits, prepayments and other receivables	*21*	1,192	6,356
Amounts due from shareholders	*23*	346	–
Time deposits	*25*	–	35,414
Cash and cash equivalents	*25*	–	72,854
		1,538	114,624
Current liabilities			
Other payables	*26*	186	6,284
Amounts due to a subsidiary	*23*	1,825	16,012
Financial liabilities at FVTPL	*28*	–	311,525
		2,011	333,821
Net current liabilities		(473)	(219,197)
Total assets less current liabilities		9,866	(27,160)
Net assets (liabilities)		9,866	(27,160)
Capital and reserves			
Share capital	*29A*	322	322
Reserves	*29B*	9,544	(27,482)
Total equity (deficit)		9,866	(27,160)

CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

			Reserves			
	Share capital *RMB'000*	**Treasury stock** *RMB'000*	**Capital reserve** *RMB'000*	**Share-based payment reserve** *RMB'000*	**Accumulated losses** *RMB'000*	**Total** *RMB'000*
As at January 1, 2022	322	(29)	8,940	2,644	(143,427)	(131,550)
Loss and total comprehensive expense for the year	–	–	–	–	(51,988)	(51,988)
Recognition of equity-settled share-based payments expenses *(note 30)*	–	–	–	2,039	–	2,039
Reclassification of vested equity-settled share-based payments	–	–	2,720	(2,720)	–	–
Loan waived by Nanjing Bode Biological Pharmaceutical Co., Ltd * (南京博德生物製藥有限公司) ("Nanjing Bode") *(note 23(b)(i))*	–	–	180,000	–	–	180,000

* *English name for identification purpose only*

		Reserves				
	Share capital *RMB'000*	Treasury stock *RMB'000*	Capital reserve *RMB'000*	Share-based payment reserve *RMB'000*	Accumulated losses *RMB'000*	Total *RMB'000*
As at December 31, 2022	322	(29)	191,660	1,963	(195,415)	(1,499)
Loss and total comprehensive expense for the year	–	–	–	–	(132,701)	(132,701)
Recognition of equity-settled share-based payments expenses *(note 30)*	–	–	–	30,081	–	30,081
Reclassification of vested equity-settled share-based payments	–	10	32,044	(32,044)	–	10
As at December 31, 2023	322	(19)	223,704	–	(328,116)	(104,109)

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year ended December 31,	
	2022	2023
	RMB'000	*RMB'000*
OPERATING ACTIVITIES		
Loss before tax	(51,988)	(132,701)
Adjustments for:		
Finance costs	5,074	692
Interest income	(15)	(3,471)
Net foreign exchange (gain) loss	(27)	8,290
Share-based payment expenses	2,039	30,081
Realized gain on other financial assets at FVTPL	(62)	–
Loss from changes in fair value of financial liabilities at FVTPL	–	41,345
Depreciation of property and equipment	6,602	6,402
Depreciation of right-of-use assets	2,206	2,238
Operating cash flow before movements in working capital	(36,171)	(47,124)
Decrease in inventories	292	63
Decrease (increase) in deposits, prepayments and other receivables	2,740	(2,923)
(Decrease) increase in trade and other payables	(1,447)	9,331
NET CASH USED IN OPERATING ACTIVITIES	(34,586)	(40,653)
INVESTING ACTIVITIES		
Interest received from banks	15	2,742
Acquisition of property and equipment	(1,439)	(1,030)
Acquisition of intangible asset	–	–
Purchase of financial assets at FVTPL	(17,500)	–
Purchase of other financial assets	–	(49,701)
Redemption of financial assets at FVTPL	17,562	–
Placement of time deposits with maturity of more than three months	–	(35,899)
NET CASH USED IN INVESTING ACTIVITIES	(1,362)	(83,888)

	Year ended December 31,	
	2022	**2023**
	RMB'000	*RMB'000*
FINANCING ACTIVITIES		
Borrowings from Nanjing Bode	42,700	23,000
Repayments to Nanjing Bode	(15,140)	(34,515)
Proceeds from issuance of shares by the Company	–	270,517
Payment of lease liabilities	–	(23)
[**REDACTED**] paid	[**REDACTED**]	[**REDACTED**]
NET CASH FROM FINANCING ACTIVITIES	27,104	255,497
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(8,844)	130,956
CASH AND CASH EQUIVALENTS AT THE BEGINNING OF THE YEAR	10,665	1,821
Effect of foreign exchange rate changes	–	(7,703)
CASH AND CASH EQUIVALENTS AT THE END OF THE YEAR	1,821	125,074

NOTES TO THE HISTORICAL FINANCIAL INFORMATION

1. GENERAL INFORMATION

The Company was incorporated in the Cayman Islands as an exempted company registered under the Company Laws of the Cayman Islands on May 14, 2021. The addresses of the registered office and principal place of business of the Company are disclosed in the section "Corporate Information" of the Document.

The Company is an investment holding company. The Company and its subsidiaries (collectively referred to as the "Group") are mainly committed to the develop regulate immune microenvironment by directly modulating both the innate and adaptive immune systems. Particulars and principal activities of the subsidiaries are disclosed in note 36.

The immediate and ultimate parent of the Company is Sunho Wisdom Investments Limited ("Sunho Wisdom"), which is incorporated in the British Virgin Islands (the "BVI") with limited liability, and wholly owned and controlled by Mr. Zhang Feng ("Mr. Zhang").

The functional currency of the Company is RMB, which is the same as the presentation currency of the Historical Financial Information.

2. BASIS OF PREPARATION OF THE HISTORICAL FINANCIAL INFORMATION

The Historical Financial Information has been prepared based on the accounting policies which conform with IFRSs issued by the IASB.

In preparing the Historical Financial Information, the directors of the Company have given careful consideration to the future liquidity of the Group in light of the fact that as at December 31, 2023, its current liabilities exceeded its current assets by approximately RMB[160,522,000], its liabilities exceeded its assets by approximately RMB[104,109,000] and capital commitments of approximately RMB16,110,000 (note 32). Taking into account of conversion of Series A Preferred Shares (defined in note 28) into ordinary shares upon [**REDACTED**], such that immediately after the conversion, the Group will no longer in net liability position. In addition, considering the Group's historical performance and management's operating and financing plans, the directors believe that the Group will have sufficient working capital to finance its operations and to meet its financial obligations as and when they fall due for not less than next twelve months after December 31, 2023. Consequently, the Historical Financial Information has been prepared on a going concern basis, which contemplates the realisation of assets and settlement of liabilities in the normal course of business.

No audited statutory financial statements of the Company have been prepared since its date of incorporation as it is incorporated in the jurisdiction where there are no statutory audit requirements.

3. APPLICATION OF NEW AND AMENDMENTS TO IFRSs

For the purpose of preparing and presenting the Historical Financial Information for the Track Record Period, the Group has consistently applied the accounting policies which conform with IFRSs, which are effective for the accounting period beginning on January 1, 2023 throughout the Track Record Period.

New and amendments to IFRSs in issue but not yet effective

At the date of this report, the following new and amendments to IFRSs have been issued which are not yet effective:

Amendments to IFRS 10 and IAS 28	Sale or Contribution of Assets between an Investor and its Associate or Joint Venture[1]
Amendments to IFRS 16	Lease Liability in a Sale and Leaseback[2]
Amendments to IAS 1	Classification of Liabilities as Current or Non-current[2]
Amendments to IAS 1	Non-current Liabilities with Covenants[2]
Amendments to IAS 7 and IFRS 7	Supplier Finance Arrangements[2]
Amendments to IAS 21	Lack of Exchangeability[3]
IFRS 18	Presentation and Disclosure in Financial Statements[4]

[1] Effective for annual periods beginning on or after a date to be determined.

[2] Effective for annual periods beginning on or after January 1, 2024.

[3] Effective for annual periods beginning on or after January 1, 2025.

[4] Effective for annual periods beginning on or after January 1, 2027.

The directors of the Company anticipate that the application of these new and amendments to IFRSs will have no material impact on the Historical Financial Information in the foreseeable future.

4. MATERIAL ACCOUNTING POLICY INFORMATION

The Historical Financial Information has been prepared in accordance with the following accounting policies which conform with IFRSs issued by the IASB. For the purpose of preparation of the Historical Financial Information, information is considered material if such information is reasonably expected to influence decisions made by primary users. In addition, the Historical Financial Information includes the applicable disclosures required by the Rules Governing the Listing of Securities on the Stock Exchange of Hong Kong Limited and by the Hong Kong Companies Ordinance.

Basis of consolidation

The Historical Financial Information incorporate the financial statements of the Company and entities controlled by the Company and its subsidiaries. Control is achieved when the Company:

- has power over the investee;
- is exposed, or has rights, to variable returns from its involvement with the investee; and
- has the ability to use its power to affect its returns.

The Group reassesses whether or not it controls an investee if facts and circumstances indicate that there are changes to one or more of the three elements of control listed above.

Consolidation of a subsidiary begins when the Group obtains control over the subsidiary and ceases when the Group loses control of the subsidiary. Specifically, income and expenses of a subsidiary acquired or disposed of during the year are included in the consolidated statement of profit or loss and other comprehensive income from the date the Group gains control until the date when the Group ceases to control the subsidiary.

When necessary, adjustments are made to the financial information of subsidiaries to bring their accounting policies in line with the Group's accounting policies.

All intragroup assets and liabilities, equity, income, expenses and cash flows relating to transactions between members of the Group are eliminated in full on consolidation.

Financial instruments

Financial assets and financial liabilities are recognized when a group entity becomes a party to the contractual provisions of the instrument. All regular way purchases or sales of financial assets are recognized and derecognized on a trade date basis. Regular way purchases or sales are purchases or sales of financial assets that require delivery of assets within the time frame established by regulation or convention in the market place.

Financial assets and financial liabilities are initially measured at fair value. Transaction costs that are directly attributable to the acquisition or issue of financial assets and financial liabilities (other than financial assets or financial liabilities at FVTPL) are added to or deducted from the fair value of the financial assets or financial liabilities, as appropriate, on initial recognition. Transaction costs directly attributed to the acquisition of financial assets or financial liabilities at FVTPL are recognized immediately in profit or loss.

The effective interest method is a method of calculating the amortized cost of a financial asset or financial liability and of allocating interest income and interest expense over the relevant period. The effective interest rate is the rate that exactly discounts estimated future cash receipts and payments (including all fees and points paid or received that form an integral part of the effective interest rate, transaction costs and other premiums or discounts) through the expected life of the financial asset or financial liability, or, where appropriate, a shorter period, to the net carrying amount on initial recognition.

Financial assets

Classification and subsequent measurement of financial assets

Financial assets that meet the following conditions are subsequently measured at amortized cost:

- the financial asset is held within a business model whose objective is to collect contractual cash flows; and

- the contractual terms give rise on specified dates to cash flows that are solely payments of principal and interest on the principal amount outstanding.

All other financial assets the Group hold are subsequently measured at FVTPL.

(i) Amortized cost and interest income

Interest income is recognized using the effective interest method for financial assets measured subsequently at amortized cost and calculated by applying the effective interest rate to the gross carrying amount of a financial asset except for financial assets that have subsequently become credit-impaired (see below). For financial assets that have subsequently become credit-impaired, interest income is recognized by applying the effective interest rate to the amortized cost of the financial asset from the next reporting period. If the credit risk on the credit-impaired financial instrument improves so that the financial asset is no longer credit-impaired, interest income is recognized by applying the effective interest rate to the gross carrying amount of the financial asset from the beginning of the reporting period following the determination that the asset is no longer credit-impaired.

(ii) Financial assets at FVTPL

Financial assets that do not meet the criteria for being measured at amortized cost or fair value through other comprehensive income ("FVTOCI") or designated as FVTOCI are measured at FVTPL.

Financial assets at FVTPL are measured at fair value at the end of each reporting period, with any fair value gains or losses recognized in profit or loss. The net gain or loss recognized in profit or loss includes any interest earned on the financial asset and is included in the "other gains and losses, net" line item.

Impairment of financial assets subject to impairment assessment under IFRS 9

The Group performs impairment assessment under expected credit loss ("ECL") model on financial assets (including other financial assets, amounts due from shareholders, other receivables and refundable fulfillment deposits which are subject to impairment assessment under IFRS 9). The amount of ECL is updated at each reporting date to reflect changes in credit risk since initial recognition.

Lifetime ECL represents the ECL that will result from all possible default events over the expected life of the relevant instrument. In contrast, 12-month ECL ("12m ECL") represents the portion of lifetime ECL that is expected to result from default events that are possible within 12 months after the reporting date. Assessments are done based on the Group's historical credit loss experience, adjusted for factors that are specific to the debtors, general economic conditions and an assessment of both the current conditions at the reporting date as well as the forecast of future conditions.

For all the financial assets, the Group measures the loss allowance equal to 12m ECL, unless there has been a significant increase in credit risk since initial recognition, in which case the Group recognizes lifetime ECL.

The measurement of ECL is a function of the probability of default, loss given default (i.e. the magnitude of the loss if there is a default) and the exposure at default. The assessment of the probability of default and loss given default is based on historical data and forward-looking information. Estimation of ECL reflects an unbiased and probability-weighted amount that is determined with the respective risks of default occurring as the weights.

Generally, the ECL is the difference between all contractual cash flows that are due to the Group in accordance with the contract and the cash flows that the Group expects to receive, discounted at the effective interest rate determined at initial recognition.

The Group recognizes an impairment gain or loss in profit or loss for all financial instruments by adjusting their carrying amount, with the exception of financial assets at amortized cost, amounts due from shareholders, other receivables and refundable fulfillment deposits where the corresponding adjustment is recognized through a loss allowance account.

Foreign exchange gains and losses

The carrying amount of financial assets that are denominated in a foreign currency is determined in that foreign currency and translated at the spot rate at the end of each reporting period. Specifically for financial assets measured at amortized cost that are not part of a designated hedging relationship, exchange differences are recognized in profit or loss in the 'Other gains and losses, net' line item (note 8) as part of the net foreign exchange (losses) gains.

Derecognition of financial assets

The Group derecognizes a financial asset only when the contractual rights to the cash flows from the assets expire.

On derecognition of a financial asset measured at amortized cost, the difference between the asset's carrying amount and the sum of the consideration received and receivable is recognized in profit or loss.

Financial liabilities and equity

Classification as debt or equity

Debt and equity instruments are classified as either financial liabilities or as equity in accordance with substance of the contractual arrangements and the definitions of a financial liability and an equity instrument.

Equity instruments

An equity instrument is any contract that evidences a residual interest in the assets of an entity after deducting all of its liabilities. Equity instruments issued by a group are recognized at the proceeds received, net of direct issue costs.

Financial liabilities

All financial liabilities are subsequently measured at amortized cost using the effective interest method or at FVTPL.

Financial liabilities at FVTPL

Financial liabilities are classified as at FVTPL when the financial liability is designated as at FVTPL.

A financial liability other than a financial liability held for trading or contingent consideration of an acquirer in a business combination may be designated as at FVTPL upon initial recognition if:

- such designation eliminates or significantly reduces a measurement or recognition inconsistency that would otherwise arise; or
- the financial liability forms part of a group of financial assets or financial liabilities or both, which is managed and its performance is evaluated on a fair value basis, in accordance with the Group's documented risk management or investment strategy, and information about the grouping is provided internally on that basis; or
- it forms part of a contract containing one or more embedded derivatives, and IFRS 9 permits the entire combined contract to be designated as at FVTPL.

For financial liabilities that are designated as at FVTPL, the amount of change in the fair value of the financial liability that is attributable to changes in the credit risk of that liability is recognized in other comprehensive income, unless the recognition of the effects of changes in the liability's credit risk in other comprehensive income would create or enlarge an accounting mismatch in profit or loss. For financial liabilities that contain embedded derivatives, the changes in fair value of the embedded derivatives are excluded in determining the amount to be presented in other comprehensive income. Changes in fair value attributable to financial liability's credit risk that are recognized in other comprehensive income are not subsequently reclassified to profit or loss; instead, they are transferred to accumulated losses upon derecognition of the financial liability.

Financial liabilities at amortized cost

Financial liabilities including trade and other payables, amounts due to a related party and amounts due to a subsidiary are subsequently measured at amortized cost, using the effective interest method.

Foreign exchange gains and losses

The carrying amount of financial liabilities that are denominated in a foreign currency is determined in that foreign currency and translated at the spot rate at the end of each reporting period. Specifically for financial assets measured at amortized cost that are not part of a designated hedging relationship, exchange differences are recognized in profit or loss in the "Other gains and losses" line item (note 8) as part of the net foreign exchange (losses) gains.

Derecognition of financial liabilities

The Group derecognizes financial liabilities when, and only when, the Group's obligations are discharged, cancelled or have expired. The difference between the carrying amount of the financial liability derecognized and the consideration paid and payable is recognized in profit or loss.

Foreign currencies

In preparing the financial statements of each individual group entity, transactions in currencies other than the functional currency of that entity (foreign currencies) are recognized at the rates of exchanges prevailing on the dates of the transactions. At the end of the reporting period, monetary items denominated in foreign currencies are retranslated at the rates prevailing at that date. Non-monetary items that are measured in terms of historical cost in a foreign currency are not retranslated.

Exchange differences arising on the settlement of monetary items, and on the retranslation of monetary items, are recognized in profit or loss in the period in which they arise.

Intangible assets

Intangible assets acquired separately

Intangible assets with finite useful lives, which are acquired separately, are carried at costs less accumulated amortization and any accumulated impairment losses. Amortization for intangible assets with finite useful lives is recognized on a straight-line basis over their estimated useful lives when the assets are available for use. The estimated useful life and amortization method are reviewed at the end of each reporting period, with the effect of any changes in estimate being accounted for on a prospective basis.

Internally-generated intangible assets – research and development expenditure

Expenditure on research activities is recognized as an expense in the period in which it is incurred.

An internally-generated intangible asset arising from development activities is recognized if, and only if, all of the following have been demonstrated:

- the technical feasibility of completing the intangible asset so that it will be available for use or sale;
- the intention to complete the intangible asset and use or sell it;
- the ability to use or sell the intangible asset;
- how the intangible asset will generate probable future economic benefits;
- the availability of adequate technical, financial and other resources to complete the development and to use or sell the intangible asset; and
- the ability to measure reliably the expenditure attributable to the intangible asset during its development.

The amount initially recognized for internally-generated intangible asset is the sum of the expenditure incurred from the date when the intangible asset first meets the recognition criteria listed above. Where no internally-generated intangible asset can be recognized, development expenditure is recognized in profit or loss in the period in which it is incurred.

Subsequent to initial recognition, internally-generated intangible assets are reported at cost less accumulated amortization and accumulated impairment losses (if any), on the same basis as intangible assets that are acquired separately.

Employee benefits

Retirement benefit costs

The Group participates in state-managed retirement benefit schemes, which are defined contribution schemes, pursuant to which the Group pays a fixed percentage of its staff's wages as contributions to the plans. Payments to such retirement benefit schemes are recognized as an expense when employees have rendered service entitling them to the contributions.

Short-term employee benefits

Short-term employee benefits are recognized at the undiscounted amount of the benefits expected to be paid as and when employees rendered the services. All short-term employee benefits are recognized as an expense unless another IFRS requires or permits the inclusion of the benefit in the cost of an asset.

A liability is recognized for benefits accruing to employees (such as wages and salaries and annual leave) after deducting any amount already paid.

Share-based payments

Equity-settled share-based payment transactions

Restricted share units ("RSU") granted to employees and other share incentive plan

Equity-settled share-based payments to employees and others providing similar services are measured at the fair value of the equity instruments at the grant date.

The fair value of the equity-settled share-based payments determined at the grant date without taking into consideration all non-market vesting conditions is expensed on a straight-line basis over the vesting period, based on the Group's estimate of equity instruments that will eventually vest, with a corresponding increase in equity (share-based payment reserve). At the end of each reporting period, the Group revises its estimate of the number of equity instruments expected to vest based on assessment of all relevant non-market vesting conditions. The impact of the revision of the original estimates, if any, is recognized in profit or loss such that the cumulative expense reflects the revised estimate, with a corresponding adjustment to the share-based payment reserve. For shares that vest immediately at the date of grant, the fair value of the shares granted is expensed immediately to profit or loss.

When RSU are vested, the amount previously recognized in share-based payments reserve will be transferred to capital reserve.

Shares granted to non-employees

Equity-settled share-based payments transactions with parties other than employees are measured at the fair value of the goods or services received, except where that fair value cannot be estimated reliably, in which case they are measured at the fair value of the equity instruments granted, measured at the date the entity obtains the goods or the counterparty renders the service. The fair values of the goods or services received are recognized as expenses (unless the goods or services qualify for recognition as assets).

Leases

Definition of a lease

A contract is, or contains, a lease if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration.

For contracts entered into or modified on or after the date of initial application of IFRS 16, the Group assesses whether a contract is or contains a lease based on the definition under IFRS 16 at inception, modification date or acquisition date, as appropriate. Such contract will not be reassessed unless the terms and conditions of the contract are subsequently changed.

The Group as a lessee

Allocation of consideration to components of a contract

For a contract that contains a lease component and one or more additional lease or non-lease components, the Group allocates the consideration in the contract to each lease component on the basis of the relative stand-alone price of the lease component and the aggregate stand-alone price of the non-lease components.

Non-lease components are separated from lease component and are accounted for by applying other applicable standards.

Short-term leases

The Group applies the short-term lease recognition exemption to leases that have a lease term of 12 months or less from the commencement date and do not contain a purchase option. Lease payments on short-term leases are recognized as expense on a straight-line basis over the lease term.

Right-of-use assets

The cost of right-of-use assets includes:

- the amount of the initial measurement of the lease liability;
- any lease payments made at or before the commencement date, less any lease incentives received.

Right-of-use assets are measured at cost, less any accumulated depreciation and impairment losses, and adjusted for any remeasurement of lease liabilities.

Right-of-use assets are depreciated on a straight-line basis over the shorter of its estimated useful life and the lease term.

The Group presents right-of-use assets as a separate line item on the consolidated statements of financial position.

Refundable rental deposits

Refundable rental deposits paid are accounted under IFRS 9 *Financial Instruments* and initially measured at fair value. Adjustments to fair value at initial recognition are considered as additional lease payments and included in the cost of right-of-use assets.

Lease liabilities

At the commencement date of a lease, the Group recognizes and measures the lease liability at the present value of lease payments that are unpaid at that date. In calculating the present value of lease payments, the Group uses the incremental borrowing rate at the lease commencement date if the interest rate implicit in the lease is not readily determinable.

The lease payments are fixed payments (including in-substance fixed payments) less any lease incentives receivable.

After the commencement date, lease liabilities are adjusted by interest accretion and lease payments.

The Group remeasures lease liabilities (and makes a corresponding adjustment to the related right-of-use assets) whenever the lease term has changed, in which case the related lease liability is remeasured by discounting the revised lease payments using a revised discount rate at the date of reassessment.

The Group presents lease liabilities as a separate line item on the consolidated statements of financial position.

Lease modifications

The Group accounts for a lease modification as a separate lease if:

- the modification increases the scope of the lease by adding the right to use one or more underlying assets; and
- the consideration for the leases increases by an amount commensurate with the stand-alone price for the increase in scope and any appropriate adjustments to that stand-alone price to reflect the circumstances of the particular contract.

For a lease modification that is not accounted for as a separate lease, the Group remeasures the lease liability based on the lease term of the modified lease by discounting the revised lease payments using a revised discount rate at the effective date of the modification.

The Group accounts for the remeasurement of lease liabilities by making corresponding adjustments to the relevant right-of-use assets.

When the modified contract contains a lease component and one or more additional lease or non-lease components, the Group allocates the consideration in the modified contract to each lease component on the basis of the relative stand-alone price of the lease component and the aggregate stand-alone price of the non-lease components.

Property and equipment

Property and equipment are tangible assets that are held for use in the production or supply of goods or services, or for administrative purposes other than construction in progress as described below are stated in the consolidated statements of financial position at cost less subsequent accumulated depreciation and subsequent accumulated impairment losses, if any.

Properties and equipment in the course of construction for production, supply or administrative purposes are carried at cost, less any recognized impairment loss. Costs include any costs directly attributable to bringing the asset to the location and condition necessary for it to be capable of operating in the manner intended by management, including costs of testing whether the related assets are functioning properly and, for qualifying assets, borrowing costs capitalized in accordance with the Group's accounting policy. Depreciation of these assets, on the same basis as other property assets, commences when the assets are ready for their intended use.

Depreciation is recognized so as to write off the cost of assets other than properties under construction less their residual values over their estimated useful lives, using the straight-line method. The estimated useful lives, residual values and depreciation method are reviewed at the end of each reporting period, with the effect of any changes in estimate accounted for on a prospective basis.

An item of property and equipment is derecognized upon disposal or when no future economic benefits are expected to arise from the continued use of the asset. Any gain or loss arising on the disposal or retirement of an item of property and equipment is determined as the difference between the sales proceeds and the carrying amount of the asset and is recognized in profit or loss.

Impairment on property and equipment, right-of-use assets and intangible assets

At the end of each reporting period, the Group reviews the carrying amounts of its property and equipment and right-of-use assets to determine whether there is any indication that these assets have suffered an impairment loss. If any such indication exists, the recoverable amount of the relevant asset is estimated in order to determine the extent of the impairment loss (if any). Intangible assets not yet available for use are tested for impairment at least annually, and whenever there is an indication that may be impaired.

The recoverable amount of property and equipment, intangible assets and right-of-use assets are estimated individually. When it is not possible to estimate the recoverable amount individually, the Group estimates the recoverable amount of the cash-generating unit to which the asset belongs.

In testing a cash-generating unit for impairment, corporate assets are allocated to the relevant cash-generating unit when a reasonable and consistent basis of allocation can be established, or otherwise they are allocated to the smallest group of cash-generating units for which a reasonable and consistent allocation basis can be established. The recoverable amount is determined for the cash-generating unit or group of cash-generating units to which the corporate asset belongs, and is compared with the carrying amount of the relevant cash-generating unit or group of cash-generating units.

Recoverable amount is the higher of fair value less costs of disposal and value in use. In assessing the recoverable amount, the estimated future cash flows are discounted to their present value using a discount rate that reflects current market assessments of the time value of money and the risks specific to the asset (or a cash-generating unit) for which the estimates of future cash flows have not been adjusted.

If the recoverable amount of an asset (or a cash-generating unit) is estimated to be less than its carrying amount, the carrying amount of the asset (or a cash-generating unit) is reduced to its recoverable amount. For corporate assets or portion of corporate assets which cannot be allocated on a reasonable and consistent basis to a cash-generating unit, the Group compares the carrying amount of a group of cash-generating units, including the carrying amounts of the corporate assets or portion of corporate assets allocated to that group of cash-generating units, with the recoverable amount of the group of cash-generating units. In allocating the impairment loss, the impairment loss is allocated first to reduce the carrying amount of any goodwill (if applicable) and then to the other assets on a pro-rata basis based on the carrying amount of each asset in the unit or the group of cash-generating units. The carrying amount of an asset is not reduced below the highest of its fair value less costs of disposal (if measurable), its value in use (if determinable) and zero. The amount of the impairment loss that would otherwise have been allocated to the asset is allocated pro rata to the other assets of the unit or the group of cash-generating units. An impairment loss is recognized immediately in profit or loss.

Where an impairment loss subsequently reverses, the carrying amount of the asset (or cash-generating unit) is increased to the revised estimate of its recoverable amount, but so that the increased carrying amount does not exceed the carrying amount that would have been determined had no impairment loss been recognized for the asset (or a cash-generating unit) in prior years. A reversal of an impairment loss is recognized immediately in profit or loss.

Borrowing costs

All borrowing costs not directly attributable to the acquisition, construction or production of qualifying assets are recognized in profit or loss in the period in which they are incurred.

Government grants

Government grants are not recognized until there is reasonable assurance that the Group will comply with the conditions attaching to them and that the grants will be received.

Government grants are recognized in profit or loss on a systematic basis over the periods in which the Group recognizes as expenses the related costs for which the grants are intended to compensate.

Government grants related to income that are receivable as compensation for expenses or losses already incurred or for the purpose of giving immediate financial support to the Group with no future related costs are recognized in profit or loss in the period in which they become receivable. Such grants are presented under "other income".

Inventories

Inventories are stated at the lower of cost and net realizable value. Costs of inventories are determined on a weighted average method. Net realizable value represents the estimate selling price for inventories less all estimated costs of completion and costs necessary to make the sale. Costs necessary to make the sale include incremental costs directly attributable to the sale and non-incremental costs which the Group must incur to make the sale.

Cash and cash equivalents

Cash and cash equivalents presented on the consolidated statement of financial position include:

(a) cash, which comprises of cash on hand and demand deposits, excluding bank balances that are subject to regulatory restrictions that result in such balances no longer meeting the definition of cash; and

(b) cash equivalents, which comprises of short-term (generally with original maturity of three months or less), highly liquid investments that are readily convertible to a known amount of cash and which are subject to an insignificant risk of changes in value. Cash equivalents are held for the purpose of meeting short-term cash commitments rather than for investment or other purposes.

For the purposes of the consolidated statement of cash flows, cash and cash equivalents consist of cash and cash equivalents as defined above.

Contingent liabilities

A contingent liability is a present obligation arising from past events but is not recognized because it is not probable that an outflow of resources embodying economic benefits will be required to settle the obligation or the amount of the obligation cannot be measured with sufficient reliability.

Where the Group is jointly and severally liable for an obligation, the part of the obligation that is expected to be met by other parties is treated as a contingent liability and it is not recognized in the Historical Financial Information.

The Group assesses continually to determine whether an outflow of resources embodying economic benefits has become probable. If it becomes probable that an outflow of future economic benefits will be required for an item previously dealt with as a contingent liability, a provision is recognized in the Historical Financial Information in the reporting period in which the change in probability occurs, except in the extremely rare circumstances where no reliable estimate can be made.

Taxation

Income tax expense represents the sum of the current and deferred income tax expenses.

The tax currently payable is based on taxable profit for the year. Taxable profit differs from "loss before tax" because of income or expense that are taxable or deductible in other years and items that are never taxable or deductible. The Group's liability for current tax is calculated using tax rates that have been enacted or substantively enacted by the end of each reporting period.

Deferred tax is recognized on temporary differences between the carrying amounts of assets and liabilities in the Historical Financial Information and the corresponding tax base used in the computation of taxable profit. Deferred tax liabilities are generally recognized for all taxable temporary differences. Deferred tax assets are generally recognized for all deductible temporary difference to the extent that it is probable that taxable profits will be available against which those deductible temporary differences can be utilized. Such deferred tax assets and liabilities are not recognized if the temporary difference arises from the initial recognition of assets and liabilities in a transaction that affects neither the taxable profit nor the accounting profit and at the time of the transaction does not give rise to equal taxable and deductible temporary difference.

Deferred tax liabilities are recognized for taxable temporary differences associated with investments in subsidiaries, except where the Group is able to control the reversal of the temporary difference and it is probable that the temporary differences will not reverse in the foreseeable future. Deferred tax assets arising from deductible temporary differences associated with such investments are only recognized to the extent that it is probable that there will be sufficient taxable profits against which to utilize the benefits of the temporary differences and they are expected to reverse in the foreseeable future.

The carrying amount of deferred tax assets is reviewed at the end of each reporting period and reduced to the extent that it is no longer probable that sufficient taxable profits will be available to allow all or part of the asset to be recovered.

Deferred tax assets and liabilities are measured at the tax rates that are expected to apply in the period in which the liability is settled or the asset is realized, based on tax rate (and tax laws) that have been enacted or substantively enacted by the end of each reporting period.

The measurement of deferred tax liabilities and assets reflects the tax consequences that would follow from the manner in which the Group expects, at the end of each reporting period, to recover or settle the carrying amount of its assets and liabilities.

For the purposes of measuring deferred tax for leasing transactions in which the Group recognizes the right-of-use assets and the related lease liabilities, the Group first determines whether the tax deductions are attributable to the right-of-use assets or the lease liabilities.

For leasing transactions in which the tax deductions are attributable to the lease liabilities, the Group applies IAS 12 *Income Taxes* requirements to the lease liabilities, and the related assets separately. The Group recognizes a deferred tax asset related to lease liabilities to the extent that it is probable that taxable profit will be available against which the deductible temporary difference can be utilized and a deferred tax liability for all taxable temporary differences.

Deferred tax assets and liabilities are offset when there is a legally enforceable right to set off current tax assets against current tax liabilities and when they relate to income tax levied to the same taxable entity by the same taxation authority.

Current and deferred tax are recognized in profit or loss.

5. CRITICAL ACCOUNTING JUDGMENTS AND KEY SOURCES OF ESTIMATION UNCERTAINTY

In the application of the Group's accounting policies, which are described in note 4, the directors of the Company are required to make judgments, estimates and assumptions about the carrying amounts of assets and liabilities that are not readily apparent from other sources. The estimates and underlying assumptions are based on historical experience and other factors that are considered to be relevant. Actual results may differ from these estimates.

The estimates and underlying assumptions are reviewed on an on-going basis. Revisions to accounting estimates are recognized in the period in which the estimate is revised if the revision affects only that period, or in the period of the revision and future periods if the revision affects both current and future periods.

Critical judgments in applying accounting policies

The following is the critical judgment, that the directors of the Company have made in the process of applying the Group's accounting policies and that has the most significant effect on the amounts recognized in the Historical Financial Information.

Research and development expenses

Development expenses incurred on the Group's drug product pipelines are capitalized and deferred only when the Group can demonstrate (i) the technical feasibility of completing the intangible asset so that it will be available for use or sale; (ii) the Group's intention to complete and the Group's ability to use or sell the asset; (iii) how the asset will generate future economic benefits; (iv) the availability of resources to complete the pipeline; and (v) the ability to measure reliably the expenditure during the development. Research and development expenses which do not meet these criteria are expensed when incurred. Management assesses the progress of each of the research and development projects and determine whether the criteria are met for capitalization. During the Track Record Period, all research and development costs are expensed when incurred.

Key sources of estimation uncertainty

The key assumptions concerning the future, and other key sources of estimation uncertainty at the end of each reporting periods, that may have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the coming twelve months, are described below.

Fair value of other financial liabilities

The Company has issued several series of financial liabilities to certain investors in 2023 as set out in Note 28. The financial liabilities at FVTPL are measured at fair value for which no quoted prices in an active market exist. The fair value of the financial liabilities at FVTPL is established by using valuation techniques, which include discounted cash flows ("DCF") method and equity allocation model involving various parameters and inputs. Valuation techniques are certified by an independent qualified professional valuer before being implemented for valuation and are calibrated to ensure that outputs reflect market conditions. However, some inputs, such as volatility, possibilities under different scenarios such as [**REDACTED**] and liquidation, discount rate, require management estimates. Management estimates and assumptions are reviewed periodically and are adjusted if necessary. Should any of the estimates and assumptions changed, it may lead to a change in the fair value of the financial liabilities at FVTPL which may be charged into profit or loss. The fair value of the financial liabilities at FVTPL of the Group as at December 31, 2022 and 2023 are nil and RMB311,525,000 respectively.

Useful lives of property and equipment

The management of the Group determines the estimated useful lives and the depreciation method in determining the related depreciation charges for its property and equipment. This estimate is reference to the useful lives of property and equipment of similar nature and functions in the industry. Management will increase the depreciation charge where useful lives are expected to be shorter than expected or will write off or write down obsolete assets that have been abandoned or sold.

6. SEGMENT INFORMATION

Operating segments are identified on the basis of internal reports about components of the Group that are regularly reviewed by the chief operating decision maker ("CODM"), which is also identified as the chief executive officer of the Group, in order to allocate resources and to assess the performance.

During the Trade Record Period, the CODM reviews the overall results and financial position of the Group as a whole. Accordingly, the Group has only one single segment and no further analysis of the single segment is presented.

Geographical information

The Group has not generated any revenue during the Track Record Period.

As at December 31, 2022 and 2023, all non-current assets are located in the People's Republic of China ("PRC").

7A. OTHER INCOME

	Year ended December 31,	
	2022	**2023**
	RMB'000	*RMB'000*
Relocation incentive *(note i)*	11,930	–
Government grants *(note ii)*	119	17,326
Sales income from contract manufacturing services *(note iii)*	1,731	208
Interest income from financial institutions	15	3,471
	13,795	21,005

Notes:

i. The amount represents incentive received from Nanjing Economic Development Zone Management Committee* (南京經濟技術開發區管理委員會) as incentive for the Group's relocation. The incentive was conditional and was recognized when condition met.

ii. The amount represents subsidies granted by the PRC local government authorities as incentives for the Group's research and development activities. The government grants including unconditional and conditional, and had been approved by the PRC local government authorities. The unconditional government grants are recognized when payments were received. The conditional government grants are recognized when condition met and the corresponding grants are received.

iii. Contract manufacturing services income was primarily related to production and sales of clinical samples on contract manufacturing basis under customer's specific order. It is recognized when the goods have been delivered, which is the point of time being when the goods are accepted by customers. The credit term is 5 to 15 days upon delivered. The Group applies the practical expedient of not disclosing the transaction price allocated to performance obligations that were unsatisfied in respect of contract manufacturing services income as the related contracts have an original expected duration of less than one year.

* English name for identification purpose only

7B. OTHER EXPENSES

The amount represented the raw materials, labor costs, depreciation and other production costs attributable to contract manufacturing services.

8. OTHER GAINS AND LOSSES, NET

	Year ended December 31,	
	2022	**2023**
	RMB'000	*RMB'000*
Realized gain on other financial assets measured at FVTPL	62	–
Loss from fair value change of financial liabilities at FVTPL	–	(41,345)
Net foreign exchange gains (losses)	27	(8,290)
Others	8	20
	97	(49,615)

9. FINANCE COSTS

	Year ended December 31,	
	2022	**2023**
	RMB'000	*RMB'000*
Interest expenses on borrowing from Nanjing Bode	5,055	491
Interest expenses on lease liabilities	19	201
	5,074	692

10. RESEARCH AND DEVELOPMENT EXPENSES

	Year ended December 31,	
	2022	**2023**
	RMB'000	*RMB'000*
Contract research expenses	19,273	11,263
Staff costs	16,089	15,231
Materials consumed	4,317	3,239
Depreciation and amortization expenses	7,694	8,005
Share-based compensation	2,039	756
Application fees	1,330	1,180
Others	2,429	3,367
	53,171	43,041

11. LOSS BEFORE TAX

	Year ended December 31,	
	2022	**2023**
	RMB'000	*RMB'000*
Loss before tax for the year has been arrived at after charging:		
Depreciation of property and equipment	6,602	6,402
Depreciation of right-of-use assets	2,206	2,238
	8,808	8,640
Auditors' remuneration	–	2,573
[**REDACTED**]	[**REDACTED**]	[**REDACTED**]
Directors' emoluments (note 13(a))	4,159	32,032
Other staff costs:		
– salaries and other benefits	15,343	14,930
– retirement benefit scheme contributions	1,263	1,240
– share-based payments	–	–
	20,765	48,202

12. INCOME TAX EXPENSE

The Company was incorporated in the Cayman Islands and Sunho bio Investments was incorporated in the BVI that are tax exempted.

Under the Law of the PRC on Enterprise Income Tax (the "EIT Law") and Implementation Regulation of the EIT Law, the tax rate of the PRC subsidiaries is 25% for the Track Record Period.

No Hong Kong profits tax was provided as there was no assessable profit that was subjected to Hong Kong Profits Tax during the Track Record Period.

Pursuant to Caishui 2018 circular No. 99, Caishui 2022 circular No. 28 and Caishui 2023 circular No. 7, 盛禾(中國)生物製藥有限公司 Sunho (China) Biopharmaceutical Co., Ltd.* ("Sunho (China) Biopharmaceutical") enjoyed super deduction of 175% on qualified research and development expenditures for the nine months ended September 30, 2022. In addition, Sunho (China) Biopharmaceutical enjoyed super deduction of 200% on qualified research and development expenditures during the three months from October 1, 2022 to December 31, 2022 and the year ended December 31, 2023.

The income tax expense for the Track Record Period can be reconciled to the loss before tax per the consolidated statements of profit or loss and other comprehensive expense as follows:

	Year ended December 31,	
	2022	**2023**
	RMB'000	*RMB'000*
Loss before tax	(51,988)	(132,701)
Tax at the applicable PRC income tax rate of 25%	(12,997)	(33,175)
Tax effect of expenses that are not deductible for tax purpose	762	24,166
Tax effect of deductible temporary differences not recognized	1,799	613
Utilization of deductible temporary differences previously not recognized	(1,324)	(2,212)
Tax effect of additional deductible research and development expenses	(9,771)	(9,686)
Tax effect of tax losses not recognized	–	20,294
Tax effect of loan waived by Nanjing Bode that is regarded as taxable income *(note 23(b)(i))*	45,000	–
Utilization of tax losses previously not recognized	(23,469)	–
Income tax expense	–	–

As at December 31, 2022 and 2023, the Group has unused tax losses of approximately RMB93,183,000 and RMB174,358,000 respectively. No deferred tax asset has been recognized in respect of the tax losses due to the unpredictability of future profit streams.

As at December 31, 2022 and 2023, the Group has deductible temporary differences of approximately RMB7,330,000 and RMB934,000, respectively. No deferred tax asset has been recognized in relation to such deductible temporary difference as it is not probable that taxable profit will be available against which the deductible temporary differences can be utilized.

The unused tax losses will be carried forward and expire in years as follows:

	At December 31,	
	2022	**2023**
	RMB'000	*RMB'000*
2023	–	–
2024	–	–
2025	–	–
2026	93,183	93,183
2027	–*	–*
2028	–	81,175
	93,183	174,358

* *Amount less than RMB1,000*

13. DIRECTORS' AND CHIEF EXECUTIVE OFFICER'S EMOLUMENTS AND FIVE HIGHEST PAID EMPLOYEES

Details of the emoluments paid or payable to the individuals who were appointed as directors and the chief executive officer ("CEO") of the Company (including emoluments for services as employees/directors of the group entities prior to becoming the directors of the Company) during the Track Record Period are as follows:

(a) Executive and non-executive directors

	Date of appointment	Director's fee	Salaries and other benefits	Retirement benefit scheme contributions	Discretionary bonus	Share-based payments	Total
		RMB'000	*RMB'000*	*RMB'000*	*RMB'000*	*RMB'000*	*RMB'000*
For the year ended December 31, 2022							
Executive directors:							
Mr. Zhang	May 14, 2021	–	–	–	–	–	–
Dr. Yin	July 21, 2023	–	1,501	38	–	2,039	3,578
Ms. Jiang Xiaoling	July 21, 2023	–	299	8	274	–	581
Non-executive director:							
Mr. Fan Rongkui	July 21, 2023	–	–	–	–	–	–
Independent non-executive directors:							
Mr. Chan Heung Wing Anthony	*(note vi)*	–	–	–	–	–	–
Ms. Feng Lan	*(note vi)*	–	–	–	–	–	–
Mr. Shi Luwen	*(note vi)*	–	–	–	–	–	–
		–	1,800	46	274	2,039	4,159

	Date of appointment	Director's fee	Salaries and other benefits	Retirement benefit scheme contributions	Discretionary bonus	Share-based payments	Total
		RMB'000	*RMB'000*	*RMB'000*	*RMB'000*	*RMB'000*	*RMB'000*
For the year ended December 31, 2023							
Executive directors:							
Mr. Zhang	May 14, 2021	–	–	–	–	29,325	29,325
Dr. Yin	July 21, 2023	–	1,498	38	–	756	2,292
Ms. Jiang Xiaoling	July 21, 2023	–	297	9	109	–	415
Non-executive director:							
Mr. Fan Rongkui	July 21, 2023	–	–	–	–	–	–
Independent non-executive directors:							
Mr. Chan Heung Wing Anthony	*(note vi)*	–	–	–	–	–	–
Ms. Feng Lan	*(note vi)*	–	–	–	–	–	–
Mr. Shi Luwen	*(note vi)*	–	–	–	–	–	–
		–	1,795	47	109	30,081	32,032

Notes:

i. None of the directors of the Company waived or agreed to waive any emoluments during the Track Record Period.

ii. The executive directors' emoluments shown above were for their services in connection with the management of the affairs of the Group and the Company, respectively.

iii. The discretionary bonuses were determined with reference to their duties and responsibilities of the relevant individuals within the Group and the Group's performance.

iv. Dr. Yin was appointed as CEO of the Company on July 22, 2023.

v. Dr. Yin and Mr. Zhang were granted RSU, in respect of their service and contribution to the Group. Details of the Employee Share Incentive Plan are set out in note 30 to the Historical Financial Information.

vi. The appointment of independent non-executive directors will be effective from the date of [**REDACTED**].

(b) Five highest paid employees

The five highest paid employees of the Group during the years ended December 31, 2022 and 2023 included two and two directors, respectively, details of whose remuneration are set out above. Details of the remuneration for the remaining three, three and three highest paid employees for the years ended December 31, 2022 and 2023, respectively, are as follows:

	Year ended December 31,	
	2022	**2023**
	RMB'000	*RMB'000*
Salaries and other benefits	619	717
Discretionary bonus	356	805
Retirement benefit scheme contributions	48	38
	1,023	1,560

The emoluments of these employees (including the directors) are within the following bands:

	Number of individuals Year ended December 31,	
	2022	**2023**
Hong Kong Dollars ("HK$")		
1 to HK$500,000	3	1
HK$500,001 to HK$1,000,000	1	2
HK$2,500,001 to HK$3,000,000	–	1
HK$4,000,001 to HK$4,500,000	1	–
HK$32,500,001 to HK$33,000,000	–	1
	5	5

During the Track Record Period, no emoluments were paid by the Group to the directors of the Company or the five highest paid individuals (including directors and employees) as an inducement to join or upon joining the Group or as compensation for loss of office.

(c) Transactions, arrangements or contracts in which directors of the Company have material interests

Save as disclosed in note 23 and note 31, no significant transactions, arrangements and contracts in relation to the Group's business to which the Group was a party and in which a director of the Company had a material interest, whether directly or indirectly, subsisted at the end of the Track Record Period or at any time during the Track Record Period.

14. LOSS PER SHARE

The calculation of the basic and diluted loss per share attributable to the owners of the Company is based on the following data:

	Year ended December 31,	
	2022	2023
Loss for the year (RMB'000)		
Loss for the year attributable to the owners of the Company for the purpose of calculating basic and diluted loss per share	(51,988)	(132,701)
Number of shares ('000)		
Weighted average number of ordinary shares for the purpose of calculating basic and diluted loss per share	91,000	92,882

The basic loss per share is calculated based on the loss attributable to the owners of the Company and the weighted average number of ordinary shares excluded shares of treasury stock under the employee incentive schemes (note 29A) on the assumption that the subdivision of each Shares with a par value of US$1.00 in the Company into 2,000 Shares with a par value of US$0.0005 each ("Share Subdivision") has been effective on January 1, 2022.

No diluted loss per share for the year ended December 31, 2022 was presented as there were no potential ordinary shares in issue for this year.

The computation of diluted loss per share for the year ended December 31, 2023 does not assume the conversion of the Series A Preferred Shares (as defined in note 28) and the vesting of share-based awards granted to employees (note 30) since their assumed conversion or vesting would result in a decrease in loss per share.

15. DIVIDENDS

No dividend was declared or paid by the Company during the Track Record Period.

16. PROPERTY AND EQUIPMENT

The Group

	Machinery and equipment	Furniture and office equipment	Leasehold improvements	Construction in progress	Total
	RMB'000	*RMB'000*	*RMB'000*	*RMB'000*	*RMB'000*
COST					
As at January 1, 2022	51,730	797	489	721	53,737
Additions	167	11	–	2,107	2,285
As at December 31, 2022	51,897	808	489	2,828	56,022
Additions	1,867	12	–	142	2,021
Transfers	1,922	–	–	(1,922)	–
As at December 31, 2023	55,686	820	489	1,048	58,043

	Machinery and equipment *RMB'000*	Furniture and office equipment *RMB'000*	Leasehold improvements *RMB'000*	Construction in progress *RMB'000*	Total *RMB'000*
DEPRECIATION					
As at January 1, 2022	3,675	227	18	–	3,920
Provided for the year	6,404	103	95	–	6,602
As at December 31, 2022	10,079	330	113	–	10,522
Provided for the year	6,207	100	95	–	6,402
As at December 31, 2023	16,286	430	208	–	16,924
CARRYING AMOUNT					
As at December 31, 2022	41,818	478	376	2,828	45,500
As at December 31, 2023	39,400	390	281	1,048	41,119

The above items of property and equipment, other than construction in progress, are depreciated on a straight-line basis, after taking into account of the residual value, over the following period:

Machinery and equipment	5-8 years
Furniture and office equipment	5-8 years
Leasehold improvements	Over the shorter of the relevant lease terms or 5 years

17. INTANGIBLE ASSET

The Group

	In process research and development project ("IPR&D") *RMB'000*
COST AND CARRYING AMOUNT	
As at January 1, 2022, December 31, 2022 and December 31, 2023	10,000

The above IPR&D will be amortized on a straight-line basis over the following periods:

IPR&D	Over the residual useful life when ready for use

(i) IPR&D

In 2019, the Group entered into an in-license agreement with an independent third party under which the Group was granted all of IBC0966's rights and interest in Mainland China, Hong Kong, Macau and Taiwan, for the purpose of conducting preclinical development, clinical research and commercialization of certain drug. In exchange of such rights aforementioned, the Group obligated to pay RMB20,000,000 assignment fee by installments and sales royalties based on annual sales. As at December 31, 2022 and 2023, the Group had paid an upfront payment of RMB10,000,000 and such payment was capitalized as intangible asset. Once the new drug certificate of IBC0966 have been granted, the Group shall pay the rest RMB10,000,000 within 10 working days.

As the intangible asset is not ready for use up to December 31, 2023 and the date of this report, the management of the Group performed impairment testing annually, which was further disclosed in note 19. In the opinion of directors of the Company, no impairment loss was recognized in profit or loss during the Track Record Period.

18. RIGHT-OF-USE ASSETS

The Group

	Leased property *RMB'000*	Leased machinery and equipment *RMB'000*	Total *RMB'000*
As at December 31, 2022			
Carrying amount	551	–	551
As at December 31, 2023			
Carrying amount	9,587	–	9,587
For the year ended December 31, 2022			
Depreciation for the year	2,206	–	2,206
For the year ended December 31, 2023			
Depreciation for the year	2,238	–	2,238

	Year ended December 31,	
	2022 *RMB'000*	**2023** *RMB'000*
Expenses relating to short-term leases	63	76
Total cash outflow for leases	63	99
Additions to right-of-use assets	–	11,274

During the Track Record Period, the Group leases property and equipment for its operations. Lease contracts are entered into for fixed term of 5 to 10 years. Lease terms are negotiated on an individual basis and contain a wide range of different terms and conditions. There were no extension options in the lease contracts. In determining the lease term and assessing the length of the non-cancellable period, the Group applies the definition of a contract and determines the period for which the contract is enforceable.

Save for disclosed hereinabove, there was no other outstanding lease commitments relating to offices and equipment.

Restrictions or covenants on leases

As at December 31, 2022 and 2023, the Group's lease liabilities of nil and RMB9,074,000 are recognized with related right-of-use assets of RMB551,000 and RMB9,587,000 respectively. The lease agreements do not impose any covenants other than the security interests in the leased assets that are held by the lessor. Leased assets may not be used as security for borrowing purposes.

Rental concessions

During the Track Record Period, no rental concessions provided by the lessor.

19. IMPAIRMENT TESTING ON INTANGIBLE ASSETS NOT READY FOR USE

Impairment test

IPR&D, which is intangible assets not yet ready for use, is tested impairment annually based on the recoverable amount of the cash-generating unit to which the intangible asset is related. The appropriate cash-generating unit is at the pipeline level.

Impairment review on the IPR&D of the Group has been conducted by the management of the Group by engaging an independent qualified professional valuer, 藍策亞洲(北京)企業管理諮詢有限公司 Valuelink Asia (Beijing) Enterprise Management Consulting Co., Ltd.* ("ValueLink"), to estimate the recoverable amount of the cash-generating unit at the end of each year. The address of ValueLink is Room 511, Jiasheng Center, No. A19, Dongsanhuan Road, Chaoyang District, Beijing, the PRC. For the purpose of impairment review, the recoverable amount of the cash-generating unit is determined based on value in use by using the discounted cash flow approach.

With the assistance of ValueLink, the management determined the recoverable amount of the above cash-generating unit based on the following approach and the key assumptions:

- The cash-generating unit will generate cash inflows starting from year 2027 based on the timing of clinical development and regulatory approval, commercial ramp up to reach expected peak revenue potential till year 2032, and up to the end of the exclusivity for the product; The management considers the length forecast period is appropriate because it generally takes longer for a biopharma company to generate positive cash flows, compared to companies in other industries, especially when the related products are under clinical trial. Hence, the management believes that a forecast period for the cash generating unit longer than five years is justifiable and consistent with industry practice;

- The expected market penetration rate was based on the expected selling conditions considering the features of marketing and technology development;

- The discount rate used is pre-tax and reflect specific risks relating to the relevant products that would be considered by market participants; and

- The expected success rate of commercialization by reference to practices of pharmaceutical industries, development of technologies and related regulations from administrations.

The key parameters used for recoverable amount calculations are as follows:

	As at December 31,	
	2022	**2023**
Expected annual growth rates till 2032	18%~516%	18~516%
Expected market penetration rate	0.6%~11.7%	0.6%~11.7%
Pre-tax discount rate	21.76%	21.05%
Expected success rate of commercialization	13.0%	16.22%

The revenue growth rate for the forecast period and budgeted gross margin were determined by the management based on their expectation for market and product development.

Taking into account that the marketing features and technological advancements related to the indication have remained materially unchanged throughout the Track Record Period, and given that the R&D process of IBC0966 has proceeded as planned, the directors of the Company anticipate that both the "Expected annual growth rates until 2032" and the "Expected market penetration rate" remained consistent throughout the Track Record Period.

Based on the result of the IPR&D impairment testing, the recoverable amount of the cash-generating unit exceeded its carrying amount as at December 31, 2022 and 2023. Thus, no impairment is noted.

* *English name for identification purpose only.*

Impairment test – sensitivity analysis

The Company performed sensitivity test by increasing 1% of discount rate or decreasing of 5% revenue growth rate, which are the key assumptions determine the recoverable amount of the intangible asset, with all other variables held constant. The impacts on the amount by which the intangible asset's recoverable amount above its carrying amount (headroom) are as below:

	As at December 31,	
	2022	**2023**
	RMB'000	*RMB'000*
Headroom	14,900	18,300
Impact by increasing discount rate	(3,800)	(4,700)
Impact by decreasing annual revenue growth rate	(5,900)	(9,000)

If the pre-tax discount rate used as at December 31, 2022 and 2023 was changed to 27.4% and 25.6% respectively, while other parameters remain constant, the recoverable amount of the cash-generating unit would equal its carrying amount. If the annual revenue growth rate used as at December 31, 2022 and 2023 was decreased by 10.1% and 8.0% respectively, while other parameters remain constant, the recoverable amount of the cash-generating unit would equal its carrying amount. Management believes that any reasonably possible changes in key assumptions would not lead to impairment as of December 31, 2022 and 2023.

20. INVESTMENT IN A SUBSIDIARY

The Company

	As at December 31,	
	2022	**2023**
	RMB'000	*RMB'000*
Cost of investment	10,339	192,037

21. DEPOSITS, PREPAYMENTS AND OTHER RECEIVABLES

The Group

	As at December 31,	
	2022	**2023**
	RMB'000	*RMB'000*
Value-added tax recoverable	685	999
Prepayments for research and development costs	6,733	8,303
Relocation incentive *(note 7A (i))*	2,380	–
Prepayments for [**REDACTED**]	[**REDACTED**]	[**REDACTED**]
Deferred [**REDACTED**]	[**REDACTED**]	[**REDACTED**]
Refundable fulfillment deposits	–	2,500
Others	623	1,288
	11,613	18,756
Analyzed as:		
Non-current	–	2,500
Current	11,613	16,256
	11,613	18,756

The Company

	As at December 31,	
	2022	**2023**
	RMB'000	*RMB'000*
Prepayments for [**REDACTED**]	[**REDACTED**]	[**REDACTED**]
Deferred [**REDACTED**]	[**REDACTED**]	[**REDACTED**]
Others	–	690
	1,192	6,356
Analyzed as:		
Current	1,192	6,356

22. INVENTORIES

The Group

	As at December 31,	
	2022	**2023**
	RMB'000	*RMB'000*
Raw materials and consumables	881	818

23. AMOUNTS DUE FROM SHAREHOLDERS/AMOUNTS DUE TO A RELATED PARTY/AMOUNTS DUE TO A SUBSIDIARY

The Group

(a) Amounts due from shareholders

The amounts due from shareholders were non-trade in nature, interest free, unsecured, repayable on demand and were settled on August 3, 2023.

(b) Amounts due to a related party

	As at December 31,	
	2022	**2023**
	RMB'000	*RMB'000*
Non-trade and unsecured		
Loans from Nanjing Bode *(note i)*	11,025	–
Amounts due to Nanjing Bode *(note ii)*	52,556	–
	63,581	–
Analyzed as:		
Non-current	6,206	–
Current	57,375	–
	63,581	–

	As at December 31,	
	2022	2023
	RMB'000	*RMB'000*
Loans from Nanjing Bode analyzed as:		
Within one year	4,819	–
Within a period of more than one year but not exceeding two years	3,255	–
Within a period of more than two years but not exceeding five years	2,951	–
	11,025	–

Notes:

i. On July 1, 2020, December 31, 2020 and December 31, 2021, Sunho (China) Biopharmaceutical and Nanjing Bode entered into three loan agreements, pursuant to which Nanjing Bode agreed to make available a revolving loan facility at a maximum daily balance (excluding the accrued interests) of RMB100,000,000 each, with a term of three years at a fixed interest rate of 3% per annum. On December 31, 2022, the Group entered into an irrevocable and unconditional loan waiver agreement with Nanjing Bode for the loan amount of RMB180,000,000. In December 2023, loans from Nanjing Bode and interests had been fully settled. The maximum amount outstanding during years ended December 31, 2022 and 2023 was RMB191,025,000 and RMB34,515,000, respectively.

ii. The amounts due to Nanjing Bode were non-trade in nature, interest free, repayable on demand and unsecured. On July 6, 2023, Mr. Zhang transferred his entire equity interests in Nanjing Bode to an independent third party. As a result, Nanjing Bode ceased to be a related party to the Group since July 2023, the balance of amounts due to Nanjing Bode had been reclassified to other payables (note 26). These amounts will be settled before [**REDACTED**].

The Company

(a) Amounts due from shareholders

The amounts due from shareholders were non-trade in nature, interest free, unsecured, repayable on demand and were settled on August 3, 2023.

(b) Amounts due to a subsidiary

The amounts due to a subsidiary were non-trade in nature, interest free, unsecured and repayable on demand.

24. OTHER FINANCIAL ASSETS

Other financial assets represented a principal protected short-term investment with an original maturity of three months which carry interest at 5.65% per annum and were issued by an asset management company.

25. CASH AND CASH EQUIVALENTS/TIME DEPOSITS

Cash and cash equivalents include demand deposits and short term deposits for the purpose of meeting the Group's short term cash commitments, which carry interest at market rates range from 0.05% to 5.53%.

Cash and cash equivalents that are denominated in currencies other than the functional currency of the respective group entities are set out below:

	As at December 31,	
	2022	**2023**
	RMB'000	*RMB'000*
USD	–	120,181

Time deposit is denominated in USD and carry fixed rates of 5.7% per annum with original maturity of six months.

26. TRADE AND OTHER PAYABLES

The Group

	As at December 31,	
	2022	**2023**
	RMB'000	*RMB'000*
Payables for research and development costs	3,562	1,305
Accrued research and development costs	1,688	1,833
Accrued staff costs and benefits	2,908	2,561
Accrued [**REDACTED**] and [**REDACTED**]	[**REDACTED**]	[**REDACTED**]
Other payables:		
Payable for equipment	221	1,137
Other payables to Nanjing Bode *(note)*	–	60,285
Others	153	578
Other tax payables	61	53
	8,779	73,960
Analyzed as:		
Current	8,779	73,960

The average credit period on purchases of materials and services of the Group is 10-60 days.

Note: The other payables to Nanjing Bode were non-trade in nature, interest free, unsecured and repayable on demand, and will be settled before [**REDACTED**].

The following is an aging analysis of payables for payables for research and development costs, presented based on the invoice dates at the end of each reporting period:

	As at December 31,	
	2022	**2023**
	RMB'000	*RMB'000*
0 - 30 days	–	140
31 - 60 days	73	–
61 - 90 days	19	–
Over 90 days	3,470	1,165
	3,562	1,305

The Company

	As at December 31,	
	2022	**2023**
	RMB'000	*RMB'000*
Other payables		
[**REDACTED**] and [**REDACTED**]	[**REDACTED**]	[**REDACTED**]
Others	–	76
	186	6,284
Analyzed as:		
Current	186	6,284

27. LEASE LIABILITIES

The Group

	As at December 31,	
	2022	**2023**
	RMB'000	*RMB'000*
Lease liabilities payable:		
Within one year	–	2,178
Within a period of more than one year but not exceeding two years	–	2,245
Within a period of more than two years but not exceeding five years	–	4,651
	–	9,074
Less: Amounts due for settlement with 12 months shown under current liabilities	–	2,178
Amounts due for settlement after 12 months shown under non-current liabilities	–	6,896

The weighted average incremental borrowing rates applied to the lease liabilities was 3.00% per annum for the years ended December 31, 2022 and 2023.

28. FINANCIAL LIABILITIES AT FVTPL

On May 31, 2023, the Company entered into a convertible non-redeemable preferred shares ("Series A Preferred Shares") subscription agreement with two independent investors, pursuant to which the investors made a total investment of RMB210,000,000 in USD equivalent in the Company as consideration for subscription of the Company's 17,500,000 Series A Preferred Shares ("Series A Financing"). In July and August, 2023, the total consideration had been fully settled.

On August 30, 2023, the Company entered into an investment agreement with an independent investor, pursuant to which the investor will subscribe for 5,015,000 Series A Preferred Shares at a total consideration of RMB60,180,000 in USD equivalent ("Series A+ Financing", collectively with "Series A Financing" as "Pre-[**REDACTED**] Investments"). On September 27, 2023, the total consideration had been fully settled.

The key terms of the Pre-[**REDACTED**] Investments are summarized as follows:

Conversion rights

The number of ordinary shares to which a holder shall be entitled upon conversion of each Series A Preferred Share shall be the quotient of the issue price divided by the then effective conversion price, which shall initially be the conversion price resulting in an initial conversion ratio for Series A Preferred Shares of 1:1 subject to adjustment for conversion price.

Any Series A Preferred Share may, at the option of the holder thereof, be converted at any time after the date of issuance of such shares, without the payment of any additional consideration, into fully-paid ordinary shares based on the then-effective conversion price.

Each Series A Preferred Share shall automatically be converted, based on the then-effective conversion price, without the payment of any additional consideration, into fully-paid and non assessable ordinary shares upon the earlier of (i) the [**REDACTED**] or (ii) the date specified by written consent or agreement of the holders representing at least 51% of the then outstanding Series A Preferred Shares.

Liquidation preferences

In the event of any liquidation including deemed liquidation, dissolution or winding up of the Company (the "Liquidation Event"), each holder of Pre-[**REDACTED**] Investments shall be entitled to receive the amount equal to higher of (i) the investment cost; and (ii) the pro rata share of liquidation assets.

Anti-dilution rights

If the Company increases its share capital at a price lower than the price paid by the investors of Pre-[**REDACTED**] Investments on a per share capital basis, the investors have a right to require the Company to issue more new share capital for nil consideration to the investors.

Presentation and classification

The Company elected to designate the Series A Preferred Shares as financial liabilities at FVTPL. The fair value change of the Series A Preferred Shares is charged to fair value change of Series A Preferred Shares in profit or loss except for the portion attributable to credit risk change which shall be charged to other comprehensive income, if any. The management considered that there is no credit risk change on the financial liabilities that drives the fair value change of the Series A Preferred Shares during the Track Record Period.

The fair value of the Pre-[**REDACTED**] Investments at the end of each reporting period is as follows:

	Series A Preferred Share *RMB'000*
As at January 1, 2022 and 2023	–
Recognition of financial liabilities from Series A Financing	210,000
Recognition of financial liabilities from Series A+ Financing	60,180
Change in fair value	41,345
As at December 31, 2023	311,525

29A. PAID-IN/SHARE CAPITAL

The Company was incorporated in the Cayman Islands on May 14, 2021, with authorized share capital of United States dollars ("USD") 100,000 divided into 100,000 shares with a par value of USD1.00 each. On the same date, 45,500 shares of the Company with nominal value of USD45,500 (equivalent to approximately RMB293,000) had been issued to the Company's shareholders.

As at August 30, 2023, the authorized share capital of the Company was re-designated and subdivided from US$100,000 divided into 100,000 Shares with a par value of US$1.00 each to US$100,000 divided into 177,485,000 Shares with a par value of US$0.0005 each and 22,515,000 Series A Preferred Shares with a par value of US$0.0005 each.

	Number of shares	Par value *USD*	Share capital *USD'000*
Authorized			
As at January 1, 2022 and 2023	100,000	1	100
Subdivision on August 30, 2023	200,000,000	0.0005	100
Re-designated to Series A Preferred Shares	(22,515,000)	0.0005	(11)
As at December 31, 2023	177,485,000	0.0005	89

	Number of shares	Par value *USD*	Amount *USD'000*	Equivalent amount of ordinary shares *RMB'000*
Issued and fully paid				
As at January 1, 2022 and 2023	50,000	1	50	322
As at date of Subdivision (August 30, 2023) and December 31, 2023	100,000,000	0.0005	50	322

29B. RESERVES OF THE COMPANY

	Capital reserve *RMB'000*	Share-based payment reserve *RMB'000*	Accumulated losses *RMB'000*	Total *RMB'000*
As at January 1, 2022	6,940	1,360	(3)	8,297
Loss and total comprehensive expense for the year	–	–	(792)	(792)
Recognition of equity-settled share-based payments expenses	–	2,039	–	2,039
Reclassification of vested equity-settled share-based payments	2,720	(2,720)	–	–
As at December 31, 2022	9,660	679	(795)	9,544
Loss and total comprehensive expense for the year	–	–	(67,107)	(67,107)
Recognition of equity-settled share-based payments expenses	–	30,081	–	30,081
Reclassification of vested equity-settled share-based payments	30,760	(30,760)	–	–
As at December 31, 2023	40,420	–	(67,902)	(27,482)

30. SHARE-BASED PAYMENT TRANSACTIONS

Restricted Share Unit Plan

The purpose of the Employee Share Incentive Plan ("Restricted Share Unit/RSU Plan") was to provide incentives to employees and directors in order to promote the success of the business of the Group. To implement the RSU Plan, the Company used employee stock ownership platforms (the "Shareholding Platforms"), namely Sunho Stellar Investments Limited which was established in April 2021 to hold the Company issued 4,500 shares, representing 9% of the shares of the Company.

Under the RSU Plan, eligible employees, directors and consultants shall be nominated as the beneficiary owner of the Shareholding Platforms. No RSU has been granted under the RSU plan as at December 31, 2022.

On May 6, 2023, the employees of the Group and director of the Company were granted a total of 3,000 shares of the Shareholding Platforms, representing 6% of the shares of the Company.

For the RSUs granted to the employees of the Group and directors of the Company, 20% portion of RSUs will be vested on each of the first, second, third, forth and fifth anniversary of the date of completion of [**REDACTED**] ("[**REDACTED**]-based RSU").

On May 16, 2023, the Shareholding Platform transferred 1,500 Shares, representing 3% of the shares of the Company, to Sunho Wisdom, controlled by Mr. Zhang, at par value.

1,500 shares transferred to Sunho Wisdom did not attached any condition and were fully vested during the year ended December 31, 2023 ("Wisdom RSU").

The number of RSU disclosed below has been retrospectively adjusted to reflect the Share Subdivision as described in note 29A.

Set out below are details of the movements of equity-settled share-based payment transactions during the Track Record Period:

	As at January 1, 2022 and December 31, 2022	Granted during the year	Forfeited during the year	Vested during the year	As at December 31, 2023
[**REDACTED**]-based RSU	–	6,000,000	–	–	6,000,000
Wisdom RSU	–	3,000,000	–	(3,000,000)	–
	–	9,000,000	–	(3,000,000)	6,000,000
Directors	–	3,500,000	–	(3,000,000)	500,000
Employees	–	5,500,000	–	–	5,500,000
	–	9,000,000	–	(3,000,000)	6,000,000
Weighted average exercise price (USD)	–	–	–	–	–

Fair value of RSUs granted

Back-solve method were used to determine the underlying equity fair value of the Company and Binomial Option Pricing Model was used to determine the fair value of the RSU granted. The fair value of shares at grant date was valued by directors of the Company with reference to valuation reports carried out by an independent qualified professional valuer, ValueLink, whose address is disclosed in note 19. The fair value of RSU at grant date was determined by taking into account of the fair value of the equity of the Company amounting to RMB9.78 per share and the purchase price of the RSU is nil. The inputs into the model were as follows:

	May 2023
Expected volatility	33.25%
Risk-free rate	2.34%
Expected dividend yield	0%

The Group recognized the total expense of RMB29,325,000 for the year ended December 31, 2023 in relation to RSUs transferred to Mr. Zhang.

As of December 31, 2023, the director of the Company believes that it is not probable that there will be a successful [**REDACTED**]; therefore, the number of equity instruments expected to vest is zero. As a result, no expenses recognized for the year ended December 31, 2023.

Other Share Incentive Plan

To reward Dr. Yin's contribution, Dr. Yin had been granted 5% equity interest of Sunho (China) Biopharmaceutical in November 2020, 50% of granted shares would be vested from the first anniversary year from the grant date, 25% of granted shares would be vested from the second and third anniversary year from the grant date. The fair value of aforementioned shares at grant date was RMB10,878,000. In 2021, the equity interest granted to Dr. Yin had been replaced as the issued shares of the Company ("Share Replacement"), the Share Replacement had no material impact on neither the vesting conditions nor fair value. Discounted cash flows method was used to determine the fair value of the shares granted. The Group recognized expense of RMB2,039,000 and RMB756,000 for the years ended December 31, 2022 and 2023 in relation to shares granted.

The key parameters used in discounted cash flows method are as follows:

	As at November 30, 2020
Expected annual growth rates till 2032	3%~516%
Expected market penetration rate	0.1%~14.8%
Terminal growth rate	2%
Discount rate	17.5%
Expected success rate of commercialization	4.6%~9.2%

31. RELATED PARTY TRANSACTIONS

Save for disclosed in note 23 and note 30, the Group has the following transactions and balances with the related parties during the Track Record Period.

(a) Names and relationships with related parties

The following companies are related parties of the Group that had transactions with the Group during the Track Record Period.

Name of related parties	Relationships
Sunho Wisdom	Shareholder of the Company
No5XJR Limited	Shareholder of the Company
Sunho Stellar Investments Limited	Shareholder of the Company
Nanjing Bode *(note)*	Controlled by Mr. Zhang

Note: As disclosed in note 23(b)(ii), Nanjing Bode ceased to be a related party to the Group since July 6, 2023. Consequently, the transactions disclosed below only shows the transactions occurred before July 6, 2023.

(b) Transactions with related parties

Details of the transactions with related parties are set out below.

	Year ended December 31,	
	2022	**2023**
	RMB'000	*RMB'000*
Loan waived by Nanjing Bode *(note 23(b)(i))*	180,000	–
Purchase of machinery and equipment from Nanjing Bode	–	–
Interest expenses on borrowing from Nanjing Bode	5,055	164

(c) Leases with a related party

The Group entered into several leases with Nanjing Bode in previous years. For each reporting period, the Group recognized lease liabilities and interest expenses as follows:

	As at December 31,	
	2022	**2023**
	RMB'000	*RMB'000*
Lease liabilities of Nanjing Bode	–	–

	Year ended December 31,	
	2022	**2023**
	RMB'000	*RMB'000*
Interest expenses on lease liabilities of Nanjing Bode	19	44

(d) Other outstanding balances with related parties

Save for the amounts due to a related party disclosed in note 23, details of the amounts due from shareholders are set out below.

	As at January 1, 2022	As at December 31, 2022	As at December 31, 2023	Maximum amount outstanding during the year ended December 31, 2022	Maximum amount outstanding during the year ended December 31, 2023
	RMB'000	*RMB'000*	*RMB'000*	*RMB'000*	*RMB'000*
Amounts due from shareholders					
Sunho Wisdom	271	296	–	296	315
No5XJR Limited	19	21	–	21	22
	290	317	–		

The amounts due from shareholders were non-trade in nature, interest free, unsecured, repayable on demand and were settled on August 3, 2023.

(e) Compensation of key management personnel

The remuneration of the directors of the Company and key management of the Group during the Track Record Period were as follows:

	Year ended December 31, 2022	Year ended December 31, 2023
	RMB'000	*RMB'000*
Salaries and other benefits	2,230	2,346
Discretionary bonus *(note)*	337	360
Retirement benefit scheme contributions	87	76
Share-based payments	2,039	30,081
	4,693	32,863

Note: Discretionary bonus is determined based on their duties and responsibilities of the relevant individuals within the Group and the Group's performance.

32. CAPITAL COMMITMENT

	As at December 31, 2022	As at December 31, 2023
	RMB'000	*RMB'000*
Capital expenditure contracted for but not provided in the Historical Financial Information:		
– Leasehold land and equipment	1,015	18,610

33. CAPITAL RISK MANAGEMENT

The Group manages its capital to ensure that entities in the Group will be able to continue as a going concern while maximizing the return to investors through the optimization of the debt and equity balance. The Group's overall strategy remains unchanged throughout the Track Record Period.

The capital structure of the Group consists of net debts, which includes financial liabilities at FVTPL disclosed in note 28, amounts due to Nanjing Bode disclosed in note 26, lease liabilities disclosed in note 27, net of bank balances and time deposits disclosed in note 25, other financial assets disclosed in note 24 and equity attributable to owners of the Company, comprising share capital and reserves.

The management of the Group reviews the capital structure regularly. As part of this review, the management of the Group considers the cost of capital. Based on recommendations of the management of the Group, the Group will balance its overall capital structure through the new share issues as well as the issue of new debt.

34. FINANCIAL INSTRUMENTS

(a) Categories of financial instruments

The Group

	As at December 31,	
	2022	**2023**
	RMB'000	*RMB'000*
Financial assets		
Amortized cost		
Refundable fulfillment deposit *(note 21)*	–	2,500
Other receivables *(note 21)*	2,380	729
Amounts due from shareholders *(note 23)*	317	–
Other financial assets *(note 24)*	–	49,579
Time deposits *(note 25)*	–	35,414
Cash and cash equivalents *(note 25)*	1,821	125,074
Financial liabilities		
Amortized cost		
Amounts due to a related party *(note 23)*	63,581	–
Trade and other payables *(note 26)*	3,936	63,305
FVTPL		
Financial liabilities at FVTPL *(note 28)*	–	311,525

The Company

	As at December 31,	
	2022	**2023**
	RMB'000	*RMB'000*
Financial assets		
Amortized cost		
Other receivables *(note 21)*	–	690
Amounts due from shareholders *(note 23)*	346	–
Time deposits *(note 25)*	–	35,414
Cash and cash equivalents *(note 25)*	–	72,854
Financial liabilities		
Amortized cost		
Other payables *(note 26)*	186	–
Amounts due to a subsidiary *(note 23)*	1,825	16,012
FVTPL		
Financial liabilities at FVTPL *(note 28)*	–	311,525

(b) Financial risk management objectives and policies

The Group's major financial assets and liabilities include refundable fulfillment deposit, other receivables, other financial assets, time deposits, cash and cash equivalents, trade and other payables and financial liabilities at FVTPL. The Company's major financial assets and liabilities include other receivables, time deposits, cash and cash equivalents, other payables, amounts due to a subsidiary and financial liabilities at FVTPL. Details of these financial assets and liabilities are disclosed in respective notes.

The risks associated with these financial assets and liabilities include market risks (currency risk and interest rate risk), credit risk and liquidity risk. The policies on how to mitigate these risks are set out below. The management of the Group manages and monitors these exposures to ensure appropriate measures are implemented on a timely and effective manner.

Market risk

The Group's and the Company's activities expose it primarily to currency risk, interest rate risk and other price risk. There has been no change in the manner in which the Group and the Company manages and measures the risks.

(i) Currency risk

Certain financial assets and liabilities are denominated in foreign currency of respective group entities which are exposed to foreign currency risk. The Group currently does not have a foreign currency hedging policy. However, the management monitors foreign exchange exposure and will consider hedging significant foreign currency exposure should the need arise.

The carrying amounts of the Group's and the Company's foreign currency denominated monetary assets and liabilities at the end of each reporting period are mainly as follows:

The Group

	As at December 31,	
	2022	**2023**
	RMB'000	*RMB'000*
Assets		
USD	317	155,595
Liabilities		
USD	–	(5,869)

The Company

	As at December 31,	
	2022	**2023**
	RMB'000	*RMB'000*
Assets		
USD	346	108,258
Liabilities		
USD	–*	(5,869)

* *Amount less than RMB1,000*

Sensitivity analysis

The following table details the Group's and the Company's sensitivity to a 5% increase and decrease in RMB against USD, the foreign currency with which the Group and the Company may have a material exposure. 5% represents management's assessment of the reasonably possible change in foreign exchange rate. The sensitivity analysis uses outstanding foreign currency denominated monetary items as a base and adjusts their translation at the end of each reporting period for a 5% change in foreign currency rate. A negative number below indicates an increase in loss where RMB strengthens 5% against USD. For a 5% weakening of RMB against USD, there would be an equal and opposite impact on loss for the year.

	Year ended December 31,	
	2022	**2023**
	RMB'000	*RMB'000*
Impact on profit or loss		
The Group		
USD	(16)	(7,486)

	Year ended December 31,	
	2022	**2023**
	RMB'000	*RMB'000*
Impact on profit or loss		
The Company		
USD	(17)	(5,119)

(ii) Interest rate risk

The Group is primarily exposed to fair value interest rate risk in relation to lease liabilities and loan from Nanjing Bode. The Group currently does not have an interest rate hedging policy to mitigate interest rate risk; nevertheless, the management monitors interest rate exposure and will consider hedging significant interest rate risk should the need arise.

The Group considers that the exposure of cash flow interest rate risk arising from variable-rate bank balances is insignificant because the current market interest rates are relatively low and stable.

(iii) Other price risk

The Group and the Company are exposed to other price risk arising from other financial liabilities at FVTPL.

Sensitivity analysis

The sensitivity analysis below have been determined based on the exposure to equity price risk at the reporting date for financial liabilities at FVTPL.

If the equity value of the Company had been changed based on the 5% higher/lower:

The Group and the Company

- the post-tax loss of the Group for the year ended December 31, 2023 would increase by approximately RMB13,027,000 and decrease by approximately RMB13,249,000.

Credit risk

The Group's maximum exposure to credit risk which will cause a financial loss to the Group is arising from the amount of bank balances, other financial assets, refundable fulfillment deposits and other receivables disclosed in the consolidated statements of financial position. The Group does not hold any collateral or other credit enhancements to cover its credit risks associated with its financial assets.

Bank balances and other financial assets

The credit risk on bank balances and other financial assets is limited because the counterparties are reputable financial institutions. The Group assessed 12m ECL for bank balances and other financial assets by reference to information relating to probability of default and loss given default of the respective credit rating grades published by external credit rating agencies. Based on the average loss rates, the 12m ECL on bank balances and other financial assets is considered to be insignificant and therefore no loss allowance was recognized.

Refundable fulfilment deposits and other receivables

For refundable fulfilment deposits and other receivables, the management makes periodic individual assessment on the recoverability of refundable fulfilment deposits and other receivables based on historical settlement records, past experience, and also quantitative and qualitative information that is reasonable and supportive forward-looking information. The management believes that there are no significant increase in credit risk of these amounts since initial recognition and the Group provided impairment based on 12m ECL. For the years ended December 31, 2022 and 2023, the Group assessed the ECL for refundable fulfilment deposits and other receivables are insignificant and thus no loss allowance is recognised.

Liquidity risk

In the management of the liquidity risk, the Group and the Company monitors and maintains a level of cash and cash equivalents deemed adequate by the management to finance the Group's and the Company's operations and mitigate the effects of fluctuations in cash flows.

The following table details the Group's and the Company's remaining contractual maturity for its financial liabilities. The table has been drawn up based on the undiscounted cash flows of financial liabilities based on the earliest date on which the Group can be required to pay. The table includes both interest and principal cash flows.

	Weighted Average effective interest rate	**Within 1 year or on demand**	**1 to 2 years**	**2 to 5 years**	**Total**	**Carrying amount**
		RMB'000	*RMB'000*	*RMB'000*	*RMB'000*	*RMB'000*
The Group						
As at December 31, 2022						
Trade and other payables	–	3,936	–	–	3,936	3,936
Amounts due to a related party	–	52,556	–	–	52,556	52,556
Loan from a related party	3.00%	4,819	3,255	3,794	11,868	11,025
		61,311	3,255	3,794	68,360	67,517
As at December 31, 2023						
Trade and other payables	–	63,305	–	–	63,305	63,305
Financial liabilities at FVTPL	–	311,525	–	–	311,525	311,525
Lease liabilities	3.00%	2,400	2,400	4,756	9,556	9,074
		377,230	2,400	4,756	384,386	383,904

	Weighted Average effective interest rate	Within 1 year or on demand	1 to 2 years	2 to 5 years	Total	Carrying amount
		RMB'000	*RMB'000*	*RMB'000*	*RMB'000*	*RMB'000*
The Company						
As at December 31, 2022						
Other payables	–	186	–	–	186	186
Amounts due to a subsidiary	–	1,825	–	–	1,825	1,825
		2,011	–	–	2,011	2,011
As at December 31, 2023						
Amounts due to a subsidiary	–	16,012	–	–	16,012	16,012
Financial liabilities at FVTPL	–	311,525	–	–	311,525	311,525
		327,537	–	–	327,537	327,537

(c) Fair value measurements of financial instruments

The fair value of financial assets and financial liabilities are determined in accordance with general accepted pricing models.

(i) Fair value of the Group's financial liabilities that are measured at fair value on a recurring basis

Some of the Group's financial liabilities are measured at fair value at the end of each reporting period. The following table gives information about how the fair values of the financial liabilities are determined (in particular, the valuation techniques and inputs used).

Financial liabilities	Fair value as at December 31, 2022 *RMB'000*	2023 *RMB'000*	Fair value hierarchy	Valuation Techniques and key inputs	Significant Unobservable inputs	Relationship of unobservable inputs to fair value
The Group						
Financial liabilities at FVTPL	–	311,525	Level 3	Discounted cash flow method – the key input is discount rate Binomial Option Pricing Model – the key inputs are: [**REDACTED**] probability, risk free interest rate, volatility and dividend yield.	Volatility 2023: [32.8%] Discount rate: 2023: [16.0]%	Volatility and fair value are nonlinear related; *(note i)* The higher the discount rate, the lower the fair value *(note ii)*

Notes:

i. A 5% increase/decrease in volatility, while all other variables keep constant, would increase the carrying amount of other financial liabilities at FVTPL of the Group as at December 31, 2023 by RMB2,909,000, decrease the carrying amount as at December 31, 2023 by RMB2,898,000.

ii. A 1% increase/decrease in discount rate, while all other variables keep constant, would decrease the carrying amount of other financial liabilities at FVTPL of the Group as at December 31, 2023 by RMB31,713,000, increase the carrying amount as at December 31, 2023 by RMB39,411,000.

There were no transfers between level 1 and level 2 during the Track Record Period.

(ii) Fair value measurement and valuation process

In estimating the fair value of an asset or a liability, the Group uses market-observable data to the extent it is available. For instruments with significant unobservable inputs under Level 3, the Group engages third party qualified valuers to perform the valuation at the end of each reporting period. The finance department of the Company works closely with the qualified external valuers to establish the appropriate valuation techniques and inputs to the model.

Of the total gains or losses for the year ended December 31, 2023 included in profit or loss, RMB41,345,000 loss relates to financial liabilities at FVTPL held during the Track Record Period. Fair value gains or losses on other financial liabilities as at FVTPL are included in 'other gains and losses, net'.

(iii) Fair value of financial assets and financial liabilities that are not measured at fair value

The directors of the Company consider that the carrying amount of the Group's and the Company's financial assets and financial liabilities recorded at amortized cost in the Historical Financial Information approximate to their fair values. Such fair values have been determined in accordance with generally accepted pricing models based on a discounted cash flow analysis.

35. RETIREMENT BENEFIT PLANS

The employees of the Group in the PRC are members of the state-sponsored retirement benefit scheme organized by the relevant local government authority in the PRC. The PRC entities are required to contribute, based on a certain percentage of the payroll costs of their employees, to the retirement benefit scheme and has no further obligations for the actual payment of pensions or post-retirement benefits beyond the annual contributions. The total amount provided by the Group to the scheme in the PRC and charged to profit or loss are RMB1,309,000 and RMB1,287,000 for the years ended December 31, 2022 and 2023 respectively.

36. PARTICULARS OF SUBSIDIARIES

As at December 31, 2022 and 2023 and as at the date of the report, the Group's subsidiaries are as follows:

Name of subsidiaries	Place/country and date of establishment/ incorporation/ operations	Issued share/ registered capital	Equity interest attributable to the Company			Principal activities
			As at December 31,		As at the date of the report	
			2022	2023		
Directly held						
Sunho bio Investments *(note i)*	The BVI/ June 1, 2021	USD1	100%	100%	[100%]	Investment holding
Indirectly held						
Sunho (HK) Limited *(note ii)*	Hong Kong/ July 9, 2021	HK$1	100%	100%	[100%]	Investment holding
Sunho Pharmaceutical Technology (Zhejiang Anji) Co., Ltd.* (盛禾醫藥科技(浙江安吉)有限公司) *(note iii)*	The PRC/ December 30, 2021	RMB155,000,000	100%	100%	[100%]	Research and development of immune drugs
Sunho (China) Biopharmaceutical *(note iii)*	The PRC/ April 2, 2018	RMB187,682,553	100%	100%	[100%]	Research and development of immune drugs
Nanjing Sunho Medical Technology Co., Ltd.* (南京盛禾醫學技術有限公司) *(note iii)*	The PRC/ August 13, 2020	RMB5,000,000	100%	100%	[100%]	Research and development of immune drugs
Sunho (Zhejiang) Biopharmaceutical Co., Ltd.* (盛禾(浙江)生物製藥有限公司) *(note iv)*	The PRC/ March 17, 2023	RMB30,000,000	N/A	100%	[100%]	Research and development of immune drugs

* *English name for identification purpose only*

All of the subsidiaries adopted December 31 as financial year end.

None of the subsidiaries has issued any debt securities as at December 31, 2022 and 2023.

Notes:

i No statutory audited financial statements of the entity have been prepared since its date of incorporation as it is incorporated in a jurisdiction where there are no statutory audit requirements.

ii The statutory financial statement of this subsidiary for the period from July 9, 2021 to December 31, 2022 was prepared in accordance with the Hong Kong Small and Medium-sized Entity Financial Reporting Standard and were audited by ICS CPA Limited registered in Hong Kong. The statutory financial statements of this subsidiary for the year ended December 31, 2023 has not been issued.

iii The statutory financial statement of these subsidiaries for the year ended December 31, 2022 were prepared in accordance with China's Accounting Standards for Smaller Business Enterprises and were audited by 江蘇蘇瑞華會計師事務所有限公司/Jiangsu Suruihua Certified Public Accountants Co., Ltd.* registered in the PRC. The statutory financial statements of these subsidiaries for the year ended December 31, 2023 have not been issued.

iv No statutory financial statements have been prepared for this subsidiary since its respective date of establishment as it is not due or required for issue.

37. RECONCILIATION OF ASSETS AND LIABILITIES ARISING FROM FINANCING ACTIVITIES

The table below details changes in the Group's assets and liabilities arising from financing activities, including both cash and non-cash changes. Liabilities arising from financing activities are those for which cash flows were, or future cash flows will be, classified in the Group's consolidated statement of cash flows as cash flows from financing activities.

	Amounts due from shareholders *RMB'000*	**Amounts due to a related party** *RMB'000*	**Financial liabilities at FVTPL** *RMB'000*	**Deferred [REDACTED]** *RMB'000*	**Other payables** *RMB'000*	**Lease liabilities** *RMB'000*	**Total** *RMB'000*
As at January 1, 2022	(290)	173,094	–	[REDACTED]	–	2,450	175,254
Financing cash flow	–	27,560	–	[REDACTED]	–	–	27,104
Non-cash changes							
Net foreign exchange gain	(27)	–	–	[REDACTED]	–	–	(27)
Finance costs	–	–	–	[REDACTED]	–	19	19
Reclassification of amounts due to Nanjing Bode	–	2,469	–	[REDACTED]	–	(2,469)	–
Interest expenses on borrowing from Nanjing Bode	–	5,055	–	[REDACTED]	–	–	5,055
Loan waived by Nanjing Bode *(note 23(b)(i))*	–	(180,000)	–	[REDACTED]	–	–	(180,000)
Accrued [REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
As at December 31, 2022	(317)	28,178	–	[REDACTED]	47	–	27,405

	Amounts due from shareholders *RMB'000*	Amounts due to a related party *RMB'000*	Financial liabilities at FVTPL *RMB'000*	Deferred [REDACTED] *RMB'000*	Other payables *RMB'000*	Lease liabilities *RMB'000*	Total *RMB'000*
Financing cash flow	337	23,000	270,180	[REDACTED]	(34,515)	(23)	255,497
Non-cash changes							
Net foreign exchange gain	(20)	–	–	[REDACTED]	–	–	(20)
Finance cost	–	–	–	[REDACTED]	–	201	201
New lease entered	–	–	–	[REDACTED]	–	11,274	11,274
Reclassification of amounts due to Nanjing Bode	–	(51,342)	–	[REDACTED]	53,720	(2,378)	–
Interest expenses on borrowing from Nanjing Bode	–	164	–	[REDACTED]	327	–	491
Accrued [REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Loss from fair value change of financial liabilities at FVTPL	–	–	41,345	[REDACTED]	–	–	41,345
As at December 31, 2023	–	–	311,525	[REDACTED]	20,815	9,074	336,193

38. MAJOR NON-CASH TRANSACTIONS

During the Track Record Period, the Group entered into new lease agreements for property for 5 years. On the lease commencement, the Group recognized right-of-use assets amounting to RMB11,274,000 and lease liabilities amounting to RMB11,274,000 for the year ended December 31, 2023.

On December 31, 2022, the Group entered into an irrevocable and unconditional loan waiver agreement with Nanjing Bode for the loan amount of RMB180,000,000.

39. CONTINGENT LIABILITIES

During the Track Record Period, certain subsidiaries of the Group failed to make full contributions to the social insurance and housing provident fund for their employees in accordance with the relevant regulations and provisions. Based on the relevant rules and regulations, the under provision of the social insurance and housing provident fund contributions are approximately RMB2,841,000 and RMB2,845,000 for the years ended December 31, 2022 and 2023, respectively. The management of the Group has, taking into account the relevant facts and circumstances, and advice sought from the Group's PRC legal advisers, considered that it is not probable for the Company to be requested by the relevant authorities to pay such outstanding amounts and relevant material penalties, therefore, no provision has been made as at each reporting date and during the Track Record Period.

40. SUBSEQUENT EVENTS

There are no material subsequent events undertaken by the Company or by the Group after December 31, 2023 and up to the date of this report.

41. SUBSEQUENT FINANCIAL STATEMENTS

No audited financial statements of the Group, the Company or any of its subsidiaries have been prepared in respect of any period subsequent to [December 31, 2023] and up to the date of this report.

[**REDACTED**]

[**REDACTED**]

[**REDACTED**]

[**REDACTED**]

[**REDACTED**]

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SUMMARY OF THE CONSTITUTION OF THE COMPANY

1 Memorandum of Association

The Memorandum of Association of the Company was conditionally adopted on [●] and states, inter alia, that the liability of the members of the Company is limited, that the objects for which the Company is established are unrestricted and the Company shall have full power and authority to carry out any object not prohibited by the Companies Act or any other law of the Cayman Islands.

The Memorandum of Association is on display on the websites of the Stock Exchange and the Company as specified in Appendix V in the section headed "Documents Delivered to the Registrar of Companies and Documents on Display".

2 Articles of Association

The Articles of Association of the Company were conditionally adopted on [●] and include provisions to the following effect:

2.1 Directors

(a) Power to allot and issue Shares

Subject to the provisions in the Memorandum of Association (and to any direction that may be given by the Company in general meeting) and without prejudice to any rights attached to any existing shares, the Directors may allot, issue, grant options over or otherwise dispose of shares with or without preferred, deferred or other rights or restrictions, whether in regard to dividend or other distribution, voting, return of capital or otherwise and to such persons, at such times and on such other terms as the Directors think proper.

(b) Power to dispose of the assets of the Company or any subsidiary

Subject to the provisions of the Companies Act, the Memorandum and Articles of Association and to any directions given by special resolution, the business of the Company shall be managed by the Directors who may exercise all the powers of the Company. No alteration of the Memorandum and Articles of Association and no such direction shall invalidate any prior act of the Directors which would have been valid if that alteration had not been made or that direction had not been given.

(c) Compensation or payment for loss of office

There are no provisions in the Articles of Association relating to compensation or payment for loss of office of a Director.

(d) Loans to Directors

There are no provisions in the Articles of Association relating to making of loans to Directors.

(e) Financial assistance to purchase Shares

There are no provisions in the Articles of Association relating to the giving of financial assistance by the Company to purchase shares in the Company or its subsidiaries.

(f) Disclosure of interest in contracts with the Company or any of its subsidiaries

No person shall be disqualified from the office of Director or alternate Director or prevented by such office from contracting with the Company, either as vendor, purchaser or otherwise, nor shall any such contract or any contract or transaction entered into by or on behalf of the Company in which any Director or alternate Director shall be in any way interested be or be liable to be avoided, nor shall any Director or alternate Director so contracting or being so interested be liable to account to the Company for any profit realised by or arising in connection with any such contract or transaction by reason of such Director or alternate Director holding office or of the fiduciary relationship thereby established, provided that the nature of the interest of any Director or any alternate Director in any such contract or transaction shall be disclosed by them at or prior to its consideration and any vote thereon.

A Director shall not be entitled to vote on (nor shall the Director be counted in the quorum in relation to) any resolution of the Directors in respect of any contract or arrangement or any other proposal in which the Director or any of his close associates has any material interest, and if he shall do so his vote shall not be counted (nor shall he be counted in the quorum for the resolution), but this prohibition shall not apply to any of the following matters, namely:

(i) the giving to such Director or any of his close associates of any security or indemnity in respect of money lent or obligations incurred or undertaken by him or any of them at the request of or for the benefit of the Company or any of its subsidiaries;

(ii) the giving of any security or indemnity to a third party in respect of a debt or obligation of the Company or any of its subsidiaries for which the Director or any of his close associates has himself/themselves assumed responsibility in whole or in part and whether alone or jointly under a guarantee or indemnity or by the giving of security;

(iii) any proposal concerning an offer of shares, debentures or other securities of or by the Company or any other company which the Company may promote or be interested in for subscription or purchase where the Director or any of his close associates is/are or is/are to be interested as a participant in the underwriting or sub-underwriting of the offer;

(iv) any proposal or arrangement concerning the benefit of employees of the Company or any of its subsidiaries including:

(A) the adoption, modification or operation of any employees' share scheme or any share incentive scheme or share option scheme under which the Director or any of his close associates may benefit; or

(B) the adoption, modification or operation of a pension fund or retirement, death or disability benefits scheme which relates to the Director, his close associates and employees of the Company or any of its subsidiaries and does not provide in respect of any Director or any of his close associates, as such any privilege or advantage not generally accorded to the class of persons to which such scheme or fund relates; and

(v) any contract or arrangement in which the Director or any of his close associates is/are interested in the same manner as other holders of shares or debentures or other securities of the Company by virtue only of their interest in shares or debentures or other securities of the Company.

(g) Remuneration

The remuneration to be paid to the Directors, if any, shall be such remuneration as the Directors shall determine. The Directors shall also be entitled to be paid all travelling, hotel and other expenses properly incurred by them in connection with their attendance at meetings of Directors or committees of Directors, or general meetings of the Company, or separate meetings of the holders of any class of shares or debentures of the Company, or otherwise in connection with the business of the Company or the discharge of their duties as a Director, or to receive a fixed allowance in respect thereof as may be determined by the Directors, or a combination partly of one such method and partly the other.

The Directors may approve additional remuneration to any Director for any services which in the opinion of the Directors go beyond that Director's ordinary routine work as a Director. Any fees paid to a Director who is also counsel, attorney or solicitor to the Company, or otherwise serves it in a professional capacity shall be in addition to their remuneration as a Director.

(h) Retirement, appointment and removal

The Company may by ordinary resolution appoint any person to be a Director, either to fill a vacancy or as an additional Director.

The Company may by ordinary resolution remove any Director (including a managing or other executive Director) before the expiration of such Director's term of office, notwithstanding anything in the Articles of Association or in any agreement between the Company and such Director, and may by ordinary resolution elect another person in their stead. Nothing shall be taken as depriving a Director so removed of compensation or damages payable to such Director in respect of the termination of his appointment as Director or of any other appointment or office as a result of the termination of his appointment as Director.

The Directors may appoint any person to be a Director, either to fill a vacancy or as an additional Director provided that the appointment does not cause the number of Directors to exceed any number fixed by or in accordance with the Articles of Association as the maximum number of Directors. Any Director so appointed shall hold office only until the first annual general meeting of the Company after such Director's appointment and shall then be eligible for re-election at that meeting.

There is no shareholding qualification for Directors nor is there any specified age limit for Directors.

The office of a Director shall be vacated if:

(i) the Director gives notice in writing to the Company that he resigns the office of Director;

(ii) the Director is absent (for the avoidance of doubt, without being represented by proxy or an alternate Director appointed by him) for a continuous period of 12 months without special leave of absence from the Directors, and the Directors pass a resolution that he has by reason of such absence vacated office;

(iii) the Director dies, becomes bankrupt or makes any arrangement or composition with his creditors generally;

(iv) the Director is found to be or becomes of unsound mind; or

(v) the Director is removed from office by notice in writing served upon such Director signed by not less than three-fourths in number (or, if that is not a round number, the nearest lower round number) of the Directors then in office (including such Director).

At every annual general meeting of the Company, one-third of the Directors for the time being, or, if their number is not three or a multiple of three, then the number nearest to, but not less than, one-third, shall retire from office by rotation, provided that every Director (including those appointed for a specific term) shall be subject to retirement by rotation at least once every three years. A retiring Director shall retain office until the close of the meeting at which he retires and shall be eligible for re-election at such meeting. The Company at any annual general meeting at which any Directors retire may fill the vacated office by electing a like number of persons to be Directors.

(i) Borrowing powers

The Directors may exercise all the powers of the Company to borrow money and to mortgage or charge its undertaking, property and assets (present and future) and uncalled capital or any part thereof and to issue debentures, debenture stock, mortgages, bonds and other such securities whether outright or as security for any debt, liability or obligation of the Company or of any third party.

2.2 Alteration to constitutional documents

No alteration or amendment to the Memorandum or Articles of Association may be made except by special resolution.

2.3 Variation of rights of existing shares or classes of shares

If at any time the share capital of the Company is divided into different classes of shares, all or any of the rights attached to any class for the time being issued (unless otherwise provided by the terms of issue of the shares of that class) may, whether or not the Company is being wound up, be varied only with the consent in writing of the holders of not less than three-fourths of the voting rights of the issued shares of that class, or with the approval of a resolution passed by not less than three-fourths of the votes cast at a separate meeting of the holders of the shares of that class. To any such meeting, all the provisions of the Articles of Association relating to general meetings shall apply *mutatis mutandis*, except that the necessary quorum shall be one or more persons holding or representing by proxy or duly authorised representative at least one-third of the voting rights of the issued shares of that class.

The rights conferred upon the holders of shares of any class shall not, unless otherwise expressly provided in the rights attaching to or the terms of issue of the shares of that class, be deemed to be varied by the creation or issue of further shares ranking *pari passu* therewith.

2.4 Alteration of capital

The Company may by ordinary resolution:

(a) increase its share capital by such sum as the ordinary resolution shall prescribe and with such rights, priorities and privileges annexed thereto, as the Company in general meeting may determine;

(b) consolidate and divide all or any of its share capital into shares of larger amount than its existing shares. On any consolidation of fully paid shares and division into shares of larger amount, the Directors may settle any difficulty which may arise as they think expedient and in particular (but without prejudice to the generality of the foregoing) may as between the holders of shares to be consolidated determine which particular shares are to be consolidated into each consolidated share, and if it shall happen that any person shall become entitled to fractions of a consolidated share or shares, such fractions may be sold by some person appointed by the Directors for that purpose and the person so appointed may transfer the shares so sold to the purchasers thereof and the validity of such transfer shall not be questioned, and so that the net proceeds of such sale (after deduction of the expenses of such sale) may either be distributed among the persons who would otherwise be entitled to a fraction or fractions of a consolidated share or shares rateably in accordance with their rights and interests or may be paid to the Company for the Company's benefit;

(c) by subdivision of its existing shares or any of them divide the whole or any part of its share capital into shares of smaller amount than is fixed by the Memorandum of Association or into shares without par value; and

(d) cancel any shares that at the date of the passing of the ordinary resolution have not been taken or agreed to be taken by any person and diminish the amount of its share capital by the amount of the shares so canceled.

The Company may by special resolution reduce its share capital or any capital redemption reserve fund, subject to the provisions of the Companies Act.

2.5 Special resolution – majority required

A "special resolution" is defined in the Articles of Association to have the same meaning as in the Companies Act, for which purpose, the requisite majority shall be not less than three-fourths of the votes of such members of the Company as, being entitled to do so, vote in person or, in the case of corporations, by their duly authorised representatives or, where proxies are allowed, by proxy at a general meeting of which notice specifying the intention to propose the resolution as a special resolution has been

duly given and includes a special resolution approved in writing by all of the members of the Company entitled to vote at a general meeting of the Company in one or more instruments each signed by one or more of such members, and the effective date of the special resolution so adopted shall be the date on which the instrument or the last of such instruments (if more than one) is executed.

In contrast, an "ordinary resolution" is defined in the Articles of Association to mean a resolution passed by a simple majority of the votes of such members of the Company as, being entitled to do so, vote in person or, in the case of corporations, by their duly authorised representatives or, where proxies are allowed, by proxy at a general meeting held in accordance with the Articles of Association and includes an ordinary resolution approved in writing by all the members of the Company aforesaid.

2.6 Voting rights

Subject to any rights or restrictions attached to any shares, at any general meeting every member of the Company present in person (or, in the case of a member being a corporation, by its duly authorised representative) or by proxy shall have (a) the right to speak; (b) one vote on a show of hands; and (c) one vote for every share of which he is the holder on a poll.

Where any member is, under the Listing Rules, required to abstain from voting on any particular resolution or restricted to voting only for or only against any particular resolution, any votes cast by or on behalf of such member in contravention of such requirement or restriction shall not be counted.

In the case of joint holders the vote of the senior holder who tenders a vote, whether in person or by proxy (or in the case of a corporation or other non-natural person, by its duly authorised representative or proxy) shall be accepted to the exclusion of the votes of the other joint holders, and seniority shall be determined by the order in which the names of the holders stand in the register of members of the Company.

A member of unsound mind, or in respect of whom an order has been made by any court having jurisdiction in lunacy, may vote, whether on a show of hands or on a poll, by their committee, receiver, curator bonis, or other person on such member's behalf appointed by that court, and any such committee, receiver, curator bonis or other person may vote by proxy.

No person shall be counted in a quorum or be entitled to vote at any general meeting unless he is registered as a member on the record date for such meeting, nor unless all calls or other monies then payable by him in respect of shares have been paid.

At any general meeting a resolution put to the vote of the meeting shall be decided by way of a poll save that the chairperson of the meeting may allow a resolution which relates purely to a procedural or administrative matter as prescribed under the Listing Rules to be voted on by a show of hands.

Any corporation or other non-natural person which is a member of the Company may in accordance with its constitutional documents, or in the absence of such provision by resolution of its directors or other governing body, authorise such person as it thinks fit to act as its representative at any meeting of the Company or of any class of members, and the person so authorised shall be entitled to exercise the same powers as the corporation could exercise if it were an individual member.

If a recognised clearing house (or its nominee(s)) is a member of the Company it may authorise or appoint such person or persons as it thinks fit to act as its representative(s) or proxy(ies) at any general meeting of the Company or at any general meeting of any class of members of the Company, provided that, if more than one person is so authorised or appointed, the authorisation or form of proxy shall specify the number and class of shares in respect of which each such person is so authorised or appointed. A person authorised or appointed pursuant to this provision shall be entitled to exercise the same rights and powers on behalf of the recognised clearing house (or its nominee(s)) which that person represents as that recognised clearing house (or its nominee(s)) could exercise as if such person were an individual member of the Company holding the number and class of shares specified in such authorisation or form of proxy, including, the right to speak and, where a show of hands is allowed, the right to vote individually on a show of hands.

2.7 Annual general meetings and extraordinary general meetings

The Company shall hold a general meeting as its annual general meeting for each financial year within six months (or such other period as may be permitted by the Listing Rules or the Stock Exchange) after the end of such financial year. An annual general meeting shall be specified as such in the notices calling it.

The Directors may call general meetings, and they shall on a members' requisition forthwith proceed to convene an extraordinary general meeting of the Company. A members' requisition is a requisition of one or more members holding at the date of deposit of the requisition not less than 10% of the voting rights, on a one vote per share basis, of the issued shares which as at that date carry the right to vote at general meetings of the Company. The members' requisition must state the objects and the resolutions to be added to the agenda of the meeting and must be signed by the requisitionists and deposited at the principal office of the Company in Hong Kong or, in the event the Company ceases to have such a principal office, the registered office of the Company, and may consist of several documents in like form each signed by one or more requisitionists. If there are no Directors as at the date of the deposit of the members' requisition or if the Directors do not within 21 days from the date of the deposit of the members' requisition

duly proceed to convene a general meeting to be held within a further 21 days, the requisitionists, or any of them representing more than one-half of the total voting rights of all the requisitionists, may themselves convene a general meeting, but any meeting so convened shall be held no later than the day which falls three months after the expiration of the said 21-day period. A general meeting convened by requisitionists shall be convened in the same manner as nearly as possible as that in which general meetings are to be convened by Directors.

2.8 Accounts and audit

The Directors shall cause proper books of account to be kept with respect to all sums of money received and expended by the Company and the matters in respect of which the receipt or expenditure takes place, all sales and purchases of goods by the Company and the assets and liabilities of the Company. Such books of account must be retained for a minimum period of five years from the date on which they are prepared. Proper books shall not be deemed to be kept if there are not kept such books of account as are necessary to give a true and fair view of the state of the Company's affairs and to explain its transactions.

The Directors shall determine whether and to what extent and at what times and places and under what conditions or regulations the accounts and books of the Company or any of them shall be open to the inspection of members of the Company not being Directors, and no member (not being a Director) shall have any right of inspecting any account or book or document of the Company except as conferred by the Companies Act or authorised by the Directors or by the Company in general meeting.

The Directors shall cause to be prepared and to be laid before the Company at every annual general meeting a profit and loss account for the period since the preceding account, together with a balance sheet as at the date to which the profit and loss account is made up, a Directors' report with respect to the profit or loss of the Company for the period covered by the profit and loss account and the state of the Company's affairs as at the end of such period, an auditors' report on such accounts and such other reports and accounts as may be required by law.

2.9 Auditors

The Company shall at every annual general meeting by ordinary resolution appoint an auditor or auditors of the Company who shall hold office until the next annual general meeting. The Company may by ordinary resolution remove an auditor before the expiration of his period of office. No person may be appointed as an auditor of the Company unless such person is independent of the Company. The remuneration of the auditors shall be fixed by the Company at the annual general meeting at which they are appointed by ordinary resolution, or in the manner specified in such resolution.

2.10 Notice of meetings and business to be conducted thereat

An annual general meeting shall be called by not less than 21 days' notice and any extraordinary general meeting shall be called by not less than 14 days' notice, which shall be exclusive of the day on which it is served or deemed to be served and of the day for which it is given. The notice convening an annual general meeting shall specify the meeting as such, and the notice convening a meeting to pass a special resolution shall specify the intention to propose the resolution as a special resolution. Every notice shall specify the place, the day and the hour of the meeting, particulars of the resolutions and the general nature of the business to be conducted at the meeting. Notwithstanding the foregoing, a general meeting of the Company shall, whether or not the notice specified has been given and whether or not the provisions of the Articles of Association regarding general meetings have been complied with, be deemed to have been duly convened if it is so agreed:

(a) in the case of an annual general meeting, by all members of the Company entitled to attend and vote at the meeting; and

(b) in the case of an extraordinary general meeting, by a majority in number of the members having a right to attend and vote at the meeting, together holding not less than 95% in par value of the shares giving that right.

If, after the notice of a general meeting has been sent but before the meeting is held, or after the adjournment of a general meeting but before the adjourned meeting is held (whether or not notice of the adjourned meeting is required), the Directors, in their absolute discretion, consider that it is impractical or unreasonable for any reason to hold a general meeting on the date or at the time and place specified in the notice calling such meeting, they may change or postpone the meeting to another date, time and place.

The Directors also have the power to provide in every notice calling a general meeting that in the event of a gale warning or a black rainstorm warning is in force at any time on the day of the general meeting (unless such warning is canceled at least a minimum period of time prior to the general meeting as the Directors may specify in the relevant notice), the meeting shall be postponed without further notice to be reconvened on a later date.

Where a general meeting is postponed:

(a) the Company shall endeavour to cause a notice of such postponement, which shall set out the reason for the postponement in accordance with the Listing Rules, to be placed on the Company's website and published on the Stock Exchange's website as soon as practicable, provided that failure to place or publish such notice shall not affect the automatic postponement of a general meeting due to a gale warning or black rainstorm warning being in force on the day of the general meeting;

(b) the Directors shall fix the date, time and place for the reconvened meeting and at least seven clear days' notice shall be given for the reconvened meeting; and such notice shall specify the date, time and place at which the postponed meeting will be reconvened and the date and time by which proxies shall be submitted in order to be valid at such reconvened meeting (provided that any proxy submitted for the original meeting shall continue to be valid for the reconvened meeting unless revoked or replaced by a new proxy); and

(c) only the business set out in the notice of the original meeting shall be transacted at the reconvened meeting, and notice given for the reconvened meeting does not need to specify the business to be transacted at the reconvened meeting, nor shall any accompanying documents be required to be recirculated. Where any new business is to be transacted at such reconvened meeting, the Company shall give a fresh notice for such reconvened meeting in accordance with the Articles of Association.

2.11 Transfer of shares

Transfers of shares may be effected by an instrument of transfer, which shall be in writing and in any standard form of transfer as prescribed by the Stock Exchange or such other form as the Directors may approve. The instrument of transfer shall be executed by or on behalf of the transferor and, unless the Directors otherwise determine, the transferee, and the transferor shall be deemed to remain the holder of the share until the name of the transferee is entered in the register of members of the Company.

The Directors may decline to register any transfer of any share which is not fully paid up or on which the Company has a lien. The Directors may also decline to register any transfer of any shares unless:

(a) the instrument of transfer is lodged with the Company accompanied by the certificate for the shares to which it relates (which shall upon the registration of the transfer be canceled) and such other evidence as the Directors may reasonably require to show the right of the transferor to make the transfer;

(b) the instrument of transfer is in respect of only one class of shares;

(c) the instrument of transfer is properly stamped (in circumstances where stamping is required);

(d) in the case of a transfer to joint holders, the number of joint holders to whom the share is to be transferred does not exceed four;

(e) the shares concerned are free of any lien in favour of the Company; and

(f) a fee of such amount not exceeding the maximum amount as the Stock Exchange may from time to time determine to be payable (or such lesser sum as the Directors may from time to time require) is paid to the Company in respect thereof.

If the Directors refuse to register a transfer of any share they shall notify the transferor and the transferee within two months of such refusal.

The registration of transfers shall be suspended during such periods as the register of members of the Company is closed. The Directors may, on at least 10 business days' notice (or on at least 6 business days' notice in the case of a rights issue) being given by advertisement published on the Stock Exchange's website, or, subject to the Listing Rules, in the manner in which notices may be served by the Company by electronic means as provided in the Articles of Association or by advertisement published in the newspapers, close the register of members at such times and for such periods as the Directors may from time to time determine, provided that the register of members shall not be closed for more than 30 days in any year (or such longer period as the members of the Company may by ordinary resolution determine, provided that such period shall not be extended beyond 60 days in any year).

2.12 Power of the Company to purchase its own shares

Subject to the provisions of the Companies Act, the Company may purchase its own shares provided that (a) the manner of purchase has first been authorised by the members of the Company by ordinary resolution, and (b) any such purchase shall only be made in accordance with any relevant code, rules or regulations issued by the Stock Exchange or the Securities and Futures Commission of Hong Kong from time to time in force.

2.13 Power of any subsidiary of the Company to own shares

There are no provisions in the Articles of Association relating to the ownership of shares by a subsidiary.

2.14 Dividends and other methods of distribution

Subject to the Companies Act and the Articles of Association, the Company may by ordinary resolution resolve to pay dividends and other distributions on shares in issue and authorise payment of the dividends or other distributions out of the funds of the Company lawfully available therefor, provided no dividends shall exceed the amount recommended by the Directors. No dividend or other distribution shall be paid except out of the realised or unreleased profits of the Company, out of the share premium account or as otherwise permitted by law.

The Directors may from time to time pay to the members of the Company such interim dividends as appear to the Directors to be justified by the profits of the Company. The Directors may in addition from time to time declare and pay special dividends on shares of such amounts and on such dates as they think fit.

Except as otherwise provided by the rights attached to any shares, all dividends and other distributions shall be paid according to the amounts paid up on the shares that a member holds during any portion or portions of the period in respect of which the dividend is paid. For this purpose no amount paid up on a share in advance of calls shall be treated as paid up on the share.

The Directors may deduct from any dividends or other distribution payable to any member of the Company all sums of money (if any) then payable by the member to the Company on account of calls or otherwise. The Directors may retain any dividends or other monies payable on or in respect of a share upon which the Company has a lien, and may apply the same in or towards satisfaction of the debts, liabilities or engagements in respect of which the lien exists.

No dividend shall carry interest against the Company. Except as otherwise provided by the rights attached to any shares, dividends and other distributions may be paid in any currency.

Whenever the Directors or the Company in general meeting have resolved that a dividend be paid or declared on the share capital of the Company, the Directors may further resolve: (a) that such dividend be satisfied wholly or in part in the form of an allotment of shares credited as fully paid up on the basis that the shares so allotted are to be of the same class as the class already held by the allottee, provided that the members of the Company entitled thereto will be entitled to elect to receive such dividend (or part thereof) in cash in lieu of such allotment; or (b) that the members of the Company entitled to such dividend will be entitled to elect to receive an allotment of shares credited as fully paid up in lieu of the whole or such part of the dividend as the Directors may think fit on the basis that the shares so allotted are to be of the same class as the class already held by the allottee. The Company may upon the recommendation of the Directors by ordinary resolution resolve in respect of any one particular dividend of the Company that notwithstanding the foregoing a dividend may be satisfied wholly in the form of an allotment of shares credited as fully paid without offering any right to members of the Company to elect to receive such dividend in cash in lieu of such allotment.

Any dividend, interest or other monies payable in cash in respect of shares may be paid by wire transfer to the holder or by cheque or warrant sent through the post directed to the registered address of the holder or, in the case of joint holders, to the registered address of the holder who is first named on the register of members of the Company or to such person and to such address as the holder or joint holders may in writing direct.

Every such cheque or warrant shall be made payable to the order of the person to whom it is sent. Any one of two or more joint holders may give effectual receipts for any dividends, other distributions, bonuses, or other monies payable in respect of the shares held by them as joint holders.

Any dividend or other distribution which remains unclaimed after a period of six years from the date on which such dividend or distribution becomes payable shall be forfeited and shall revert to the Company.

The Directors, with the sanction of the members of the Company by ordinary resolution, may resolve that any dividend or other distribution be paid wholly or partly by the distribution of specific assets, and in particular (but without limitation) by the distribution of shares, debentures, or securities of any other company or in any one or more of such ways, and where any difficulty arises in regard to such distribution, the Directors may settle it as they think expedient, and in particular may disregard fractional entitlements, round the same up or down or provide that the same shall accrue to the benefit of the Company, and may fix the value for distribution of such specific assets or any part thereof and may determine that cash payments shall be made to any members of the Company upon the basis of the value so fixed in order to adjust the rights of all members, and may vest any such specific assets in trustees as may seem expedient to the Directors.

2.15 Proxies

A member of the Company entitled to attend and vote at a general meeting of the Company shall be entitled to appoint another person who must be an individual as his proxy to attend and vote instead of him and a proxy so appointed shall have the same right as the member to speak at the meeting. Votes may be given either personally or by proxy. A proxy need not be a member of the Company. A member may appoint any number of proxies to attend in his stead at any one general meeting or at any one class meeting.

The instrument appointing a proxy shall be in writing and shall be executed under the hand of the appointor or of his attorney duly authorised in writing, or, if the appointor is a corporation or other non-natural person, under the hand of its duly authorised representative.

The Directors shall, in the notice convening any meeting or adjourned meeting, or in an instrument of proxy sent out by the Company, specify the manner (including by electronic means) by which the instrument appointing a proxy shall be deposited and the place and the time (being not later than the time appointed for the commencement of the meeting or adjourned meeting to which the proxy relates) at which the instrument appointing a proxy shall be deposited.

The instrument appointing a proxy may be in any usual or common form (or such other form as the Directors may approve) and may be expressed to be for a particular meeting or any adjournment thereof or generally until revoked.

2.16 Calls on shares and forfeiture of shares

Subject to the terms of the allotment and issue of any shares, the Directors may make calls upon the members of the Company in respect of any monies unpaid on their shares (whether in respect of par value or premium), and each member of the Company shall (subject to receiving at least 14 clear days' notice specifying the times or times of payment) pay to the Company at the time or times so specified the amount called on his shares. A call may be revoked or postponed, in whole or in part, as the Directors may determine. A call may be required to be paid by instalments. A person upon whom a call is made shall remain liable for calls made upon him, notwithstanding the subsequent transfer of the shares in respect of which the call was made.

A call shall be deemed to have been made at the time when the resolution of the Directors authorising the call was passed. The joint holders of a share shall be jointly and severally liable to pay all calls and instalments due in respect of such share.

If a call remains unpaid after it has become due and payable, the person from whom it is due shall pay interest on the amount unpaid from the day it became due and payable until it is paid at such rate as the Directors may determine (and in addition all expenses that have been incurred by the Company by reason of such non-payment), but the Directors may waive payment of the interest or expenses wholly or in part.

If any call or instalment of a call remains unpaid after it has become due and payable, the Directors may give to the person from whom it is due not less than 14 clear days' notice requiring payment of the amount unpaid together with any interest which may have accrued and any expenses incurred by the Company by reason of such non-payment. The notice shall specify where payment is to be made and shall state if the notice is not complied with the shares in respect of which the call was made will be liable to be forfeited.

If such notice is not complied with, any share in respect of which it was given may, before the payment required by the notice has been made, be forfeited by a resolution of the Directors. Such forfeiture shall include all dividends, other distributions or other monies payable in respect of the forfeited shares and not paid before the forfeiture.

A forfeited share may be sold, re-allotted or otherwise disposed of on such terms and in such manner as the Directors think fit.

A person any of whose shares have been forfeited shall cease to be a member of the Company in respect of the forfeited shares and shall surrender to the Company for cancellation the certificate for the shares forfeited and shall remain liable to pay to the Company all monies which at the date of forfeiture were payable by him to the Company in respect of the shares, together with interest at such rate as the Directors may determine, but that person's liability shall cease if and when the Company shall have received payment in full of all monies due and payable by them in respect of those shares.

2.17 Inspection of register of members

The Company shall maintain or cause to be maintained the register of members of the Company in accordance with the Companies Act. The Directors may, on giving 10 business days' notice (or 6 business days' notice in the case of a rights issue) by advertisement published on the Stock Exchange's website or, subject to the Listing Rules, in the manner in which notices may be served by the Company by electronic means as provided in the Articles of Association or by advertisement published in the newspapers, close the register of members at such times and for such periods as the Directors may determine, either generally or in respect of any class of shares, provided that the register shall not be closed for more than 30 days in any year (or such longer period as the members of the Company may by ordinary resolution determine, provided that such period shall not be extended beyond 60 days in any year).

Except when the register is closed, the register of members shall during business hours be kept open for inspection by any member of the Company without charge.

2.18 Quorum for meetings and separate class meetings

No business shall be transacted at any general meeting unless a quorum is present. Two members of the Company present in person or by proxy, or if a corporation or other non-natural person by its duly authorised representative or proxy, shall be a quorum unless the Company has only one member entitled to vote at such general meeting in which case the quorum shall be that one member present in person or by proxy, or in the case of a corporation or other non-natural person by its duly authorised representative or proxy.

The quorum for a separate general meeting of the holders of a separate class of shares of the Company is described in paragraph 2.3 above.

2.19 Rights of minorities in relation to fraud or oppression

There are no provisions in the Articles of Association concerning the rights of minority shareholders in relation to fraud or oppression.

2.20 Procedure on liquidation

Subject to the Companies Act, the Company may by special resolution resolve that the Company be wound up voluntarily.

Subject to the rights attaching to any shares, in a winding up:

(a) if the assets available for distribution amongst the members of the Company shall be insufficient to repay the whole of the Company's paid-up capital, such assets shall be distributed so that, as nearly as may be, the losses shall be borne by the members of the Company in proportion to the capital paid up, or which ought to have been paid up, on the shares held by them at the commencement of the winding up;

(b) if the assets available for distribution amongst the members of the Company shall be more than sufficient to repay the whole of the Company's paid up capital at the commencement of the winding up, the surplus shall be distributed amongst the members of the Company in proportion to the capital paid up on the shares held by them at the commencement of the winding up.

If the Company shall be wound up, the liquidator may with the approval of a special resolution of the Company and any other approval required by the Companies Act, divide amongst the members of the Company in kind the whole or any part of the assets of the Company (whether such assets shall consist of property of the same kind or not) and may, for that purpose, value any assets and determine how the division shall be carried out as between the members or different classes of members of the Company. The liquidator may, with the like approval, vest the whole or any part of such assets in trustees upon such trusts for the benefit of the members of the Company as the liquidator, with the like approval, shall think fit, but so that no member of the Company shall be compelled to accept any assets, shares or other securities in respect of which there is a liability.

2.21 Untraceable members

The Company shall be entitled to sell any shares of a member of the Company or the shares to which a person is entitled by virtue of transmission on death or bankruptcy or operation of law if: (a) all cheques or warrants, not being less than three in number, for any sums payable in cash to the holder of such shares have remained uncashed for a period of 12 years; (b) the Company has not during that time or before the expiry of the three-month period referred to in (d) below received any indication of the whereabouts or existence of the member; (c) during the 12-year period, at least three dividends in respect of the shares in question have become payable and no dividend during that period has been claimed by the member; and (d) upon expiry of the 12-year period, the Company has caused an advertisement to be published in the newspapers or, subject to the Listing Rules, by electronic communication in the manner in which notices may be served by the

Company by electronic means as provided in the Articles of Association, giving notice of its intention to sell such shares and a period of three months has elapsed since such advertisement and the Stock Exchange has been notified of such intention. The net proceeds of any such sale shall belong to the Company and upon receipt by the Company of such net proceeds it shall become indebted to the former member for an amount equal to such net proceeds.

SUMMARY OF CAYMAN ISLANDS COMPANY LAW AND TAXATION

1 Introduction

The Companies Act is derived, to a large extent, from the older Companies Acts of England, although there are significant differences between the Companies Act and the current Companies Act of England. Set out below is a summary of certain provisions of the Companies Act, although this does not purport to contain all applicable qualifications and exceptions or to be a complete review of all matters of corporate law and taxation which may differ from equivalent provisions in jurisdictions with which interested parties may be more familiar.

2 Incorporation

The Company was incorporated in the Cayman Islands as an exempted company with limited liability on 14 May 2021 under the Companies Act. As such, its operations must be conducted mainly outside the Cayman Islands. The Company is required to file an annual return each year with the Registrar of Companies of the Cayman Islands and pay a fee which is based on the size of its authorised share capital.

3 Share Capital

The Companies Act permits a company to issue ordinary shares, preference shares, redeemable shares or any combination thereof.

The Companies Act provides that where a company issues shares at a premium, whether for cash or otherwise, a sum equal to the aggregate amount of the value of the premia on those shares shall be transferred to an account called the "share premium account". At the option of a company, these provisions may not apply to premia on shares of that company allotted pursuant to any arrangement in consideration of the acquisition or cancellation of shares in any other company and issued at a premium. The Companies Act provides that the share premium account may be applied by a company, subject to the provisions, if any, of its memorandum and articles of association, in such manner as the company may from time to time determine including, but without limitation:

(a) paying distributions or dividends to members;

(b) paying up unissued shares of the company to be issued to members as fully paid bonus shares;

(c) in the redemption and repurchase of shares (subject to the provisions of section 37 of the Companies Act);

(d) writing-off the preliminary expenses of the company;

(e) writing-off the expenses of, or the commission paid or discount allowed on, any issue of shares or debentures of the company; and

(f) providing for the premium payable on redemption or purchase of any shares or debentures of the company.

No distribution or dividend may be paid to members out of the share premium account unless immediately following the date on which the distribution or dividend is proposed to be paid the company will be able to pay its debts as they fall due in the ordinary course of business.

The Companies Act provides that, subject to confirmation by the Grand Court of the Cayman Islands, a company limited by shares or a company limited by guarantee and having a share capital may, if so authorised by its articles of association, by special resolution reduce its share capital in any way.

Subject to the detailed provisions of the Companies Act, a company limited by shares or a company limited by guarantee and having a share capital may, if so authorised by its articles of association, issue shares which are to be redeemed or are liable to be redeemed at the option of the company or a shareholder. In addition, such a company may, if authorised to do so by its articles of association, purchase its own shares, including any redeemable shares. The manner of such a purchase must be authorised either by the articles of association or by an ordinary resolution of the company. The articles of association may provide that the manner of purchase may be determined by the directors of the company. At no time may a company redeem or purchase its shares unless they are fully paid. A company may not redeem or purchase any of its shares if, as a result of the redemption or purchase, there would no longer be any member of the company holding shares. A payment out of capital by a company for the redemption or purchase of its own shares is not lawful unless immediately following the date on which the payment is proposed to be made, the company shall be able to pay its debts as they fall due in the ordinary course of business.

There is no statutory restriction in the Cayman Islands on the provision of financial assistance by a company for the purchase of, or subscription for, its own or its holding company's shares. Accordingly, a company may provide financial assistance if the directors of the company consider, in discharging their duties of care and to act in good faith, for a proper purpose and in the interests of the company, that such assistance can properly be given. Such assistance should be on an arm's-length basis.

4 Dividends and Distributions

With the exception of section 34 of the Companies Act, there are no statutory provisions relating to the payment of dividends. Based upon English case law which is likely to be persuasive in the Cayman Islands in this area, dividends may be paid only out of profits. In addition, section 34 of the Companies Act permits, subject to a solvency test and the provisions, if any, of the company's memorandum and articles of association, the payment of dividends and distributions out of the share premium account (see paragraph 3 above for details).

5 Shareholders' Suits

The Cayman Islands courts can be expected to follow English case law precedents. The rule in *Foss v. Harbottle* (and the exceptions thereto which permit a minority shareholder to commence a class action against or derivative actions in the name of the company to challenge (a) an act which is *ultra vires* the company or illegal, (b) an act which constitutes a fraud against the minority where the wrongdoers are themselves in control of the company, and (c) an action which requires a resolution with a qualified (or special) majority which has not been obtained) has been applied and followed by the courts in the Cayman Islands.

6 Protection of Minorities

In the case of a company (not being a bank) having a share capital divided into shares, the Grand Court of the Cayman Islands may, on the application of members holding not less than one-fifth of the shares of the company in issue, appoint an inspector to examine into the affairs of the company and to report thereon in such manner as the Grand Court shall direct.

Any shareholder of a company may petition the Grand Court of the Cayman Islands which may make a winding up order if the court is of the opinion that it is just and equitable that the company should be wound up.

Claims against a company by its shareholders must, as a general rule, be based on the general laws of contract or tort applicable in the Cayman Islands or their individual rights as shareholders as established by the company's memorandum and articles of association.

The English common law rule that the majority will not be permitted to commit a fraud on the minority has been applied and followed by the courts of the Cayman Islands.

7 Disposal of Assets

The Companies Act contains no specific restrictions on the powers of directors to dispose of assets of a company. As a matter of general law, in the exercise of those powers, the directors must discharge their duties of care and to act in good faith, for a proper purpose and in the interests of the company.

8 Accounting and Auditing Requirements

The Companies Act requires that a company shall cause to be kept proper books of account with respect to:

(a) all sums of money received and expended by the company and the matters in respect of which the receipt and expenditure takes place;

(b) all sales and purchases of goods by the company; and

(c) the assets and liabilities of the company.

Proper books of account shall not be deemed to be kept if there are not kept such books as are necessary to give a true and fair view of the state of the company's affairs and to explain its transactions.

9 Register of Members

An exempted company may, subject to the provisions of its articles of association, maintain its principal register of members and any branch registers at such locations, whether within or without the Cayman Islands, as its directors may from time to time think fit. There is no requirement under the Companies Act for an exempted company to make any returns of members to the Registrar of Companies of the Cayman Islands. The names and addresses of the members are, accordingly, not a matter of public record and are not available for public inspection.

10 Inspection of Books and Records

Members of a company will have no general right under the Companies Act to inspect or obtain copies of the register of members or corporate records of the company. They will, however, have such rights as may be set out in the company's articles of association.

11 Special Resolutions

The Companies Act provides that a resolution is a special resolution when it has been passed by a majority of at least two-thirds of such members as, being entitled to do so, vote in person or, where proxies are allowed, by proxy at a general meeting of which notice specifying the intention to propose the resolution as a special resolution has been duly given, except that a company may in its articles of association specify that the required majority shall be a number greater than two-thirds, and may additionally so provide that such majority (being not less than two-thirds) may differ as between matters required to be approved by a special resolution. Written resolutions signed by all the members entitled to vote for the time being of the company may take effect as special resolutions if this is authorised by the articles of association of the company.

12 Subsidiary Owning Shares in Parent

The Companies Act does not prohibit a Cayman Islands company acquiring and holding shares in its parent company provided its objects so permit. The directors of any subsidiary making such acquisition must discharge their duties of care and to act in good faith, for a proper purpose and in the interests of the subsidiary.

13 Mergers and Consolidations

The Companies Act permits mergers and consolidations between Cayman Islands companies and between Cayman Islands companies and non-Cayman Islands companies. For these purposes, (a) "merger" means the merging of two or more constituent companies and the vesting of their undertaking, property and liabilities in one of such companies as the surviving company, and (b) "consolidation" means the combination of two or more constituent companies into a consolidated company and the vesting of the undertaking, property and liabilities of such companies to the consolidated company. In order to effect such a merger or consolidation, the directors of each constituent company must approve a written plan of merger or consolidation, which must then be authorised by (a) a special resolution of each constituent company and (b) such other authorisation, if any, as may be specified in such constituent company's articles of association. The written plan of merger or consolidation must be filed with the Registrar of Companies of the Cayman Islands together with a declaration as to the solvency of the consolidated or surviving company, a list of the assets and liabilities of each constituent company and an undertaking that a copy of the certificate of merger or consolidation will be given to the members and creditors of each constituent company and that notification of the merger or consolidation will be published in the Cayman Islands Gazette. Dissenting shareholders have the right to be paid the fair value of their shares (which, if not agreed between the parties, will be determined by the Cayman Islands court) if they follow the required procedures, subject to certain exceptions. Court approval is not required for a merger or consolidation which is effected in compliance with these statutory procedures.

14 Reconstructions

There are statutory provisions which facilitate reconstructions and amalgamations approved by (a) 75% in value of shareholders, or (b) a majority in number representing 75% in value of creditors, depending on the circumstances, as are present at a meeting called for such purpose and thereafter sanctioned by the Grand Court of the Cayman Islands. Whilst a dissenting shareholder would have the right to express to the Grand Court his view that the transaction for which approval is sought would not provide the shareholders with a fair value for their shares, the Grand Court is unlikely to disapprove the transaction on that ground alone in the absence of evidence of fraud or bad faith on behalf of management and if the transaction were approved and consummated the dissenting shareholder would have no rights comparable to the appraisal rights (i.e. the right to receive payment in cash for the judicially determined value of his shares) ordinarily available, for example, to dissenting shareholders of United States corporations.

15 Take-overs

Where an offer is made by a company for the shares of another company and, within four months of the offer, the holders of not less than 90% of the shares which are the subject of the offer accept, the offeror may at any time within two months after the expiration of the said four months, by notice require the dissenting shareholders to transfer their shares on the terms of the offer. A dissenting shareholder may apply to the Grand Court of the Cayman Islands within one month of the notice objecting to the transfer. The burden is on the dissenting shareholder to show that the Grand Court should exercise its discretion, which it will be unlikely to do unless there is evidence of fraud or bad faith or collusion as between the offeror and the holders of the shares who have accepted the offer as a means of unfairly forcing out minority shareholders.

16 Indemnification

Cayman Islands law does not limit the extent to which a company's articles of association may provide for indemnification of officers and directors, except to the extent any such provision may be held by the Cayman Islands courts to be contrary to public policy (e.g. for purporting to provide indemnification against the consequences of committing a crime).

17 Restructuring

A company may present a petition to the Grand Court of the Cayman Islands for the appointment of a restructuring officer on the grounds that the company:

(a) is or is likely to become unable to pay its debts; and

(b) intends to present a compromise or arrangement to its creditors (or classes thereof) either pursuant to the Companies Act, the law of a foreign country or by way of a consensual restructuring.

The Grand Court may, among other things, make an order appointing a restructuring officer upon hearing of such petition, with such powers and to carry out such functions as the court may order. At any time (i) after the presentation of a petition for the appointment of a restructuring officer but before an order for the appointment of a restructuring officer has been made, and (ii) when an order for the appointment of a restructuring officer is made, until such order has been discharged, no suit, action or other proceedings (other than criminal proceedings) shall be proceeded with or commenced against the company, no resolution to wind up the company shall be passed, and no winding up petition may be presented against the company, except with the leave of the court. However, notwithstanding the presentation of a petition for the appointment of a restructuring officer or the appointment of a restructuring officer, a creditor who has security over the whole or part of the assets of the company is entitled to enforce the security without the leave of the court and without reference to the restructuring officer appointed.

18 Liquidation

A company may be placed in liquidation compulsorily by an order of the court, or voluntarily (a) by a special resolution of its members if the company is solvent, or (b) by an ordinary resolution of its members if the company is insolvent. The liquidator's duties are to collect the assets of the company (including the amount (if any) due from the contributories (shareholders)), settle the list of creditors and discharge the company's liability to them, rateably if insufficient assets exist to discharge the liabilities in full, and to settle the list of contributories and divide the surplus assets (if any) amongst them in accordance with the rights attaching to the shares.

19 Stamp Duty on Transfers

No stamp duty is payable in the Cayman Islands on transfers of shares of Cayman Islands companies except those which hold interests in land in the Cayman Islands.

20 Taxation

Pursuant to section 6 of the Tax Concessions Act (As Revised) of the Cayman Islands, the Company may obtain an undertaking from the Financial Secretary of the Cayman Islands:

(a) that no law which is enacted in the Cayman Islands imposing any tax to be levied on profits, income, gains or appreciations shall apply to the Company or its operations; and

(b) in addition, that no tax to be levied on profits, income, gains or appreciations or which is in the nature of estate duty or inheritance tax shall be payable:

  (i) on or in respect of the shares, debentures or other obligations of the Company; or

  (ii) by way of the withholding in whole or in part of any relevant payment as defined in section 6(3) of the Tax Concessions Act (As Revised).

The Cayman Islands currently levy no taxes on individuals or corporations based upon profits, income, gains or appreciations and there is no taxation in the nature of inheritance tax or estate duty. There are no other taxes likely to be material to the Company levied by the Government of the Cayman Islands save certain stamp duties which may be applicable, from time to time, on certain instruments executed in or brought within the jurisdiction of the Cayman Islands. The Cayman Islands are not party to any double tax treaties that are applicable to any payments made by or to the Company.

21 Exchange Control

There are no exchange control regulations or currency restrictions in the Cayman Islands.

22 General

Maples and Calder (Hong Kong) LLP, the Company's legal advisers on Cayman Islands law, have sent to the Company a letter of advice summarising aspects of Cayman Islands company law. This letter, together with a copy of the Companies Act, is on display on the websites as referred to in the section headed "Documents Delivered to the Registrar of Companies and Documents on Display" in Appendix V. Any person wishing to have a detailed summary of Cayman Islands company law or advice on the differences between it and the laws of any jurisdiction with which he/she is more familiar is recommended to seek independent legal advice.

A. FURTHER INFORMATION ABOUT OUR GROUP

1. Incorporation of Our Company

Our Company was incorporated in the Cayman Islands as an exempted company with limited liability under the Cayman Companies Act on May 14, 2021. Our registered office address is at PO Box 309, Ugland House, Grand Cayman, KY1-1104, Cayman Islands. As our Company is incorporated in the Cayman Islands, our operation is subject to the relevant laws and regulations of the Cayman Islands, the Articles and the Memorandum. A summary of the relevant laws and regulations of the Cayman Islands and of our constitution is set out in Appendix III to this document.

Our Company was registered as a non-Hong Kong company in Hong Kong under Part 16 of the Companies Ordinance on June 20, 2023. Our principal place of business in Hong Kong is at 31/F, Tower Two, Times Square, 1 Matheson Street, Causeway Bay, Hong Kong. Ms. WONG Hoi Ting (黃凱婷) has been appointed as our authorized representative for the acceptance of service of process and notices in Hong Kong. The address of service of process is 31/F, Tower Two, Times Square, 1 Matheson Street, Causeway Bay, Hong Kong.

As of the date of this document, our Company's headquarters are located at Room 302, Building 3, No. 198 Peninsula Middle Road, Dipu Street, Anji County, Huzhou City, Zhejiang Province, PRC and No. 5 Xingjian Road, Nanjing Economic and Technological Development Zone, PRC.

2. Changes in the Share Capital of Our Company

As of the date of incorporation of our Company, our authorized share capital was US$100,000 divided into 100,000 ordinary shares with a par value of US$1.00 each.

On August 2, 2023, our Company alloted and issued 5,833.33 Shares to Huzhou Efung Ansheng Venture Capital Partnership (Limited Partnership) (湖州市倚鋒安盛創業投資合夥企業(有限合夥)) ("**Efung Ansheng**") and 2,916.67 Shares to Huzhou Efung Anhe Venture Capital Partnership (Limited Partnership) (湖州市倚鋒安禾創業投資合夥企業(有限合夥) ("**Efung Anhe**")).

On August 30, 2023, 11,257.5 authorized but unissued Shares with a par value of US$1.00 each were re-designated and reclassified into 11,257.5 Series A Preferred Shares with a par value of US$1.00 each (the "**Re-designation of Share Capital**"). Following the Re-designation of Share Capital, the authorized share capital of our Company became US$100,000 divided into 88,742.5 Shares with a par value of US$1.00 each and 11,257.5 Series A Preferred Shares with a par value of US$1.00 each. Upon completion of the Re-designation of Share Capital, on the same date, our Company repurchased (i) the 5,833.33 Shares each held by Efung Ansheng in consideration of the issuance and allotment of 5,833.33 Series A Preferred Shares to Efung Ansheng, and (ii) the 2,916.67 Shares held by Efung Anhe in consideration of the issuance and allotment of 2,916.67 Series A Preferred Shares to Efung Ansheng (the "**Repurchase of Shares**"). Following the Repurchase of Shares, on the same date, each of the

authorized issued and unissued Shares with a par value of US$1.00 each was subdivided into 2,000 Shares with a par value of US$0.0005 each, and each of the authorized issued and unissued Series A Preferred Shares with a par value of US$1.00 each was subdivided into 2,000 Series A Preferred Shares with a par value of US$0.0005 each. Upon completion of the Share Subdivision, the authorized share capital of our Company became US$100,000 divided into 177,485,000 Shares with a par value of US$0.0005 each and 22,515,000 Series A Preferred Shares with a par value of US$0.0005 each, and Sunho Wisdom, Sunho Stellar, No5XJR, Efung Ansheng and Efung Anhe held 88,000,000 Shares, 6,000,000 Shares, 6,000,000 Shares, 11,666,660 Series A Preferred Shares and 5,833,340 Series A Preferred Shares, respectively.

On October 10, 2023, our Company alloted and issued 5,015,000 Series A Preferred Shares to Beijing Yuehe Enterprise Management Development Center (Limited Partnership) (北京越禾企業管理發展中心(有限合夥)).

Save as disclosed above, there has been no alternation in our share capital within the two years immediately preceding the date of this document.

3. Changes in the Share Capital of Our Subsidiaries

A summary of the corporate information and the particulars of our subsidiaries is set out in note 35 to the Accountants' Report as set out in Appendix I to this document.

The following sets out the changes in the share capital of our subsidiaries within the two years immediately preceding the date of this document:

SunHo (China) BioPharmaceutical

On August 30, 2023, the registered capital of SunHo (China) BioPharmaceutical increased from RMB180,000,000 to RMB187,682,553.

Sunho Pharmaceutical Technology

On August 21, 2023, the registered capital of Sunho Pharmaceutical Technology increased from RMB5 million to RMB105 million.

On November 29, 2023, the registered capital of Sunho Pharmaceutical Technology increased from RMB105 million to RMB155 million.

SunHo (Zhejiang) BioPharmaceutical

SunHo (Zhejiang) BioPharmaceutical was incorporated in the PRC as a limited liability company on March 17, 2023 with an initial registered capital of RMB30 million.

Save as disclosed above, there has been no alteration in the share capital of any of the subsidiaries of our Company within the two years immediately preceding the date of this document.

4. Resolutions of Our Shareholders

Written resolutions of our Shareholders were passed on [●] pursuant to which, among others:

(a) subject to the conditions of the [**REDACTED**] stated in the paragraph headed "Structure of the [**REDACTED**]" in this document being fulfilled or waived by the Sole Sponsor and the [**REDACTED**] (for itself and on behalf of the [**REDACTED**]):

(i) the [**REDACTED**] be approved, and the proposed [**REDACTED**] and [**REDACTED**] of the Shares under the [**REDACTED**] were approved, and our Directors were authorized to determine the [**REDACTED**] for, and to [**REDACTED**] and [**REDACTED**] the Shares under the [**REDACTED**];

(ii) a general unconditional mandate be given to our Directors to exercise all powers of our Company to allot, issue and deal with Shares or securities convertible into Shares and to make or grant offers, agreements or options (including any warrants, bonds, notes and debentures conferring any rights to subscribe for or otherwise receive Shares) which might require Shares to be allotted and issued or dealt with subject to the requirement that the aggregate nominal value of the Shares to allotted and issued or agreed conditionally or unconditionally to be allotted and issued, otherwise than by way of the [**REDACTED**], rights issue, pursuant to the exercise of any subscription rights attaching to any warrants which may be allotted and issued by our Company from time to time, or allotment and issue of Shares in lieu of the whole or part of a dividend on Shares in accordance with the Memorandum and the Articles of Association on a specific authority granted by our Shareholders at general meetings, shall not exceed 20% of the aggregate nominal value of the Shares in issue immediately following completion of the [**REDACTED**];

(iii) a general unconditional mandate (the "**Repurchase Mandate**") be given to our Directors to exercise all powers of our Company to repurchase Shares on [**REDACTED**] or on any other [**REDACTED**] on which the Shares may be [**REDACTED**] and which is recognized by the SFC and [**REDACTED**] for this purpose, such number of Shares as will represent up to 10% of the aggregate nominal value of the Shares in issue immediately following completion of the [**REDACTED**];

(iv) the general unconditional mandate as mentioned in paragraph (ii) above be extended by the addition to the aggregate nominal value of the Shares which may be allotted and issued or dealt with or agreed to be allotted and issued or dealt with by our Directors pursuant to such general unconditional mandate of an amount representing the aggregate nominal value of the Shares repurchased

by our Company pursuant to the Repurchase Mandate up to 10% of the aggregate nominal value of the Shares in issue immediately following completion of the [**REDACTED**]; and

(v) the conversion of all of the authorized issued and unissued Series A Preferred Shares into Shares on [a one-to-one basis] by re-designation and re-classification, each having the rights and restrictions as set out in the Memorandum and Articles, be approved with effect upon completion of the [**REDACTED**]; and

(b) the Memorandum and the Articles were conditionally approved and adopted with effect from the [**REDACTED**].

Each of the general mandates referred to in paragraphs (a)(ii), (a)(iii) and (a)(iv) above will remain in effect until whichever is the earliest of:

- the conclusion of the next annual general meeting of our Company;
- the expiration of the period within which the next annual general meeting of our Company is required to be held by any applicable law or the Articles; or
- the time when such mandate is revoked or varied by an ordinary resolution of the Shareholders in a general meeting.

5. Repurchase of Our Own Securities

The following paragraphs include, among others, certain information required by the Stock Exchange to be included in this document concerning the repurchase of our own [**REDACTED**].

(a) Provision of the Listing Rules

The Listing Rules permit companies with a primary listing on the Stock Exchange to repurchase their own securities on the Stock Exchange subject to certain restrictions, the most important of which are summarized below:

(i) Shareholders' Approval

All proposed repurchases of securities (which must be fully paid up in the case of shares) by a company with a primary listing on the Stock Exchange must be approved in advance by an ordinary resolution of the shareholders at a general meeting, either by way of general mandate or by specific approval of a particular transaction.

Pursuant to a resolution passed by our Shareholders on [●], the Repurchase Mandate was given to our Directors authorizing them to exercise all powers of our Company to repurchase Shares on [**REDACTED**] or on any other [**REDACTED**] on which the securities of our Company may be [**REDACTED**] and which is recognized by the SFC and [**REDACTED**] for this purpose, with a total nominal value up to 10% of the aggregate nominal value of our Shares in issue immediately following completion of the [**REDACTED**], with such mandate to expire at the earliest of (i) the conclusion of the next annual general meeting of our Company (unless otherwise renewed by an ordinary resolution of our Shareholders in a general meeting, either unconditionally or subject to conditions), (ii) the expiration of the period within which the next annual general meeting of our Company is required by the Articles of Association or any other applicable laws to be held, and (iii) the date when it is varied or revoked by an ordinary resolution of our Shareholders in a general meeting.

(ii) Source of Funds

Repurchases must be funded out of funds legally available for such purpose in accordance with the Memorandum and the Articles and the applicable laws and regulations of Hong Kong and the Cayman Islands. A listed company may not repurchase its own securities on the Stock Exchange for a consideration other than cash or for settlement otherwise than in accordance with the trading rules of the Stock Exchange from time to time. As a matter of Cayman Islands laws, any repurchases by our Company may be made out of profits or out of the proceeds of a new issue of shares made for the purpose of the repurchase or from sums standing to the credit of our share premium account or out of capital, if so authorized by the Articles of Association and subject to the Cayman Companies Act. Any premium payable on the repurchase over the par value of the shares to be purchased must have been provided for out of profits or from sums standing to the credit of our share premium account or out of capital, if so authorized by the Articles of Association and subject to the Cayman Companies Act.

(iii) Trading Restrictions

The total number of shares which a listed company may repurchase on the Stock Exchange is the number of shares representing up to 10% of the aggregate number of shares in issue. A company may not issue or announce a proposed issue of new securities for a period of 30 days immediately following a repurchase (other than an issue of securities pursuant to an exercise of warrants, share options or similar instruments requiring the company to issue securities which were outstanding prior to such repurchase) without the prior approval of the Stock Exchange. In addition, a listed company is prohibited from repurchasing its shares on the Stock Exchange if the purchase price is 5% or more than the average closing market price for the five preceding trading days on which its shares were traded on the Stock Exchange. The Listing Rules also prohibit a listed company from repurchasing its securities if the repurchase would result in the number of listed securities which are in the hands of the public falling below the

relevant prescribed minimum percentage as required by the Stock Exchange. A company is required to procure that the broker appointed by it to effect a repurchase of securities discloses to the Stock Exchange such information with respect to the repurchase as the Stock Exchange may require.

(iv) Status of Repurchased Shares

The listing of all purchased securities (whether on the Stock Exchange or otherwise) is automatically canceled and the relevant certificates must be canceled and destroyed. Under the laws of the Cayman Islands, unless our Directors resolve to hold the shares purchased by our Company as treasury shares prior to the purchase, shares purchased by our Company shall be treated as canceled and the amount of our Company's issued share capital shall be diminished by the nominal value of those shares. However, the purchase of shares will not be taken as reducing the amount of the authorized share capital under the laws of the Cayman Islands.

(v) Suspension of Repurchase

A listed company may not make any repurchase of securities after inside information has come to its knowledge until the information is made publicly available. In particular, during the period of one month immediately preceding the earlier of (a) the date of the board meeting (as such date is first notified to the Stock Exchange in accordance with the Listing Rules) for the approval of a listed company's results for any year, half-year, quarterly or any other interim period (whether or not required under the Listing Rules); and (b) the deadline for a listed company to announce its results for any year or half-year under the Listing Rules, or quarterly or any other interim period (whether or not required under the Listing Rules) and ending on the date of the results announcement, the listed company may not repurchase its shares on the Stock Exchange, other than in exceptional circumstances. In addition, the Stock Exchange may prohibit a repurchase of securities on the Stock Exchange if a listed company has breached the Listing Rules.

(vi) Reporting Requirements

Certain information relating to repurchases of securities on the Stock Exchange or otherwise must be reported to the Stock Exchange not later than 30 minutes before the earlier of the commencement of the morning trading session or any pre-opening session on the following business day on which a listed company makes a purchase of its shares. In addition, a listed company's annual report is required to disclose details regarding repurchases of securities made during the year, including the number of securities purchased each month (whether on the Stock Exchange or otherwise), the purchase price per share or the highest and lowest price paid for all such purchases, where relevant, and the aggregate price paid.

(vii) Core Connected Persons

The Listing Rules prohibit a company from knowingly purchasing securities on the Stock Exchange from a "core connected person", that is, a director, chief executive or substantial shareholder of the company or any of its subsidiaries or a close associate of any of them (as defined under the Listing Rules), and a core connected person shall not knowingly sell its securities to the company.

(b) Reasons for Repurchases

Our Directors believe that it is in the best interests of our Company and Shareholders for our Directors to have a general authority from the Shareholders to enable our Company to repurchase Shares in the [**REDACTED**]. Such repurchases may, depending on [**REDACTED**] and funding arrangements at the time, lead to an enhancement of the net asset value per Share and/or earnings per Share, and will only be made where our Directors believe that such repurchases will benefit our Company and Shareholders.

(c) Funding of Repurchases

Repurchase of the Shares must be funded out of funds legally available for such purpose in accordance with the Memorandum and the Articles of Association and the applicable laws and regulations of Hong Kong and the Cayman Islands. Our Directors may not repurchase the Shares on [**REDACTED**] for a consideration other than cash or for settlement otherwise than in accordance with the [**REDACTED**] of [**REDACTED**]. Subject to the foregoing, our Directors may make repurchases with profits of our Company or out of the proceeds of a new issuance of shares made for the purpose of the repurchase or, if authorized by the Articles of Association and subject to the Cayman Companies Act, out of capital and, in the case of any premium payable on the repurchase, out of profits of our Company or from sums standing to the credit of the share premium account of our Company or, if authorized by the Articles of Association and subject to Cayman Companies Act, out of capital.

In the event that the Repurchase Mandate is exercised in full, there might be a material adverse impact on the working capital or gearing position of our Company, as compared with the position as of December 31, 2023 as disclosed in the Accountants' Report. However, our Directors do not propose to exercise the Repurchase Mandate to such an extent as would, in the circumstances, have a material adverse effect on the working capital of our Company or its gearing levels which, in the opinion of our Directors, are from time to time appropriate for our Company.

(d) General

A full exercise of the Repurchase Mandate, on the basis of [**REDACTED**] Shares in issue immediately following completion of the [**REDACTED**], could accordingly result in up to [**REDACTED**] Shares being repurchased by our Company during the period prior to the earliest of:

(i) the conclusion of the next annual general meeting of our Company (unless otherwise renewed by an ordinary resolution of our Shareholders in a general meeting, either unconditionally or subject to conditions);

(ii) the expiration of the period within which the next annual general meeting of our Company is required by the Articles of Association or any other applicable laws to be held; or

(iii) the date when it is varied or revoked by an ordinary resolution of the Shareholders in a general meeting.

None of our Directors and, to the best of their knowledge having made all reasonable enquiries, their respective close associates currently intends to sell any Shares to our Company.

Our Directors will exercise the Repurchase Mandate in accordance with [**REDACTED**] and the applicable laws in the Cayman Islands.

If, as a result of any repurchase of Shares, a Shareholder's proportionate interest in the voting rights of our Company increases, such increase will be treated as an acquisition for the purposes of the Takeovers Codes. Accordingly, a Shareholder or a group of Shareholders acting in concert could obtain or consolidate control of our Company and become obliged to make a mandatory offer in accordance with Rule 26 of the Takeovers Codes. Save as aforesaid, our Directors are not aware of any consequence which would arise under the Takeovers Codes as a consequence of any repurchase pursuant to the Repurchase Mandate.

Any repurchase of Shares that results in the number of Shares held by [**REDACTED**] being reduced to less than 25% of the Shares then in issue could only be implemented if [**REDACTED**] agrees to waive the requirements under [**REDACTED**] regarding the [**REDACTED**] as referred to above. It is believed that a waiver of this provision would not normally be given other than in exceptional circumstances.

No core connected person of our Company has notified our Company that he/she/it has a present intention to sell Shares to our Company, or has undertaken not to do so, if the Repurchase Mandate is exercised.

B. FURTHER INFORMATION ABOUT OUR BUSINESS

1. Summary of Material Contract

The following contract (not being a contract entered into in the ordinary course of business) was entered into by members of our Group within the two years immediately preceding the date of this document which is or may be material:

(a) [**REDACTED**].

2. Intellectual Property Rights

(a) Trademarks

As of the Latest Practicable Date, we had registered the following trademarks, which we consider to be material to our Group's business:

No.	Trademark	Registered Owner	Place of Registration	Registration No.	Class	Expiry Date
1.		Our Company	Hong Kong	306206319	5, 35	March 28, 2033
2.	益洛佳	SunHo (China) BioPharmaceutical	PRC	51256630	5	July 27, 2031
3.	思瑞替	SunHo (China) BioPharmaceutical	PRC	51265321	5	July 27, 2031
4.	利菲妥	SunHo (China) BioPharmaceutical	PRC	51231587	5	August 6, 2031
5.	美明科	SunHo (China) BioPharmaceutical	PRC	51245967	5	August 6, 2031
6.	科优宁	SunHo (China) BioPharmaceutical	PRC	51251792	5	August 13, 2031
7.	可泰优	SunHo (China) BioPharmaceutical	PRC	51256610	5	August 13, 2031
8.	达优尼	SunHo (China) BioPharmaceutical	PRC	51240426	5	August 13, 2031
9.	希芙优	SunHo (China) BioPharmaceutical	PRC	51236985	5	August 20, 2031
10.	庆迪	SunHo (China) BioPharmaceutical	PRC	51236957	5	October 20, 2031
11.	力美优	SunHo (China) BioPharmaceutical	PRC	51256599	5	October 27, 2031
12.	可优美	SunHo (China) BioPharmaceutical	PRC	51256596	5	October 27, 2031

No.	Trademark	Registered Owner	Place of Registration	Registration No.	Class	Expiry Date
13.	畅乐君	SunHo (China) BioPharmaceutical	PRC	51256324	5	November 13, 2031
14.		SunHo (China) BioPharmaceutical	PRC	57110769	5	April 20, 2032
15.	SUNHO BIOPHARMA	SunHo (China) BioPharmaceutical	PRC	57097848	35	April 13, 2032
16.		SunHo (China) BioPharmaceutical	PRC	57115322	5, 35	April 13, 2032
17.	盛禾	SunHo (China) BioPharmaceutical	PRC	57114012	5	April 13, 2032
18.	盛禾生物制药	SunHo (China) BioPharmaceutical	PRC	57112172	5	April 13, 2032
19.	盛禾生物	SunHo (China) BioPharmaceutical	PRC	57093252	5	April 13, 2032
20.		SunHo (China) BioPharmaceutical	PRC	57103922	5	January 13, 2032
21.		SunHo (China) BioPharmaceutical	PRC	57095012	5	January 13, 2032
22.		SunHo (China) BioPharmaceutical	PRC	62036544	5	October 6, 2032

(b) Domain Names

As of the Latest Practicable Date, we had registered the following domain names:

No.	Domain Name	Registered Owner	Registration Date	Expiry Date
1.	sunho-bio.com.cn	SunHo (China) BioPharmaceutical	April 23, 2018	April 23, 2026
2.	sunho-bio.com	SunHo (China) BioPharmaceutical	April 23, 2018	April 23, 2026

(c) Patents

For a discussion of the details of the material patents and patent applications in connection with our products, see "Business – Intellectual Property" in this document.

Save as aforesaid, as of the Latest Practicable Date, there was no other trade or service mark, patent, intellectual or industrial property right which was material in relation to our business.

C. FURTHER INFORMATION ABOUT OUR DIRECTORS

1. Disclosure of Interests

(a) Interests and short positions of our Directors and chief executive in the share capital of our Company and its associated corporations following completion of the [**REDACTED**]

Immediately following completion of the [**REDACTED**], so far as our Directors are aware, the interests and/or short positions (as applicable) of our Directors and chief executive in the Shares, underlying shares and debentures of our Company and its associated corporations (within the meaning of Part XV of the SFO), which will have to be notified to our Company and [**REDACTED**] pursuant to [**REDACTED**] of the SFO (including interests and/or short positions (as applicable) which they are taken or deemed to have taken under such provisions of the SFO), or which will be required, pursuant to [**REDACTED**] of the SFO, to be recorded in the register referred to therein, or which will be required to be notified to our Company and [**REDACTED**] pursuant to [**REDACTED**], will be as follows:

Name of Director	Nature of Interest	Number of Shares held following completion of the [REDACTED]	Approximate percentage of interest immediately following completion of the [REDACTED][(1)] *(%)*
Mr. Zhang[(2)]	Interests in controlled corporations	100,000,000	[**REDACTED**]
Ms. JIANG Xiaoling (姜曉玲)[(3)]	Beneficial owner	500,000	[**REDACTED**]

Notes:

(1) The calculation is based on the total number of [**REDACTED**] Shares in issue immediately following completion of the [**REDACTED**].

(2) Sunho Wisdom is owned as to 99.9% by Sunho Fortune (as a nominee which is wholly owned by a trust established by Mr. Zhang as the settlor and beneficiary) and 0.1% by Innovalue Investments (a wholly-owned subsidiary of Mr. Zhang), respectively. Further, Mr. Zhang is entitled to exercise approximately 73.19% voting rights in No5XJR through Innovalue Investments, details of which are set out in the section headed "History, Reorganization and Corporate Structure" in this document. Sunho Stellar is wholly owned by an independent professional trustee who shall exercise all voting rights attached to the Shares held by Sunho Stellar in accordance with the instructions of Mr. Zhang. As such, under the SFO, Mr. Zhang is deemed to be interested in the Shares held by Sunho Wisdom, No5XJR and Sunho Stellar.

(3) These Shares represent the entitlement of Ms. JIANG Xiaoling (姜曉玲) to receive up to 500,000 Shares pursuant to the RSUs granted to her under the RSU Scheme, subject to the terms and conditions of these RSUs.

(b) Interests and short positions discloseable under [**REDACTED**] *of the SFO*

For information on the persons who will, immediately following completion of the [**REDACTED**], have interests or short position in our Shares or underlying Shares which would be required to be disclosed to our Company and [**REDACTED**] under the provisions of [**REDACTED**] of the SFO, or directly or indirectly be interested in 10% or more of the nominal value of any class of share capital carrying rights to vote in all circumstances at general meetings of any other member of our Group, see "Substantial Shareholders" in this document.

Save as disclosed above, as of the Latest Practicable Date, our Directors were not aware of any persons who would, immediately following completion of the [**REDACTED**], be interested, directly or indirectly, in 10% or more of the nominal value of any class of share capital carrying rights to vote in all circumstances at general meetings of any member of our Group or had option(s) in respect of such share capital.

2. Particulars of Directors' Service Contracts and Appointment Letters

(a) Executive Directors and Non-executive Director

Each of our executive Directors and non-executive Director has entered into a service contract with us under which the initial term of their service contracts shall be three years commencing from the date of their appointment until terminated in accordance with the terms and conditions of the service contract or by either party giving to the other party not less than one month's prior notice in writing.

(b) Independent non-executive Directors

Each of our independent non-executive Directors has entered into an appointment letter with us for an initial term of three years from the [**REDACTED**] until terminated in accordance with the terms and conditions of the appointment letter or by either party giving to the other party not less than one month's prior notice in writing.

3. Remuneration of Directors

Save as disclosed in the section headed "Directors and Senior Management" and note 13 to the Accountants' Report as set out in Appendix I to this document, for the two financial years ended December 31, 2022 and 2023, none of our Directors received other remunerations of benefits in kind from us.

4. Disclaimers

Save as disclosed in this document:

(i) there is no existing or proposed service contract (excluding any contract expiring or determinable by the employer within one year without payment of compensation (other than statutory compensation)) between our Directors and any member of our Group;

(ii) none of our Directors 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;

(iii) taking no account of any Shares which may be taken up under the [**REDACTED**], so far as is known to any Director or chief executive of our Company, no other person (other than a Director or chief executive of our Company) will, immediately following completion of the [**REDACTED**], have interests or short positions in the Shares or underlying Shares which would fall to be disclosed to our Company and [**REDACTED**] under the provisions of [**REDACTED**] of the SFO or be interested, directly or indirectly, in 10% or more of the nominal value of any class of share capital carrying rights to vote in all circumstances at general meetings of any member of our Group; and

(iv) none of our Directors and the chief executive of our Company has any interests or short positions in the Shares, underlying Shares or debentures of our Company or its associated corporations (within the meaning of Part XV of the SFO) which will have to be notified to our Company and [**REDACTED**] pursuant to [**REDACTED**] of the SFO (including interests and short positions which he is taken or deemed to have under such provisions of the SFO) or which will be required, pursuant to [**REDACTED**] of the SFO, to be entered into the register referred to therein, or will be required, pursuant to [**REDACTED**], to be notified to our Company and [**REDACTED**].

D. RSU SCHEME

Our Company has adopted the RSU Scheme. The following is a summary of the principal terms of the RSU Scheme:

1. Purposes of the RSU Scheme

The purpose of the RSU Scheme is to recognize and motivate the contributions by the Participants (as defined below) and give incentives thereto in order to retain them, as well as to attract suitable personnel for further development of our Group.

2. Awards

An award of RSU(s) under the RSU Scheme (an "**Award**") gives a Participant (as defined below) a conditional right upon vesting of the Award to obtain either Share(s) or an equivalent value in cash with reference to the value of the Share(s) on or about the date of vesting, as determined by our Board at its absolute discretion, less any tax, fees, levies, stamp duty and other applicable charges. An Award may include, if so specified by our Board in its entire discretion, cash and non-cash income, dividends or distributions and/or the sale proceeds of non-cash and non-scrip distributions in respect of those Shares underlying the RSU(s) from the date that the Award is granted to the date that it vests.

3. RSU Scheme Limit

Unless otherwise duly approved by our Shareholders, the total number of Shares underlying this Scheme shall not exceed 3,000 Shares (6,000,000 Shares as adjusted after the Share Subdivision), subject to any adjustment pursuant to any reorganization of capital structure from time to time.

4. Participants in the RSU Scheme

Participants of the RSU Scheme include employees or officers of our Group, including executive, non-executive and independent non-executive directors of our Group and any prospective employees who receive a grant as an inducement to join our Group ("**Participants**").

5. Term of the RSU Scheme

Subject to any early termination as may be determined by our Board pursuant to the termination clause of the RSU Scheme, the RSU Scheme shall be valid and effective for a period of ten years commencing on the date of adoption, after which no Awards will be granted, but the provisions of the RSU Scheme shall in all other respects remain in full force and effect and the Awards granted during the term of the RSU Scheme may continue to be valid and exercisable in accordance with their terms of grant.

6. Administration of the RSU Scheme

The RSU Scheme shall be subject to the administration of our Board (or a duly authorized administrator or committee) and the decision of our Board shall be final and binding on all parties. Our Board shall have the right to (i) interpret and construe the provisions of the RSU Scheme, (ii) determine the persons who will be granted Awards under the RSU Scheme, the terms on which Awards are granted and when the RSUs granted pursuant to the RSU Scheme may vest, (iii) make such appropriate and equitable adjustments to the terms of the Awards granted under the RSU Scheme as it deems necessary, (iv) appoint one or more independent third party professionals and contractors to assist in the administration of the RSU Scheme and delegate such powers and/or functions relating to the administration of the RSU Scheme as our

Board deems appropriate, and (v) make such other decisions or determinations as it shall deem appropriate in the administration of the RSU Scheme. Our Board may delegate any or all of its authority to administer the RSU Scheme to such committee or person(s) as it may see fit.

7. Appointment of RSU Trustee

Our Board may appoint one or more independent trustee(s) (the "**Trustee(s)**") to assist with the administration and vesting of the Awards.

8. Grant of RSU

On and subject to the terms of the RSU Scheme and the terms and conditions that our Board imposes, our Board shall be entitled at any time during the term of the RSU Scheme to make an offer of the grant of an Award in accordance with the RSU Scheme (a "**Grant**") to any Participant, as our Board may at its absolute discretion determine.

Awards may be granted on such terms and conditions (e.g. by linking the vesting of RSUs to the attainment or performance of milestones by any member of our Group, any Participant who accepts a Grant in accordance with the RSU Scheme (a "**Grantee**") or any group of Grantees) as our Board may determine, provided that such terms and conditions shall not be inconsistent with any other terms and conditions of the RSU Scheme.

Each Participant does not need pay any consideration to accept the Awards granted to such Participant.

A Grant shall be made to a Participant by a letter and/or any such notice or document in such form as our Board may from time to time determine (the "**Notice of Grant**") and such Grant shall be subject to the terms as specified in the RSU Scheme and the Notice of Grant. By accepting the Award, the Participant shall undertake to hold the Award on the terms on which it is granted and be bound by the provisions of the RSU Scheme and the Notice of Grant. To the extent that the Award is not accepted within the period as specified by our Board at its sole discretion in the Notice of Grant, it shall be deemed to have been irrevocably declined and shall immediately lapse.

9. Acceptance of Award

If the selected Participant accepts the offer of grant of Award, he/she is required to sign an acceptance notice and return it to our Company within the period and in a manner prescribed in the Notice of Grant. Upon the receipt from the Participant of a duly executed acceptance notice, the Award is granted to such Participant, who becomes a Grantee under the RSU Scheme.

10. Restrictions on Grants

No Grant shall be made to, nor shall any Grant be capable of acceptance by, any selected Participant at a time when the selected Participant would or might be prohibited from dealing in the Shares by any applicable laws, regulations or rules.

A Grant must not be made after inside information has come to the knowledge of our Company until such inside information has been announced in accordance with the requirements of the applicable laws and regulations, including but not limited to the Listing Rules. In particular, no Award may be granted during the period commencing one month immediately preceding the earlier of:

(i) the date of the meeting of our Board (as such date is first notified to [**REDACTED**] in accordance with the [**REDACTED**]) for the approval of our Company's results for any year, half-year, quarterly or any other interim period (whether or not required under the [**REDACTED**]); and

(ii) the deadline for our Company to publish an announcement of its results for any year or half-year under the [**REDACTED**], or quarterly or any other interim period (whether or not required under the [**REDACTED**]), and ending on the date of the results announcement.

Such period will cover any period of delay in the publication of a results announcement.

Our Board may not grant any Awards to any Participants in any of the following circumstances:

(i) the requisite approvals for that Grant from any applicable regulatory authorities have not been obtained;

(ii) the securities laws, regulations or rules require that a prospectus or other offering documents be issued in respect of the Grant or the RSU Scheme, unless our Board determines otherwise;

(iii) the Grant would result in a breach of any applicable securities laws, rules or regulations by any member of our Group or any of its directors; or

(iv) the Grant would result in a breach of the RSU Scheme limit or other rules of the RSU Scheme.

11. Grant to Directors

Where any Award is proposed to be granted to a director of any member of our Group, it shall not be granted on any day on which the financial results of our Company are published or during the periods of:

(i) 60 days immediately preceding the publication date of the annual results, or if shorter, the period from the end of the relevant financial year up to the publication date of the results; and

(ii) 30 days immediately preceding the publication date of the quarterly results (if any) and half-yearly results, or if shorter, the period from the end of the relevant quarterly or half-yearly period up to the publication date of the results.

12. Grant to Connected Persons

Any Grant to any Director, chief executive or substantial shareholder of our Company, or any of their respective associates, shall be subject to the prior approval of our independent non-executive Directors (excluding any independent non-executive Director who is a proposed Grantee of the Awards in question) and shall otherwise be subject to compliance with applicable requirements of the Listing Rules.

Notwithstanding the foregoing, any grant of an Award to a Director pursuant to Rules 14A.73(6) and 14A.95 of the Listing Rules will be exempted from reporting, announcement and independent Shareholders' approval requirements if the Award forms part of the relevant Director's remuneration under his/her service contract.

13. Rights attached to Awards

The RSUs do not carry any right to vote at general meetings of our Company. No Grantee shall enjoy any of the rights of a Shareholder by virtue of the grant of RSUs pursuant to the RSU Scheme, unless and until such Shares underlying the RSUs are actually transferred to the Grantee upon the vesting of the RSUs according to the RSU Scheme. Unless otherwise specified by our Board at its sole discretion in the Notice of Grant, Grantees do not have any rights to any cash or non-cash income, dividends or distributions and/or the sale proceeds of non-cash and non-scrip distributions from any Shares underlying the RSUs from the date that the Award is granted to the date of vesting (the "**RSU Income**").

14. Awards to be Personal to the Grantee

Unless otherwise approved by our Company in writing (to the extent permitted by law), an Award shall be personal to the Grantee and shall not be assignable or transferable by the Grantee except assignment or transfer from a Grantee to a company wholly owned by him/her or between two companies both of which are wholly owned by him/her and provided that following the Grantee's death, our Board shall, at its absolute discretion, determine whether the RSUs (and where applicable, the RSU Income) under the Award made to the deceased Grantee shall be deemed to have vested immediately prior to his/her death. Subject to certain conditions, such vested RSU(s) may be transferred by will or by the laws of testacy and distribution. The terms of the RSU Scheme and the Notice of Grant shall be binding upon the executors, administrators, heirs, successors and assignees of the deceased Grantee.

Subject to the above, no Grantee shall in any way sell, transfer, assign, charge, mortgage, pledge, encumber, hedge or create any interest in favor of any person over or in relation to any RSU (and where applicable, the RSU Income) or any property held by the Trustee on trust for the Grantees, Awards, Shares underlying any Awards or any interest or benefits therein (irrespective of whether such has been completed or created).

15. Vesting

Subject to compliance with the requirements of the Listing Rules, our Board has the sole discretion to determine the vesting period and vesting conditions (if any) for any grant of Award(s) to any Grantee, which may also be adjusted and re-determined by our Board from time to time.

Upon fulfillment or waiver of the vesting period and vesting conditions (if any) applicable to the Award(s) granted to a Grantee, a vesting notice in such form as our Board may from time to time determine (the "**Vesting Notice**") will be sent to the Grantee and the Trustee(s) by our Board or by any other means as determined by our Board at its sole discretion from time to time confirming (a) the extent to which the vesting period and vesting conditions (if any) have been fulfilled or otherwise waived, and (b) the number of Shares (and, if applicable, the RSU Income) or the amount of cash that the Grantee will receive.

The Grantee is required to execute, after receiving the Vesting Notice, certain documents as set out in the Vesting Notice that our Board considers necessary (which may include, without limitation, a certification to our Company that he/she has complied with all the applicable terms and conditions as set out in the RSU Scheme and the Notice of Grant).

If any of the vesting conditions is not satisfied and no waiver of such condition is granted, the RSU(s) under the Award, to the extent that such vesting conditions relate, shall lapse and be canceled in a manner to be determined by our Board at its absolute discretion.

Notwithstanding the foregoing, if any relevant parties of the RSU Scheme would or might be prohibited from [**REDACTED**] the Shares by the [**REDACTED**] or by any other applicable laws, regulations or rules within any period specified above, the date on which the relevant Shares shall be transferred to the Grantee shall occur as soon as possible after the date when such [**REDACTED**] is permitted by the [**REDACTED**] or by any other applicable laws, regulations or rules.

16. Rights on a Takeover

In the event a general offer by way of voluntary offer, takeover or otherwise (other than by way of scheme of arrangement) is made to all the Shareholders (or all such Shareholders other than the offeror and/or any person controlled by the offeror and/or any person acting in association or concert with the offeror) and such offer becomes or is declared unconditional prior to the vesting date of any RSU, our Board shall, prior to the offer becoming or being declared unconditional, determine at its absolute discretion whether such RSU shall vest and the period within which such RSU shall vest. If our Board determines that such RSU shall vest, it shall notify the Grantee that the RSU shall vest and the period within which such RSU shall vest.

17. Rights on a Scheme of Arrangement

In the event a general offer for Shares by way of scheme of arrangement is made to all our Shareholders and has been approved by the necessary number of Shareholders at the requisite meeting prior to the vesting of any RSU, our Board shall, prior to such meeting, determine at its absolute discretion whether such RSU shall vest and the period within which such RSU shall vest. If our Board determines that such RSU shall vest, it shall notify the Grantee that the RSU shall vest and the period within which such RSU shall vest.

18. Rights on a Voluntary Winding-up

In the event a notice is given by our Company to its Shareholders to convene a Shareholders' meeting for the purpose of considering and, if thought fit, approving a resolution to voluntarily wind up our Company prior to the vesting date of any RSU, our Board shall determine at its discretion whether such RSU shall vest and the period within which such RSU shall vest, provided that where such RSU shall vest, the unvested RSUs must be vested and effected by no later than two Business Days before the date of the proposed Shareholders' meeting. If our Board determines that such RSU shall vest, it shall notify the Grantee that the RSU shall vest and the period within which such RSU shall vest.

19. Rights on a Compromise or Arrangement

In the event a compromise or arrangement, other than a scheme of arrangement contemplated above, between our Company and our Shareholders and/or creditors being proposed in connection with a scheme for the reconstruction of our Company or our amalgamation, our Board shall determine at its discretion whether such RSU shall vest and the period when such RSU shall vest. If our Board determines that such RSU shall vest, it shall notify the Grantee that the RSU shall vest and the period within which such RSU shall vest.

20. Lapse of RSU

Unless our Board determines otherwise at its absolute discretion, any unvested RSU shall automatically lapse and be canceled upon the earliest of:

(a) the date of the termination of the Grantee's employment or service by any member of our Group for certain grounds of termination of employment or office or rights under the RSU (as specified in the RSU Scheme) or by reasons that the relevant entity with which the Grantee is employed ceased to be a Subsidiary;

(b) the date on which the Grantee is convicted of any criminal offense or imposed any serious administrative penalty;

(c) the date on which the Grantee engages in any act of disloyalty to our Company or any act that harms the interest of our Company (including but not limited to engaging in or assisting any third party to engage in any business other than our Group's business (irrespective of whether such business competes with our Group's business) without the approval of our Board during the Grantee's employment or service with any member of our Group);

(d) the date on which the Grantee commits a breach of the prohibition of paragraph 14 above, any terms or conditions under the Notice of Grant, the Acceptance Notice or the Vesting Notice, or any term or provision under any other agreement between the Grantee and any member of our Group (including but not limited to any confidentiality or non-competition provision);

(e) the date on which the Grantee causes, whether directly or indirectly, any loss, damage or injury to any assets, reputation, employees or directors of any member of our Group as a result of his/her illegal act or violation of discipline (including but not limited to corruption, bribery, solicitation of bribes, theft, leaking of confidential information and violation of any rule and regulation of any member of our Group);

(f) the date on which the Grantee commits any act that has a material adverse impact on the business, reputation or financial position of any member of our Group;

(g) the date on which the Grantee fails to devote sufficient time and effort to the business of our Group during the Grantee's employment or service with any member of our Group;

(h) the date on which the offer (or, as the case may be, revised offer) as referred to in paragraph 16 above closes;

(i) the record date for determining entitlements under the scheme of arrangement as referred to in paragraph 17 above;

(j) the date of the commencement of the winding-up of our Company; and

(k) the date on which it is no longer possible to satisfy any outstanding conditions to vesting.

Notwithstanding the above, in each case, our Board may at its absolute discretion decide that any RSU shall not be canceled or shall be subject to such conditions or limitations as our Board may decide.

21. Reorganization of Capital Structure

In the event of an alteration in the capital structure of our Company (whilst any RSU has not vested) by way of capitalization issue, bonus issue, rights issue, open offer, subdivision or consolidation of Shares, reduction of the share capital of our Company or otherwise howsoever in accordance with legal requirements and requirements of the Stock Exchange (save for certain exceptions as set out in the RSU Scheme), such corresponding alterations (if any) shall be made to the number or nominal amount of Shares subject to the RSU so far as unvested as the auditors of our Company or an approved independent financial adviser shall certify in writing, either generally or as regards any particular Grantee, to have in their opinion, fairly and reasonably satisfied the requirement that such adjustments give a Participant the same proportion (or rights in respect of the same proportion) of the share capital of our Company as that to which that Grantee was previously entitled, but that no such adjustments be made to the extent that a Share would be issued at less than its nominal value.

However, in the case of any capitalization issue or subdivision of Shares to be implemented by our Company as required for the purpose of the [**REDACTED**], no such certification by the auditors of our Company or a financial adviser shall be required.

22. Amendment of the RSU Scheme

The terms of the RSU Scheme may be altered, amended or waived in any respect by our Board provided that no such amendment shall operate to affect materially and adversely any subsisting rights of any Grantee hereunder without the consent in writing of the majority Grantees whose RSUs amount to three-fourths or more in nominal value of all Shares so held by the Trustee on the effective date of such alternation, amendment or waiver. Our Board's determination as to whether any proposed alteration, amendment or waiver to the terms and conditions of the RSU Scheme or the terms of the RSUs granted (as the case may be) is material shall be final and conclusive, provided in each case that such decision is made in accordance with the Articles of Association and any applicable laws.

23. Termination of the RSU Scheme

Our Board may at any time terminate the operation of the RSU Scheme and in such event, no further Awards shall be offered but the provisions of the RSU Scheme shall remain in full force and effect in all other respects in respect of RSUs which have been granted during the life of the RSU Scheme and which remain unvested immediately prior to the termination of the operation of the RSU Scheme.

24. General

An application has been made to the [**REDACTED**] of [**REDACTED**] for the [**REDACTED**] of, and permission to [**REDACTED**], the Shares underlying any Awards which may be granted pursuant to the RSU Scheme.

The following table summarizes the number of RSUs under the RSU Scheme granted to Directors and senior management of our Company as of the date of this document:

Name of Grantee	Position	Number of Shares underlying the RSUs granted (as adjusted after the Share Subdivision)	Date of Grant[(2)]	Vesting Period	Approximate percentage of issued Shares upon completion of the [REDACTED]
Ms. JIANG Xiaoling (姜曉玲)	Executive Director and vice president	500,000	May 6, 2023	Note (1)	[**REDACTED**]%
Ms. XU Chunqin (徐春芹)	Chief financial officer and joint company secretary	500,000	May 6, 2023	Note (1)	[**REDACTED**]%
Mr. JIANG Dongcheng (姜東成)	Vice president	5,000,000	May 6, 2023	Note (1)	[**REDACTED**]%

Notes:

(1) 20% of the RSUs granted shall vest on each of the first, second, third, fourth and fifth anniversary of the [**REDACTED**], provided that certain conditions (including certain performance targets of our Group and certain performance ratings of the grantees) are met.

(2) The above grantees were granted share incentives on May 6, 2023, the terms of which (including the performance targets) were amended upon the formal adoption of the RSU Scheme on August 2, 2023.

E. OTHER INFORMATION

1. Litigation

As of the Latest Practicable Date, we were not involved in any litigation, arbitration or claim of material importance and no litigation, arbitration or claim of material importance is known to our Directors to be pending or threatened against any member of our Group, which would have a material adverse effect on our Group's results of operations or financial condition, taken as a whole.

2. Preliminary Expenses

As of the Latest Practicable Date, we have not incurred any material preliminary expense.

3. Estate Duty

Our Directors have been advised that no material liability for estate duty is likely to fall on our Company or any of our subsidiaries.

4. Promoters

Our Company has no promoter for the purpose of the Listing Rules. 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 in connection with the [**REDACTED**] and the related transactions described in this document.

5. Sole Sponsor

The Sole Sponsor has made an application on our behalf to [**REDACTED**] for the [**REDACTED**] of, and permission to [**REDACTED**], (i) the Shares in issue (including the Shares to be converted from Series A Preferred Shares upon completion of the [**REDACTED**]), and (ii) the Shares to be [**REDACTED**] pursuant to the [**REDACTED**].

The Sole Sponsor satisfies the independence criteria applicable to sponsors set out in Rule 3A.07 of the Listing Rules. The Sole Sponsor will receive a fee of US$1,000,000 for acting as a sponsor to our Company in connection with the [**REDACTED**].

6. Qualification of Experts

The qualifications of the experts (as defined under the Listing Rules and the Companies (Winding Up and Miscellaneous Provisions) Ordinance) who have given opinions and/or advice in this document are as follows:

Name	Qualification
China International Capital Corporation Hong Kong Securities Limited	A licensed corporation under the SFO 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
Deloitte Touche Tohmatsu	Certified public accountants under the Professional Accountant Ordinance (Chapter 50 of the laws of Hong Kong) and a registered public interest entity auditor under the Accounting and Financial Reporting Council Ordinance (Chapter 588 of the Laws of Hong Kong)
Jingtian & Gongcheng	Legal adviser to our Company as to PRC laws
Maples and Calder (Hong Kong) LLP	Legal adviser to our Company as to Cayman Islands laws
Jingtian & Gongcheng	Legal adviser to our Company as to PRC intellectual property laws

Name	Qualification
Venture Partner, LLC	Legal adviser to our Company as to U.S. intellectual property laws
Frost & Sullivan (Beijing) Inc., Shanghai Branch Co.	Industry consultant

7. Consents

Each of the experts as referred to in the paragraph headed "– E. Other Information – 6. Qualification of Experts" in this appendix has given and has not withdrawn its respective written consents to the issue of this document with the inclusion of certificates, letters, opinions or reports and the references to its name included herein in the form and context in which it respectively included.

8. No Material Adverse Change

Our Directors confirm that there has been no material adverse change in the financial or trading position of our Group since December 31, 2023 (being the date to which the latest audited financial statements of our Group were made up).

9. Binding Effect

This document shall have the effect, if an application is made in pursuance hereof, of rendering all persons concerned bound by all the provisions (other than the penal provisions) of [**REDACTED**] of the Companies (Winding Up and Miscellaneous Provisions) Ordinance so far as applicable.

10. Miscellaneous

Save as otherwise disclosed in this document:

(i) none of our Directors or experts referred to in the paragraph headed "– E. Other Information – 6. Qualification of Experts" in this appendix has any direct or indirect interest in the promotion of, or in any assets which have been, within the two years immediately preceding the date of this document, 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;

(ii) none of the experts referred to in the paragraph headed "– E. Other Information – 6. Qualification of Experts" in this appendix has any shareholding interest in our Company or any of our subsidiaries or the right (whether legally enforceable or not) to subscribe for or to nominate persons to subscribe for securities in any member of our Group;

(iii) within the two years immediately preceding the date of this document, no share or loan capital or debenture of our Company or any of our subsidiaries has been issued or agreed to be issued or is proposed to be issued as fully or partly paid either for cash or for a consideration other than cash;

(iv) 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;

(v) no commission, discount, brokerage or other special term has been granted or agreed to be granted within the two years immediately preceding the date of this document in connection with the issue or sale of any share or loan capital of our Company or any of our subsidiaries;

(vi) within the two years preceding the date of this document, no commission has been paid or is payable (except commissions to [**REDACTED**]) for subscribing or agreeing to subscribe, or procuring or agreeing to procure the subscriptions, for any Shares in our Company;

(vii) there is no founder, management or deferred share in our Company or any of our subsidiaries;

(viii) our Company has no outstanding convertible debt securities or debentures;

(ix) there is no arrangement under which future dividends are waived or agreed to be waived;

(x) no member of our Group is presently listed on any stock exchange or traded on any trading system, and no listing or permission to deal is being or proposed to be sought; and

(xi) there is no restriction affecting the remittance of profits or repatriation of capital of our Company into Hong Kong from outside Hong Kong.

11. Bilingual Document

The English language and Chinese language versions of this document are being published separately in reliance upon the exemption provided under [**REDACTED**] of the Companies (Exemption of Companies and Prospectuses from Compliance with Provisions) Notice (Chapter 32L of the Laws of Hong Kong).

DOCUMENTS DELIVERED TO THE REGISTRAR OF COMPANIES IN HONG KONG

The documents attached to the copy of this document and delivered to the Registrar of Companies in Hong Kong for registration were:

(i) a copy of the material contract referred to in the paragraph headed "Appendix IV – Statutory and General Information – B. Further Information about Our Business – 1. Summary of Material Contract" in this document; and

(ii) the written consents referred to in the paragraph headed "Appendix IV – Statutory and General Information – E. Other Information – 7. Consents" in this document.

DOCUMENTS ON DISPLAY

Copies of the following documents will be published on the website of the Stock Exchange at **www.hkexnews.hk** and our website at **www.sunho-bio.com.cn** during a period of 14 days from the date of this document:

(a) the Memorandum of Association and the Articles of Association;

(b) the Accountants' Report prepared by Deloitte Touche Tohmatsu, the text of which is set out in Appendix I to this document;

(c) the audited consolidated financial statements of our Company for the two financial years ended December 31, 2022 and 2023;

(d) the report prepared by Deloitte Touche Tohmatsu on the unaudited [**REDACTED**] financial information of our Group, the text of which is set out in Appendix II to this document;

(e) the PRC legal opinion issued by Jingtian & Gongcheng, our PRC Legal Adviser, in respect of certain general corporate matters and property interests of our Group under PRC laws;

(f) the letter of advice prepared by Maples and Calder (Hong Kong) LLP, our legal adviser as to Cayman Islands laws, summarizing certain aspects of the Cayman Islands company law referred to in Appendix III to this document;

(g) the legal opinion issued by Jingtian & Gongcheng, our legal adviser as to PRC intellectual property laws, summarizing certain intellectual property matters of our Group under PRC laws;

(h) the intellectual property due diligence report prepared by Venture Partner, LLC, our legal adviser as to U.S. intellectual property laws, summarizing certain intellectual property matters of our Group under U.S. laws;

(i) the industry report prepared by Frost & Sullivan (Beijing) Inc., Shanghai Branch Co.;

(j) the material contract referred to in the paragraph headed "Appendix IV – Statutory and General Information – B. Further Information about Our Business – 1. Summary of Material Contract" in this document;

(k) the service contracts and the appointment letters referred to in the paragraph headed "Appendix IV – Statutory and General Information – C. Further Information about Our Directors – 2. Particulars of Directors' Service Contracts and Appointment Letters" in this document;

(l) the written consents referred to in the paragraph headed "Appendix IV – Statutory and General Information – E. Other Information – 7. Consents" in this document; and

(m) the Cayman Companies Act.