Application Proof of

Duality Biotherapeutics, Inc.
映恩生物

(the "**Company**")

(Incorporated under the laws of the Cayman Islands with limited liability)

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Duality Biotherapeutics, Inc.
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(Incorporated under the laws of the Cayman Islands with limited liability)

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EXPECTED TIMETABLE[1]

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CONTENTS

SUMMARY

This summary aims to give you an overview of the information contained in this document. As it is a summary, it does not contain all the information that may be important to you and is qualified in its entirety by, and should be read in conjunction with, the full document. You should read the whole document before you decide to* [REDACTED] *in the* [REDACTED]. *There are risks associated with any* [REDACTED]. *Some of the particular risks in* [REDACTED] *in the* [REDACTED] *are set forth in the section headed "Risk Factors" of this document. You should read that section carefully before you decide to* [REDACTED] *in the* [REDACTED]. *In particular, we are a biotechnology company seeking to* [REDACTED] *on the Main Board of the Stock Exchange under Chapter 18A of the Listing Rules as we do not meet the requirements under Rules 8.05(1), (2) or (3) of the Listing Rules. There are unique challenges, risks and uncertainties associated with* [REDACTED] *in companies like ours. Your* [REDACTED] *decision should be made in light of these considerations.

OVERVIEW

Incorporated in 2019, we are a global player in antibody-drug conjugate ("**ADC**") innovation, dedicated to the development of next-generation therapeutics in this fast-growing drug modality to treat cancer, autoimmune diseases, and beyond. We have self-discovered two Core Products, namely DB-1303/BNT323, a HER2 ADC candidate targeted for HER2 cancers including endometrial cancer ("**EC**") and breast cancer ("**BC**"), and DB-1311/BNT324, a B7-H3 ADC candidate targeted for B7-H3 cancers including small-cell lung cancer ("**SCLC**"), castration-resistant prostate cancer ("**CRPC**") and esophageal squamous cell carcinoma ("**ESCC**"). In addition to our Core Products, we have also self-discovered (i) five other clinical-stage ADCs with potential in a broad range of indications, each ranking among the most clinically advanced globally in terms of overall or lead indication development progress, according to Frost & Sullivan; (ii) two next-generation bispecific ADCs ("**BsADCs**") that are expected to enter into clinical stage from 2025 to 2026; and (iii) multiple other preclinical ADCs.

WE MAY NOT BE ABLE TO SUCCESSFULLY DEVELOP AND/OR MARKET OUR PIPELINE PRODUCTS, INCLUDING CORE PRODUCTS DB-1303 AND DB-1311.

Our topoisomerase-based DITAC platform has demonstrated a wide therapeutic window (i.e., safe and effective dosage range) which potentially translates into improved efficacy and safety in the clinical setting. Topoisomerase is an enzyme that plays an essential role in DNA replication and transcription. By targeting topoisomerase, ADCs derived from our DITAC platform can potentially treat various solid tumors by inhibiting DNA replication and inducing DNA damage in cancer cells. Our know-how and execution capabilities have further enabled us to design multiple modular platforms and engineer next-generation ADC therapeutics with unique features, including novel payloads (i.e., therapeutic agents delivered to the target area) and bispecific formats, that can potentially generate synergistic and combination effects, which may lead to significant improvement in patient outcomes.

Five of our clinical-stage assets had obtained investigational new drug ("**IND**") approvals from both the United States Food and Drug Administration (the "**FDA**") and the National Medical Products Administration of the PRC (the "**NMPA**") as of the Latest Practicable Date. We have seven ongoing global multi-regional clinical trials ("**MRCTs**") across 17 countries and over 230 trial sites, with over 2,000 patients enrolled (more than 50% located in the U.S., EU and Australia) as of the Latest Practicable Date. Our innovative ADC assets have attracted leading global biopharmaceutical companies, culminating in several global partnerships to date, including with BioNTech SE ("**BioNTech**"), BeiGene, Ltd. ("**BeiGene**"), Adcendo ApS ("**Adcendo**"), GSK plc ("**GSK**"), and Avenzo Therapeutics, Inc. ("**Avenzo**"), with over US$6.0 billion in total deal value (of which approximately US$400 million had been received as of the Latest Practicable Date).

SUMMARY

The pipeline chart below summarizes the development status of our clinical-stage drug candidates and selected preclinical assets, all of which are in-house discovered.

Note: (1) Abbreviations: Mono = Monotherapy, Combo = Combination Therapy, IND = Investigational New Drug, NCT = National Clinical Trial, ADC = Antibody-drug Conjugate, HER2 = Human Epidermal Growth Factor Receptor 2, HER2-expressing = HER2 Status of Tumor Cells Identified with a Test Score of IHC 1+ or Above, EC = Endometrial Cancer, HR+ = Hormone Receptor Positive, HER2-low=HER2 Status of Tumor Cells Identified with a Test Score of IHC 1+ or IHC 2+/ISH-, BC = Breast Cancer, Chemo = Chemotherapy, HER2+ = HER2 Status of Tumor Cells Identified with a Test Score of Either IHC 3+ or IHC 2+/ISH+, OC = Ovarian Cancer, CRC = Colorectal Cancer, SCLC = Small Cell Lung Cancer, CRPC = Castration-resistant Prostate Cancer, ESCC= Esophageal Squamous Cell Carcinoma, NSCLC = Non-small Cell Lung Cancer, HNSCC = Head and Neck Squamous Cell Carcinoma, HCC= Hepatocellular Carcinoma, CC = Cervical Cancer, HER3 = Human Epidermal Growth Factor Receptor 3, EGFRm = EGFR Mutant, TKI = Tyrosine Kinase Inhibitor, KRASm = Kirsten Rat Sarcoma Virus Mutant, BTC = Biliary Tract Cancer, TROP2 = Human Trophoblast Cell-surface Antigen 2, TNBC = Triple-negative Breast Cancer, PD-L1 = PD-1 Ligand 1, VEGF = Vascular Endothelial Growth Factor, bsAb = Bispecific Antibody, EGFR = Epidermal Growth Factor Receptor, BDCA2 = Blood Dendritic Cell Antigen 2, MOA = Mechanism of Action, SLE = Systemic Lupus Erythematosus, CLE = Cutaneous Lupus Erythematosus, FDA = U.S. Food and Drug Administration, NMPA = National Medical Products Administration of the PRC, 1L: first-line treatment, 2L+: second-line or later treatment

(2) For each drug candidate, our clinical development typically begins with a combined phase 1/2a trial, where multiple patient groups across different tumor types or indications are enrolled to assess both safety and efficacy of the drug candidate. Based on the results from these phase 1/2 trials, we determine which indications to prioritize for advancement into later-stage clinical development. All ongoing clinical trials are subject to regulatory oversight by both the FDA and NMPA, except for DB-1303's phase 3 trial in HER2+ BC patients, which is conducted solely in China and regulated by the NMPA.

* BioNTech was the sponsor of this global trial as of the Latest Practicable Date.

** BeiGene was serving as the sponsor of this trial as of the Latest Practicable Date.

OUR BUSINESS MODEL

Since our inception, we have focused primarily on the independent discovery and development of ADC assets. We have assembled a highly experienced team of experts in all facets of ADC drug development. Their accumulated experience and expertise have driven our technology platform and pipeline development, executed with quality and operational efficiency. With our commitment to organic in-house R&D, we have developed four cutting-edge technology platforms and a pipeline of 12 internally discovered ADC candidates covering a diverse range of indications, which reflects our understanding of disease biology and unique insights into target selection.

In the rapidly iterating and highly competitive ADC market, we understand that development speed is as crucial as asset quality in determining the ultimate success of an ADC drug. As a biotech company founded in 2019, we have strategically focused our core competencies on our technology platforms and the critical initial phases of drug development, from drug discovery to proof-of-concept clinical trials. For late-stage clinical development (such as global MRCTs) across multiple drug assets, we have taken a strategic and flexible approach to drug development, leveraging both our internal resources and external partnerships to rapidly bring our drugs to market. This efficient model allows us to maintain our agility and innovation as a young biotech company while tapping into the scale and experience necessary for successful late-stage global development.

Our successful in-house R&D has drawn the attention of global biopharmaceutical companies, and we have entered into collaborations to accelerate the global expansion of our drug programs and maximize their impact on patients worldwide. These collaborations are win-win for us and our partners. We have retained development and commercialization rights to these assets in certain territories, and have continued to play a core role in the overall development strategy and direction of these assets on a global level. The partnerships enable us to maximize the clinical value of our in-house discovered assets and provide financial resources to further invest in our pipeline development. Moreover, these collaborations provide our partners with high-quality clinical-stage ADC assets to complement their drug portfolios and support their long-term strategies.

Going forward, we expect to continue to implement this business model. We will continue to lead the development activities of our clinical-stage assets in the regions where we retain rights, and expect to have multiple assets entering the clinic in the next few years and more in preclinical studies. We will also continue to optimize our ADC platforms to support further innovation and remain open to value-accretive R&D partnerships that support our growth. Anticipating commercialization of our late-stage ADCs, we are proactively developing a tailored commercial strategy for each asset, harnessing both our in-house capabilities and external collaboration.

OUR PIPELINE

We have built a pipeline of 12 in-house discovered ADC candidates, comprising: (i) seven clinical-stage ADCs with potential in a broad range of indications; (ii) two next-generation BsADCs that are expected to enter into clinical stage from 2025 to 2026; and (iii) multiple other preclinical ADCs. Three of our clinical-stage assets, including our Core Products DB-1303 and DB-1311 and key product DB-1305, have received Fast Track Designation from the FDA, and DB-1303 has received Breakthrough Therapy Designations from both the FDA and NMPA, for certain indications.

Core Products

- **DB-1303/BNT323** is a late clinical-stage HER2 ADC candidate with two ongoing registrational trials (one global trial and one in China) and one potential global registrational study, with the first indication (HER2-expressing EC) projected to file for accelerated approval with the FDA as early as 2025. DB-1303 is designed with a stable, cleavable linker (i.e., molecule that connects the payload to the antibody of an ADC to deliver the therapeutic agent to target cells) and proprietary topoisomerase-based payload that aim to lower off-target toxicity and enhance anti-tumor activity, including bystander killing effects. These features may enable DB-1303 to potentially serve as a new therapeutic option for patients with HER2-expressing advanced solid tumors, including both patients with high and low expression levels of HER2. The global HER2 ADC market is expected to increase from US$4.8 billion in 2023 to US$18.5 billion by 2028, representing a CAGR of 30.8%, according to Frost & Sullivan.

  As of the Latest Practicable Date, there were two HER2 ADCs approved both in the U.S. and in China, namely Enhertu® and Kadcyla®, and one additional approved in China, Aidixi®. As of the same date, there were three HER2 ADCs (including Enhertu®) in phase 3 clinical development or beyond under global MRCTs. Among these HER2 ADC candidates, DB-1303 is the most clinically advanced HER2 ADC candidate globally that targets EC across HER2-expression levels and a candidate in advanced clinical development for HER2 low-expressing BC, according to Frost & Sullivan, with potential for extension to other underserved cancer indications. DB-1303 has obtained Fast Track and Breakthrough Therapy Designations from the FDA and Breakthrough Therapy Designation from the NMPA for the treatment of advanced EC in patients who progressed on or after treatment with immune checkpoint inhibitors, demonstrating DB-1303's potential to treat advanced EC patients who currently have low survival rates and a strong medical need for new and more effective treatments. Moreover, DB-1303's antitumor activity has been observed in a range of tumors, including BC, EC, ovarian cancer ("**OC**"), colorectal cancer ("**CRC**") and esophageal cancer, supported by global clinical data from patients across the U.S., China and Australia to date. To further advance DB-1303, we formed a global strategic partnership with BioNTech in 2023 to accelerate its development and maximize its global value.

The following table sets forth a summary of DB-1303's clinical trial data to date.

	Efficacy results	Safety results
DB-1303		
Potential Registrational Study for HER2 Expressing EC	Based on the preliminary results from the dose escalation and expansion studies, DB-1303 demonstrated promising antitumor activity with high disease control in patients with advanced/metastatic EC, including serous and carcinosarcomas. • As of May 8, 2023, 17 patients were evaluable for response. Ten patients (58.8%) had objective partial tumor response per RECIST v1.1. The ORRs for patients at 7 and 8 mg/kg dose were 50.0% (2/4) and 61.5% (8/13), respectively. The overall DCR was 94.1%.	Based on the preliminary results from the dose escalation and expansion studies, DB-1303 showed a manageable safety profile. As of May 8, 2023, no TEAEs leading to death or dose discontinuation occurred. No adverse event of special interest ("AESI") occurred, and no DLT was observed in dose escalation.
Phase 1/2a Global Clinical Trial for Advanced/Metastatic Solid Tumors	Based on the preliminary results from the phase 1 dose escalation study, promising antitumor activity was observed in heavily pretreated patients with HER2-expressing solid tumors. • The unconfirmed ORR ("**uORR**") was 44.2% (23/52) and DCR was 88.5% (46/52). • Encouraging anti-tumor activity of DB-1303 was observed in advanced BC patients, including 26 with HER2+ BC and 13 with HER2-low BC. • Antitumor activity of DB-1303 was also observed in non-BC tumor types, including CRC, EC, OC and esophageal cancer.	Based on the preliminary results from the phase 1 dose escalation study, DB-1303 was well tolerated and all AEs were manageable. As of January 13, 2023, no DLT was observed in all six dose levels during dose escalation and no TEAEs associated with death occurred.

For details, see "Business — Our Pipeline — ADC Assets Developed from DITAC Technology Platform — DB-1303/BNT323, a late clinical stage HER2 ADC candidate, our Core Product — Summary of Clinical Trial Data."

- **DB-1311/BNT324** is a clinically advanced B7-H3 ADC candidate under global development. B7-H3 is a prominent member of the B7 family that plays a critical role in promoting tumor progression and metastasis. DB-1311 is designed to harness the potential of B7-H3 as a therapeutic target, leveraging its widespread overexpression in a broad range of tumor types, including SCLC, non-small cell lung cancer (**"NSCLC**"), BC, CRPC, ESCC and head and neck squamous cell carcinoma ("**HNSCC**"). Notably, DB-1311 demonstrates strong selectivity by targeting a specific isoform predominantly found on B7-H3-overexpressing tumor cells, which, combined with its potent payload, stable linker-payload and fragment crystallizable region silenced ("**Fc-silenced**") monoclonal antibody ("**mAb**"), potentially translates into a favorable safety profile and a wide therapeutic window.

  As of the Latest Practicable Date, there were no approved B7-H3-targeted therapies, including ADCs, globally or in China, and there were six B7-H3 ADCs under global MRCTs, with DB-1311 being a candidate in advanced clinical development. In collaboration with BioNTech, we are actively pursuing a comprehensive clinical development plan to unlock the full potential of DB-1311, both as monotherapy and in combination with immunotherapy. DB-1311 has shown encouraging antitumor activity and a manageable safety profile in its ongoing phase 1/2a trial, including in patients with advanced SCLC, CRPC and multiple other solid tumors. Besides SCLC and CRPC, we are also investigating DB-1311's treatment potential in HNSCC, HCC, CC, and melanoma. In 2024, the FDA granted DB-1311 Fast Track Designation for the treatment of patients with advanced/unresectable, or metastatic CRPC and Orphan Drug Designations for the treatment of ESCC and SCLC.

  The following table sets forth a summary of DB-1311's clinical trial data to date.

	Efficacy results	Safety results
DB-1311		
Phase 1/2a Clinical Trial in Patients with Advanced/Metastatic Solid Tumors	Based on the preliminary results from the phase 1 dose escalation study, which were presented in an oral session at the 2024 European Society of Medical Oncology Asia Annual Meeting ("**ESMO Asia**"), DB-1311 showed encouraging antitumor activity in advanced solid tumors. As of September 27, 2024, the data cut-off date for 2024 ESMO Asia, among all evaluable patients with at least one post-baseline tumor assessment (n=238), the overall uORR was 32.4%, and the DCR was 82.4%. As of the same date, among patients with SCLC (n=73), the uORR was 56.2%, and the DCR was 89.0%. Among patients with CRPC (n=32), DB-1311 demonstrated early antitumor activity with a uORR of 28.0% and a DCR of 92.0%; radiographic progression-free survival ("**rPFS**") data were not yet mature, with a median rPFS of 7.2 months and a 6-month rPFS rate of 94.7%.	Based on the preliminary results from the phase 1 dose escalation study, DB-1311 showed an acceptable and manageable safety profile, with low rates of TRAEs associated with drug discontinuation, dose reduction, drug interruption or death.

For details, see "Business — Our Pipeline — ADC Assets Developed from DITAC Technology Platform — DB-1311/BNT324, a B7-H3 ADC candidate with global market potential, our Core Product — Summary of Clinical Trial Data."

Key Products

- **DB-1310** is one of the world's most clinically advanced HER3 ADC candidates, according to Frost & Sullivan, for which we hold global rights. HER3, along with EGFR and HER2, are growth factor receptors in the HER family that play crucial roles in tumor survival and growth. Despite the growing research and clinical interest in HER3, it remains under-explored and has faced two decades of drug development challenges due to the complexity in achieving signaling inhibition and the potential for escape pathway activation. Guided by our team of leading experts in HER3 research, we have built a deep knowledge base in HER3 biology, including its dimerization patterns (i.e., the way in which two molecules combine to form a complex structure) and intricate interactions with EGFR and HER2, and its involvement in resistance mechanisms. These insights have informed DB-1310's innovative design and equipped it with a high internalization capability (i.e., the ability to be absorbed by target cells) to deliver payloads directly into HER3-expressing cancer cells, which leads to targeted tumor killing and improved therapeutic outcomes.

  We believe HER3 ADCs present opportunities to cover a broad patient population with limited reliance on biomarker-based patient selection and overcome resistance to standard of care. We have developed a rational and differentiated clinical development strategy focused on carefully selected indications that maximize its commercial potential. For EGFR-mutant ("**EGFRm**") NSCLC, while our peers explore HER3 ADCs as a second-line or later monotherapy, we have taken a differentiated strategy to investigate DB-1310's combination potential with osimertinib in EGFRm NSCLC patients resistant to osimertinib or other third-generation tyrosine kinase inhibitor ("**TKI**") therapy, with opportunity to be a first-line treatment covering a broader patient population. DB-1310 is also one of the few global clinical-stage HER3 ADCs being investigated as a potential treatment for KRAS-mutant ("**KRASm**") NSCLC. We are also exploring the efficacy signals of DB-1310 in various other solid tumors, including BC, CRPC, HNSCC, ESCC and biliary tract cancer ("**BTC**").

- **DB-1305/BNT325** is a TROP2 ADC candidate with a global development strategy. TROP2, a validated and highly expressed ADC target across a wide spectrum of cancers, plays a pivotal role in tumor progression. To date, there is only one TROP2 ADC approved globally, indicated for advanced triple-negative breast cancer ("**TNBC**"), urothelial cancer ("**UC**") and HR+/HER2- BC, according to Frost & Sullivan. The global TROP2 ADC market is expected to increase from US$1.1 billion in 2023 to US$7.7 billion by 2028, representing a CAGR of 48.8%.

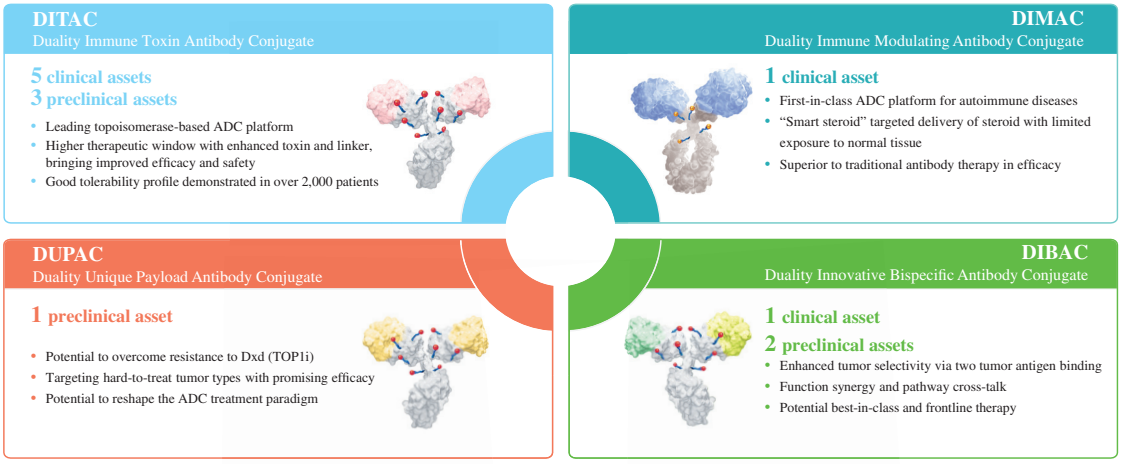
DB-1305 targets indications currently under-explored by other TROP2 ADC candidates, such as OC. DB-1305 also has combination potential as a backbone therapy in earlier lines of treatment, starting from NSCLC, OC, cervical cancer ("**CC**") and TNBC. We believe this well-rounded strategy may position DB-1305 as a potential backbone therapy in the TROP2 ADC landscape. In collaboration with BioNTech, we are advancing DB-1305's global clinical development, including an ongoing phase 1/2a global trial in patients with advanced solid tumors, where encouraging preliminary efficacy signals in NSCLC and multiple other solid tumors have been observed.

- **DB-1419** is a potential first-in-class B7-H3xPD-L1 BsADC candidate with a DNA topoisomerase I inhibitor, being the only B7-H3xPD-L1 BsADC currently under clinical development globally, according to Frost & Sullivan. The simultaneous action of delivering the toxin to tumor cell and modulate T cell activation provides potential synergistic anti-tumor effect. Combining payload mediated cytotoxicity with antibody mediated immunotherapy activity, DB-1419 provides an innovative approach for cancer treatment. We have obtained IND approval from the FDA for DB-1419 and we initiated DB-1419's phase 1/2a global trial in September 2024.

- **DB-2304** is a potential first-in-class BDCA2 ADC candidate for systemic lupus erythematosus ("**SLE**") and cutaneous lupus erythematosus ("**CLE**"), being one of the most advanced BDCA2 ADCs in terms of development progress, according to Frost & Sullivan. DB-2304 offers a selective therapeutic approach specifically targeting the upstream signaling pathways of SLE/CLE pathogenesis, differentiating it from existing lupus treatments that often have broader effects on the immune system. We believe DB-2304 holds promise to substantially improve upon the standard of care for SLE and CLE, such as glucocorticoids and immunosuppressants, and represents a major step in the innovation of autoimmune ADCs. We initiated a phase 1 study in healthy adults for DB-2304 in Australia in October 2024. We have submitted IND applications to both the FDA and NMPA for DB-2304 and, subject to regulatory approval, expect to complete DB-2304's phase 1 global trial in 2026.

OUR TECHNOLOGY PLATFORMS

Leveraging our experienced R&D team, insights into ADC design, and strong execution capabilities, we have established four cutting-edge ADC technology platforms: DITAC, DIBAC, DIMAC, and DUPAC, to push the boundaries of ADC treatment. Our technology platforms serve as the foundation for continuous and sustained innovation and value creation, whose value and versatility have been validated by our pipeline assets and recognized by global multinational corporation ("**MNC**") partners.



Notes:

Topoisomerase: An enzyme that plays an essential role in DNA replication and transcription. By targeting topoisomerase, ADCs derived from our DITAC platform can potentially treat various solid tumors by inhibiting DNA replication and inducing DNA damage in cancer cells.

Payload: Therapeutic agents delivered to the target area.

Linker: Molecule that connects the payload to the antibody of an ADC to deliver the therapeutic agent to target cells.

- **Duality Immune Toxin Antibody Conjugate (DITAC)**, our proprietary topoisomerase inhibitor-based ADC platform, is validated by the global clinical data from over 2,000 patients across the U.S., China, Europe, Australia and other major markets. Compared to non-topoisomerase ADCs, topoisomerase-based ADCs have demonstrated a wide therapeutic window which potentially translates into improved efficacy and safety in the clinical setting. This platform is developed by screening and optimizing a library of proprietary ADC components, including our proprietary payloads P1003 and P1021, through meaningful technological improvements. As such, DITAC provides critical flexibility to design our ADCs with improved systemic stability, tumor-specific payload release, bystander-killing effects, and rapid payload clearance.

- **Duality Innovative Bispecific Antibody Conjugate (DIBAC)**, one of the few BsADC platforms in the world, is leading a new wave of ADC innovation. BsADCs can potentially offer improved efficacy over traditional monospecific ADCs and combination therapies, by incorporating two distinct binding moieties in a single therapeutic entity. While promising, the complexity of BsADCs introduces new challenges in antibody engineering, stability and manufacturing, setting a high entry barrier. Our innovative DIBAC platform features our understanding of disease and target biology, rich experience in bispecific antibody engineering, and artificial intelligence-empowered target selection and antibody design.

- **Duality Immune-Modulating Antibody Conjugate (DIMAC)**, empowered by our proprietary immune-modulating payload, holds the potential to open the ADC modality to a significant white-space market in autoimmune and other therapeutic areas. DIMAC is one of the very few ADC platforms in the world that targets major autoimmune diseases. Many patients with chronic autoimmune diseases, such as SLE and CLE, are currently treated with therapies that often lead to severe side effects. Long term use of glucocorticoids, for example, are commonly associated with increased risks of bone fractures, weight gain, diabetes, immune system suppression, and other chronic conditions. We believe ADCs can reshape the treatment paradigm of autoimmune diseases by offering a targeted treatment with low systemic exposure, enhanced efficacy and reduced side effects. Molecules designed under our DIMAC platform have demonstrated potent and broad anti-inflammatory activity, long duration of action, sustained stability, and low systemic exposure in preclinical studies.

- **Duality Unique Payload Antibody Conjugate (DUPAC)** reflects our foresight into the future landscape of ADC innovation. DUPAC is one of the few ADC platforms globally dedicated to the development of linker-payload complexes with novel mechanisms of action, beyond traditional cytotoxic agents, to combat growing drug resistance and hard-to-treat tumors. We have made promising progress in a number of unique payload mechanism and have obtained prototypes with broad-spectrum anti-tumor activity across multiple solid tumors, and potent direct and bystander killing effects in preclinical studies.

As of the Latest Practicable Date, we owned one patent family in relation to DITAC and DIBAC, and one patent family in relation to DIMAC, and both patent families include multiple patents and patent applications in different jurisdictions. For details, please see "Business — Intellectual Property."

OUR COMPETITIVE STRENGTHS

We believe that the following competitive strengths have differentiated us from our competitors: (i) we are a global ADC powerhouse with insights and strong execution capabilities to lead ADC innovation, (ii) we have clinically advanced ADC assets with promising global data as validation of our leading DITAC platform, (iii) we are an innovator in ADC development powered by versatile platforms to target underserved therapeutic areas, (iv) we have established strategic and value-enhancing partnerships with confidence in our platforms and pipeline to sustain long-term global development, and (v) we are led by a world-class management team of ADC experts and seasoned entrepreneurs with a proven track record. For details, see "Business — Our Competitive Strengths."

OUR DEVELOPMENT STRATEGIES

Our mission is to become a global powerhouse in the discovery, development, and commercialization of innovative ADC therapies. Led by our founder and chief executive officer Dr. ZHU Zhongyuan and an experienced scientific team, we have established a dedicated global ADC development engine. Building upon these efforts, we intend to capitalize on our competitive strengths by pursuing the following development strategies: (i) accelerating global development and commercialization of clinical-stage assets, (ii) rapidly advance next wave of ADC assets by leveraging accumulated global R&D and regulatory expertise, (iii) continue technology innovation to unlock the full potential of ADCs and disrupt treatment landscape, (iv) maximize clinical and commercial potential of our assets through value accretive partnerships, and (v) continue to build our global presence and teams across drug research, clinical development, regulatory affairs and commercialization. For details, see "Business — Our Business Strategies."

COLLABORATION AND LICENSING ARRANGEMENTS

In line with our global strategy, we have established an array of strategic partnerships to accelerate the development of our pipeline across key global markets, expand our global clinical development capabilities, and fuel our future innovation and long-term growth. In our short operating history, we have entered into several out-licensing and collaboration deals with leading industry players worldwide to date, including BioNTech (for DB-1303, DB-1311 and DB-1305), BeiGene (for DB-1312), Adcendo (for ADC assets using our proprietary payload linkers), GSK (for DB-1324), and Avenzo (for DB-1418), with over US$6.0 billion in total deal value (of which approximately US$400 million had been received as of the Latest Practicable Date). Additionally, we have entered into in-license agreements for advanced antibody technologies, enhancing our drug development efficiency. For details, see "Business — Our Collaboration and Licensing Arrangements."

Strategic Partnership with BioNTech

BioNTech is a global leader in next-generation immunotherapy, pioneering innovative treatments for cancer, infectious diseases, and other serious conditions. Headquartered in Germany, BioNTech has operations across five continents and a global workforce of over 6,000 employees. In recent years, BioNTech has strategically enhanced its clinical pipeline through global partnerships, including collaboration with our Company to add next-generation ADC assets into its oncology portfolio.

Our partnership with BioNTech, which originated from the two companies' meetings at industry conferences, is driven by a shared strategy to develop innovative therapies that could potentially complement or replace chemotherapy, addressing the needs of cancer patients across the entire disease continuum.

The table below summarizes the key terms of our three licensing and collaboration agreements with BioNTech. Each of the three agreements relates to one of our in-house discovered ADC assets, namely DB-1303, DB-1311 and DB-1305.

	DB-1303	DB-1311	DB-1305
Date of agreement	March 16, 2023	March 31, 2023	August 4, 2023
License granted	We granted to BioNTech an exclusive, royalty-bearing and sublicensable license under certain patents and know-how owned or otherwise controlled by us to develop, manufacture, commercialize or otherwise exploit the respective licensed compounds and licensed products for all uses worldwide except Mainland China, Hong Kong and Macau (the "Territory").		
Retained rights; cost & profit/loss sharing	We retain the full rights to develop, manufacture, commercialize and otherwise exploit the respective licensed compounds and licensed products in Mainland China, Hong Kong and Macau (collectively, the "Retained Territory"). For DB-1311: BioNTech granted us an exclusive option to share the development and commercialization costs and profits and losses from the exploitation of the first DB-1311 Product in the United States, in accordance with the terms set out in the agreement.[(1)]		
Milestone payments	Up to US$857.5 million (US$21.0 million paid to date)	Up to US$901.0 million (US$24.0 million paid to date)	Up to US$826.0 million (nil due to date)

	DB-1303	DB-1311	DB-1305
Royalties	BioNTech agreed to pay tiered royalties between high-single-digit to low-double-digit percentage on the annual net sales of all licensed products in the Territory (subject to certain adjustments) during the respective royalty term upon commercialization.		
Ownership of IP rights	Intellectual property generated, developed, conceived solely by one of the parties or jointly by us and BioNTech during the performance of this agreement shall be solely owned by one of the parties or jointly and equally owned by both parties depending on inventorship, subject matter and/or by which party it was funded.		
Clinical development	BioNTech shall be responsible, at its own expense, for the development of the licensed products in the Territory under the oversight of the Joint Steering Committee ("**JSC**"). BioNTech agrees to reimburse us for the reasonable costs and expenses incurred in the Territory in relation to each of the licensed products, subject to certain limitations and in accordance with the terms of the respective agreements.		
Regulatory filings	Except for the DB-1303 Ongoing Clinical Trial[(2)], DB-1311 Planned Trials[(3)], DB-1305 Planned Trials[(4)] and other additional trials for which BioNTech may designate us to be the sponsor, BioNTech shall (i) be the sponsor and holder of all regulatory approvals for the licensed products in the Territory, and (ii) lead and control the preparation and submission of all regulatory filings related to the licensed compounds and licensed products in the Territory at its sole cost and expense.[(5)] For clarity, we shall be the sponsor of any clinical trial for the licensed products conducted solely in the Retained Territory (unless otherwise agreed), and are responsible for the preparation and submission of any regulatory filings in the Retained Territory at our sole cost and expense.		
Termination rights	In general, either party may terminate an agreement in the event of the other party's uncured material breach or insolvency. BioNTech may also terminate such agreement without cause, in whole or in part, by giving us prior written notice.		

Notes:

(1) As of the Latest Practicable Date, we had not exercised the DB-1311 Cost & Profit/Loss Sharing Option and retained the right to do so in the future.

(2) We will continue to be the sponsor of DB-1303's ongoing phase 1/2a global clinical trial (NCT05150691) ("DB-1303 Ongoing Clinical Trial") in both the Territory and the Retained Territory, to ensure that the DB-1303 Ongoing Clinical Trial can proceed without interruption.

(3) We will conduct all clinical trials for DB-1311, including those in the Territory, until the completion of the phase II study (being the phase 2a dose expansion study) of DB-1311's ongoing phase 1/2a trial (NCT05914116) (together, the "DB-1311 Planned Trials").

(4) We will conduct all clinical trials for DB-1305, including those in the Territory, until the completion of the phase II study (being the phase 2a dose expansion study) of DB-1305's ongoing phase 1/2a clinical trial (NCT05438329) (together, the "DB-1305 Planned Trials").

(5) Following the completion of the DB-1303 Ongoing Clinical Trial, DB-1311 Planned Trials and DB-1305 Planned Trials, as applicable, we shall transfer and assign to BioNTech our right, title and interest in all regulatory approvals in the Territory with respect to the respective licensed compounds and licensed products.

Collaboration with BeiGene

BeiGene is a global oncology company that is discovering and developing innovative treatments that are more affordable and accessible to cancer patients worldwide. With a broad portfolio, BeiGene is expediting development of its diverse pipeline of novel therapeutics through internal capabilities and collaborations. BeiGene's growing global team of more than 10,000 colleagues spans five continents. BeiGene is investing in impactful therapeutic modalities such as ADCs to complement its pipeline in solid tumors.

We have entered into a strategic partnership with BeiGene, where we granted to BeiGene a global license to develop and commercialize DB-1312, our in-house discovered B7-H4-targeted ADC. This collaboration enables BeiGene to advance DB-1312 globally in conjunction with its internally discovered ADC assets, leveraging our industry-leading research capabilities and BeiGene's end-to-end ADC manufacturing expertise and creating a synergistic approach to drug development.

The table below summarizes the key terms of our licensing and collaboration agreement with BeiGene.

Date of agreement	July 9, 2023 (option agreement); February 18, 2024 (option exercised)
License granted	We granted to BeiGene (i) an exclusive, non-transferable, royalty-bearing license, with the right to grant sublicenses, of certain know-how and patent rights controlled by us (the "**DB-1312 Licensed IP**"), excluding patent rights specifically related to DB-1312's linker-payload, and (ii) a non-exclusive, non-transferable, royalty-bearing license, with the right to grant sublicenses, of patent rights specifically related to DB-1312's linker-payload (together, the "**BeiGene License**"), to exploit DB-1312 and all modifications, derivatives, mutations, and variants thereof that is a monospecific ADC against B7-H4 controlled by us (the "**DB-1312 Compound**"), or any biological or pharmaceutical product incorporating the DB-1312 Compound (the "**DB-1312 Product**"), for all uses in humans worldwide.
Retained rights	We retain the rights not expressly licensed to BeiGene, including the rights under the DB-1312 Licensed IP to perform our obligations under this agreement.
Milestone payments	Up to US$1,287.0 million (US$5.0 million paid to date)
Royalties	Upon commercialization, we are eligible for tiered royalties of high-single-digit to low-double-digit percentage on the annual net sales of each DB-1312 Product, subject to certain adjustment, during the royalty term.
Ownership of IP rights	Inventions conceived or first reduced to practice jointly by or on behalf of BeiGene and us shall be jointly owned, with each party having the right to freely practice and license any such jointly owned inventions without accounting to the other.

Clinical development	BeiGene shall be responsible, at its own costs and expenses, for all development activities with respect to the DB-1312 Compounds and DB-1312 Products as permitted under the BeiGene License.
Regulatory filings	BeiGene shall be responsible, at its sole cost and expense, for the conduct of all regulatory activities with respect to the DB-1312 Compound(s) and any DB-1312 Products for all uses in humans worldwide.
Termination rights	BeiGene may terminate the BeiGene Agreement at any time in its entirety or on a product-by-product, country-by-country basis by providing prior written notice to us. We may terminate the BeiGene Agreement if BeiGene or its affiliates or sublicensees challenge the validity of the patent rights under the DB-1312 Licensed IP by providing prior written notice to BeiGene. In addition, either party may terminate the BeiGene Agreement in the event of the other party's uncured material breach or insolvency.

Collaboration with Adcendo

Adcendo was founded in 2017 as a spin-out from The University of Copenhagen and Rigshospitalet, dedicated to the development of breakthrough ADCs. Our strategic partnership with Adcendo was established in 2022, which reflects the mutual recognition of each party's unique strengths in ADC discovery and development. This collaboration enables Adcendo to utilize our proprietary DITAC platform in the advancement of their novel programs, including uPARAP-directed ADCs.

The table below summarizes the key terms of our licensing and collaboration agreement with Adcendo dated December 23, 2022.

Date of agreement	December 23, 2022
License granted	We granted to Adcendo an irrevocable, exclusive, royalty-bearing and sublicensable license under certain of our technologies, including payload-linkers derived from our proprietary DITAC platform, to develop, manufacture and commercialize Adcendo's uPARAP-ADC product (the "Adcendo ADC Product") worldwide.

Retained rights	We shall have an exclusive option to negotiate to acquire (i) an exclusive license from Adcendo to develop and commercialize the Adcendo ADC Product in Greater China and (ii) a nonexclusive license from Adcendo to manufacture the Adcendo ADC Product in Greater China.
Milestone payments	Up to US$414.25 million (US$3.3 million paid to date)
Royalties	Adcendo agrees to pay us tiered royalties of low-single-digit percentage on the annual net sales of the Adcendo ADC Product, subject to certain adjustments, during the royalty term.
Ownership of IP rights	Each party shall solely own all inventions made solely by its personnel. We and Adcendo shall jointly own all inventions made jointly by personnel of both parties, provided that, subject to the rights and licenses granted under and the restrictions set forth in the Adcendo Agreement, each party may practice and exploit any such jointly owned invention without the consent of the other party. Inventorship shall generally be determined in accordance with the rules of inventorship under U.S. patent law or other applicable law.
Clinical development	Adcendo shall be responsible for developing and commercializing the Adcendo ADC Product at its own cost and expense.
Regulatory filings	Adcendo shall be responsible for all regulatory activities and interaction with regulatory authorities for the Adcendo ADC Product and will notify us of any decision by any regulatory authorities.
Termination rights	Adcendo has the right to terminate the Adcendo Agreement without cause upon prior written notice to us. In addition, either party may terminate the Adcendo Agreement in the event of the other party's uncured material breach or insolvency.

On November 4, 2024, Adcendo entered into a new license agreement with us to develop ADC products directed to an additional target using our proprietary DITAC platform, with terms similar to the existing agreement with Adcendo dated December 23, 2022.

In-licensing of Antibody Technologies for ADC Development

We have strategically in-licensed advanced antibody technologies to enhance our drug development efficiency, while complementing our in-house capabilities in antibody research and drug discovery. In-licensing components for innovative drug development has emerged as a common practice, especially for complex therapeutics like ADCs, according to Frost & Sullivan. It has enabled us to focus on our core competencies– notably our proprietary payload technology– while leveraging external innovations to rapidly advance our ADC pipeline. For example, in May 2022, we obtained an exclusive and sublicensable license to utilize a novel B7-H3-targeted antibody and the underlying IP rights for the development and commercialization of DB-1311 and other B7-H3 ADC products worldwide.

While using in-licensed antibody components, we retain independence over the development of our novel ADC assets. Our in-licensing agreements are carefully structured to ensure we maintain ownership and control over our ADC assets and the intellectual property generated during drug development, including the ability to out-license the full drug candidate. Meanwhile, the upstream licensors' rights are generally limited to the specific antibody components licensed to us, and do not extend to the entire ADC candidates. For further details, see "Business — Our Collaboration and Licensing Arrangements."

RESEARCH AND DEVELOPMENT

We conduct R&D activities primarily through our in-house R&D team. We also engage contract research organization ("**CROs**") from time to time to support our preclinical research and clinical trials. In addition, we have established strategic partnerships in relation to our pipeline assets and R&D programs, details of which are set out in "Business — Our Collaboration and Licensing Arrangements."

We have built an in-house R&D team that represent the leaders and experts of ADC development. Our R&D team is led by Dr. QIU Yang, our chief scientific officer, Ms. GU Wei, our chief medical officer, and Dr. HUA Haiqing, our senior vice president and head of drug discovery, each of whom have extensive prior experience in ADC research and a demonstrated track record contributing to the advancement of this innovative drug modality.

Dr. Qiu drives the strategic direction of our pipeline programs, highlighted by our Core Products and key products. She has over two decades of experience in drug discovery and translational medicine at MNCs, including at Daiichi Sankyo where she served as co-chair of the cross-functional ADC forum and senior director of translational medicine and was a leading contributor to the development of innovative ADC therapy, most notably HER3-DXd (U3-1402, patritumab deruxtecan), which received FDA Breakthrough Therapy Designation in 2021. Dr. Qiu's understanding of the ADC landscape and track record are foundational to our continued success as we develop cutting-edge ADC technologies that transform patient care. Ms. Gu leads the clinical development of our pipeline programs. She brings over ten years of expertise in clinical development across the globe, with extensive experience leading numerous clinical studies. Ms. Gu has built a successful track record for clinical development at

renowned MNCs, and her strategic oversight plays a key role in our efficient trial execution and alignment with regulatory standards. Dr. Hua leads our strategies for novel drug discovery and CMC development. Over the past 15 years, Dr. Hua has led the discovery of innovative drugs and their advancement into the clinic at multiple MNCs. Dr. Hua's extensive experience and leadership in drug discovery and CMC development contribute to the seamless integration of cutting-edge science with robust manufacturing processes, facilitating the efficient translation of our ADC research into transformative therapies.

Supporting and executing the strategic vision of our senior management team are 119 R&D personnel as of September 30, 2024, who had an average industry experience of over 12 years with over 80% holding a doctoral or master' degree. As of the Latest Practicable Date, we had over 20 core R&D team members, including scientists and experts with over 10 to 20 years of experience in diverse specialties who worked at global MNCs, such as BMS, Novartis and Daiichi Sankyo, and leading domestic biopharma companies. In particular, each core member of our drug discovery team has extensive and specific experience and know-how relating to our four technology platforms, such as topoisomerase-based ADCs, autoimmune drugs, bispecific antibodies and novel payloads, and designing and developing ADCs based on such technologies. Their efforts, along with the expertise of our other R&D personnel, collectively contribute to the development of pipeline programs, including our Core Products, and the continued iteration of our technology platforms. Substantially all our core R&D team members remained employed by us during the Track Record Period and up to the Latest Practicable Date. Our core R&D team members are led by our seasoned senior management team and strategically placed to be responsible for different aspects of drug discovery and development, all of which contribute to the success of a drug program. In addition, employee work products are classified as service inventions and are the property of our Company. As such, we believe that the departure of certain core R&D personnel during the Track Record Period did not have material impact on our business operations.

We have also built strong relationships with renowned industry experts. Regularly, we engage our scientific advisory board of distinguished scientists to advise on our research strategy and clinical development plan. Our scientific advisory board is led by Dr. Antoine Yver and Dr. Pasi A. Jänne, two leading minds in ADC drug development in the world.

In addition to our in-house R&D activities, we also collaborate with reputable CROs to manage, conduct, and support our preclinical research and clinical trials. When selecting CRO partners, we consider a range of factors such as their professional qualifications, relevant research experience, service quality and efficiency, industry reputation, and pricing competitiveness. We currently expect to continue in the engagement of our key existing CROs and do not expect delays from them within or outside China. To the best knowledge of our Directors, except for WuXi Biologics (Cayman) Inc., our CROs are independent of the Company. Wuxi Venture, a wholly-owned subsidiary of WuXi Biologics (Cayman) Inc. is one of our Shareholders.

In 2022, 2023 and for the nine months ended September 30, 2024, our costs and expenses in relation to R&D activities, which represented our cost of revenue and research and development expenses, were RMB339.9 million, RMB986.7 million and RMB1,404.4 million, respectively. In particular, costs and expenses in relation to R&D activities incurred for our Core Products were RMB137.0 million, RMB635.3 million and RMB878.9 million during the same periods, respectively, accounting for 40.3%, 64.4% and 62.6% of our total costs and expenses in relation to R&D activities for the corresponding periods. In 2022, 2023 and for the nine months ended September 30, 2024, our research and development expenses accounted for 91.4%, 89.9% and 82.6% of our total operating expenses (which equals the sum of research and development expenses and administrative expenses), respectively.

MANUFACTURING

To date, our manufacturing activities are conducted through contract development and manufacturing organizations ("**CDMOs**") to support our drug development process. We currently outsource our manufacturing activities to industry recognized CDMOs in China. We intend to continue this practice in the near term and at the initial stage of commercialization, as we believe it is cost-effective and efficient to engage CDMOs for manufacturing activities and enables us to focus on, and allocate our resources to, the discovery and clinical development of our ADC candidates. We plan to continue to work together with our industry-leading CDMO partners to optimize our manufacturing process, technologies, and know-how to enhance product quality, improve cost efficiency, and shorten the time from bench to bedside. We have maintained a relationship with the majority of our six existing CDMOs for over three years.

COMMERCIALIZATION

As of the Latest Practicable Date, we had not obtained marketing approval for any drug candidates, nor had we generated any revenue from product sales. Anticipating commercialization of our late-stage ADCs in the next few years, we plan to maximize the value of our drug candidates by selecting the optimal commercial model, including building our in-house commercialization capabilities, and/or collaboration with third parties such as distributors, contract sales organizations ("**CSOs**"), and licensing partners.

INTELLECTUAL PROPERTY

We are committed to the development and protection of our intellectual properties. Our future success depends significantly on our ability to obtain and maintain robust patent coverage, as well as other forms of intellectual property and proprietary protections, for the key technologies, inventions, and know-how fundamental to our ADC pipeline and technology platforms. We have a global portfolio of patents to protect our drug candidates and technologies. As of the Latest Practicable Date, we owned (i) three issued patents in China, (ii) six issued patents in the U.S., (iii) two issued patents in other jurisdictions, and (iv) 158 patent applications, including 37 in China, eight in the U.S., 19 under the Patent Cooperation Treaty (the "**PCT**"), ten in Europe, and 84 in other jurisdictions. As of the same date, with respect to

our two Core Products, DB-1303 and DB-1311, we owned three issued patents in China and six issued patents in the U.S., one issued patent in other jurisdiction, and also owned or in-licensed 38 patent applications, including three in China, one in the U.S., two pending PCT patent applications, and 32 in other jurisdictions. The following table summarizes the details of the material granted patents and patent applications in connection with our Core Products and our technology platforms. For details, please see "Business — Intellectual Property."

Related product	Patent/patent application	Category	Patent/patent application number	Jurisdiction	Patent holder/ applicant	Application date	Date of grant	Expiration date[1]
DB-1303	Anti-tumor Compound and Preparation Method and Application Thereof (一種抗腫瘤化合物及其製備方法和應用)	Invention patent	CN115925796B	PRC	Duality Suzhou	Sept. 29, 2021	May 31, 2024	Sept. 28, 2041
DB-1303	Anti-tumor Compound and Preparation Method and Use Thereof	Invention patent	US11685742B2	U.S.	Duality Suzhou	Sept. 29, 2021	Jun. 27, 2023	Sept. 28, 2041
DB-1311	Anti-tumor Compound and Preparation Method and Use Thereof	Invention patent	US11607459B1	U.S.	Duality Suzhou	Sept. 29, 2021	Mar. 21, 2023	Sept. 28, 2041
DB-1311	Anti-B7H3 Antibody-Drug Conjugates and Uses Thereof (抗B7H3抗體-藥物偶聯物及其用途)[2]	Invention patent	PCT/CN2023/098596	PCT	Duality Suzhou	Jun. 6, 2023	N/A	N/A
DITAC and DIBAC	Antitumor Compound, and Preparation Method Therefor and Use Thereof (一種抗腫瘤化合物及其製備方法和應用)[3]	Invention patent	PCT/CN2021/121721	PCT	Duality Suzhou	Sept. 29, 2021	N/A	N/A
DIMAC	Steroid Compound and Conjugate Thereof (一種甾體化合物及其綴合物)[3]	Invention patent	PCT/CN2022/114855	PCT	Duality Suzhou	Aug. 25, 2022	N/A	N/A

Notes:

(1) Patent expiration date does not include any applicable patent term extensions.

(2) PCT patent application which has the opportunity to enter national phases within specified deadline.

(3) PCT patent application which has entered national phases in various jurisdictions.

(4) We are applying for patent in relation to our DUPAC platform.

SUPPLIERS AND PROCUREMENT

During the Track Record Period, our major suppliers primarily included (i) CROs and CDMOs, (ii) licensing partners, and (iii) equipment and device suppliers and renovation/construction service providers for our R&D facilities and offices. For the years ended December 31, 2022 and 2023 and the nine months ended September 30, 2024, our purchases from our five largest suppliers in each year/period in aggregate accounted for 51.5%, 42.0% and 62.0% of our total purchases for the respective year/period, respectively. Our purchases from our largest supplier in each year/period accounted for 18.8%, 12.5% and 20.8% of our total purchases for the respective year/period, respectively. To the best knowledge of our Directors, none of our Directors, their respective associates or any of our Shareholders holding more than 5% of our issued share capital immediately following the completion of the [**REDACTED**] had an interest in any of our five largest suppliers during the Track Record Period. For details, please see "Business — Suppliers and Procurement."

COMPETITION

The ADC industry is competitive and subject to rapid and significant change. While we believe the strength of our pipeline, technology platforms and R&D capability gives us competitive advantages, we face potential competition from many industry players, including MNCs and leading biotechnology companies, who have commercialized, or are pursuing the development of, ADC drugs that are similar to ours or target the same indications. Any ADC candidates that we successfully develop and commercialize will compete both with approved drugs and with any new drugs that may become available in the future. Our competitors may have substantially greater financial, technical, and other resources than we do, such as those with larger research and development staff and established marketing and manufacturing infrastructure. Collaborations, mergers and acquisitions in the biopharmaceutical industry may result in even more resources being concentrated in our competitors. As a result, these companies may be able to advance their drug candidates and obtain regulatory approval from the regulatory authorities more rapidly than we do, and become more effective in selling and marketing their products. For further details on market opportunities and competition in respect of our ADC candidates, see "Business — Our Pipeline" and "Industry Overview."

SUMMARY OF KEY FINANCIAL INFORMATION

The summary of the key financial information set forth below have been derived from and should be read in conjunction with our historical financial information, including the accompanying notes, set forth in the Accountant's Report in Appendix I to this document, as well as the information set forth in the section headed "Financial Information."

Summary of Consolidated Statements of Profit or Loss

The following table sets forth a summary of our consolidated statements of comprehensive loss for the periods indicated:

	For the year ended December 31,		For the nine months ended September 30,	
	2022	2023	2023	2024
	(RMB'000)	*(RMB'000)*	*(RMB'000) (unaudited)*	*(RMB'000)*
Revenues	1,600	1,786,540	1,675,917	1,462,004
Cost of revenue	–	(427,655)	(324,161)	(802,456)
Gross profit	1,600	1,358,885	1,351,756	659,548
Research and development expenses	(339,890)	(558,997)	(372,391)	(601,930)
Administrative expenses	(31,921)	(62,567)	(43,800)	(126,836)
Other income	494	3,261	2,209	3,347
Other gains/(losses), net	1,134	40,773	38,847	(7,297)
Operating (loss)/profit	(368,583)	781,355	976,621	(73,168)
Finance income	3,268	34,483	24,160	38,809
Finance costs	(75)	(188)	(145)	(189)
Fair value change of financial liabilities at fair value through profit or loss	(21,700)	(1,017,899)	(959,200)	(501,351)
(Loss)/Profit before income tax	(387,090)	(202,249)	41,436	(535,899)
Income tax expense	–	(155,263)	(155,263)	(30,583)
Loss for the year/period attributable to the owners of the Company	**(387,090)**	**(357,512)**	**(113,827)**	**(566,482)**

During the Track Record Period, our revenue was primarily derived from our out-license and collaboration agreements, including income in relation to upfront payments, milestone payments, and reimbursement for R&D activities we undertake for our out-licensed candidates. Our cost of revenue was primarily related to the R&D activities we conducted in accordance with our out-license and collaboration agreements. Our revenue and cost of revenue increased significantly primarily because we entered into several out-license and collaboration agreements in 2023. Our research and development expenses increased primarily due to an increase in the number and scale of our ongoing clinical trials. Our administrative expenses increased primarily due to increase in staff costs and professional service expenses. Our loss for the year decreased from 2022 to 2023 due to higher revenue generated from out-license and collaboration agreements in 2023. Our loss for the nine months ended September 30, 2023 was lower compared to the same period in 2024, primarily due to (i) higher research and development expenses and administrative expenses caused by increased R&D activities and share incentive expenses in the nine months ended September 30, 2024, and (ii) higher gross profit attributable to upfront payments received pursuant to our out-license and collaboration agreements for the nine months ended September 30, 2023.

Summary of Consolidated Statements of Financial Position

The following table sets forth a summary of our consolidated statements of financial position as of the dates indicated:

	As of December 31,		As of September 30,
	2022	2023	2024
	(RMB'000)	*(RMB'000)*	*(RMB'000)*
Total non-current assets	58,857	166,014	171,428
Total current assets	404,880	1,333,895	1,633,647
Total current liabilities	(1,230,780)	(2,561,246)	(3,270,386)
Net current liabilities	(825,900)	(1,227,351)	(1,636,739)
Total assets less current liabilities	(767,043)	(1,061,337)	(1,465,311)
Total non-current liabilities	(2,074)	(62,576)	(32,515)
Net liabilities	(769,117)	(1,123,913)	(1,497,826)

We recorded net current liabilities during the Track Record Period primarily because our Preferred Shares issued to Pre-[**REDACTED**] investors are recorded as current liabilities under financial liabilities at fair value through profit or loss. These Preferred Shares will be converted into Ordinary Shares upon [**REDACTED**], after which the amount of our financial liabilities at fair value through profit or loss, which were recorded as our current liabilities during the Track Record Period, will be derecognized from our liabilities and recorded as equity, which can result in the Group turning into net current assets and net assets position. The increase in our net liabilities during the Track Record Period was also largely due to the effect of financial liabilities at fair value through profit or loss. See "Financial Information — Description of Selected Items from the Consolidated Balance Sheets — Financial Liabilities at Fair Value through Profit or Loss" for details.

Summary of Consolidated Statements of Cash Flows

The following table sets forth the components of our consolidated statements of cash flows for the periods indicated:

	For the year ended December 31,		For the nine months ended September 30,	
	2022	2023	2023	2024
	(RMB'000)	*(RMB'000)*	*(RMB'000)* *(unaudited)*	*(RMB'000)*
Operating cash flows before movement in working capital	(360,877)	790,947	978,381	140,242
Changes in working capital	58,139	239,834	215,349	(110,230)
Income tax paid	–	(248,929)	(248,929)	(48,398)
Interest received	3,268	34,483	24,160	38,809

	For the year ended December 31,		For the nine months ended September 30,	
	2022	2023	2023	2024
	(RMB'000)	*(RMB'000)*	*(RMB'000) (unaudited)*	*(RMB'000)*
Net cash (used in)/from operating activities	(299,470)	816,335	968,961	20,423
Net cash (used in) investing activities	(22,200)	(78,550)	(33,479)	(80,839)
Net cash (used in)/from financing activities	451,461	10,817	12,954	(3,312)
Net increase/(decrease) in cash and cash equivalents	129,791	748,602	948,436	(63,728)
Cash and cash equivalents at beginning of year/period	227,762	375,974	375,974	1,130,889
Effect of foreign exchange rate changes	18,421	6,313	15,388	(7,455)
Cash and cash equivalents at the end of year/period	375,974	1,130,889	1,339,798	1,059,706

We recorded net cash used in operating activities of RMB299.5 million in 2022. During the Track Record Period, we funded our operation primarily through proceeds from equity financing and payments received from our out-license and collaboration agreements. We recorded net cash inflow from operating activities in 2023 and for the nine months ended September 30, 2024 primarily attributable to payments received from our out-license and collaboration agreements. We had cash and cash equivalents, restricted cash and financial assets at fair value through profit or loss together amounting to RMB1,163.6 million as of September 30, 2024.

We expect to fund our future operations primarily with existing cash and cash equivalents, payments received from our out-license and collaboration agreements, and [**REDACTED**] from the [**REDACTED**]. Upon the successful commercialization of one or more of our drug candidates, we expect to fund our operations in part with income generated from sales of our commercialized drug products. As our business continues to expand, we may require further funding through equity offerings, debt financing, out-license and collaboration arrangements, and other sources.

Our cash burn rate refers to the average monthly amount of cash used in operating activities, payment for property, plant and equipment and payment for intangible assets, without taking into account the cash inflow from out-licensing and collaboration agreements. We estimate that we will receive [**REDACTED**] of approximately HK$[**REDACTED**] million in the [**REDACTED**], assuming an [**REDACTED**] of HK$[**REDACTED**] per Share, being the low end of the indicative [**REDACTED**] range stated in this document. Assuming an average cash burn rate going forward of 1.2 times the level in 2023, we estimate that (i) our cash and

cash equivalents as of September 30, 2024 will be able to maintain our financial viability for [**REDACTED**] months, (ii) if we take into account [**REDACTED**]% of the estimated [**REDACTED**] from the [**REDACTED**] (namely, the portion allocated for our working capital and other general corporate purposes), [**REDACTED**] months, or, (iii) if we take into account all estimated [**REDACTED**] from the [**REDACTED**], [**REDACTED**] months. We will continue to monitor our cash flows from operations closely and expect to raise our next round of financing no earlier than six months after the completion of the [**REDACTED**].

Key Financial Ratios

The following table set forth our key financial ratios as of the dates indicated:

	As of December 31,		As of September 30,
	2022	2023	2024
Current ratio[(1)]	0.3	0.5	0.5

Note:

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

RISK FACTORS

Our business faces risks including those set out in the section headed "Risk Factors." As different [**REDACTED**] may have different interpretations and criteria when determining the significance of a risk, you should read the "Risk Factors" section in its entirety before you decide to [**REDACTED**] in our Company. Some of the major risks that we face include: (i) we depend substantially on the success of our drug candidates. If we are unable to successfully complete clinical development, obtain regulatory approvals or achieve commercialization for our drug candidates, or if we experience significant delays or cost overruns in doing any of the foregoing, our business and prospects could be materially and adversely affected; (ii) we may from time to time be involved in legal proceedings and disputes to protect or enforce our intellectual property rights, or defend against infringement and other claims alleged by third parties, which could be expensive, time consuming and unsuccessful; (iii) we face intense competition and rapid technological change and the possibility that our competitors may develop therapies that are similar, more advanced, or more effective than ours, which may adversely affect our financial condition and our ability to successfully commercialize our drug candidates; (iv) the regulatory approval processes of the NMPA, the FDA and other comparable regulatory authorities are time-consuming and may evolve over time. If we are unable to obtain without undue delay any regulatory approvals for our drug candidates in our target markets, our business may be subject to actual or perceived harm; (v) if we are unable to obtain or maintain approval from the NMPA, the FDA and other comparable regulatory authorities for our drug candidates to be eligible for an expedited registration pathway as innovative or breakthrough therapy, the time and cost we incur to obtain regulatory approvals may increase; (vi) our future

success depends on our ability to attract, retain and motivate senior management, qualified medical professionals and scientific employees (vii) we have incurred net losses since our inception and anticipate that we will continue to incur net losses for the foreseeable future and may never achieve or maintain profitability; (viii) we have entered into license and collaboration agreements with third parties in the development, manufacturing and commercialization of our drug candidates, and may seek and enter into additional partnerships in the future. we may fail to identify suitable business partners or may not realize the benefits of such partnerships as expected; (ix) we may rely on third parties to manufacture our drug products for clinical development and commercial sales and to provide a stable and adequate supply of quality materials and products for our drug development and commercialization needs. Our business could be harmed if these third parties suffer substantial disruption to supply chain and production facilities, encounter problems in manufacturing or fail to deliver sufficient quantities of product or at acceptable quality or price levels; and (x) the future commercial success of our drug candidates will depend on the degree of their market acceptance among physicians, patients and others in the medical community.

PRE-[REDACTED] INVESTORS

Since the establishment of our Company, we have received four rounds of equity financing totaling approximately US$137.5 million from our Pre-[**REDACTED**] Investors. Our Pre-[**REDACTED**] Investors include certain Sophisticated Investors, such as LAV USD, King Star Med, Shanghai Yingjia, Orchids and Golden Sword. Each Sophisticated Investor has made meaningful investment in the Company at least six months before the [**REDACTED**], holding approximately [**REDACTED**]%, [**REDACTED**]%, [**REDACTED**]%, [**REDACTED**]% and [**REDACTED**]% of the total issued Shares immediately following the completion of the [**REDACTED**], assuming the [**REDACTED**] is not exercised, respectively. It is expected that lock-up undertakings will be given by the Pre-[**REDACTED**] Investors to the Joint Sponsors, pursuant to which each Pre-[**REDACTED**] Investor will agree that, subject to the terms of such lock-up undertakings, it will not, whether directly or indirectly, at any time during the period agreed by such Pre-[**REDACTED**] Investor and the Joint Sponsors [**REDACTED**] of any of the Shares held by such Pre-[**REDACTED**] Investor. We utilized the proceeds to finance our ADC platforms discovery activities, R&D development activities of pipeline products, as well as to support the working capital needs of our Group. As of the Latest Practicable Date, all of the net proceeds from the Pre-[**REDACTED**] Investments have been utilized for the aforementioned purposes. For further details of the identity and background of our Pre-[**REDACTED**] Investors, and the principal terms of the Pre-[**REDACTED**] Investments, please see "History and Corporate Structure — Pre-[**REDACTED**] Investments" in this document.

SHARE INCENTIVE PLANS

As of the Latest Practicable Date, we had one share incentive scheme, namely the Pre-[**REDACTED**] Equity Incentive Plan, the terms of which are not subject to the provisions of Chapter 17 of the Listing Rules. The maximum number of Shares that may be issued pursuant to the share awards under the Pre-[**REDACTED**] Equity Incentive Plan shall not exceed 22,287,582 Shares in the aggregate. We have conditionally granted an aggregate of 18,763,423 options (representing the right to subscribe for 18,763,423 Shares) (the "**Outstanding Pre-**[**REDACTED**] **Options**") to 102 grantees, who are our current employees or external consultants, under the Pre-[**REDACTED**] Equity Incentive Plan, all of which will remain outstanding as of the [**REDACTED**].

We are supported by a scientific advisory board of world-renowned ADC experts to guide our R&D activities and provide invaluable strategic advice. To ensure consistent, high-quality consulting services and align their interests with the Company's long-term objectives, we have granted options to three key external consultants who serve on this board. These options allow them to subscribe for an aggregate of 300,000 Shares, representing approximately [**REDACTED**]% of the total number of Shares in issue immediately after completion of the [**REDACTED**] (assuming the [**REDACTED**] is not exercised). These consultants have been engaged for a renewable three-year term to provide expert advice on R&D activities, strategic developments, and/or regulatory affairs. To the best of our Company's knowledge, information and belief having made all reasonable enquiries, save for Dr. SU Ling, a venture partner of Lilly Asia Ventures, none of the external consultants have any other past or present relationships with our Shareholders, Directors, senior management members or any of their respective associates.

The number of the Shares underlying the Outstanding Pre-[**REDACTED**] Options amounting to 18,763,423 will only be issued by our Company after the [**REDACTED**] if such Outstanding Pre-[**REDACTED**] Options are fully vested and exercised. Therefore, the Outstanding Pre-[**REDACTED**] Options will have potential dilution effect on the Shares held by our Shareholders as of the [**REDACTED**]. Assuming the [**REDACTED**] is not exercised, the shareholding of our Shareholders upon completion of the [**REDACTED**] will be diluted by approximately [**REDACTED**]% if the Outstanding Pre-[**REDACTED**] Options are fully vested and exercised. For the purpose of the [**REDACTED**], we [have adopted] the Post-[**REDACTED**] Share Incentive Plan on [●], 2025, the terms of which comply with the requirements of Chapter 17 of the Listing Rules. The Post-[**REDACTED**] Share Incentive Plan will take effect upon the [**REDACTED**]. We will comply with the requirements under Chapter 17 of the Listing Rules regarding the operation and administration of the Post-[**REDACTED**] Share Scheme. For further details, please see "Statutory and General Information — D. Share Incentive Plans" in Appendix IV to this document.

DIVIDENDS

We did not declare or pay dividends on our Shares during the Track Record Period. We currently expect to retain all future earnings for use in operation and expansion of our business, and do not anticipate paying cash dividends in the foreseeable future. Our board of directors has complete discretion as to whether to distribute dividends, subject to certain restrictions under Cayman Islands law. In addition, our Shareholders may by ordinary resolution declare a dividend, but no dividend may exceed the amount recommended by our board of directors. Even if our board of directors decides to declare and pay dividends, the timing, amount and form of future dividends, if any, will depend on our future results of operations and cash flow, our capital requirements and surplus, the amount of distributions, if any, received by us from our subsidiaries, our financial condition, contractual restrictions and other factors deemed relevant by our board of directors. Currently, we do not have any dividend policy or intention to declare or pay any dividends in the near future. As advised by our legal advisor as to Cayman Islands law, notwithstanding that the Company may have accumulated losses, the Company may declare dividend (a) out of profits of the Company if the Company has sufficient profits, realized or unrealized, unless such is contrary to the accounting principles adopted by the Company or (b) out of the share premium of the Company if following the date on which the dividend is proposed to be paid, the Company is able to pay its debts as they fall due in the ordinary course of business. In determining whether to declare a dividend, our Board will need to be satisfied that the declaration of dividend is in the best interest of the Company and may make provision for losses. [**REDACTED**] should not purchase our Shares with the expectation of receiving cash dividends.

[**REDACTED**] STATISTICS[(1)]

	Based on an [REDACTED] of HK$[REDACTED] per Share	**Based on an [REDACTED] of HK$[REDACTED] per Share**
[**REDACTED**] of our Shares	HK$[**REDACTED**] million	HK$[**REDACTED**] million
Unaudited [**REDACTED**] adjusted net tangible assets of the Group per Share	HK$[**REDACTED**]	HK$[**REDACTED**]

Notes:

(1) All [**REDACTED**] statistics in the table are on the assumptions that the [**REDACTED**] is not exercised.

(2) The calculation of [**REDACTED**] of our Shares is based on [**REDACTED**] Shares expected to be in issue immediately after completion of the [**REDACTED**].

(3) The unaudited [**REDACTED**] adjusted consolidated net tangible assets attributable to owners of our Company as of September 30, 2024 per Share is calculated after making the adjustments referred to in "Appendix II — Unaudited [**REDACTED**] Financial Information."

[**REDACTED**]

We estimate that we will receive [**REDACTED**] from the [**REDACTED**] of approximately HK$[**REDACTED**] million, after deducting [**REDACTED**] commissions, fees and estimated expenses payable by us in connection with the [**REDACTED**], and assuming an [**REDACTED**] of HK$[**REDACTED**] per Share, being the mid-point of the indicative [**REDACTED**] range stated in this document. We currently intend to apply these [**REDACTED**] for the following purposes: (i) approximately [**REDACTED**]%, or HK$[**REDACTED**] million, will be used for the research, development and commercialization of our Core Products, namely, DB-1303 and DB-1311; (ii) approximately [**REDACTED**]%, or HK$[**REDACTED**] million, will be used for the research and development of our key products; (iii) approximately [**REDACTED**]%, or HK$[**REDACTED**] million, will be used to fund the continued development of our ADC technology platforms, advance our other pipeline assets, and explore and develop new drug assets; and (iv) approximately [**REDACTED**]%, or HK$[**REDACTED**] million, will be used for working capital and other general corporate purposes.

[**REDACTED**]

[**REDACTED**] to be borne by us are estimated to be approximately HK$[**REDACTED**] million (assuming an [**REDACTED**] of HK$[**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 estimate [**REDACTED**] from the [**REDACTED**] assuming no Shares are issued pursuant to the [**REDACTED**]. The [**REDACTED**] consist of (i) [**REDACTED**]-related expenses, including [**REDACTED**] commission, of approximately HK$[**REDACTED**] million, and (ii) non-[**REDACTED**]-related expenses of approximately HK$[**REDACTED**] million, comprising (a) fees and expenses of our legal advisors and reporting accountants of approximately HK$[**REDACTED**] million, and (b) other fees and expenses of approximately HK$[**REDACTED**] million. During the Track Record Period, [**REDACTED**] of RMB19.8 million was charged to our consolidated statements of profit or loss. After the Track Record Period, approximately HK$[**REDACTED**] million is expected to be charged to our consolidated statements of profit or loss, and approximately HK$[**REDACTED**] million is expected to be accounted for as a deduction from equity upon the [**REDACTED**]. 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

Business Updates

Since the end of the Track Record Period, we have continuously developed our business and continued to advance our pipeline. In October 2024, we received IND approval from the NMPA to initiate a phase 1/2a trial for DB-1305 in combination with BNT327, a bsAb targeting PD-L1 and VEGF, in patients with late-stage/metastatic solid tumors. In November 2024, we were awarded the "Best New Drug Developer" at the 15th World ADC San Diego conference.

In December 2024, we entered into an exclusive option agreement with GSK for DB-1324, a preclinical ADC asset developed with our DITAC platform. Pursuant to the agreement, we will grant GSK an exclusive option to obtain a license to develop and commercialize DB-1324 worldwide, excluding Mainland China, Hong Kong, and Macau. GSK has agreed to pay US$30 million in upfront payment, which we had received as of the Latest Practicable Date, and additional pre-option milestone payments. If GSK exercises the option, we are eligible to receive an option exercise fee as well as potential development, regulatory and commercial milestone payments totalling up to US$975 million, plus tiered royalties on DB-1324's global net sales outside Mainland China, Hong Kong, and Macau. GSK is eligible to receive potential royalties on DB-1324's net sales in Mainland China, Hong Kong, and Macau.

In December 2024, we entered into a collaboration and license agreement with Avenzo, a clinical-stage biotechnology company developing next-generation oncology therapies, pursuant to which we granted Avenzo an exclusive license to develop, manufacture and commercialize DB-1418, our EGFR/HER3 BsADC, globally excluding Greater China. We have received an upfront payment of US$50 million and will be eligible to receive up to approximately US$1.15 billion in development, regulatory and commercial milestone payments. In addition, we are eligible to receive tiered royalties on sales in Avenzo's territory upon DB-1418's commercialization.

Regulatory Updates

On December 20, 2023, the U.S. Senate introduced a legislation that would prohibit U.S. federal government contracts, grants or loans to entities that use biotechnology equipment or services provided by certain Chinese biotechnology companies. On September 9, 2024, the U.S. House of Representatives voted in favor of a similar version of such legislation titled the BIOSECURE Act (the "**BIOSECURE Act**"), which is currently pending a vote in the full U.S. Senate. We are of the view that the proposed BIOSECURE Act, if enacted in its current form, would not have a material and adverse impact on our business, primarily because we are not a recipient of any U.S. federal government contracts, loans, grants or funding and do not anticipate applying for such contracts, loans, grants or funding in the future. Furthermore, to our best knowledge, none of our licensing partners are using any services provided by us under the respective licensing arrangements in connection with any federal contracts, loans, grants or funding.

The landscape of PRC cybersecurity, data privacy and security laws is also constantly evolving. On September 30, 2024, the State Council promulgated the Administration Regulations on Cyber Data Security (《網絡數據安全管理條例》) (the "**Data Security Regulations**"), which came into effect on January 1, 2025. The Data Security Regulations reiterate and refine the general regulations for cyber data processing activities, rules of personal information protection, important data security protection, cyber data cross-border transfer management, and the responsibilities of online platform service providers. For risks relating to the evolving data privacy and cybersecurity laws and policies, see "Risk Factors — Risks Relating to Government Regulations — We are subject to stringent data privacy and cybersecurity laws and policies, and we may be restricted from transferring data abroad or using human genetic resources collected within the PRC."

We will continue to closely monitor and evaluate the potential impacts of the proposed BIOSECURE Act and recent updates on Chinese data privacy policies on our business and operations, including maintaining strong business relationships with our existing suppliers and a list of qualified alternative suppliers capable of providing equivalent services.

No Material Adverse Change

Our Directors confirm that, except as disclosed above and up to the date of this document, there has been no material adverse change in our financial or trading position or prospects since September 30, 2024, which is the end date of the periods reported on in the Accountant's Report included in Appendix I to this document, and there is no event since September 30, 2024 that would materially affect the information as set out in the Accountant's Report included in Appendix I to this document.

IMPACT OF COVID-19

As of the Latest Practicable Date, we had not experienced material disruptions in our operations as a result of COVID-19. During the COVID-19 pandemic, we maintained operational continuity through remote work arrangements in Shanghai and Beijing. Through effective coordination with our CRO and CDMO partners across various locations, we sustained the smooth progress of our research activities and achieved key regulatory milestones, including securing IND approval from the FDA for DB-1303 in December 2021, followed by IND approval from the NMPA in April 2022. As COVID-19's global impact continued to lessen as of the Latest Practicable Date, our Directors do not expect COVID-19 to have a material adverse impact on our business going forward. See also "Risk Factors — Risks Relating to Our Operations — We may be subject to natural disasters, health epidemics, acts of war or terrorism or other factors beyond our control."

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

"AACR"	American Association for Cancer Research
"Accountant's Report"	the accountant's report of our Company, the text of which is set out in Appendix I to this document
"Adcendo"	Adcendo ApS, a biotech company organized under the laws of Denmark on January 7, 2017
"affiliate"	any other person, directly or indirectly, controlling or controlled by or under direct or indirect common control with such specified person
"AFRC"	Accounting and Financial Reporting Council
"Articles" or "Articles of Association"	the eighth amended and restated articles of association of our Company conditionally adopted by a special resolution passed on [●] with effect from the [**REDACTED**], and as amended from time to time, a summary of which is set out in "Summary of the Constitution of our Company and Cayman Islands Company Law" in Appendix III to this document
"ASCO"	American Society of Clinical Oncology Annual Meeting
"associate(s)"	has the meaning ascribed to it under the Listing Rules
"Audit Committee"	the audit committee of the Board
"BeiGene"	BeiGene, Ltd., an exempted company with limited liability incorporated under the laws of Cayman Islands on October 28, 2010, whose shares are listed on the Hong Kong Stock Exchange (HKEX: 6160), Nasdaq Stock Market (Nasdaq: BGNE), and Shanghai Stock Exchange (SSE: 688235)

"Duality Beijing"	Beijing Duality Biologics Co., Ltd. (北京映恩生物科技有限公司), a limited liability company incorporated under the laws of the PRC on January 9, 2020, which is a wholly-owned subsidiary of Duality Suzhou and one of our wholly-owned subsidiaries
"BioNTech"	BioNTech SE, a European stock corporation (Societas Europaea, or SE) under the laws of Germany and the European Union whose shares are listed on the Nasdaq Stock Market (Nasdaq: BNTX). The company was incorporated on June 2, 2008 as Petersberg 91, V AG, a German stock corporation
"Board" or "Board of Directors"	the board of Directors of our Company
"business day" or "Business Day"	any day (other than a Saturday, Sunday or public holiday in Hong Kong) on which banks in Hong Kong are generally open for normal banking business
"BVI"	the British Virgin Islands
	[**REDACTED**]
"Cayman Companies Act" or "Companies Act"	the Companies Act, Cap 22 (Act 3 of 1961, as consolidated and revised) of the Cayman Islands as amended, supplemented, or otherwise modified from time to time
	[**REDACTED**]
"CDE"	the Center for Drug Evaluation of the NMPA (國家藥品監督管理局藥品審評中心), a division of the NMPA mainly responsible for the review and approval of IND and NDA/BLA
"China" or "Mainland China" or "the PRC"	the People's Republic of China excluding, for the purpose of this document and for geographical reference only, Hong Kong, the Macau Special Administrative Region and Taiwan
"close associate(s)"	has the meaning ascribed to it under the Listing Rules

"Companies Ordinance"	the Companies Ordinance (Chapter 622 of the Laws of Hong Kong), as amended, supplemented or otherwise modified from time to time
"Companies (Winding Up and Miscellaneous Provisions) Ordinance"	the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Chapter 32 of the Laws of Hong Kong), as amended, supplemented or otherwise modified from time to time
"Company," "our Company," or "the Company"	Duality Biotherapeutics, Inc., an exempted company limited by shares incorporated in the Cayman Islands on July 3, 2019
"Compliance Advisor"	First Shanghai Capital Limited
"connected person(s)"	has the meaning ascribed to it under the Listing Rules
"connected transaction(s)"	has the meaning ascribed to it under the Listing Rules
"Core Product(s)"	has the meaning ascribed thereto in Chapter 18A of the Listing Rules; for the purpose of this document, our Core Products refer to DB-1303 and DB-1311
"CSRC"	the China Securities Regulatory Commission (中國證券監督管理委員會)
"Director(s)"	the director(s) of our Company
"Duality Shanghai"	Duality Biologics (Shanghai) Co., Ltd. (映恩生物科技(上海)有限公司), a limited liability company incorporated under the laws of the PRC on April 26, 2020, which is a wholly owned subsidiary of Duality Suzhou and one of our wholly owned subsidiaries
"Duality Suzhou"	Duality Biologics (Suzhou) Co., Ltd. (映恩生物製藥(蘇州)有限公司), a limited liability company incorporated under the laws of the PRC on March 23, 2020, which is a wholly owned subsidiary of DualityBio HK and one of our wholly owned subsidiaries
"Duality U.S."	Dualitybio Inc., a limited liability company incorporated under the laws of the State of Delaware of the United States on May 3, 2021, which is one of our wholly owned subsidiaries

"DualityBio HK"	DualityBio HK Limited (映恩生物香港有限公司), a limited company incorporated in Hong Kong on January 21, 2020, which is one of our wholly owned subsidiaries
"CIT Law"	Corporate Income Tax Law of the PRC (中華人民共和國企業所得税法) which was adopted by the National People's Congress on March 16, 2007, as last amended and effective on December 29, 2018
"EORTC"	European Organization for Research and Treatment of Cancer
"ESG"	environmental, social and governance
"ESGO"	European Society of Gynaecological Oncology Congress
"ESMO"	European Society for Medical Oncology Congress
"Extreme Conditions"	extreme conditions caused by a super typhoon as announced by the government of Hong Kong
"FDA"	the United States Food and Drug Administration
"FIL"	the Foreign Investment Law of the PRC (《中華人民共和國外商投資法》) adopted by the National People's Congress on March 15, 2019 and became effective on January 1, 2020
	[**REDACTED**]
"Founder Holdco"	DualityBio Ltd., a company with limited liability incorporated under the laws of BVI and wholly owned by Dr. ZHU Zhongyuan
"Frost & Sullivan"	Frost & Sullivan (Beijing) Inc., Shanghai Branch Co.
"Frost & Sullivan Report"	the report prepared by Frost & Sullivan as commissioned by us
"FVTPL"	fair value through profit or loss

[**REDACTED**]

"Greater China"	Mainland China, Hong Kong, the Macau Special Administrative Region and Taiwan
"Group," "our Group," "the Group," "we," "us," or "our"	our Company and its subsidiaries from time to time, and where the context requires, in respect of the period prior to our Company becoming the holding company of its present subsidiaries, such subsidiaries as if they were subsidiaries of our Company at the relevant time
"HK" or "Hong Kong"	the Hong Kong Special Administrative Region of the People's Republic of China

[**REDACTED**]

"Hong Kong dollars" or "HK dollars" or "HK$"	Hong Kong dollars, the lawful currency of Hong Kong

[**REDACTED**]

"IFRS(s)"	International Financial Reporting Standards and International Accounting Standards, which include standards, amendments and interpretations promulgated by the International Accounting Standards Board and the International Accounting Standards and Interpretation issued by the International Accounting Standards Committee
"IFRS Accounting Standards"	International Financial Reporting Standards issued by the International Accounting Standards Board
"Independent Third Party(ies)"	individual(s) or company(ies) which, to the best of our Directors' knowledge, information, and belief, having made all reasonable enquiries, is/are not our connected persons

[**REDACTED**]

"Latest Practicable Date"	February 19, 2025, being the latest practicable date for ascertaining certain information in this document before its publication
"Listing Committee"	the listing committee of the Stock Exchange

[**REDACTED**]

"Listing Guide"	the Guide for New Listing Applicants published by the Stock Exchange, as amended, supplemented or otherwise modified from time to time
"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
	[**REDACTED**]
"Main Board"	the stock exchange (excluding the option market) operated by the Stock Exchange which is independent from and operates in parallel with the GEM of the Stock Exchange
"Memorandum" or "Memorandum of Association"	the eighth amended and restated memorandum of association of our Company conditionally adopted by a special resolution passed on [●] with effect from the [**REDACTED**], and as amended from time to time, a summary of which is set out in "Summary of the Constitution of our Company and Cayman Islands Company Law" in Appendix III to this document
"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)
"Nomination Committee"	the nomination committee of the Board

[**REDACTED**]

[**REDACTED**]

"Post-[**REDACTED**] Share Incentive Plan"	the post-[**REDACTED**] share incentive scheme adopted by our Company on [●], 2025, the principal terms of which are set out in the section headed "Statutory and General Information — D. Share Incentive Plans — 2. Post-[**REDACTED**] Share Incentive Plan" in Appendix IV
"PRC Legal Advisor"	CM Law Firm, PRC legal advisor to our Company
"PRC Patent Law"	the Patent Law of the PRC (中華人民共和國專利法), which was adopted by the National People's Congress on March 12, 1984, as last amended on October 17, 2020 and became effective on June 1, 2021
"Preferred Share(s)"	the Series Seed Preferred Shares, Series A-1 Preferred Shares, Series A-2 Preferred Shares, Series B-1 Preferred Shares and Series B-2 Preferred Shares we issued during the series financings
"Pre-[**REDACTED**] Equity Incentive Plan"	the pre-[**REDACTED**] equity incentive plan adopted by our Company on February 28, 2021 and amended on June 25, 2023, the principal terms of which are set out in the section headed "Statutory and General Information — D. Share Incentive Plans — 1. Pre-[**REDACTED**] Equity Incentive Plan" in Appendix IV

"Pre-[**REDACTED**] Investment(s)"	the pre-[**REDACTED**] investment(s) in our Company undertaken by the Pre-[**REDACTED**] Investors, details of which are set out in the section headed "History and Corporate Structure — Pre-[**REDACTED**] Investments" in this document
"Pre-[**REDACTED**] Investor(s)"	the investor(s) who participated in the Pre-[**REDACTED**] Investments

[**REDACTED**]

"Regulation S"	Regulation S under the U.S. Securities Act
"Remuneration Committee"	the remuneration committee of the Board
"RMB" or "Renminbi"	Renminbi, the lawful currency of the PRC
"Rule 144A"	Rule 144A under the U.S. Securities Act
"SAFE"	the State Administration of Foreign Exchange of the PRC (中華人民共和國國家外匯管理局)
"Series A-1 Investor(s)"	the holder(s) of the Series A-1 Preferred Share(s)
"Series A-1 Preferred Share(s)"	the series A-1 preferred share(s) of our Company with a par value of US$0.0001 per Share
"Series A-2 Investor(s)"	the holder(s) of the Series A-2 Preferred Share(s)
"Series A-2 Preferred Share(s)"	the series A-2 preferred share(s) of our Company with a par value of US$0.0001 per Share
"Series B Investor(s)"	the holder(s) of the Series B-1 Preferred Share(s) and Series B-2 Preferred Share(s)
"Series B-1 Preferred Share(s)"	the series B-1 preferred share(s) of our Company with a par value of US$0.0001 per Share

"Series B-2 Preferred Share(s)"	the series B-2 preferred share(s) of our Company with a par value of US$0.0001 per Share
"Series Seed Investor(s)"	the holder(s) of the Series Seed Preferred Share(s)
"Series Seed Preferred Share(s)"	the series seed preferred share(s) of our Company with a par value of US$0.0001 per Share
"SFC"	the Securities and Futures Commission of Hong Kong
"SFO" or "Securities and Futures Ordinance"	Securities and Futures Ordinance (Chapter 571 of the Laws of Hong Kong), as amended, supplemented or otherwise modified from time to time
"Share(s)" or "Ordinary Share(s)"	ordinary share(s) in the share capital our Company with a par value of US$0.0001 each
"Shareholder(s)"	holder(s) of our Share(s)
"Sophisticated Investor(s)"	has the meaning ascribed to it under the Chapter 2.3 of the Listing Guide

[**REDACTED**]

"Stock Exchange"	The Stock Exchange of Hong Kong Limited
"subsidiary(ies)"	has the meaning ascribed to it in section 15 of the Companies Ordinance
"substantial shareholder(s)"	has the meaning ascribed to it in the Listing Rules
"Takeovers Code"	Code on Takeovers and Mergers and Share Buy-backs issued by the SFC, as amended, supplemented or otherwise modified from time to time
"Track Record Period"	the two years ended December 31, 2022 and 2023, and the nine months ended September 30, 2024
"Treasury Share(s)"	the Shares repurchased and held by the Company in treasury, if any

"U.S. dollars," "US$" or "USD"	United States dollars, the lawful currency of the United States
"U.S. Securities Act"	the United States Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder
"U.S." or "United States"	the United States of America, its territories, its possessions and all areas subject to its jurisdiction
	[**REDACTED**]
"VAT"	value-added tax
	[**REDACTED**]
"%"	per cent

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

GLOSSARY OF TECHNICAL TERMS

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

"advanced CRPC"	metastatic and/or non-metastatic progressive castration-resistant prostate cancer despite prior androgen deprivation therapy
"advanced EC"	locally advanced and/or metastatic endometrial cancer, commonly refers to Stages III and IV EC
"ADA"	anti-drug antibody, an antibody produced by the immune system against a biologic. ADAs may adversely affect the efficacy and safety of the biologic
"ADC"	antibody-drug conjugate, a class of biopharmaceutical drugs that comprise an antibody conjugated to a payload molecule, typically a cytotoxic agent, via a chemical linker
"ADCC"	antibody dependent cell-mediated cytotoxicity or antibody-dependent cellular cytotoxicity, a mechanism of cell-mediated immune defense whereby an effector cell of the immune system actively lyses a target cell whose membrane-surface antigens have been bound by specific antibodies
"ADT"	androgen deprivation therapy, which is designed to either stop testosterone from being produced or to directly block it from acting on prostate cancer cells
"AE"	adverse event, which may be mild, moderate, or severe, any untoward medical occurrence in a patient or subject receiving a drug or other pharmaceutical product in a clinical trial and which does not necessarily have a causal relationship with the treatment
"AESI"	adverse event of special interest
"agonist"	a chemical that binds to and activates a receptor or other protein to produce a biological response

"AKT"	a serine/threonine protein kinase with 3 isoforms (AKT1, AKT2 and AKT3) that participate in multiple pathways regulating several cellular processes, including survival, proliferation, tissue invasion, and metabolism
"AUC"	area under the curve, a pharmacokinetic parameter that measures the body's exposure to a drug, i.e., how much of the drug reaches a person's bloodstream over a given period of time after a dose is administered
"BC"	breast cancer
"BDCA2"	Blood Dendritic Cell Antigen 2, a type II C-type lectin receptor expressed on the surface of plasmacytoid dendritic cells
"BICR"	Blinded Independent Central Review, a process used in clinical trials to ensure the objectivity and accuracy of data analysis
"biomarker"	a naturally occurring molecule, gene, or characteristic by which a particular pathological or physiological process, disease, etc. can be identified
"bispecific ADCs" or "BsADCs"	a novel type of ADCs in which the payload molecule is conjugated to a bispecific antibody which confers targeting ability against two different antigens
"bispecific antibody" or "bsAb"	an antibody that combines two antigen-recognizing elements into a single construct, capable of binding to two different antigens simultaneously
"BLA"	biologics license application
"Breakthrough Therapy Designation"	a designation by the NMPA and/or the FDA to expedite the development and review of therapies intended for the treatment of serious diseases for which there is no effective treatment and where preliminary evidence indicates the therapy may demonstrate a substantial improvement over available treatment options
"BTC"	biliary tract cancer

GLOSSARY OF TECHNICAL TERMS

"bystander effect"	a cytotoxic effect that occurs when the cytotoxic payload from an ADC is released either from the target cell following internalization and degradation of the ADC or after cleavage within the extracellular space, resulting in the payload being taken up by and killing surrounding cells that may or may not express the ADC's target antigen
"B7H3" or "B7-H3"	anti- B7 homolog 3 protein
"B7H4" or "B7-H4"	anti- B7 homolog 4 protein
"CAGR"	compound annual growth rate
"CC"	cervical cancer
"CD276"	cluster of differentiation 276, a molecule that regulates T cell activation and function
"CDK"	cyclin dependent kinase, a conserved family of proline-directed serine/threonine kinases that perform critical roles in regulating the stepwise progression through the eukaryotic cell cycle
"CDK4"	cyclin dependent kinase 4, a type of CDK
"CDK6"	cyclin dependent kinase 6, a type of CDK
"CDMO"	contract development and manufacturing organization, a company that provides support to the pharmaceutical, biotechnology, and medical device industries in the form of development and manufacturing services outsourced on a contract basis
"cell line"	a population of cells which descend from a single cell and contain the same genetic makeup, thereby producing the same proteins. The productivity of a cell line determines the cost of manufacturing, and the quality of a cell line is directly related to the quality of the relevant biologics
"chemo naïve"	a term used to describe patients who have not previously received chemotherapy treatment

"chemotherapy" or "chemo"	a drug treatment that uses cytotoxic chemicals to kill fast-growing cells in a patient's body. It is most often used as a cancer treatment because cancer cells grow and multiply much faster than most other cells in the body
"cGMP"	current good manufacturing practice
"CLE"	cutaneous lupus erythematosus
"C_{max}"	maximum plasma concentration, a pharmacokinetic parameter that measures the highest concentration of a drug in the blood, cerebrospinal fluid, or target organ after a dose is given
"CMC"	chemistry, manufacturing and controls, also commonly referred to as process development, covering the various procedures used to assess the physical and chemical characteristics of drug products, and to ensure their quality and consistency during manufacturing
"cohort"	a group of patients as part of a clinical trial who share a common characteristic or experience within a defined period and who are monitored over time
"combination therapy"	a treatment that uses more than one medication or modality
"CR"	complete response, the disappearance of all signs of cancer in response to treatment
"CRC"	colorectal cancer, a type of cancer arising from the colon or rectum
"CRPC"	castration-resistant prostate cancer
"CRO"	contract research organization, a company that provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis

"CSO"	contract sales organization, a company that provides support to the pharmaceutical, biotechnology, and medical device industries in the form of services for the development and commercialization of new drugs, medical devices, and other healthcare products
"cytokine"	a broad category of small proteins that are important in cell signaling, whose release has an effect on the behavior of cells expressing corresponding receptors
"cytotoxic"	toxic to living cells
"DAR"	drug-to-antibody ratio, the average number of drug molecules attached to each antibody in an ADC
"DC"	dendritic cell
"DCR"	disease control rate, the total proportion of patients who demonstrate a response to treatment, equal to the sum of complete responses (CR), partial responses (PR) and stable disease (SD)
"DOR"	duration of response, the length of time that a tumor continues to respond to treatment without the cancer growing or spreading
"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
"dose escalation study"	a type of study where different doses of an agent (e.g. a drug) are tested against each other to establish which dose works best and/or is least harmful
"dose expansion study"	a type of study that enrolls additional participants to typically further evaluate efficacy, safety, tolerability, pharmacokinetics, and pharmacodynamics
"EC"	endometrial cancer
"EGFR"	epidermal growth factor receptor

"EGFRm" or "EGFR-mutant"	cells or tissues harboring mutations in the EGFR gene, which can affect receptor function and are often associated with certain types of cancer
"ERK"	extracellular signal-regulated kinase
"ESCC"	esophageal squamous cell carcinoma
"ET"	endocrine therapy
"Fast Track Designation" or "FTD"	a designation granted by the FDA to expedite the review of drugs that treats serious or life-threatening condition or address unmet medical needs to facilitate the development of drugs
"Fc"	crystallizable fragment, which is the tail region of an antibody that interacts with cell surface receptors called Fc receptors and some proteins of the complement system
"first-line" or "1L"	with respect to any disease, the first line treatment refers to the treatment regimen or regimens that are generally accepted by the medical establishment for initial treatment. It is also called primary treatment or therapy
"five-year survival rate"	a type of survival rate used to estimate the prognosis of a particular disease, referring to the percentage of patients who are still alive five years after cancer diagnosis
"FRα"	folate receptor alpha, a cell surface receptor that binds and transports folate (vitamin B9) into cells
"GC"	gastric cancer
"GCP"	good clinical practice, an international ethical and scientific quality standard for the performance of a clinical trial on medicinal products involving humans
"GEA"	gastroesophageal adenocarcinoma
"GJA"	gastroesophageal junction adenocarcinoma

"glucocorticoid"	steroid hormones produced by the adrenal glands that regulate metabolism, immune response, and stress, and are used to treat conditions like inflammation, allergies, and autoimmune diseases
"GLP"	good laboratory practice
"GR"	glucocorticoid receptor
"HCC"	hepatocellular carcinoma
"HER"	human epidermal growth factor receptor, a group of four closely related receptor tyrosine kinases that play important roles in cell growth, survival, and differentiation
"HER2"	human epidermal growth factor receptor 2
"HER2-expressing"	HER2 status of tumor cells identified with a test score of IHC 1+ or above
"HER2-low"	HER2 status of tumor cells identified with a test score of IHC 1+ or IHC 2+/ISH-
"HER2m"	HER2 status identified with one or more mutations, or alterations, in the nucleotide sequence of HER2, which may or may not result in HER2 amplification or overexpression
"HER2-negative" or "HER2-"	HER2 status of tumor cells identified with a test score of IHC 0, IHC 1+ or IHC 2+/ISH-, which can be further classified into HER2-low and HER2-null
"HER2-null"	HER2 status of tumor cells identified with a test score of IHC 0
"HER2-positive" or "HER2+"	HER2 status of tumor cells identified with a test score of either IHC 3+ or IHC 2+/ISH+
"HER3"	human epidermal growth factor receptor 3
"HNSCC"	head and neck squamous cell carcinoma

"HNSTD"	the highest dose level that does not produce evidence of lethality, life-threatening toxicities or irreversible findings
"HR+"	hormone receptor positive
"HR-"	hormone receptor negative
"ICD"	immunogenic cell death
"IFNγ"	interferon gamma, a cytokine for activation and regulation of the immune system
"IFN-I"	type I interferon, a cytokine involved in the innate immune response against viral infections and other pathogens
"IgG"	immunoglobulin G, the most common type of antibody found in blood circulation that plays an important role in antibody-based immunity against invading pathogens
"IgG1"	immunoglobulin G1, a subclass of IgG
"immune checkpoint inhibitor(s)" or "ICI(s)"	a type of immunotherapy that blocks proteins called immune checkpoints, which prevent the immune system from attacking the cancer cells
"immunotherapy" or "IO"	a type of therapy that uses substances to stimulate or suppress the immune system to help the body fight cancer, infection, and other diseases
"IND"	investigational new drug or investigational new drug application, also known as clinical trial application in China or the U.S.
"*in vivo*"	Latin for "within the living", studies in vivo are those in which the effects of various biological or chemical substances are tested on whole, living organisms including animals, humans and plants, as opposed to a partial or dead organism, or those done *in vitro*

GLOSSARY OF TECHNICAL TERMS

"*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
"IRC"	an independent review committee
"key opinion leaders" or "KOLs"	experts and influencers who have significant knowledge in a specific field
"LC"	lung cancer
"linker"	one of the three core components of an ADC. A linker connects the antibody and payload via chemical bonds
"mAb" or "monoclonal antibody"	an antibody generated by identical immune cells that are all clones of the same parent cell
"Marketing Authorization Holder" or "MAH"	an individual or entity that holds the license/legal authorization to market and distribute a pharmaceutical product in a specific jurisdiction
"MAPK"	mitogen activated protein kinase, a type of protein kinase that is specific to the amino acids serine and threonine
"mCRPC"	metastatic castration-resistant prostate cancer
"melanoma"	a form of skin cancer that arises when pigment-producing cells, also known as melanocytes, mutate and become cancerous
"metastatic"	in reference to any disease, including cancer, disease producing organisms or malignant or cancerous cells transferred to other parts of the body by way of the blood or lymphatic vessels or membranous surfaces
"MMAE"	monomethyl auristatin E
"MNC"	multinational companies
"MOA"	mechanism of action
"monotherapy"	therapy that uses a single drug to treat a disease or condition

GLOSSARY OF TECHNICAL TERMS

"MRCT"	multi-regional clinical trial
"MTD"	maximum tolerated dose, the highest dose of a drug or treatment that does not cause unacceptable side effects
"NDA"	new drug application
"NRDL"	National Reimbursement Drug List
"NSAID"	non-steroidal anti-inflammatory drug
"NSCLC"	non-small cell lung cancer
"OC"	ovarian cancer
"off-target toxicity"	adverse effects that occur when a drug binds to targets other than those for which it was designed to bind
"oncology"	a branch of medicine that deals with tumors, including the study of their development, diagnosis, treatment, and prevention
"Orphan Drug Designation"	a designation granted by the NMPA and/or FDA to a drug or biological product intended to prevent, diagnose or treat a rare disease or condition, qualifying the sponsors for certain incentives
"ORR"	overall objective response rate, the proportion of patients with a complete response or partial response to treatment
"OS" or "overall survival"	the length of time from either the date of diagnosis or the start of treatment for a disease which patients diagnosed with the disease are still alive. It is used in clinical trials to measure a drug's effectiveness
"payload"	one of the three core components of an ADC. Payloads are conventionally highly active and cytotoxic molecules attached to an antibody via a chemical linker. Non-cytotoxic payloads have recently emerged as novel ADC strategies for oncology and non-oncology indications
"PC"	prostate cancer
"pDC"	plasmacytoid dendritic cell

"PDX model"	a model of cancer where tissue or cells from a patient's tumor are implanted into an immunodeficient or humanized mouse to evaluate the natural growth of the cancer, its monitoring, and corresponding treatment for the original patient
"PD-1"	programmed cell death protein 1, an immune checkpoint receptor expressed on T cells, B cells and macrophages
"PD-L1"	PD-1 ligand 1, which is a protein on the surface of a normal cell or a cancer cell that binds to its receptor, PD-1, on the surface of the T cell that causes the T cell to turn off its ability to kill the cancer cell
"PD-(L)1"	referring to PD-1 or PD-L1
"PFS"	progression free survival, the length of time during and after the treatment that a patient lives without the disease getting worse
"phase 1 clinical trial"	a study in which a drug is introduced into healthy human subjects or patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion, and if possible, to gain an early indication of its effectiveness
"phase 2 clinical trial"	a study in which a drug is administered to a limited patient population to identify possible adverse effects and safety risks, preliminarily evaluate the efficacy of the product for specific targeted diseases, and determine dosage tolerance and optimal dosage
"phase 3 clinical trial"	a study in which a drug is administered to an expanded patient population, generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to statistically evaluate the efficacy and safety of the product for approval, to provide adequate information for the product's labeling
"pharmacokinetics" or "PK"	a measurement of how fast and how completely a drug is absorbed into animal or human body, including the distribution, metabolism, and excretion of drugs in animal or human body

"pivotal trial"	a clinical trial or study designed to demonstrate clinical efficacy and safety evidence required before submission for drug marketing approval
"PI3K"	phosphoinositide 3 kinase, an important signaling node for many cellular functions such as growth control, metabolism and translation initiation
"platinum-based chemotherapy"	chemotherapy containing platinum complexes, which is used to treat multiple types of cancers
"PR"	partial response, defined as at least a 30% but less than 100% decrease in the size of a tumor or the extent of cancer in the body in response to treatment, according to RECIST
"proof-of-concept trial"	an early clinical drug development phase aimed at obtaining an initial evaluation of the potential efficacy of a treatment
"Q2W" and "Q3W"	dosing frequency referring to "once every two weeks" and "once every three weeks," respectively
"radionuclide drug conjugates"	a novel form of drug conjugates composed of an antibody linked to a radionuclide, a radioactive isotope, via a chemical linker
"RCD"	recommended combination dose
"RECIST"	Response Evaluation Criteria in Solid Tumors, a set of published rules that define when tumors in cancer patients improve ("respond"), stay the same ("stabilize"), or worsen ("progress") during treatment with a focus on measuring tumor size and its progress over time to assess treatment effectiveness. The criteria were published in February 2000 by an international collaboration including the European Organization for Research and Treatment of Cancer, National Cancer Institute of the United States, and the National Cancer Institute of Canada Clinical Trials Group. Now the majority of clinical trials worldwide evaluating cancer treatments for objective response in solid tumors use RECIST. These criteria were developed and published in February 2000, and subsequently updated in 2009

"rPFS"	radiographic progression free survival, a clinical endpoint commonly used in oncology trials to measure the length of time from when a patient is randomly assigned until objective tumor progression on imaging or death, whichever occurs first
"RP2D"	recommended phase 2 dose, typically the highest dose with acceptable toxicity, usually defined as the dose level that produces around 20% of dose-limiting toxicity
"SAE"	serious adverse event, any medical occurrence in human drug trials that, at any dose, results in death; is life-threatening; requires inpatient hospitalization or prolongs existing hospitalization; results in persistent or significant disability/incapacity; may cause a congenital anomaly/birth defect; or requires intervention to prevent permanent impairment or damage
"SCLC"	small-cell lung cancer
"second-line" or "2L"	with respect to any disease, the therapy or therapies that are given when initial treatments (first-line therapy) do not work, or stop working
"SLE"	systemic lupus erythematosus
"solid tumors"	abnormal masses of tissue that usually do not contain cysts or liquid areas. Solid tumors may be benign (not cancer), or malignant (cancer). Different types of solid tumors are named for the type of cells that form them, such as carcinomas (cancers starting in epithelial cells) and lymphomas (cancers originating in lymphocytes)
"standard of care" or "SoC"	treatment accepted by medical experts as proper for a certain type of disease and widely used by healthcare professionals
"TAA"	tumor-associated antigen, an antigen with elevated level on tumor cells and lower levels on normal cells

"targeted therapy"	a major type of treatment modalities that works by targeting a particular molecule or molecules implicated in or essential to the pathogenesis of cancer and non-oncology indications, including but not limited to small molecule drugs and monoclonal antibodies
"T cell"	a lymphocyte produced or processed by the thymus gland, actively participating in the immune response and playing a central role in cell-mediated immunity. T cells are distinguished from other lymphocytes, such as B cells and NK cells, by the presence of a T cell receptor on their surface
"TEAE"	treatment-emergent adverse event, either an adverse event that starts after the initiation of the study medication or one that existed before study medication but worsened in severity after the initiation of study medication
"TGI"	tumor growth inhibition, a measurement of the reduction in the growth of tumors or tumor cells by a certain treatment
"therapeutic window"	the range of drug dosages that can treat disease effectively without having toxic effects, or the time interval during which a particular therapy can be given safely and effectively
"third-line" or "3L"	with respect to any disease, the therapy or therapies given when both initial treatment (first-line therapy) and subsequent treatment (second-line therapy) do not work, or stop working
"TKI"	tyrosine kinase inhibitor, a type of targeted therapy that inhibits tyrosine kinases
"TME"	tumor microenvironment
"TNBC"	triple-negative breast cancer
"topoisomerase"	any of a class of enzymes that reduce winding in DNA by breaking and rejoining one or both strands of the DNA molecule

"TRAE"	treatment-related adverse event, an adverse event that, in the investigator's opinion, may have been caused by the study medication with reasonable possibility
"TROP2"	human trophoblast cell-surface antigen 2, a transmembrane protein frequently over-expressed in many types of solid tumors
"TTR"	time to response, the time from the start of treatment to the first objective tumor response observed in patients who achieve a complete response (CR) or partial response (PR)
"tumor growth inhibition"	a measure of the reduction in the growth of tumors or tumor cells by a certain treatment
"UC"	urothelial cancer
"unresectable"	referring to any tumor that cannot be surgically removed due to factors making surgery either technically impossible or medically inadvisable
"uORR"	unconfirmed overall response rate, which is a metric used to measure the proportion of patients who achieve a complete or partial response to a treatment, but the response has not yet been confirmed by follow-up assessments. It is often used in early stages of clinical trials to assess preliminary effectiveness
"VEGF"	vascular endothelial growth factor

FORWARD-LOOKING STATEMENTS

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

- the timing of initiation and completion, and the progress of our preclinical studies and clinical trials;
- the timing and likelihood of regulatory filings and approvals, such as INDs and new drug applications ("**NDAs**")/biologics license application ("**BLAs**");
- our license and collaboration agreements;
- the market opportunities of our drug candidates;
- our operations and business prospects;
- our business strategies and plans to achieve these strategies;
- the competitive environment of the industry and markets in which we operate;
- the commercialization strategies and pricing policy of our drug candidates;
- our ability to defend our intellectual rights and protect our trade secrets;
- our financial conditions and operating results and performance;
- our ability to control costs and expenses;
- changes or volatility in interest rates, foreign exchange rates, equity prices, trading volumes, commodity prices and overall market trends;
- changes to regulatory and operating conditions in the industry and markets in which we operate;

- general economic, political and business conditions in the markets in which we operate;
- our future debt levels and capital needs;
- our ability to attract and retain senior management and key employees;
- certain statements in the sections headed "Business," "Industry Overview" and "Financial Information" in this document with respect to trends in prices, operations, margins, overall market trends, and risk management; and
- all other risks and uncertainties described in the section headed "Risk Factors" in this document.

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

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

An* [REDACTED] *in our Shares involves various risks. You should carefully read and consider all of the information in this document, including the risks and uncertainties described below before deciding to make any* [REDACTED] *in our Shares.

The occurrence of any of the following events could materially and adversely affect our business, financial condition, results of operations or prospects. If any of these events occurs, the* [REDACTED] *of our Shares could decline and you may lose all or part of your* [REDACTED]. *You should seek professional advice from your relevant advisers regarding your prospective* [REDACTED] *in the context of your particular circumstances.

RISKS RELATING TO THE DEVELOPMENT OF OUR DRUG CANDIDATES

We depend substantially on the success of our drug candidates. If we are unable to successfully complete clinical development, obtain regulatory approvals or achieve commercialization for our drug candidates, or if we experience significant delays or cost overruns in doing any of the foregoing, our business and prospects could be materially and adversely affected.

Our revenue and profitability are substantially dependent on our ability to complete the development of our drug candidates, obtain requisite regulatory approvals and successfully commercialize our drug candidates. We have invested a significant portion of our efforts and capital resources in the development of our existing drug candidates, and we expect to incur substantial and increasing expenditures for the development and commercialization of our drug candidates in the future.

The success of our drug candidates will depend on a number of factors, including:

- favorable safety and efficacy data from our preclinical studies and clinical trials;
- sufficient resources to discover or acquire additional drug candidates and successful identification of potential drug candidates based on our research or business development methodology or search criteria and process;
- successful enrollment of patients in, and completion of, clinical trials;
- sufficient supplies of drug products that are used in our clinical trials;
- modifications to the protocols, which may delay the clinical program, regulatory approvals or commercialization, and require us to supplement, modify, or withdraw and refile our applications for regulatory approvals;

- the performance by CROs, CDMOs, or other third parties we engage to conduct clinical trials and preclinical studies and their compliance with our protocols and applicable laws without damaging or compromising the integrity of the resulting data;

- the capabilities and competence of our collaborators;

- the success of clinical trials conducted by, or jointly with, our collaborators;

- receipt of regulatory approvals for planned clinical trials or drug registrations, manufacturing and commercialization;

- commercial manufacturing capabilities, including through the CDMOs we engage;

- successful launch of commercial sales of our drug candidates, if and when approved;

- the obtaining and maintenance of favorable reimbursement from third-party payers for drugs, if and when approved;

- competition with other drug products;

- the obtaining, maintenance and enforcement of patents, trademarks, trade secrets and other intellectual property protections and regulatory exclusivity for our drug candidates;

- successful defense against any claims brought by third parties that we have infringed, misappropriated or otherwise violated any intellectual property of any such third party; and

- the continued acceptable safety profile of our drug candidates following regulatory approval.

Some of our drug candidates represent a novel approach to therapeutic needs compared with more commonly used modalities. For example, we have built a highly differentiated portfolio of novel ADC drugs — one of the fastest-growing treatment modalities for cancers with vast market potential. Our ADC assets and other drug candidates, given their novelty and differentiated features, may carry inherent development risks that could result in delays and cost overruns in clinical development, regulatory approvals or commercialization. Furthermore, a substantial amount of education and training may need to be provided to patients and medical personnel in connection with our drug candidates, which potentially increases our sales and marketing expenses. This may have a material and adverse effect on future profits generated from our drug candidates, which in turn may materially and adversely affect our competitive position, business, financial condition and results of operations.

As of the Latest Practicable Date, all of our drug candidates were in various phases of preclinical and clinical development. If we fail to achieve drug development milestones as disclosed in this document, our business prospects could be adversely affected. Our costs will also increase if we experience delays in the development of drug candidates or in obtaining regulatory approvals, which could result in us having to delay or suspend the trial until sufficient funding is procured, or we would have to abandon developing of the drug candidate completely. Significant preclinical study or clinical trial delays also could allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our drug candidates. Any of the above negative developments could have a material and adverse effect on our business, financial condition and results of operation.

We face intense competition and rapid technological change and the possibility that our competitors may develop therapies that are similar, more advanced, or more effective than ours, which may adversely affect our financial condition and our ability to successfully commercialize our drug candidates.

The biopharmaceutical industry in which we operate is intensely competitive and subject to rapid and significant technological changes. While we focus on developing drug candidates with the potential to become novel or highly differentiated drugs, we continue to face competition with respect to our current drug candidates, and any drug candidates that we may seek to develop or commercialize in the future. For instance, our Core Products, DB-1303 and DB-1311, and other pipeline products may face competition from existing ADCs directed against the same molecular targets and approved for the same target indications upon potential marketing approval in the future.

Our competitors may include multinational pharmaceutical companies, biotechnology companies, and research institutions worldwide. For example, in recent years, an increasing number of biopharmaceutical companies have joined the competition in the research and development of ADCs, with large pharmaceutical companies leading the competition and biotechnology companies making frequent breakthroughs. Some of these competitive drugs and therapies are based on scientific approaches that are similar to our approach. For details, see "Business — Our Pipeline." Potential competitors also include academic institutions, governmental authorities and other public and private research organizations that invest in the development, manufacturing and commercialization of innovative drugs.

Many of our competitors have substantially greater financial, technical, and other resources than we do, such as those with larger research and development staff and established marketing and manufacturing infrastructure. Collaborations, mergers and acquisitions in the biopharmaceutical industry may result in even more resources being concentrated in our competitors. As a result, these companies may be able to advance their drug candidates and obtain regulatory approval from the regulatory authorities more rapidly than we do, and become more effective in selling and marketing their products. Even if successfully developed and subsequently approved by the NMPA, the FDA or other comparable regulatory authorities, our drug candidates may still face competition in various aspects, including safety and efficacy,

the timing and scope of the regulatory approvals, the availability and cost of supply, sales and marketing capabilities, price and patent status. Smaller or early-stage companies may also be significant competitors, particularly through collaborative arrangements with large, established companies.

Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in the industry. Our competitors may succeed in developing, acquiring, or licensing on an exclusive basis, products that are more effective or less costly than any drug candidate that we may develop, or achieve earlier patent protection, regulatory approval, product commercialization, and market penetration than we do. To compete with an approved product, we must demonstrate compelling advantages in efficacy, safety or other aspects in order to overcome price competition and to be commercially successful. Furthermore, disruptive technologies and medical breakthroughs may further intensify the competition and render our drug candidates uneconomical or obsolete, and we may not be successful in marketing our drug candidates against competitors.

Clinical development involves a lengthy and expensive process with an uncertain outcome, and results of preclinical studies and early phases of clinical trials may not be predictive of future trial results.

Clinical development is expensive and can take many years to complete, and its outcome is inherently uncertain. For instance, despite showing vast potential in clinical trials in the 1980s for cancer treatment, ADCs have presented a major scientific challenge to researchers due to the high degree of technological sophistication required to design and produce a balanced drug. Only in recent years have ADCs begun to gain momentum, as ten of the 15 marketed ADCs to date were approved after 2019. For details, see "Industry Overview — Antibody-drug Conjugates: A Precision Treatment Revolution — Evolution of ADCs."

As of the Latest Practicable Date, several of our drug candidates, including our Core Products DB-1303 and DB-1311, and key products DB-1310, DB-1305 and DB-1419, have obtained IND approvals and are currently in clinical development. For details of our pipeline and clinical development of our drug candidates, see "Business — Our Pipeline." We may encounter unexpected difficulties while executing our drug development plans for such drug candidates and our current and future drug candidates are susceptible to the risks of failure inherent at any stage of drug development, including the occurrence of unexpected or unacceptable adverse events ("**AEs**") or the failure to demonstrate efficacy in clinical trials.

While we believe our drug candidates have the potential to be innovative and differentiated globally, we cannot guarantee that we will be able to realize such potential for any of our drug candidates, especially because they are still in clinical or preclinical development. Failure can occur at any time during the drug development process, which would result in a material and adverse effect on our business, financial condition and results of operations. For instance:

- regulators, ethics committees, or other designated review bodies may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;

- we might have to suspend or terminate clinical trials of our drug candidates for various reasons, including negative results or a finding that participants are being exposed to unacceptable health and safety risks;

- we may not be able to reach agreements on acceptable terms with prospective CROs and hospitals as trial centers, the terms of which can be subject to extensive negotiation;

- we may encounter various manufacturing issues, including inability to reach agreements on acceptable terms with CDMOs, problems with quality control, or ensuring sufficient quantities of our drug candidates for use in a clinical trial;

- subject enrolment may be insufficient or slower than we anticipate, or subjects may drop out at a higher rate than anticipated;

- patent disputes or the failure to secure patents or other intellectual property protection for our drug candidates may affect the drug development process; and

- our drug candidates may cause AEs and undesirable side effects, among other unexpected characteristics, which could result in a suspension or termination of an ongoing trial.

The results of preclinical studies and early clinical trials of our drug candidates may not be predictive of the results of later-stage clinical trials. Drug candidates during later stages of clinical trials may fail to show the desired results in safety and efficacy despite having progressed through preclinical studies and initial clinical trials, and despite the level of scientific rigor in the design of such studies and trials and the adequacy of their execution. In some instances, there can be significant variability in safety and/or efficacy results among different trials of the same drug candidate due to numerous factors, including differences in the size and demographics of the enrolled patients, conditions of the individual subjects and their adherence to the treatment regimen and other compounding factors, such as other medications or pre-existing medical conditions. Differences in the number of clinical trial sites and regions involved may also lead to variability between clinical trials.

Many companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to a lack of efficacy or adverse safety profiles, notwithstanding promising results at an earlier stage. We cannot guarantee that the results from our future research and development efforts will be favorable based on currently available clinical and preclinical data, which could result in delays in the completion of clinical trials, regulatory approvals and commencement of commercialization of our drug candidates. See also "— Risks Relating to Government Regulations — The regulatory approval processes of the NMPA, the FDA and other comparable regulatory authorities are time-consuming and may evolve over time. If we are unable to obtain without undue delay any regulatory approvals for our drug candidates in our target markets, our business may be subject to actual or perceived harm."

We may not be able to discover or identify new drug candidates, or to expand the therapeutic opportunities for our drug candidates.

Besides the continued clinical testing, potential approvals and commercialization of our existing drug candidates, the success of our business depends in part upon our ability to discover or identify additional drug candidates. There can be no assurance that we will be successful in identifying new drug candidates in the future. For example, although we have developed our proprietary ADC technology platforms, which we believe enables us to design, evaluate and select candidates and continue to enrich our pipeline, we cannot guarantee that we will successfully identify potential drug candidates as expected. Some drug candidates may be technically challenging to develop and manufacture. Drug candidates that we identify may later show side effects or other characteristics that make them unmarketable or unlikely to receive regulatory approvals. We have also pursued, and may continue to pursue, collaboration with third parties in the discovery and development of potential drug candidates. However, there can be no assurance that such license and collaboration will deliver the expected results.

Research programs to identify new drug candidates and to develop our drug candidates for additional indications require substantial technical, financial, and human resources. We may invest efforts and resources in potential drug candidates or indication expansions that ultimately prove to be unsuccessful. Any of the foregoing events will have a material and adverse effect on our business, results of operations and prospects.

We may allocate our limited resources to pursue a particular drug candidate or indication and fail to capitalize on 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 on research programs and drug candidates for specific indications. As a result, we may forgo or delay pursuit of opportunities with other drug candidates or for other indications that later may prove to have greater commercial potential or a greater likelihood of success. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Furthermore, 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 licensing, collaboration or royalty arrangements in cases where 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, which could materially adversely affect our future growth and prospects.

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

We may not be able to initiate or continue clinical trials for our drug candidates if we are unable to locate and enroll a sufficient number of eligible subjects to participate in these trials, or if there are delays in the enrollment of eligible subjects as a result of the competitive clinical enrollment environment. The inability to enroll a sufficient number of subjects who meet the applicable criteria set out in the protocol could result in significant delays in our clinical trials. In addition, some of our competitors may have ongoing clinical trials for drug candidates that treat the same indications as our drug candidates, and subjects who would otherwise be eligible for our clinical trials may instead enroll in the clinical trials of our competitors' drug candidates, which may further delay our clinical trial enrollments.

Subject enrollment for our clinical trials may be affected by a variety of factors, including but not limited to the following:

- total size and nature of the relevant patient population;
- design and eligibility criteria for the clinical trial in question;
- perceived risks and benefits of the drug candidate under study;
- severity of the disease under investigation;
- our resources to facilitate timely subject enrollment in clinical trials;
- patient referral practices of physicians;
- availability of competing therapies also undergoing clinical trials;
- our ability to obtain and maintain subject consents;
- our investigators' or clinical trial sites' efforts to screen and recruit eligible patients;
- proximity and availability of clinical trial sites for prospective patients; and
- occurrence of natural disasters, health epidemics, acts of war or other public events.

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

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

AEs and undesirable side effects caused by our drug candidates could cause us or regulatory authorities to interrupt or halt clinical trials and may result in a narrowed scope of indications, a more restrictive label, a delay or denial of regulatory approval by the NMPA, the FDA or other comparable regulatory authorities, or a significant change in our clinical protocol or even our development plan. In particular, as is the case with other drugs treating cancers, it is likely that there may be side effects associated with the use of certain of our drug candidates. Results of trials conducted by us or by our collaboration partners with respect to our drug candidates could reveal a high and unacceptable severity or prevalence of certain AEs, including grade 3 or above TRAEs. In such an event, such trials could be suspended or terminated and the NMPA, the FDA or other comparable regulatory authorities could order us or our collaboration partners, as applicable, to cease further development of, or deny approval of, our drug candidates for any or all targeted indications. AEs related to our drug candidates may also affect subject recruitment or the ability of enrolled subjects to complete the trial, and could result in potential liability claims. Any of these occurrences may significantly harm our reputation, business, financial condition and prospects.

Additionally, if we, our collaboration partners, or others identify undesirable side effects caused by our drug candidates after they receive regulatory approval, this may lead to potentially significant negative consequences which include, but are not limited to, the following:

- regulatory authorities may withdraw their approvals of or revoke the licenses for the drug candidate;
- we, or our collaboration partners, may have to suspend marketing of the drug candidate;
- regulatory authorities may require additional warnings on the label;
- the NMPA, the FDA or a comparable regulatory authority may require the establishment of a Risk Evaluation and Mitigation Strategy ("**REMS**"), or similar strategy that may, for instance, restrict distribution of our drugs and impose burdensome implementation requirements on us;

- we, or our collaboration partners, may be required to conduct specific post-marketing studies;

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

- our reputation may suffer.

Further, combination therapy using our drug candidates together with third-party agents may involve unique AEs that could be exacerbated compared with AEs from monotherapies. Any of these events could prevent us or our collaboration partners, as applicable, from achieving or maintaining market acceptance of any particular drug candidate that is approved and could significantly harm our business, financial condition, results of operations and prospects.

We may be unable to successfully develop or market our drug candidates or may experience significant regulatory delays, if safety, efficacy or other issues arise from any of our drug candidates or from any pharmaceutical product or medical treatment used, or intended to be used, in combination with our drug candidates.

We plan to develop certain of our drug candidates for use as a combination therapy. For instance, together with BioNTech, we are actively exploring the combination potential of DB-1305. For details, see "Business — Our Pipeline." We may also seek to develop our drug candidates in combination with other drugs in the future. If the NMPA, the FDA or another comparable regulatory authority revokes its approval of such treatments or drugs we intend to use in combination with our drug candidates, we may not be able to develop or market our drug candidates as a combination therapy as planned. If safety or efficacy issues arise with such treatments or drugs that we seek to combine with our drug candidates in the future, we may experience significant regulatory delays, and we may be required to redesign or terminate the applicable clinical trials. For instance, we are investigating DB-1310's combination potential with osimertinib in EGFRm NSCLC patients resistant to osimertinib or other third-generation tyrosine kinase inhibitor ("**TKI**") therapy. While this combination strategy is designed to potentially address the challenge of osimertinib resistance, our success will depend on demonstrating that DB-1310, when combined with osimertinib, can effectively overcome resistance mechanisms and provide meaningful clinical benefit to patients. In addition, if manufacturing or other issues result in a supply shortage of any drugs we use in combination with, we may not be able to complete clinical development of our drug candidates as a combination therapy on our current timeline or within our current budget, or at all.

In addition, we generally have no influence over the availability and pricing of such drugs. If other pharmaceutical companies discontinue these combination drugs, or if these drugs become prohibitively expensive, regimens that use these combination drugs may no longer be prescribed, and we may not be able to introduce or find an alternative drug to be used in combination with our drugs in a timely manner and on commercially reasonable terms, or at all. As a result, clinical development of our drug candidates may be affected or future demands for our drugs may be lowered, which would in turn materially and adversely affect our business, financial condition, results of operations and prospects.

The data and information we gather or otherwise rely on in our research and development process could be inaccurate or incomplete, which could harm our trial results, reputation and prospect.

We collect, aggregate, process, and analyze data and information from preclinical studies, clinical trials and other research and development programs. We also engage in substantial information gathering following the identification of a potential drug candidate. Because data in the healthcare industry is fragmented in origin, inconsistent in format, and incomplete, the overall quality of data collected or accessed is often subject to challenge, the degree or amount of data which is knowingly or unknowingly absent or omitted can be material, and data issues and errors are frequently discovered. If mistakes are made 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 also engage in the procurement of regulatory approvals necessary for the development and commercialization of our products under development, for which we manage and submit data to governmental entities. These processes and submissions are governed by complex data processing and validation policies and regulations. We may be exposed to liability if it is concluded that our storage, handling, submission, delivery, or display of health information or other data was wrongful or erroneous.

In addition, we rely on third parties, including our collaborators, to collect, monitor and manage data for some of the ongoing preclinical and clinical programs for our drug candidates and have limited control over their activities. For instance, data from clinical trials conducted or to be conducted by BioNTech, our collaboration partner, for DB-1303, DB-1311 and DB-1305 outside Mainland China, Hong Kong and Macau may affect our clinical development of these drug candidates in China. If there are any inaccuracies, mistakes or incompleteness in the preclinical and clinical data of any of our collaborators, our clinical development activities may be negatively impacted as a result.

We invest substantial human and capital resources in research and development in order to develop our drug candidates and enhance our technologies, but we cannot guarantee that such efforts will lead to successful outcomes.

The global biopharmaceutical market is constantly evolving, and we must keep pace with new technologies and methodologies to maintain our competitive position. For example, we have made significant efforts to develop our core technology platforms, including our proprietary DITAC platform, DIBAC platform, DIMAC platform, and DUPAC platform which allow us to continuously develop a strong pipeline of drug candidates. For details, see "Business — Our Pipeline." In 2022, 2023 and for the nine months ended September 30, 2023 and 2024, our costs and expenses in relation to R&D activities, which represented our cost of revenue and research and development expenses, were RMB339.9 million, RMB986.7 million, RMB696.6 million and RMB1,404.4 million, respectively. We intend to continue to strengthen our technical capabilities in the development of our drug candidates, which requires substantial capital and time. We cannot assure you that we will be able to develop, improve or adapt to new technologies and methodologies, successfully identify new technological opportunities,

develop and bring new or enhanced products to market, or obtain sufficient or any patent or other intellectual property protection for such new or enhanced products in a timely and cost-effective manner. Any failure to do so may render our previous efforts obsolete, which could significantly reduce the competitiveness of our technology platforms and drug candidates, and harm our business and prospects.

RISKS RELATING TO DEPENDENCE ON THIRD PARTIES

We have entered into license and collaboration agreements with third parties in the development, manufacturing and commercialization of our drug candidates, and may seek and enter into additional partnerships in the future. We may fail to identify suitable business partners or may not realize the benefits of such partnerships as expected.

We have in the past formed, and may continue to seek, strategic partnerships or other collaborations, including entering into licensing arrangements with third parties that we believe will complement or augment our drug development, manufacturing and commercialization efforts with respect to our drug candidates and any future drug candidates that we may develop. To date, we have entered into several out-licensing and collaboration deals with leading industry players worldwide, including BioNTech, BeiGene and Adcendo. See "Business — Our Collaboration and Licensing Arrangements" for details.

Our results of operations have been, and may continue to be, affected by our collaboration and licensing arrangements. During the Track Record Period, substantially all of our revenue was generated from such arrangements. Collaboration and licensing agreements involving our drug candidates are subject to various risks, which may include the followings:

- collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration;

- the collaboration and licensing agreements could be terminated upon a short notice, and our collaborators may elect to cease collaboration due to change in their strategic focus, potential acquisition of competitive drugs, availability of funding, or other external factors;

- collaborators may delay clinical trials, provide insufficient funding for a clinical trial, discontinue a clinical trial, repeat or conduct new clinical trials, or require a new formulation of a drug candidate for clinical testing;

- the milestone payments and royalties under the agreements are conditioned upon the achievements of certain regulatory, development and commercialization targets. We cannot guarantee that we will be able to receive the aggregate amount as set out in the relevant collaboration and licensing agreements;

- collaborators 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 litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;

- disputes may arise between us and a collaborator that cause a 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;

- collaborators could independently develop, or develop with third parties, drugs that compete with our drug candidates or future drugs;

- collaborators may own or co-own intellectual property covering our drug candidates or future drugs that results from our collaborating with them, and in such cases, we would not have the exclusive right over such intellectual property; and

- the collaboration and licensing relationships may be affected by cross-border data transmission restrictions and geopolitical tensions, including trade policies and export controls.

For these and other reasons, we may not achieve the outcomes and synergies expected from our collaboration and licensing arrangements. These collaboration and licensing arrangements are inherently uncertain, and are subject to significant business, economic and competitive uncertainties and contingencies, many of which are difficult to predict and are beyond our control. We may face operational and financial risks including increase in near- and long-term expenditures, exposure to unknown liabilities, disruption of our business and diversion of our management's time and attention. Even if we achieve the expected benefits, we may not be able to do so within the anticipated time frame. In addition, any material and adverse changes to our relationships with our collaborating partners may have an impact on the technological and financial resources available to us under these collaboration and licensing arrangements, which may in turn affect our R&D activities and business operations.

We face significant competition in seeking appropriate strategic partners and the negotiation process can be 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 of a stage of development for collaborative effort, and third parties may not view our drug candidates as having the requisite potential to demonstrate safety and efficacy or commercial viability. If and when we collaborate with a third party for development and commercialization of a drug candidate, we may be required to relinquish some or all of the control over the future success of that drug candidate to the third party. The collaborators may also consider alternative drug candidates or technologies that may be available.

If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail 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, manufacturing or commercialization activities at our own expenses. If we elect to fund and undertake development, manufacturing 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. Even with existing collaboration agreements in place, we may not receive sufficient or timely reimbursement from our collaborators for development costs, or our collaborators may delay or withhold payments due to disputes over compliance with agreement terms or other factors. Additionally, development costs may exceed our initial estimates or agreed reimbursement caps, requiring us to fund the excess amounts while any reimbursement disputes are being resolved, which could be prolonged and may not result in full recovery of our costs. These situations could strain our financial resources and potentially impair our ability to advance our development programs as planned. If we fail to enter into collaboration and licensing arrangements face difficulties in securing adequate reimbursement from existing collaborators, or do not have sufficient funds or expertise to undertake the necessary development, manufacturing 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, financial condition, results of operations and prospects.

As a result, we cannot be certain that, following a collaboration and licensing arrangement, we will achieve the revenue or net income that justifies such transaction or such other benefits that caused us to enter into the arrangement. Any of the foregoing could materially and adversely affect our business, financial condition, results of operations and prospects.

Our rights to develop and commercialize our drug candidates are subject, in part, to the terms and conditions of licenses granted to us by others.

We rely on licenses to certain patent rights and other intellectual property from third parties that are important or necessary to the development, manufacture or commercialization of our certain drug candidates. For details, see "Business — Our Collaboration and Licensing Arrangements." The licenses we hold may not provide exclusive rights to use such intellectual property in all relevant fields of use or in all territories in which we may wish to develop or commercialize our future approved drugs. As a result, we may not be able to develop, export or sell our drug products outside of the fields or territories as stipulated by the license and collaboration agreements or prevent competitors from developing and commercializing competitive drug products in territories included in all of our licenses. Our existing or future collaboration partners may rely on third-party collaborators or on upstream licenses from third parties.

In addition, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement or defense of patents and patent applications covering the drug candidates and components we license from third parties, or the technology underlying such drug candidates and components. Therefore, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced and defended in a manner consistent with the best interests of our business. If our existing or future collaboration partners fail to prosecute, maintain, enforce or defend such patents, or lose rights to those

patents or patent applications, the rights we have licensed may be reduced or eliminated, and our right to research, develop and commercialize any of our drugs that are subject to such licensed rights could be adversely affected.

Such license agreements set out various procedures and timelines with respect to, among other matters, clinical development, commercialization, and financial obligations such as milestone payments and royalties. The terms of these agreements are complex and can be subject to multiple interpretations. The resolution of any disagreements arising from these agreements could, for example, eliminate or narrow what we believe to be the scope of our rights to the relevant intellectual properties or technologies, or increase what we believe to be our financial or other obligations under the relevant agreements. If we fail to comply with our obligations under our current or future license agreements, our counterparties may have the right to terminate such agreements, in which event we might lose the ability to develop, manufacture or market certain drugs, or face claims for monetary damages or other penalties under the respective agreements. Reduction or elimination of our rights under such agreements may force us to negotiate new or restated agreements with less favorable terms, or cause disruptions to our ongoing activities carried out in reliance of such rights, including our rights to important intellectual properties and technologies.

Moreover, if any of our collaboration partners encounter financial problems, enter into liquidation, dissolution, bankruptcy, or similar insolvency proceedings, or experience changes in business focus, some or all of our rights under the license agreements may be affected. For details, see "Business — Our Collaboration and Licensing Arrangements." Any of these events could have a material and adverse effect on our competitive position, business, financial condition, results of operations and prospects.

We rely on third parties to monitor, support and/or conduct clinical trials and preclinical studies of our drug candidates. 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 affected.

We have relied on and plan to continue to rely on third-party CROs and other third parties to monitor and manage data for some of our ongoing preclinical and clinical programs. We rely on these parties for the execution of our preclinical 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 and legal, regulatory and scientific standards, and our reliance on the CROs and other third parties does not relieve us of our regulatory responsibilities.

We and our CROs are required to comply with good clinical practice ("**GCP**"), good clinical practice ("**GLP**") and other regulatory regulations and guidelines enforced by the NMPA, the FDA and other comparable regulatory authorities for all of our drug candidates in clinical development. Regulatory authorities may enforce these GCP, GLP or other regulatory

requirements through periodic inspections of trial sponsors, investigators and trial sites. In addition, our clinical trials must be conducted with drug candidates or products manufactured under current good manufacturing practice ("**cGMP**") requirements.

The CROs we engage may not always perform to our standards, may not produce results in a timely manner or may fail to perform at all. Notwithstanding the remedies available to us under our agreements with our CROs, we cannot control whether or not such CROs will devote sufficient time and resources to our ongoing clinical, nonclinical and preclinical programs. If we or any of our CROs fail to comply with the applicable GCP, GLP, cGMP or other regulatory requirements, the relevant data generated in our clinical trials may be deemed unreliable and the NMPA, the FDA or other comparable regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. There can be no assurance the regulatory authorities will determine that our clinical trials comply with all the applicable requirements. Failure to comply with these regulations may lead us to repeat preclinical studies and clinical trials, which would delay the regulatory approval process.

Similarly, if other third parties fail to meet expected deadlines, timely transfer to us any requisite information, adhere to protocols or act in accordance with regulatory requirements or our agreements with them, or if they otherwise perform in a sub-standard manner or in a way that compromises the quality or accuracy of their activities or the data they obtain, the clinical trials of our drug candidates may be compromised, delayed, prolonged, suspended or terminated, or our data may be rejected by the NMPA, the FDA, or other comparable regulatory authorities.

Because we rely on third parties, our internal capacity to perform these functions is limited. To the extent we are unable to identify and successfully manage the performance of third-party service providers in the future, our business may be adversely affected. In addition, the use of third-party service providers requires us to disclose our proprietary information or confidential information concerning the subjects enrolled in our clinical trials to these third parties, which could increase the risk that such information will be misappropriated. Though we carefully manage our relationships with our CROs and other third-party service providers, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material and adverse impact on our business, financial condition, results of operations and prospects.

In addition, we may not be able to enter into arrangements with alternative CROs and other third parties in a timely manner or do so on commercially reasonable terms, if our existing relationships with these third parties terminate. Switching or adding CROs and other third parties involves additional cost and delays, which can materially affect 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, financial condition and prospects.

We may rely on third parties to manufacture our drug products for clinical development and commercial sales and to provide a stable and adequate supply of quality materials and products for our drug development and commercialization needs. Our business could be harmed if these third parties suffer substantial disruption to supply chain and production facilities, encounter problems in manufacturing or fail to deliver sufficient quantities of product or at acceptable quality or price levels.

To date, we have relied primarily on third-party service provides, including CDMOs, to manufacture our drug candidates. See "Business — Manufacturing" for details. Going forward, we intend to continue to engage third-party CDMOs to manufacture our drug candidates for our research and development activities and commercial sales, while gradually establishing our in-house manufacturing capabilities. Our reliance on third-party CDMOs exposes us to certain risks, including, but not limited to, the following:

- we may be unable to identify CDMOs that may meet some or all acceptable terms because the number of potential manufacturers is limited and the NMPA, the FDA or other comparable regulatory authorities must approve any manufacturers as part of their regulatory oversight of our drug candidates;

- our CDMOs may have limited capacity or limited manufacturing slots, which may affect the timeline for the production of our drugs;

- our CDMOs are subject to periodic inspections and other government regulations by the NMPA, the FDA or other comparable regulatory authorities, including to ensure strict compliance with the cGMP. We do not have full control over our CDMOs' compliance with these regulations and requirements;

- our CDMOs might be unable to timely manufacture our drug candidates or produce the quantity and quality required to meet our clinical and future commercial needs, if any;

- our CDMOs may not be able to execute our manufacturing procedures and other logistical support requirements appropriately, or may otherwise fail to perform as agreed;

- our CDMOs may not properly obtain, protect, maintain, defend or enforce our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;

- our CDMOs may infringe, misappropriate, or otherwise violate the patent, trade secret, or other intellectual property rights of third parties;

- our CDMOs could terminate their agreements with us;

- raw materials and products supplied by certain CDMOs may not be readily obtainable elsewhere; and

- our CDMOs and critical reagent suppliers may be subject to inclement weather, as well as natural or man-made disasters, which may lead to interruption of supply.

See also "— Risks Relating to the Manufacturing and Commercialization of our Drug Candidates — The manufacturing of biopharmaceutical products is a complex process, and we have limited experience in manufacturing biopharmaceutical products on a large commercial scale."

In addition, during the Track Record Period, we and our CDMOs relied on third parties to supply certain raw materials and products used in our research and development and clinical trials. We expect to continue to rely on third parties to supply raw materials for the research, development and commercialization of our drug candidates. Any disruption in production or the inability of our suppliers or suppliers of our CDMOs to provide adequate quantities to meet our or our CDMOs' needs could impair our operations and the research and development of our drug candidates. Moreover, we expect our demand for such raw materials and products to increase as we expand our business scale and commercialize our drug candidates, but there is no assurance that current suppliers have the capacity to meet our demand.

The quality of the raw materials procured and products manufactured by CDMOs will depend significantly on the effectiveness of our quality control and quality assurance and that of our CDMOs. We cannot assure you that these quality control and quality assurance procedures will be effective in consistently preventing and resolving deviations from our quality standards or that our operating procedures will be complete or updated at all times. Any significant failure or deterioration of our quality control and quality assurance protocol or standard operating procedures could render our products unsuitable for use, jeopardize our drug approvals or licenses and/or harm our market reputation and relationship with business partners. Any such developments may have a material and adverse effect on our business, financial condition and results of operations.

If our business partners fail to maintain the necessary licenses for the development, manufacturing and commercialization of our products, our business could be materially affected.

Our business partners, such as CROs, CDMOs and suppliers, on whom we may rely on to develop, manufacture, market, sell and distribute our drug candidates, may be subject to requirement of obtaining and maintaining necessary permits, licenses and certificates in their operations. Our business partners may also be subject to regular inspections, examinations, inquiries or audits by the regulatory authorities, and an adverse outcome of such inspections, examinations, inquiries or audits may result in the loss or non-renewal of the relevant permits, licenses and certificates. If our business partners fail to maintain or renew material permits, licenses and certificates, our ability to conduct our business could be materially impaired. Any changes in the standards used by governmental authorities in considering whether to renew or

reassess our business partners' licenses, permits and certifications, as well as enactment of any new regulations that may restrict the operation of our business partners' operations, may also decrease our revenue and increase our costs, which in turn could materially and adversely affect our business, financial condition and results of operations.

We may fail to effectively manage our network of distributors after our drug candidates are successfully launched. Actions taken by our distributors could materially and adversely affect our business, prospects and reputation.

We may rely in part on third-party distributors to distribute our drug candidates upon their commercialization. Our ability to maintain and grow our business will depend on our ability to maintain an effective distribution channel that ensures the timely and effective delivery of our products to the relevant markets. We cannot guarantee that we will be able to effectively manage our distributors, or that our distributors would not breach the distribution agreements and the policies and measures we have in place to manage their distribution. If our distributors take one or more of the following actions, our business, results of operations, prospects and reputation may be adversely affected:

- breaching the distribution agreements or our policies and measures;
- failing to maintain the requisite licenses, permits or approvals, or failure to comply with applicable regulatory requirements when selling our products; or
- violating anti-corruption, anti-bribery, competition or other laws and regulations of China or other jurisdictions.

Any violation or alleged violation by our distributors of the distribution agreements, our policies or any applicable laws and regulations could expose us to liabilities and monetary damages, a decrease in the market value of our brand and an unfavorable public perception about the quality of our products, resulting in a material and adverse effect on our business, financial condition, results of operations and prospects.

If we cannot maintain or develop clinical collaborations and relationships with principal investigators, KOLs, physicians and other industry experts, our results of operations and prospects could be adversely affected.

Our relationships with principal investigators, key opinion leaders ("**KOLs**"), physicians and other industry experts play an important role in our research and development and marketing activities. We have established extensive interaction channels with principal investigators, KOLs, physicians and experts to gain first-hand knowledge of unmet clinical needs and clinical practice trends, which is critical to our ability to develop market-responsive drugs. However, we cannot assure you that we will be able to maintain or strengthen our clinical collaborations and relationships with principal investigators, KOLs, physicians and other industry experts, or that our efforts to maintain or strengthen such relationships will lead to the successful development and marketing of new products.

These industry participants may leave their roles, change their business or practice focus, choose to no longer cooperate with us or cooperate with our competitors instead. Even if they continue to cooperate with us, their market insights and perceptions, which we take into account in our research and development process, may be inaccurate and lead us to develop products that do not have significant market potential. Even if their insights and perceptions are correct, we may fail to develop commercially viable products. Industry participants may no longer want to collaborate with us or attend our conferences, and our marketing strategy may no longer be able to yield results that are commensurate to our efforts spent. If we are unable to develop and maintain our relationships with industry participants as anticipated, our business, financial condition and results of operations may be materially and adversely affected.

RISKS RELATING TO THE MANUFACTURING AND COMMERCIALIZATION OF OUR DRUG CANDIDATES

The future commercial success of our drug candidates will depend on the degree of their market acceptance among physicians, patients and others in the medical community.

Even if our drug candidates receive regulatory approval, they may nonetheless fail to gain sufficient market acceptance by physicians and patients and others in the medical community. Physicians and patients may prefer other drugs or drug candidates to ours. If our drug candidates do not achieve an adequate level of acceptance, we may not generate significant revenue from sales of our drugs or drug candidates and may not become profitable.

The degree of market acceptance of our drug candidates, if and only when they are approved for commercial sale, will depend on a number of factors, including, but not limited to:

- the clinical indications for which our drug candidates are approved;
- physicians, hospitals and patients considering our drug candidates as a safe and effective treatment;
- whether our drug candidates have achieved the potential advantages of our drug candidates over alternative treatments;
- the prevalence and severity of any side effects;
- product labeling or package insert requirements of the NMPA, the FDA or other comparable regulatory authorities;
- limitations or warnings contained in the labeling approved by the NMPA, the FDA or other comparable regulatory authorities;

- timing of market introduction of our drug candidates, as well as competitive drugs also on the market;
- cost of treatment in relation to alternative treatments;
- availability of adequate coverage and reimbursement under the national and provincial reimbursement drug lists in the PRC, or from third-party payors and governmental authorities in the United States or any other jurisdictions;
- willingness of patients to pay any out-of-pocket expenses in the absence of coverage and reimbursement by third-party payors and governmental authorities;
- relative convenience and ease of administration, including as compared with alternative treatments and competitive drugs on the market; and
- the effectiveness of our sales and marketing efforts.

If our drug candidates are approved but fail to achieve market acceptance among physicians, patients, hospitals or others in the medical community, we will not be able to generate significant revenue or become profitable. Even if our drugs achieve market acceptance, we may not be able to maintain such market acceptance over time if new products or technologies are introduced which are more favorably received or cost effective than our drugs.

We have no experience in launching and marketing drug candidates. If we fail to establish, expand and optimize an effective sales and distribution network for our drugs, our business could be adversely affected.

Our operations to date have been largely focused on developing our drug candidates, primarily undertaking preclinical studies and conducting clinical trials. To date, we have no experience in marketing approved drugs. We may in the future develop an in-house marketing and sales team, which will require significant capital expenditures, management resources and time. We will have to compete with other biopharmaceutical companies to recruit, hire, train and retain marketing and sales personnel.

We also plan to partnership with established commercial team externally for quick entries into the market. 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 effective sales forces and network will be established. Any revenue we receive will partially depend on the efforts of such third parties, which may not be successful. We may 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. See also "— Risks Relating to Dependence on Third Parties — We may fail to effectively manage our network of distributors after our drug candidates are successfully launched. Actions taken by our distributors could materially and adversely affect our business, prospects and reputation." We

will also face competition in our search for reputable third parties to assist us with the sales and marketing efforts of our drug candidates. There can be no assurance that we will be able to develop in-house sales and marketing capabilities or establish or maintain relationships with third-party collaborators to successfully commercialize any product, and as a result, we may not be able to generate product sales revenue.

The size of the potential market for our current or future drug candidates is difficult to estimate and, if any of our assumptions are inaccurate, the actual markets for our current or future drug candidates may be smaller than our estimates.

Our projections of the number of patients who have the potential to benefit from treatment with our drug candidates are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations, or market research and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases. The number of patients may turn out to be fewer than expected. As a result, the potentially addressable patient population and market size for our drug candidates may be smaller than our estimates. Furthermore, there is no guarantee that any of our drug candidates, even if approved, would be approved for the line of therapy we are aiming for. For example, cancer therapies may be characterized as first line, second line or later line therapy depending on options for treatment and prior treatments received. For indications with well-established standard of care therapies, the NMPA, the FDA and other comparable regulatory authorities may approve new therapies initially only for later lines of therapy. While we may seek approval for our drug candidates as an early-line therapy for certain indications, there is no guarantee that they will be approved as such. As a result, even if we obtain market approval for our drug candidates, we may not achieve the anticipated market size and revenue unless such market approval is for the intended lines of therapy or for additional indications.

Even if we are able to commercialize any approved drug candidates, reimbursement may be limited or unavailable in certain market segments for our drug candidates, and we may be subject to unfavorable pricing regulations, which could harm our business.

The regulations that govern regulatory approvals, pricing and reimbursement for new therapeutic products vary widely from country to country. We intend to seek approval to market our drug candidates in China, the U.S. and in other jurisdictions. In China, the pricing of certain drugs and biologics is subject to governmental control, which can take considerable time even after obtaining regulatory approval. Our ability to commercialize any approved drug candidates successfully also 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.

A primary trend in the global healthcare industry is cost containment. Government authorities and these third-party payers have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. In China, the Ministry of Human Resources and Social Security of China, together with other government authorities, review the

inclusion or removal of drugs from the China's National Drug Catalog for 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》), or the National Reimbursement Drug List (the "**NRDL**"), regularly, and the tier under which a drug will be classified, both of which affect the amounts reimbursable to program participants for their purchases of those drugs.

There can be no assurance that any of our future approved drug candidates will be included in the NRDL. If we were to successfully launch commercial sales of our products but fail in our efforts to have our products included in the NRDL, our revenue from commercial sales would be highly dependent on patient self-payment, which can make our products less competitive. Patients may choose other drugs with similar efficiency but lower price which have been included in the NRDL. Additionally, even if the Ministry of Human Resources and Social Security of China or any of its local counterparts were to accept our application for the inclusion of products in the NRDL, our potential revenue from the sales of these products could still decrease as a result of the significantly lowered prices we may be required to charge for our products to be included in the NRDL.

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-effectiveness 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 drug candidates. Patients are unlikely to use any of our future approved drug candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of the drugs.

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. 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 also be significant delays in obtaining reimbursement for approved drug candidates, and reimbursement coverage may be more limited than the approved indications of the drug candidates by the NMPA, the FDA or other comparable 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. Payment rates may vary according to the uses of the drugs and the clinical setting in which the drugs are 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. Our

inability to promptly obtain reimbursement coverage at intended payment rates for our drug candidates and any new drug candidates that we develop could have a material adverse effect on our business, operating results, and overall financial conditions.

The manufacturing of biopharmaceutical products is a complex process, and we have limited experience in manufacturing biopharmaceutical products on a large commercial scale.

As of the Latest Practicable Date, we had not commercialized any drug candidates. As a result, we have limited experience in manufacturing biopharmaceutical products on a commercial scale, which is a complex process, in part due to strict regulatory requirements. We cannot assure you that issues relating to the manufacturing of our drug candidates will not occur in the future. We also face certain risks in relation to the CDMOs we engage for manufacturing activities. See "— Risks Relating to Dependence on Third Parties — We may rely on third parties to manufacture our drug products for clinical development and commercial sales and to provide a stable and adequate supply of quality materials and products for our drug development and commercialization needs. Our business could be harmed if these third parties suffer substantial disruption to supply chain and production facilities, encounter problems in manufacturing or fail to deliver sufficient quantities of product or at acceptable quality or price levels."

Issues may arise during the manufacturing process for reasons including: (i) equipment malfunction, (ii) failure to follow specific protocols and procedures, (iii) problems with raw materials, (iv) changes in manufacturing production sites or limits to manufacturing capacity due to regulatory requirements, (v) changes in the type of products produced, (vi) advances in manufacturing techniques, (vii) physical limitations that could inhibit continuous supply, and (viii) the occurrence of natural disasters.

If problems arise during the production process of certain future products, a batch or several related batches of such product may have to be discarded and cause production delays, cost increases, lost revenue and damage to customer relationships and our reputation. If problems are not discovered before the relevant products are released to the market, we may incur additional costs in connection with product recalls and product liability.

We may not be able to maintain effective quality control over our drug products.

The quality of our products, including drug candidates we used for research and development purposes, will depend significantly on the effectiveness of our quality control and quality assurance, which in turn depends on factors such as the production processes, the quality and reliability of equipment used, the capabilities of the CDMOs we engage and our ability to ensure that they adhere to our quality control and quality assurance protocol. We operate a comprehensive quality control system, which is established and refined in accordance with the rigorous regulations and guidelines. See "Business — Quality Management." 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 or

that our standard operating procedures will be complete or updated at all times. Any significant failure or deterioration of our quality control and quality assurance protocol or standard operating procedures could render our products unsuitable for use, result in gaps in the audit of our processes, and/or harm our market reputation and relationship with business partners. Any such developments may have a material and adverse effect on our business, financial condition and results of operations.

Illegal and/or parallel imports and counterfeit pharmaceutical products may reduce demand for our future approved drug candidates and could have a negative impact on our reputation and business.

The illegal importation of 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 China, the United States and other countries and regions where we commercialize our products in the future. Illegal imports may continue to occur or even increase as the ability of patients and other customers to obtain these lower priced imports continues to grow. In addition, governmental authorities may expand consumers' ability to import lower priced versions of our future approved products or competing products. Cross-border imports from lower-priced markets (which are known as parallel imports) into higher-priced markets could harm sales of our future drug products and exert commercial pressure on pricing within one or more markets. Any future legislation or regulations that increase consumer access to lower priced medicines could have a material adverse effect on our business.

Furthermore, certain products distributed or sold in the pharmaceutical market may be manufactured without proper licenses or approvals, or be fraudulently mislabeled with respect to their content or manufacturers. These products are generally referred to as counterfeit pharmaceutical products. The counterfeit pharmaceutical product control and enforcement system, particularly in developing markets such as China, may be inadequate to discourage or eliminate the manufacturing and sale of counterfeit pharmaceutical products imitating our products. Since counterfeit pharmaceutical products in many cases have similar appearances compared with the authentic pharmaceutical products but are generally sold at lower prices, counterfeits could quickly erode the demand for our drug candidates approved in the future. In addition, thefts of our inventory at warehouses, plants or while in-transit could lead to our products being wrongfully stored and handled, and eventually sold through unauthorized channels. A patient who receives a counterfeit or unauthorized pharmaceutical product may be at risk for a number of dangerous health consequences, which potentially exposes us to product liability claims, government investigations, and other disputes and negative consequences. Our reputation and business could suffer harm as a result of counterfeit or unauthorized pharmaceutical products sold under our or our collaborators' brand name(s).

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

Off-label drug use is the prescription of a product for an indication, dosage or in a dosage form that is not in accordance with regulatory approved usage and labeling. For example, certain HER2 ADCs have been prescribed off-label in selected patient populations before they were approved for such use. While regulatory authorities including the FDA, NMPA, and other comparable agencies strictly enforce regulations against the promotion of off-label use, physicians may legally prescribe drugs for unapproved uses under certain circumstances. Though a recognized aspect of medical practice, the prescription of our drug products outside their approved indications, patient populations, or dosing parameters could lead to potential risks arising from insufficient safety/efficacy data, regulatory compliance challenges, reimbursement issues, and the need for enhanced monitoring and documentation. Off-label use could also render our products less effective or entirely ineffective and may cause unexpected adverse drug reactions or AEs. Any of these occurrences can create negative publicity and materially and adversely affect our business reputation, product brand, business operations and financial conditions. These occurrences may also expose us to liability and cause a delay in the progress of our clinical trials and may ultimately result in failure to obtain regulatory approval for our drug candidates

RISKS RELATING TO OUR FINANCIAL POSITION AND NEED FOR ADDITIONAL CAPITAL

We are a clinical-stage biopharmaceutical company with a limited operating history, which may make it difficult to evaluate our current business and predict our future performance.

We are a clinical stage biopharmaceutical company with a limited operating history. Our operations to date have focused on establishing our intellectual property portfolio, conducting drug discovery, preclinical studies and clinical trials of our drug candidates, organizing and staffing our operations, business planning and raising capital. We have not yet demonstrated an ability to successfully obtain marketing approvals for, or commercialize, our drug candidates. To date, we have no products approved for commercial sale and have not generated any revenue from product sales.

Our limited operating history, particularly in light of the rapidly evolving drug research and development industry in which we operate and the changing regulatory and market environments we encounter, may make it difficult to evaluate our prospects for future performance. Consequently, any predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history. We will encounter risks and difficulties frequently experienced by early-stage companies in rapidly evolving fields as we seek to transition to a company capable of supporting commercial activities. If we do not address these risks and difficulties successfully, our business will suffer.

We have incurred net losses since our inception and anticipate that we will continue to incur net losses for the foreseeable future and may never achieve or maintain profitability.

Investment in the development of biopharmaceutical products is highly uncertain as it entails substantial upfront expenditures and significant risks that a drug candidate may fail to demonstrate efficacy and safety to gain regulatory or marketing approvals or become commercially viable. We have not generated any revenue from commercial product sales to date, and we continue to incur significant research and development costs and other expenses related to our ongoing operations. As a result, we have incurred net losses in 2022 and 2023 and for the nine months ended September 30, 2023 and 2024 of RMB387.1 million, RMB357.5 million, RMB113.8 million and RMB566.5 million, respectively.

Our net losses during the Track Record Period were primarily attributable to expenses incurred by our research and development activities, including those in relation to our preclinical studies and clinical trials, as well as fair value change of financial liabilities at fair value through profit or loss in relation to our Preferred Shares. In 2022, 2023 and for the nine months ended September 30, 2023 and 2024, our costs and expenses in relation to R&D activities, which represented our cost of revenue and research and development expenses, were RMB339.9 million, RMB986.7 million, RMB696.6 million and RMB1,404.4 million, respectively. During the same periods, we recorded fair value loss of financial liabilities at fair value through profit or loss of RMB21.7 million, RMB1,017.9 million, RMB959.2 million and RMB501.4 million, respectively. See "Financial Information — Description of Selected Components of the Consolidated Statements of Comprehensive Loss" for details. Our ability to generate revenue and achieve profitability depends significantly on our success in advancing these drug candidates into later stages of clinical development, and obtaining regulatory approvals for each drug candidate, which we may not be able to do in a timely manner or at all.

We expect to continue to incur net losses in the foreseeable future, and that these net losses may increase as we carry out certain activities relating to our development, including, but not limited to, the following:

- continue our ongoing and planned research and development activities;
- seek to discover, identify or develop additional drug candidates and further expand our product pipeline;
- continue to scale up our business to meet the requirements for our R&D activities, clinical trials and potential commercialization;
- hire additional drug discovery, clinical, quality control and administrative personnel;
- develop, maintain, expand and protect our intellectual property portfolio;
- seek regulatory approvals for any drug candidates that successfully complete clinical trials;

- establish sales, marketing and distribution infrastructure to commercialize any drug candidate for which we may obtain regulatory approval;
- expand our operations globally; and
- incur additional legal, accounting, investor relations, insurance and other expenses associated with operating as a [**REDACTED**] company following the completion of this [**REDACTED**].

The size of our future net losses will depend, among other factors, on the rate of the future growth of our expenses, our ability to generate revenues and the timing and amount of milestone payments and other payments that we receive from or pay to third parties. If any of our drug candidates fails during clinical trials or does not gain regulatory approval, or, even if approved, fails to achieve market acceptance, our business may not become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods thereafter. Our prior losses and expected future losses have had, and will continue to have, an adverse effect on our business, financial condition and results of operation.

We incurred net liabilities and net current liabilities during the Track Record Period, and net operating cash outflows in 2022 and for the nine months ended September 30, 2023, which may continue into the foreseeable future and expose us to liquidity risk.

As of December 31, 2022 and 2023 and September 30, 2024, we had net liabilities of RMB769.1 million, RMB1,123.9 million and RMB1,497.8 million, respectively. The increase from December 31, 2022 to December 31, 2023 was primarily due to an increase in financial liability at fair value through profit or loss ("**FVTPL**") mainly as a result of changes in fair value of our Preferred Shares, partially offset by an increase in cash and cash equivalents as a result of increased revenue from our out-license and collaboration agreements. In addition, we had net current liabilities of RMB825.9 million, RMB1,227.4 million and RMB1,636.7 million as of December 31, 2022 and 2023 and September 30, 2024, respectively, primarily because our Preferred Shares issued to Pre-[**REDACTED**] investors are recorded as current liabilities under financial liabilities at FVTPL. A net liabilities position and net current liabilities position can expose us to liquidity and financial risks. This in turn could require us to seek financing from external sources such as debt issuance and bank borrowings, which may not be available on terms favorably or commercially reasonable to us, or at all. See also "— Risks Relating to Our Financial Position and Need for Additional Capital — We may need to obtain substantial additional financing to fund our operations and expansion, and if we fail to do so, we may be unable to complete the development and commercialization of our drug candidates."

We had net cash outflow from operating activities of RMB299.5 million for the year ended December 31, 2022, primarily for our research and development activities. We may experience net cash outflows from our operating activities from time to time. See also "Financial Information — Liquidity and Capital Resources — Working Capital Sufficiency."

Our forecast of the period of time through which our capital resources will be adequate to support our operations is a forward-looking statement and involves risks and uncertainties. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we currently expect.

If we are unable to maintain adequate working capital or obtain sufficient financings to meet our capital needs, we may be unable to continue our operations according to our plan, default on our payment obligations and fail to meet our capital expenditure requirements, which may have a material adverse effect on our business, financial condition, results of operations and prospects.

We are subject to credit risk associated with our trade receivables. Payment delays or defaults may affect our cash flow and results of operation.

We are subject to credit risk in collecting the trade receivables. Our trade receivables amounted to RMB1.4 million, RMB100.8 million and RMB389.8 million as of December 31, 2022 and 2023 and September 30, 2024, respectively. There can be no assurance that future trade receivables incurred during our ordinary course of business would be settled on time. Accordingly, we face credit risk in collecting trade receivables due to us. Our liquidity and financial position would be adversely affected if significant amounts due to us are not settled on time or substantial impairment is incurred.

We may incur impairment losses for intangible assets, which could negatively affect our results of operations and financial condition.

We had intangible assets of RMB51.1 million, RMB54.2 million and RMB42.2 million as of December 31, 2022 and 2023 and September 30, 2024, respectively. Our intangible assets primarily consisted of (i) in-licenses, primarily in relation to certain antibodies we licensed in from third parties, and (ii) software. See "Financial Information — Description of Selected Items from the Consolidated Balance Sheets — Intangible Assets" for details.

If the carrying value of our intangible assets is considered to exceed its recoverable amount and is therefore determined to be impaired in the future, we would be required to write down the carrying value or record a provision of impairment loss for these intangible assets in our financial statements during the period in which our intangible assets are determined to be impaired. The intangible assets related to in-licenses are subject to annual impairment test based on the recoverable amount of the cash-generating unit to which the intangible asset is related to. The annual impairment test was performed by engaging an independent valuer to estimate fair value less cost to sell as the recoverable amount. The fair value is based on the multi-periods excessive earning method with key assumptions. For more details, please refer to note 16 to the Accountant's Report set out in Appendix I to this document. Impairment losses for intangible assets would adversely affect our results of operations and our financial condition.

We may need to obtain substantial additional financing to fund our operations and expansion, and if we fail to do so, we may be unable to complete the development and commercialization of our drug candidates.

During the Track Record Period, we funded our operations primarily through equity financing and revenue from our out-licensing and collaboration agreements. We expect our expenses to increase significantly in connection with our ongoing activities, particularly as we advance the clinical development of our clinical-stage drug candidates, continue the research and development of our preclinical stage drug candidates and initiate additional clinical trials of, and seek regulatory approval for, these and other future drug candidates. In addition, if we obtain regulatory approvals for any of our drug candidates, we expect to incur significant commercialization expenses relating to product manufacturing, marketing, sales and distribution and post-approval commitments to continue monitoring the efficacy and safety data of our future products on the market. We may also incur expenses as we create additional infrastructure to support our operations as a [**REDACTED**] company. Accordingly, we may need to secure substantial additional funding in connection with our continuing operations through public or private equity offerings, debt financing, collaborations or licensing arrangements or other sources.

We expect to fund our future operations primarily with existing cash and cash equivalents, revenue from our out-license and collaboration agreements, and [**REDACTED**] from the [**REDACTED**]. Upon the successful commercialization of one or more of our drug candidates, we expect to fund our operations in part with income generated from sales of our commercialized drug products. Changes in our ability to fund our operations may affect our cash flow and results of operations. If we are unable to raise capital when needed or on acceptable terms, we could be forced to delay, limit, reduce or terminate our research and development programs or any future commercialization efforts.

We have granted, and may continue to grant, certain awards under our share incentive plans, which may result in increased share-based compensation expenses.

We have adopted a share incentive plan for the purpose of granting share-based compensation awards to employees, officers, or directors to incentivize their performance and align their interests with ours. In 2022 and 2023 and for the nine months ended September 30, 2023 and 2024, we incurred RMB7.0 million, RMB24.0 million, RMB16.1 million and RMB164.0 million of share-based compensation expenses relating to share options granted under our share incentive plan, respectively. We believe the granting of share-based compensation is of significant importance to our ability to attract and retain key personnel and employees, and we may continue to grant share-based compensation awards to employees in the future. As a result, our expenses associated with share-based compensation may increase, which may affect our financial condition and results of operations. We may re-evaluate the vesting schedules, lock-up period, exercise price or other key terms applicable to the arrangements under our currently effective employee stock option plans from time to time. If we choose to do so, we may experience substantial change in our share-based compensation charges in the reporting periods following this [**REDACTED**].

We have historically received financial incentives, such as government subsidies, and we may not continue to receive such incentives in the future.

We have historically received various government subsidies, including subsidies from different PRC governmental authorities to support the research and development for our drug candidates. We recognized government grants as other income of RMB0.4 million, RMB3.2 million, RMB2.1 million and RMB3.1 million for the years ended December 31, 2022 and 2023 and the nine months ended September 30, 2023 and 2024, respectively. There is no assurance that we could continue to enjoy or maintain financial incentives or government subsidies at the historical levels, or at all, or apply for new financial incentives or government subsidies. Any change, suspension or termination of these government subsidies, or government financial incentives in other forms, may have a negative impact on our business, financial condition and results of operations.

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

The Renminbi has fluctuated against the Hong Kong dollar and U.S. dollar, at times significantly and unpredictably. In 2022 and 2023 and for the nine months ended September 30, 2023, we recorded net foreign exchange gains of RMB1.1 million, RMB41.9 million and RMB38.8 million, respectively. For the nine months ended September 30, 2024, we recorded net foreign exchange losses of RMB8.7 million. There is no assurance that we will continue to incur foreign exchange gains in the future or our foreign exchange losses will not incur in the future. The value of Renminbi against the U.S. dollar and other currencies is affected by changes in political and economic conditions and by foreign exchange policies, among other things. We cannot assure you that Renminbi will not appreciate or depreciate significantly in value against the Hong Kong dollar or U.S. dollar in the future. It is difficult to predict how market forces or PRC or U.S. government policy may impact the exchange rate between Renminbi and the Hong Kong dollar or U.S. dollar in the future.

The [**REDACTED**] from the [**REDACTED**] will be received in Hong Kong dollars. As a result, any appreciation of the Renminbi against the U.S. dollar, the Hong Kong dollar or any other foreign currencies may result in the decrease in the value of our [**REDACTED**] from the [**REDACTED**]. Conversely, any depreciation of the Renminbi may adversely affect the value of, and any dividends payable on, our Shares in foreign currency. In addition, there are limited instruments available for us to reduce our foreign currency risk exposure at reasonable costs. Furthermore, we are also currently required to complete filings with and obtain approvals from the State Administration of Foreign Exchange of the PRC (the "**SAFE**") before converting significant sums of foreign currencies into Renminbi. All of these factors could materially and adversely affect our business, financial condition, results of operations and prospects, and could reduce the value of, and dividends payable on, our Shares in foreign currency terms.

Disruptions in the financial markets and economic conditions could affect our ability to raise capital.

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 actions in an attempt to address and rectify these 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.

In addition, concerns over the recent conflicts in the Middle East, Russian-Ukraine conflicts, and unrest and terrorist threats in other territories, among others, add uncertainties to the financial markets worldwide. It is unclear whether these challenges and uncertainties will be contained or resolved, and what effects they may have on the global political and economic conditions in the long term. See also "— Risks Relating to Our Operations — We may be exposed to risks of conducting our business and operations in international markets."

RISKS RELATING TO INTELLECTUAL PROPERTY RIGHTS

We may from time to time be involved in legal proceedings and disputes to protect or enforce our intellectual property rights, or defend against infringement and other claims alleged by third parties, which could be expensive, time consuming and unsuccessful.

Litigation relating to patents and other intellectual property rights in the biopharmaceutical and pharmaceutical industries is common, including patent administrative proceedings, patent ownership and patent infringement lawsuits. The various markets in which we plan to operate are subject to frequent and extensive litigation regarding patents and other intellectual property rights. Third parties could resort to litigation against us or other parties we have agreed to indemnify, which litigation could be based on either existing intellectual property or intellectual property that arises in the future. Some claimants may be able to sustain the costs of complex intellectual property proceedings to a greater degree and for longer periods of time than we could.

Despite measures we take to obtain and maintain patent and other intellectual property rights with respect to our drug candidates, our intellectual property rights could be challenged or invalidated. We have in the past been, and may in the future be, involved in legal proceedings where third parties may challenge our intellectual property rights. In such instances, we may need to take action to enforce or defend our intellectual property rights. For example, during the Track Record Period, we were involved in certain legal proceedings where a third party filed claims against us alleging ownership rights to certain of our patent applications. Some of these patent applications were related to parts of the molecular structures used in certain of our ADC candidates. In December 2024, we received civil rulings from the court approving the plaintiff's withdrawal of these claims. Although we believe that we have

conducted our patent prosecution in accordance with a duty of candor and in good faith, the outcome following legal assertions of invalidity and unenforceability during patent litigation is subject to uncertainty. In addition, competitors or other third parties may challenge, infringe or misappropriate our patents and other intellectual property rights. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming. In any infringement proceeding, a court or governmental authority may decide that a patent of ours is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may not be an adequate remedy. Enforcing our intellectual property rights against third parties may also cause such third parties to file other counterclaims against us, which could be costly to defend and could require us to pay substantial damages. In addition, if the breadth or strength of protection provided by our patents and other intellectual property rights is threatened, it could dissuade companies from collaborating with us to license, develop, or commercialize our current or future drug candidates. Any loss of intellectual property protection could have a material adverse impact on one or more of our drug candidates and our business.

On the other hand, we cannot guarantee that our drug candidates or the sale or use of our future products do not and will not in the future infringe, misappropriate or otherwise violate third-party patents or other intellectual property rights. Third parties could allege that we are infringing their patent rights or that we have misappropriated their trade secrets, or that we are otherwise violating their intellectual property rights, whether with respect to the manner in which we have conducted our research, or with respect to the use or manufacture of the compounds we have developed or are developing.

It is also possible that we failed to identify, or may in the future fail to identify, relevant patents or patent applications held by third parties that cover our drug candidates. Publication of discoveries in the scientific or patent literature often lags behind actual discoveries. Therefore, we cannot be certain that we were the first to invent, or the first to file patent applications on, our drug candidates or for their uses, or that our drug candidates will not infringe patents that are currently issued or that are issued in the future. In the event that a third party has also filed a patent application covering one of our drug candidates or a similar invention, our patent application may be regarded as a competing application and may not be approved in the end. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our products or their use.

If a third party were to assert claims of patent infringement against us, even if we believe such third-party claims are without merit, a court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, and the holders of any such patents may be able to block our ability to commercialize the applicable product unless we obtained a license under the applicable patents, or until such patents expire or are finally

determined to be invalid or unenforceable. Similarly, if any third-party patents were held by a court of competent jurisdiction to cover aspects of our compositions, formulations, or methods of treatment, prevention, or use, the holders of any such patents may be able to block our ability to develop and commercialize the applicable product unless we obtained a license or until such patent expires or is finally determined to be invalid or unenforceable. In addition, defending such claims would cause us to incur substantial expenses and could cause us to pay substantial damages, if we are found to be infringing a third party's patent rights. These damages potentially include increased damages and attorneys' fees if we are found to have infringed such rights willfully.

In order to avoid or settle potential claims with respect to any patent or other intellectual property rights of third parties, we may choose or be required to seek a license from a third party and be required to pay license fees or royalties or both, which could be substantial. These licenses may not be available on acceptable terms, or at all. Even if we were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing a drug candidate, or be forced, by court order or otherwise, to modify or cease some or all aspects of our business operations, if, as a result of actual or threatened patent or other intellectual property claims, we are unable to enter into licenses on acceptable terms. Further, we could be found liable for significant monetary damages as a result of claims of intellectual property infringement.

An adverse result in any litigation proceedings could put one or more of our intellectual property rights at risk of being invalidated or interpreted narrowly. Even if successful, litigation may result in substantial costs and distraction of our management and other employees. 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. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If the public, securities analysts or [**REDACTED**] perceive these results to be negative, or perceive that the presence or continuation of these cases creates a level of uncertainty regarding our ability to increase or sustain products sales, it could have a substantial adverse effect on the price of our Shares. There is no assurance that our drug candidates will not be subject to the same risks.

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

Our commercial success depends, to a certain extent, on our ability to protect our proprietary technology and drug candidates from competition by obtaining, maintaining, defending and enforcing our intellectual property rights, including patent rights. We seek to

protect the drug candidates and technology that we consider commercially important primarily by filing patent applications in China, the U.S. and other countries or regions, relying on trade secrets or pharmaceutical regulatory protection or employing a combination of these methods. As of the Latest Practicable Date, we owned (i) three issued patents in China, (ii) six issued patents in the U.S., (iii) two issued patents in other jurisdictions, and (iv) 158 patent applications, including 37 in China, eight in the U.S., 19 under the PCT, ten in Europe, and 84 in other jurisdictions. See "Business — Intellectual Property" for details. This process is expensive and time-consuming, and we or our business partners may not be able to file and prosecute all necessary or desirable patent applications and secure other intellectual property protection in all jurisdictions in a timely manner. It is also possible that we or our business partners will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, we or our business partners may fail to timely identify third-party infringement of our intellectual property rights and take necessary actions to defend and enforce our rights, or at all.

The patent position of biopharmaceutical companies generally involves complex legal and factual questions, and can be frequently litigated. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our current and future patent applications may not be granted with approvals that effectively prevent third parties from commercializing competitive technologies and drug candidates. The patent examination process may require us or our business partners to narrow the scope of our or our business partners' current and future patent applications, which may then limit the scope of patent protection that could be obtained. There can be no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found. If such prior art exists, it can invalidate a patent or prevent a patent application from being issued as a patent. Moreover, if there are material defects in the form or preparation of our patents or patent applications, such patents or applications may be invalid and unenforceable.

Even if patents are issued on these applications, there can be no assurance that a third party will not challenge their validity, enforceability, or scope, which may result in the patent claims being narrowed or invalidated, or that we will obtain sufficient claim scope in those patents to prevent a third party from competing successfully with our drug candidates, or that we may not be successful in preventing unfair competition by third parties throughout the world. We or our business partners may become involved in interference, *inter partes* review, post-grant review, *ex parte* reexamination, derivation, opposition or similar other proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such proceeding could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or drug candidates and compete directly with us, or result in our inability to manufacture or commercialize drug candidates without infringing third-party patent rights. Thus, even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage.

The issuance of a patent is not conclusive as to its scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in any jurisdictions. Such challenges may result in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop or prevent us from stopping others from using or commercializing similar or identical technology and drug candidates, or limit the duration of the patent protection of our technology and drug candidates. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing drug candidates similar or identical to ours. Our competitors may also be able to circumvent our patent issuance by developing similar or alternative technologies or drug candidates in a non-infringing manner.

Filing, prosecuting, maintaining and defending patents on drug candidates in all countries throughout the world could be prohibitively expensive for us, and our intellectual property rights in some countries can have a different scope and strength than do those in some other countries. In addition, the laws of certain countries do not protect intellectual property rights to the same extent as the laws of certain other countries. Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims against us.

Consequently, we may not be able to prevent third parties from practicing our inventions in all countries, or from selling or importing drugs made using our inventions in and into certain jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own drugs and further, may export otherwise infringing drugs to certain jurisdictions where we have patent protection, but where enforcement rights are not as strong as those in certain other countries. These drugs may compete with our drug candidates and our patent rights or other intellectual property rights may not be effective or adequate to prevent them from competing.

Patent protection depends on compliance with various procedural, regulatory and other requirements, and our patent protection could be reduced or eliminated for non-compliance with these 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 China National Intellectual Property Administration (the "**CNIPA**"), the United States Patent and Trademark Office (the "**USPTO**") and other applicable patent authorities over the lifetime of a patent. The CNIPA, the USPTO and other applicable patent authorities require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. While an inadvertent failure to make payment of such fees or to comply with such provisions 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 such non-compliance will result in the abandonment or lapse of the patent or patent application, and the 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, but not limited to failure to respond to official actions within prescribed time limits, and non-payment of fees and failure to properly legalize and submit formal documents within prescribed time limits. If we or our collaboration partners fail to maintain the patents and patent applications covering our drug candidates or if we or our collaboration partners otherwise allow our patents or patent applications to be abandoned or lapse, our competitors might be able to enter the market, which would hurt our competitive position and could impair our ability to successfully commercialize our drug candidates in any indication for which they are approved. In addition, according to the Patent Law of the PRC (《中華人民共和國專利法》) (the "**PRC Patent Law**") and related regulations, we and our collaboration partners shall file the patent license agreements with the CNIPA within three months after the effective date thereof, otherwise we may lose our exclusive right to use our in-licensed patents if the licensor grants a *bona fide* third party a right to use the patent. Before such filings become effective, we may not be able to protect ourselves against challenges brought by *bona fide* third parties to whom the licensors may, for any reason, grant a right to use the same patents we have in-licensed.

If our patent terms expire before or soon after our drug candidates are approved, or if competitors successfully challenge our patents, our business may be materially harmed. Lack of protection under the applicable patent linkage and patent term extension laws and regulations could increase the risk of early generic competition.

Patents have a limited duration. Depending on the jurisdiction, various extensions may be available, but the life of a patent, and the protection it affords, is limited. For example, the expiration of a patent is generally 20 years from the date of application for inventions in China and generally 20 years from the earliest date of filing of the first non-provisional patent application to which the patent claims priority in the U.S. Even if patents covering our drug candidates, their manufacture, or use are obtained, once the patent life has expired, we may be open to competition from competitive medications, including biosimilar medications.

Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such drug candidates could 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. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

Even if we believe that we are eligible for certain patent term extensions, there can be no assurance that the applicable authorities, including the FDA and the USPTO in the U.S., and any equivalent regulatory authority in other countries, will agree with our assessment of whether such extensions are available, and such authorities may refuse to grant extensions to

our patents, or may grant more limited extensions than we request. For example, depending upon the timing, duration and specifics of any FDA marketing approval of any drug candidates we may develop, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Action of 1984, or Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent extension term of up to five years as compensation for the patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product 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. Similarly, the amendment to the PRC Patent Law which was promulgated in October 2020 introduces patent extensions to patents of new drugs that launched in the PRC, which may enable the patent owner to submit applications for a patent term extension of up to a maximum length of five years, and after the new drug is approved for marketing, the total effective term of the patent shall not exceed 14 years. 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 length of the extension could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will be shortened and our competitors may obtain approval to market competing products sooner than we expect. Also, the scope of our right to exclude during any patent term extension period may be limited or may not cover a competitor's product or product use. As a result, our revenue from applicable drug candidates, if approved, could be reduced, possibly materially.

Manufacturers of generic or biosimilar drugs may challenge the scope, validity, or enforceability of our patents in court or before a patent office, and we may not be successful in enforcing or defending those intellectual property rights and, as a result, may not be able to develop or market the relevant product exclusively, which would have a material adverse effect on any potential sales of that product. 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. On the other hand, if we launch our drug candidates prior to the expiration of patents for any competing products, we may face potential claims for patent infringement.

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

We own a number of trademarks in China and other jurisdictions. Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks, and may not be registered in all the necessary or desirable jurisdictions and categories in which we intend to sell our future products or provide our future services. Our trademarks may not be approved by one or more governmental trademark offices

or may not be approved for use on our products or services by regulatory authorities, such as the FDA. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. At times, competitors 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.

If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected. In the future, we may license our trademarks and trade names to third parties, such as business partners and collaborators. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and trade names by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names.

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

In addition to our issued patents and pending patent applications, we rely on trade secret and confidential information, including unpatented know-how, technology and other proprietary information, to maintain our competitive position and to protect our drug candidates. If we rely on third parties to manufacture or commercialize our current or any future drug candidates, or if we collaborate with third parties for the development of our current or any future drug candidates, we must, at times, share trade secrets with them, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed. We seek to protect our trade secrets and confidential information, in part, by entering into non-disclosure, confidentiality and similar agreements with parties that have access to them, such as our employees, corporate collaborators, outside scientific collaborators, sponsored researchers, CDMOs, consultants, advisers and other third parties. Any of these parties may breach such agreements and disclose our proprietary information, and we may not be able to obtain adequate remedies for such breaches. Moreover, 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.

Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any third-party collaborators. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure could have an adverse effect on our business and results of operations. 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 we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, or misappropriation of our intellectual property by third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially and adversely affect our business, financial condition, and results of operations. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us and our competitive position would be harmed.

Furthermore, many of our employees, consultants, and advisers, including our senior management, were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these employees, consultants, and advisers, including members of our senior management, executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that our employees do not wrongfully use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's former employer. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our management. See also "— Risks Relating to Intellectual Property Rights — We may from time to time be involved in legal proceedings and disputes to protect or enforce our intellectual property rights, or defend against infringement and other claims alleged by third parties, which could be expensive, time consuming and unsuccessful."

In addition, while we typically require our employees, consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Further, 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.

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

Intellectual property and other laws and regulations are subject to change, which could diminish the value of our intellectual property in general, thereby impairing our ability to protect our current and any future drug candidates.

Obtaining and enforcing patents in the biopharmaceutical industry involve a high degree of technological and legal complexity. Therefore, obtaining and enforcing biopharmaceutical patents is costly, time consuming and inherently uncertain. Changes in either the patent laws or in the interpretations of patent laws in China, the United States and other countries may diminish the value of our intellectual property and may increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. We cannot predict the breadth of claims that may be allowed or enforced in our future patents or in third-party patents. In addition, there are periodic proposals for changes to the patent laws in China, the United States and other countries that, if adopted, could impact our ability to enforce our proprietary technology.

In China, intellectual property laws are constantly evolving, with efforts being made to improve intellectual property protection in the PRC. For example, on October 17, 2020, the Standing Committee of the National People's Congress of the PRC (the "**SCNPC**") promulgated the Amendment to the PRC Patent Law effective from June 1, 2021, which provides that, among others, the patentee of an invention patent relating to the new drug that has been granted the marketing authorization in the PRC is entitled to request the patent administration department under the State Council to grant a patent term extension of up to five years, in order to compensate the time required for the regulatory evaluation and approval for the commercialization of such a new drug; provided that, the total remaining patent term of such a new drug approved for commercialization shall not exceed fourteen (14) years after such approval. As a result, the terms of our PRC patents may be eligible for extension and allow us to extend patent protection of our products, and the terms of the patents owned by third parties may also be extended, which may in turn affect our ability to commercialize our products candidates, if and when approved, without facing infringement risks. The length of any such patent term extension is uncertain. If we are required to delay commercialization for an extended period of time, technological advances may develop and new competitor products may be launched, which may render our product non-competitive. We also cannot guarantee that other changes to PRC intellectual property laws would not have a negative impact on our intellectual property protection.

Evolving judicial interpretation of patent law could also adversely affect our business. The U.S. Supreme Court and the U.S. Court of Appeals for the Federal Circuit have issued numerous precedential opinions in recent years narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on future actions by the U.S. Congress, the U.S. federal courts, the USPTO or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce or defend patents that we have licensed or that we might own or license in the future.

Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce our current and future owned and licensed patents.

Intellectual property rights do not necessarily protect us from all potential threats to our competitive advantages.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business nor permit us to maintain our competitive advantage. The following examples are illustrative:

- others may be able to make drug candidates that are the same as or similar to our drug candidates but that are not covered by the claims of the patents that we own or may have exclusively licensed;

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

- third parties 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; and

- we may not develop additional technologies that are patentable.

RISKS RELATING TO GOVERNMENT REGULATIONS

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

All jurisdictions in which we operate or intend to our business regulate the research, development, manufacturing and commercialization of biopharmaceutical products in great depth and detail. We intend to implement a global development strategy, with a focus on China and the United States, the two largest pharmaceutical markets in the world. These jurisdictions strictly regulate the pharmaceutical industry, and in doing so they employ a broad range of strategies, including regulation of product development and approval, manufacturing, and marketing, sales and distribution of products. Evolutions and differences in these regulatory regimes could lead to an increased and costly regulatory compliance burden.

We are required to obtained and maintain certain licenses and permits for conducting our business. The process of obtaining regulatory approvals and compliance with appropriate laws, regulations and guidance requires the expenditure of substantial time and financial resources. If any regulatory authorities consider that we were operating without the requisite approvals, licenses or permits or promulgates new laws and regulations that require additional approvals or licenses or imposes additional restrictions on the operation of any part of our business, it has the power, among other things, to levy fines, confiscate our income, revoke our business licenses, and require us to discontinue our relevant business or impose restrictions on the affected portion of our business. In particular, failure to comply with the applicable requirements at any time during the product development process and approval process, or after approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include refusal to approve pending applications, withdrawal of an approval, license revocation; clinical hold, voluntary or mandatory product recalls, product seizures; total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution and disgorgement, or other civil or criminal penalties. Failure to comply with these laws, regulations and guidance could have a material and adverse effect on our business and prospects.

In many countries or regions where a drug is intended to be ultimately sold, including China and the U.S., the relevant government agencies and industry regulatory bodies impose high standards on the efficacy of such drug, as well as strict rules, regulations and industry standards on how we develop such drug. For example, we may need to obtain clearance from the NMPA, the FDA or other regulatory authorities as part of an IND application to seek authorization to begin clinical trials, and file an NDA, a BLA or other similar applications to seek marketing approval. Any failure to comply with existing laws, regulations and industry standards could result in fines or other punitive actions against us, the termination of ongoing research and the disqualification of data for submission to regulatory authorities, or a ban on the future sales of our drugs, each of which could have a material adverse impact on our reputation, business, financial condition, results of operations and prospects. In addition, any action against us for violation of the relevant laws, regulations or industry standards, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management's attention from the operation of our business, and adversely affect our reputation and financial results.

The regulatory approval processes of the NMPA, the FDA and other comparable regulatory authorities are time-consuming and may evolve over time. If we are unable to obtain without undue delay any regulatory approvals for our drug candidates in our target markets, our business may be subject to actual or perceived harm.

Generally, approval from the NMPA and FDA take many years to obtain, following the commencement of preclinical studies and clinical trials. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a drug candidate's clinical development and may vary among 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 the regulatory approval of the NMPA, the FDA or a comparable regulatory authority for many reasons, including, without limitation:

- disagreement with the design or implementation of our clinical trials;
- failure to demonstrate that a drug candidate is safe and effective and potent for its proposed indication;
- failure of our clinical trial results to meet the level of statistical significance required for approval;
- failure of our clinical trial process to pass relevant GCP inspections;
- failure to demonstrate that a drug candidate's clinical and other benefits outweigh its safety risks;
- disagreement with our interpretation of data from preclinical studies or clinical trials;
- insufficient data collected from the clinical trials of our drug candidates to support the submission and filing of an NDA, a BLA or other submissions or to obtain regulatory approval;
- failure of our drug candidates to pass cGMP, inspections during the regulatory review process or across the production cycle of our drug;
- failure of our clinical sites to pass audits carried out by the NMPA, the FDA or comparable regulatory authorities, resulting in a potential invalidation of our research data;
- findings by the NMPA, the FDA or comparable regulatory authorities of deficiencies related to the manufacturing of our products;
- changes in approval policies or regulations that render our preclinical and clinical data insufficient for approval; and
- failure of our clinical trial process to keep up with any scientific or technological advancements required by approval policies or regulations.

The NMPA, the FDA or a comparable regulatory authority may require more information, including additional preclinical or clinical data, to support approval, which may delay or prevent approval and our commercialization plans. Even if we were to obtain approval, regulatory authorities may approve any of our drug candidates for fewer or more limited indications than we request, grant approval contingent on the performance of costly post-marketing clinical trials, or approve a drug candidate with an indication that is not desirable for the successful commercialization of that drug candidate. Any of the foregoing scenarios could materially harm the commercial prospects of our drug candidates.

If we are unable to obtain or maintain approval from the NMPA, the FDA and other comparable regulatory authorities for our drug candidates to be eligible for an expedited registration pathway as innovative or breakthrough therapy, the time and cost we incur to obtain regulatory approvals may increase.

The NMPA, the FDA and the comparable regulatory authorities in other jurisdictions may have implemented expedited review programs for drug candidates, among others, which are innovative drug applications, or which treat a serious or life-threatening condition and provide meaningful therapeutic benefit over available therapies. The NMPA's Breakthrough Therapy Designation, for example, is intended to facilitate and expedite the development and review of an investigational drug to treat a serious disease or condition when preliminary clinical evidence indicates that the drug has demonstrated substantial improvement over current therapies. Similarly, the FDA may facilitate the development and expedite the review of pharmaceutical products that are intended for the treatment of a serious or life-threatening condition for which there is no effective treatment and which demonstrate the potential to address medical need for the condition.

To date, three of our clinical-stage assets, including our Core Products DB-1303 and DB-1311 and key product DB-1305, have received Fast Track Designation from the FDA, and DB-1303 has received Breakthrough Therapy Designations from both the FDA and NMPA. For details, see "Business — Our Pipeline." There can be no assurance, however, that the regulatory authorities will consider granting Fast Track Designation, Breakthrough Therapy Designation or other expedited review programs for our other or future drug candidates, or that we will decide to pursue or submit any applications for accelerated approvals or any other form of expedited development, review or approvals. Similarly, there can be no assurance that, after receiving feedback from the regulatory authorities, we will continue to pursue or apply for accelerated approvals or any other form of expedited development, review or approvals, even if we initially decide to do so. Furthermore, there can be no assurance that such a submission or application will be accepted for filing, or that any expedited development, review or approvals will be granted on a timely basis, or at all. In addition, expedited registration pathways may contain certain conditions related to use restrictions for certain patient populations, warnings, precautions or contraindications, or may be subject to burdensome post-approval study or risk management requirements. Any failure to obtain accelerated approvals or any other form of expedited development, review or approvals for our drug candidates and/or any future changes to current polices and approvals with respect to the

expedited registration pathways of our drug candidates could result in a longer period of time prior to the commercialization of such drug candidate, an increase in the development expenses for such drug candidate and an adverse impact on our competitive position in the market.

Even if we receive regulatory approval for our drug candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expenses. We may be subject to penalties and other negative consequences if we fail to comply with the applicable regulatory requirements.

If the NMPA, the FDA or other comparable regulatory authorities approve any of our drug candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and record-keeping for the drug will be subject to extensive and ongoing 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 current cGMPs, and GCPs 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 other conditions of approval, including requirements for potentially costly post-marketing studies, such as studies for the surveillance and monitoring of the safety and efficacy of the drug.

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

- restrictions on the marketing or manufacturing of the drug, withdrawal of the drug from the market, or voluntary or mandatory recalls;
- fines, warning letters or holds on our clinical trials;
- refusal by the NMPA, the FDA or comparable regulatory authorities to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of drug license approvals;
- refusal by the NMPA, the FDA or comparable regulatory authorities to accept any of our other IND approvals and NDAs/BLAs;
- 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.

Moreover, regulations or policies may change or additional government regulations may be finalized that could prevent, limit or delay regulatory approval of our drug candidates.

Any government investigation of alleged violations of law could require us to expend significant time and resources and could generate negative publicity. 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 significantly harm our business, financial condition and pipeline of biopharmaceutical products.

Changes in laws and regulations relating to the biopharmaceutical industry, including the ongoing healthcare reform in China, may result in additional compliance risks and costs.

In China, the U.S. and other jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes relating to the biopharmaceutical industry and the healthcare system, including cost-containment measures that may reduce or limit coverage and reimbursement for newly approved drugs and affect our ability to profitably sell any drug candidates for which we obtain marketing approval. See also "— Risks Relating to the Manufacturing and Commercialization of Our Drug Candidates — Even if we are able to commercialize any approved drug candidates, reimbursement may be limited or unavailable in certain market segments for our drug candidates, and we may be subject to unfavorable pricing regulations, which could harm our business."

In particular, the PRC government has enacted a series of new laws and regulations in recent years aimed at improving the affordability and deterring potential over-use of oncology drugs. In December 2020, for instance, the National Health Commission (the "**NHC**") released the Notice on the Temporary Measures Regulating the Clinical Use of Oncology Drugs (《關於印發抗腫瘤藥物臨床應用管理辦法(試行)的通知》), followed by more detailed guidance announced in its Measurement Criteria for the Reasonable Clinical Use of Oncology Drugs (2021 Version) (《抗腫瘤藥物臨床合理應用管理指標》(2021年版)) in June 2021 ("**Oncology Drug Guidance**"), according to which several factors will be considered to evaluate whether the oncology drugs, especially "restricted class drugs," are under reasonable use by the medical institutions, in terms of usage rate and amount, among other criteria. The Oncology Drug Guidance sets out to designate anti-tumor drugs as "restricted class drugs" if they, among other characteristics, exhibit a poor safety profile, require sophisticated clinical administration, new to the market or prohibitively priced. If our oncology drug candidates are categorized as "restricted class drugs" after commercialization, we may face a decreased demand from the medical institutions and patients, which may adversely affect the commercialization and marketing of such drug candidates. These new laws, regulations and healthcare reform measures and others which may be adopted in the future may result in more rigorous prescription and coverage criteria, new reimbursement methods and additional downward pressure on drug prices.

Although none of our drug candidates had been commercialized as of the Latest Practicable Date, these legislative trends and regulatory measures can potentially affect the sales, profitability and prospects of our drug candidates in the future. Moreover, because these

laws and regulations are subject to varying interpretations, their application in practice may evolve over time as new guidance becomes available. This evolution may result in continuing uncertainty regarding compliance matters and additional costs necessitated by ongoing revisions to our disclosure and governance practices. If we fail to address and comply with these laws and regulations and any subsequent changes, we may be subject to penalty and our business may be harmed.

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

We and certain third parties we work with, such as our CROs, CDMOS and business partners, are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. We generally contract with third parties for the disposal of these materials and wastes and we cannot guarantee our contractors could continuously maintain their qualifications with regard to such disposal. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage, use or disposal of biological, hazardous or radioactive materials. We may also incur liabilities due to injuries to our employees resulting from the use of or exposure to hazardous materials, and we do not maintain insurance covering such potential liabilities.

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

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

Healthcare providers, doctors and others play a primary role in the recommendation and prescription of any products for which we obtain regulatory approval. If we obtain the approval for any of our drug candidates and begin commercializing our drugs in China in the future, our operations may become subject to various PRC fraud and abuse laws, including the PRC Anti-Unfair Competition Law (《中華人民共和國反不正當競爭法》) and PRC Criminal Law (《中華人民共和國刑法》). These laws may impact, among others, our proposed sales, marketing and education programs.

Law enforcement authorities are increasingly focusing on enforcing these laws. Efforts to ensure that our business arrangements with third parties are in compliance with applicable healthcare laws and regulations will involve substantial costs. Regulatory authorities could conclude that our business practices may not comply with current or future fraud, abuse or other healthcare laws or regulations. If any such actions are instituted against us, and if we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in governmental healthcare programs, contractual damages, reputational damage, 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 material adverse effect on our business and results of operations.

Furthermore, we are subject to anti-bribery laws in China that generally prohibit companies and their intermediaries from making payments to government officials for the purpose of obtaining or retaining business or securing other improper advantages. In addition, although currently our business operations are primarily in China, we are subject to the Foreign Corrupt Practices Act (the "**FCPA**") of the United States, which generally prohibits us from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business. 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. See also "— Risks Relating to Our Operations — We may be unable to detect, deter and prevent all instances of bribery, fraud or other misconduct committed by our employees or third parties."

As we expand our operations globally, we may also become subject to similar laws and regulations from other jurisdictions. There are ambiguities as to what is required to comply with any of these laws and regulations, and if we fail to comply with such requirements, we could be subject to penalties and other negative consequences. If any of the physicians or other third parties with whom we do business are found to be not in compliance with the applicable laws and regulations, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs, which may also adversely affect our business.

We face regulation and potential liability related to privacy, data protection and information security which may require significant resources and may adversely affect our business, operations and financial performance.

We and the CROs we engage may routinely receive, collect, generate, store, process, transmit and maintain medical data, treatment records and other personal details of subjects enrolled in our clinical trials, along with other personal or potentially 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 information in the various

jurisdictions in which we operate and conduct our clinical trials, as well as contractual obligations. These data protection and privacy law regimes continue to evolve and may result in ever-increasing public scrutiny and escalating levels of enforcement and sanctions and increased costs of compliance including, for example, substantial operational costs associated with changes to our data processing practices. Failure to comply with any of these laws could result in enforcement action against us, including and without limitation to fines, imprisonment of company officials and public censure, claims for damages by customers and other affected individuals, damage to our reputation and loss of goodwill, any of which could have a material and adverse effect on our business, financial condition, and results of operations or prospects.

The personal information of patients or subjects which might be involved in our clinical trials could be highly sensitive and we are subject to strict requirements under the applicable privacy protection regulations in the relevant jurisdictions. While we have adopted security policies and measures to protect our proprietary data and patients' privacy, such policies and measures might not satisfy all the requirements in every respect under the applicable laws and regulations. Data leakage and abuse and other misconduct related to data and personal information protection might not be completely avoided, due to hacking activities, human error, employee misconduct or negligence or system breakdown, among other reasons. We also cooperate with hospitals, CROs and other business partners, licensees, 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 a result of our failure. Any failure or perceived failure by us to prevent information security breaches or to comply with data/privacy policies or data/privacy-related legal obligations, or any compromise of information security that results in the unauthorized release or transfer of personal information or other patient data, could cause our customers to lose trust in us and could expose us to legal claims.

We are subject to stringent data privacy and cybersecurity laws and policies, and we may be restricted from transferring data abroad or using human genetic resources collected within the PRC.

On March 17, 2018, the General Office of the State Council promulgated the Measures for the Management of Scientific Data (《科學數據管理辦法》) (the "**Scientific Data Measures**"), which provides that enterprises in China must seek governmental approval before any scientific data involving a state secret may be transferred abroad or to foreign parties. Further, any researcher conducting research funded at least in part by the PRC government is required to submit relevant scientific data for management by the entity to which such researcher is affiliated before such data may be published in any foreign academic journal. Given that the term "state secret" is not clearly defined, if and to the extent any data collected or generated in connection with our R&D of drug candidates will be subject to the Scientific Data Measures and any subsequent laws as required by the relevant government authorities, there is no assurance that we can always obtain relevant approvals for sending scientific data (such as the results of our preclinical studies or clinical trials conducted within China) abroad or to our foreign partners in China.

In addition, the Regulations of PRC on the Administration of Human Genetic Resources (《中華人民共和國人類遺傳資源管理條例》) (the "**HGR Regulation**"), which was promulgated on May 28, 2019 and further amended on March 10, 2024, stipulates that foreign organizations, foreign individuals and the institutions established or actually controlled thereby shall not collect or preserve China's human genetic resources within the PRC, and shall not provide China's human genetic resources abroad. Where a foreign organization or an institution established or actually controlled by a foreign organization or foreign individual needs to use China's human genetic resources to conduct scientific research activities, it shall comply with the applicable laws, administrative regulations and relevant provisions in the PRC, and cooperate with China's scientific research institutions, universities, medical institutions and enterprises provided therein. In this regard, utilization of China's human genetic resources for international cooperation in scientific research, as well as transporting China's human genetic resources materials abroad shall be subject to the approval of the administrative department for health under the State Council. However, no approval is required in international clinical trial cooperation using China's human genetic resources at clinical institutions without export of human genetic resource materials for obtaining the licensing for the listing of relevant drugs and medical devices in the PRC market, provided that the type, quantity and usage of the human genetic resources to be used shall be filed with the administrative department for health under the State Council before conducting the clinical trials. If we are unable to obtain necessary approvals, complete the filings or comply with the regulatory requirements in a timely manner, or at all, our R&D of drug candidates may be hindered. Further, the Biosecurity Law (《生物安全法》), which was promulgated on October 17, 2020, became effective on April 15, 2021, and amended on April 26, 2024, 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. If the relevant government authorities consider the transmission of our scientific data or usage of human genetic resources to be in violation of the requirements under applicable PRC laws and regulations, we may be subject to fines and other administrative penalties imposed by those government authorities.

The landscape of cybersecurity and data privacy and security laws is constantly evolving. For example, on November 7, 2016, the SCNPC promulgated the Cybersecurity Law (《網絡安全法》), effective on June 1, 2017, which requires network operators to safeguard security of the network and follow the principles of legitimacy in collecting and using personal information. On June 10, 2021, the SCNPC promulgated the Data Security Law (《數據安全法》), effective on September 1, 2021, which imposes data security and privacy protection obligations on entities and individuals which carry out data activities, and introduces a data classification and hierarchical protection system. On August 20, 2021, the SCNPC promulgated the Personal Information Protection Law (《個人信息保護法》), effective on November 1, 2021, which further detailed the general rules and principles on personal information processing and further increased the potential liability of personal information processor. See "Regulatory Overview — Regulations on Information Security and Data Protection." Complying with new laws and regulations could substantially increase the costs or require us to change our business practices in a manner materially adverse to our business. Additionally,

to the extent we are found by the PRC regulators to be not in compliance with these laws and requirements, we may be subject to fines, regulatory orders to suspend our operations or other regulatory and disciplinary sanctions.

On December 28, 2021, the Cyberspace Administration of China (the "**CAC**"), together with other relevant administrative departments, jointly promulgated the revised Cybersecurity Review Measures (《網絡安全審查辦法》) with effect from February 15, 2022, according to which, the purchase of network products and services by a critical information infrastructure operator (the "**CIIO**") or the data processing activities of a network platform operator that affect or may affect national security will be subject to a cybersecurity review. In addition, an online platform operator who possesses personal information of over one million users and intends for listing in a foreign country (國外上市) must be subject to the cybersecurity review. However, there has been no further explanation or interpretation for "foreign listing" or "affect or may affect national security" under the aforementioned regulation. In addition, we cannot rule out the possibility that the relevant government authorities may conduct cybersecurity review on us according to the Cybersecurity Review Measures. If a cybersecurity review for any of our activities is required, we will actively cooperate with the CAC to conduct such cybersecurity review. Any failure to obtain such approval or clearance from the regulatory authorities could materially constrain our liquidity and have a material adverse impact on our business operations and financial results, especially if we need additional capital or financing.

On September 30, 2024, the Administration Regulations on Cyber Data Security (《網絡數據安全管理條例》) (the "**Data Security Regulations**") was promulgated by the State Council, which came into effect on January 1, 2025. The Data Security Regulations reiterate and refine the general regulations for cyber data processing activities, rules of personal information protection, important data security protection, cyber data cross-border transfer management, and the responsibilities of online platform service providers. In particular, the Data Security Regulations provide that cyber data processors whose cyber data processing activities affect or may affect national security shall be subject to national security review in accordance with the relevant regulations. However, the Data Security Regulations provide no further explanation or interpretation for the criteria on determining the risks that "affect or may affect national security". Additionally, since the Data Security Regulations are still relatively new, the interpretation and implementation of these regulations may further evolve and develop.

Moreover, the regulatory framework on cross-border transfer of personal information and data worldwide is rapidly evolving and is likely to remain uncertain due to lack of clear explanation and instruction on enforcement. For example, in recent years, China has promulgated several laws and regulations on cross-border data transfer, including but not limited to the Data Security Law, the Personal Information Protection Law, the Measures for the Security Assessment of Cross-border Data Transfer (《數據出境安全評估辦法》), the Measures for the Administration of Standard Contractual Clauses for the Cross-Border Transfer of Personal Information (《個人信息出境標準合同辦法》) and the Provisions on Promoting and Regulating Cross-Border Data Flows (《促進和規範數據跨境流動規定》). These regulations have provided that, amongst others, CIIO that provides any personal information

or important data to an overseas recipient, and other data processors that provides any important data, sensitive personal information or certain amount of non-sensitive personal information to an overseas recipient shall be subject to security assessment, standard contract filing or personal information protection certification for outbound data transfer activities, unless otherwise provided under the relevant laws and regulations. We cannot guarantee if these rules or regulations promulgated will impose additional compliance requirements, including any approval, filing and other administrative measures thereunder, and we cannot guarantee that the measures we have taken or will take in the future will always be effective or fully satisfy the relevant regulatory requirements under the relevant laws and regulations, including obtaining such approval, filing and other administrative measures in a timely manner, or at all.

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

A substantial portion of our operations are based in the PRC, our business, financial condition, results of operations and prospects may be affected by economic, political, social and legal developments in China. The Chinese government has implemented various measures to encourage economic growth and guide the allocation of resources; however, we cannot guarantee the extent to which our business operations will be able to benefit from such measures, if at all. In addition, laws, rules and regulations may also be amended from time to time, and the application, interpretation and enforcement of such evolving laws, rules and regulations may affect our business operations. Any of the foregoing may have a material and adverse effect on our business, financial condition, results of operations and prospects.

We may be classified as a "PRC resident enterprise" for PRC enterprise income tax purposes and our income may be subject to PRC tax under the relevant PRC laws.

Under the Corporate Income Tax Law of the PRC (the "**CIT Law**"), an enterprise established outside of China with "de facto management bodies" within China is considered a "resident enterprise," meaning that it will be treated in a manner similar to a Chinese enterprise for PRC enterprise income tax purposes. Under the Circular of the State Taxation Administration (the "**STA**") on Issues Concerning the Identification of Chinese-Controlled Enterprises Registered Overseas as Resident Enterprises on the Basis of Their De Facto Management Bodies (《關於境外註冊中資控股企業依據實際管理機構標準認定為居民企業有關問題的通知》) issued by the STA on April 22, 2009 and partially abolished in December 2017, or Circular 82, provides certain specific criteria for determining whether the "de facto management body" of a PRC-controlled enterprise that is incorporated offshore. Although Circular 82 only applies to offshore enterprises controlled by PRC enterprises or PRC enterprise groups, not those controlled by foreigners like us as of the Latest Practicable Date, the criteria set forth in the Circular 82 may reflect the STA's general position on how the "de facto management body" test should be applied in determining the tax resident status of all offshore enterprises. Under Circular 82, an offshore enterprise controlled by a PRC enterprise or a PRC enterprise group will be regarded as a PRC tax resident by virtue of having its "de facto management body" in China and will be subject to PRC enterprise income tax on its

global income only if all of the following conditions are met: (i) the primary location of the day-to-day operational management and their work location is in the PRC; (ii) decisions relating to the enterprise's financial and human resources matters are made or are subject to approval by organizations or personnel in the PRC; (iii) the enterprise's primary assets, accounting books and records, company seals, and board and shareholder resolutions, are located or maintained in the PRC; and (iv) at least 50% of voting board members or senior executives habitually reside in the PRC. On July 27, 2011, the STA issued Administrative Measures of Enterprise Income Tax of Chinese-Controlled Offshore Incorporated Resident Enterprises (Trial) (《境外註冊中資控股居民企業所得税管理辦法(試行)》), or Bulletin 45, which became effective on September 1, 2011 and as amended in 2015, 2016 and 2018, to provide further guidance on the implementation of Circular 82. Bulletin 45 clarifies certain issues related to determining PRC resident enterprise status, including which the competent tax authorities are responsible for determining offshore incorporated PRC resident enterprise status, as well as post-determination administration.

Despite the foregoing, the STA may take the view that the determining criteria set forth in Circular 82 and Bulletin 45 reflect the general position on how the "de facto management body" test should be applied in determining the tax resident status of all offshore enterprises. Additional implementing regulations or guidance may be issued determining that we or any of our subsidiaries incorporated out of the PRC is a "resident enterprise" for PRC enterprise income tax purposes. If the PRC tax authorities determine that we or any of our subsidiaries incorporated out of the PRC is a resident enterprise for PRC enterprise income tax purposes, a number of unfavorable PRC tax consequences could follow. First, we and our non-PRC subsidiaries may be subject to enterprise income tax at a rate of 25% on our worldwide taxable income, as well as to PRC enterprise income tax reporting obligations. Second, although under the CIT Law and its implementing rules, Circular 82 and Bulletin 45 dividends paid by a PRC tax resident enterprise to an offshore incorporated PRC tax resident enterprise controlled by PRC enterprise would qualify as tax-exempted income, we cannot assure that dividends paid by our PRC subsidiaries to us will not be subject to any withholding tax. Finally, the CIT Law and its implementing rules issued by PRC tax authorities provide that dividends paid by us to our non-PRC shareholders and, while less clear, capital gains recognized by them with respect to the sale of our Shares may be subject to tax of 10% for non-PRC resident enterprise shareholders and 20% for non-PRC resident individual shareholders. In the case of dividend payments, such PRC tax may be withheld at source.

Governmental regulations on currency exchange may affect us.

The convertibility of Renminbi into foreign currencies and, in certain cases, the remittance of currency into and out of China are subject to PRC foreign exchange regulations. Under existing PRC foreign exchange regulations, payments of current account items, such as profit distributions and trade and service-related foreign exchange transactions, can be made in foreign currencies without prior approval from SAFE by complying with certain procedural requirements. However, approval from or registration with appropriate governmental authorities is required where Renminbi is to be converted into foreign currency and remitted out of China to pay capital expenses such as the repayment of loans denominated in foreign currencies.

In July 2014, SAFE promulgated the Circular of the SAFE on Foreign Exchange Administration of Equity Financing and Round-Trip Investments by Domestic Residents via 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》) ("**Circular 37**"). Circular 37 requires PRC residents (including PRC individuals and PRC corporate entities as well as foreign individuals with a habitual residence in China due to economic interests) to register with SAFE or its local branches in connection with their direct or indirect offshore investment activities. Circular 37 further requires amendment to the SAFE registrations in the event of any changes with respect to the basic information of the offshore special purpose vehicle, such as changes of the offshore special purpose vehicle's name and operational term, or any significant changes with respect to the PRC individual shareholder, such as the increase or decrease of capital contributions, share transfer or exchange, or mergers or divisions. Circular 37 is applicable to our shareholders who are PRC residents. If our shareholders who are PRC residents fail to make the required registration or to update the previously filed registration, our PRC subsidiaries may be prohibited from distributing their profits or the proceeds from any capital reduction, share transfer or liquidation to us, and we may also be prohibited from making additional capital contributions into our PRC subsidiaries. In February 2015, SAFE promulgated a Notice on Further Simplifying and Improving Foreign Exchange Administration Policy on 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》) ("**Notice 13**"), effective from June 2015, and further amended by SAFE on December 30, 2019. Under Notice 13, applications for foreign exchange registration of inbound foreign direct investments and outbound overseas direct investments, including those required under Circular 37, will be filed with qualified banks instead of SAFE. The qualified banks will directly examine the applications and accept registrations under the supervision of SAFE. We cannot assure you that all our Shareholders will at all times comply with the registration procedures as required under these regulations. The failure or inability of the relevant shareholders to comply with the registration procedures set forth in these regulations may subject us to fines and legal sanctions. Moreover, failure to comply with the various foreign exchange registration requirements described above could result in liability under PRC law for circumventing applicable foreign exchange restrictions. As a result, our business operations and our ability to distribute profits to you could be materially and adversely affected.

PRC regulations of loans and direct investment by offshore holding companies to PRC entities may delay or prevent us from using the [REDACTED] of the [REDACTED] to make loans or additional capital contributions to our PRC subsidiaries.

Any loans provided by our offshore holding companies to our PRC subsidiaries are subject to PRC regulations and such loans must be registered with the local branch of the SAFE. Additionally, if we finance such subsidiary by means of additional capital contributions, these capital contributions must be registered, reported or filed with certain government authorities, including the Ministry of Commerce (the "**MOFCOM**"), the State Administration for Market Regulation (the "**SAMR**") and the SAFE or their local counterparts. We cannot assure you that we will be able to obtain these government registrations or approvals or to complete registration procedures on a timely basis, if at all, with respect to future loans or capital contributions by us to our subsidiaries or any of their respective subsidiaries. If we fail

to obtain such approvals or registrations, our ability to make equity contributions or provide loans to our PRC subsidiaries or to fund their operations may be materially and adversely affected. This may materially and adversely affect our PRC subsidiaries' liquidity, their ability to fund their working capital and expansion projects, and their ability to meet their obligations and commitments. As a result, this may have a material adverse effect on our business, financial condition and results of operations.

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. Any limitation on the ability of our PRC subsidiaries to make payments to us could have a material and adverse effect on our ability to conduct our business or financial condition.

We are a holding company incorporated in the Cayman Islands, and we may rely on dividends and other distributions on equity that may be paid by our subsidiaries for our cash and financing requirements, including the funds necessary to pay dividends and other cash distributions to the holders of our Shares and service any debt we may incur. If any of our subsidiaries incur debt on their own behalf in the future, the instruments governing the debt may restrict their 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, our PRC subsidiaries are required to set aside at least 10% of its after-tax profits each year, after making up previous years' accumulated losses, if any, to fund certain statutory reserve funds, until the aggregate amount of such a fund reaches 50% of its registered capital. Such reserve funds cannot be distributed to us as dividends.

Any limitation on the ability of our PRC subsidiaries to pay dividends or make other kinds of payments to us could materially and adversely limit our ability to grow, make investments or acquisitions that could be beneficial to our business, pay dividends to our [**REDACTED**] or other obligations to our suppliers, or otherwise fund and conduct our business.

Failure to comply with PRC regulations regarding the registration requirements for employee share ownership plans or share option plans may subject the PRC plan participants or us to fines and other legal or administrative sanctions.

In 2012, the SAFE, promulgated the Notices on Issues Concerning the Foreign Exchange Administration for Domestic Individuals Participating in Stock Incentive Plan of Overseas Publicly Listed Company (《關於境內個人參與境外上市公司股權激勵計劃外匯管理有關問題的通知》). Pursuant to these rules, PRC citizens and non-PRC citizens who reside in China for a continuous period of not less than one year and participate in any stock incentive plan of an overseas publicly listed company are required to register with SAFE through a domestic qualified agent, which could be the PRC subsidiaries of such overseas-listed company, and complete certain other procedures, unless certain exceptions are available. In addition, an overseas-entrusted institution must be retained to handle matters in connection with the exercise or sale of stock options and the purchase or sale of shares and interests. We and our executive officers and other employees who are PRC citizens or non-PRC citizens living in

China for a continuous period of not less than one year and have been granted options will be subject to these regulations when our company becomes an overseas-[**REDACTED**] company upon the completion of the [**REDACTED**]. Failure to complete SAFE registrations may subject them or us to fines or supervision measures. We also face regulatory uncertainties that could restrict our ability to adopt additional incentive plans for our directors, executive officers and employees.

In addition, the STA, has issued certain circulars concerning employee share options and restricted shares. Under these circulars, our employees working in China who exercise share options or are granted restricted shares will be subject to PRC individual income tax. Our PRC subsidiary has obligations to file documents related to employee share options or restricted shares with relevant tax authorities and to withhold individual income taxes for those employees who exercise their share options. If our employees fail to pay or we fail to withhold their income taxes according to relevant laws and regulations, we may face sanctions imposed by the tax authorities or other PRC government authorities.

We are subject to filings and other requirements from the CSRC or other PRC regulatory authorities for the [REDACTED] and [REDACTED] of our Shares on the Stock Exchange.

On February 17, 2023, the China Securities Regulatory Commission ("**CSRC**") promulgated the Trial Administrative Measures of Overseas Securities Offering and Listing by Domestic Companies (《境內企業境外發行證券和上市管理試行辦法》) ("**Overseas Listing Trial Measures**") and relevant supporting guidelines, which came into effect on March 31, 2023. The Overseas Listing Trial Measures have comprehensively improved and reformed the existing regulatory regime for overseas offering and listing of PRC domestic companies' securities and will regulate both direct and indirect overseas offering and listing of PRC domestic companies' securities. Any such domestic company that is deemed to conduct overseas offering and listing activities, including both the [**REDACTED**] and any further capital raising, shall file with the CSRC in accordance with the Overseas Listing Trial Measures.

We will file with the CSRC within the specific time limit as required by the Overseas Listing Trial Measures. In addition, it is uncertain whether we can or how long it will take us to complete the CSRC filing. Any failure to complete the CSRC filing may impede the [**REDACTED**] and may subject us to sanctions by the CSRC. Furthermore, such failure may adversely affect our ability to finance the development of our business and may have a material adverse effect on our business and financial condition.

RISKS RELATING TO OUR OPERATIONS

Our future success depends on our ability to attract, retain and motivate senior management, qualified medical professionals and scientific employees.

We are highly dependent on the expertise of the members of our research and development team, as well as the principal members of our management. We have entered into employment agreements with our executive officers, but each of them may terminate their employment with us.

Recruiting, retaining and motivating qualified management, scientific, clinical and sales and marketing personnel will also be critical to our success. The loss of the services of our executive officers or other key employees, in particular our core R&D team members, could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Further, replacing executive officers and key employees 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 drugs. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous biopharmaceutical companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions.

If we fail to effectively manage our anticipated growth or execute on our growth strategies, our business, financial condition, results of operations and prospects could suffer.

Our future financial performance and our ability to commercialize our drug candidates will also depend, in part, on our ability to effectively manage our growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to implement our long-term development strategies. For details, see "Business — Our Business Strategies." Pursuing our growth strategies has resulted in, and will continue to result in, substantial demands on capital and other resources. In addition, managing our growth and executing on our growth strategies will require, among other things, our ability to continue to identify and develop promising drug candidates in the competitive global and PRC biopharmaceutical market, effective coordination and integration of new facilities and new teams that we may develop, successful hiring and training of personnel, as well as effective and efficient financial and management control and quality control.

All of these endeavors will require substantial management attention and efforts and significant additional expenditures. If we fail to expand at our expected pace, we may face capacity constraints in the future which may adversely affect our business and financial condition. We cannot assure you that we will be able to execute our business strategies and

manage any future growth effectively and efficiently, and any failure to do so may materially and adversely affect our ability to capitalize on new business opportunities, which in turn may have a material and adverse effect on our business, financial condition, results of operations, and prospects.

Our potential engagement in acquisitions or strategic partnerships may increase our capital requirements, dilute the value of your [REDACTED] in our Shares, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

To enhance our growth, we may acquire businesses, products, technologies or know-how or enter into strategic partnerships that we believe would benefit us in terms of product development, technology advancement or distribution network. Any potential acquisition or strategic partnership may entail numerous risks, including, but not limited to:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- the issuance of our equity securities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the assimilation of operations, corporate culture and personnel of the acquired business;
- risks and uncertainties associated with the counterparty, including the prospects of that party and its existing drugs or drug candidates;
- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs; and
- changes in accounting principles relating to recognition and measurement of our investments that may have a significant impact on our financial results.

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. Moreover, we may not be able to locate suitable acquisition opportunities and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business.

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

From time to time, we may be involved in inspections, claims, disputes and legal proceedings in our ordinary course of business. These may concern issues relating to, among others, product liability, privacy protection, environmental and safety matters, breach of contract, employment or labor disputes and intellectual property rights. Any inspections, claims, disputes or legal proceedings initiated by us or brought against us, our management or directors, with or without merit, may result in substantial costs and diversion of resources, and if we are unsuccessful, could materially harm our reputation. Furthermore, inspections, claims, disputes or legal proceedings against us, our management or directors may be due to actions taken by our counterparties, such as our suppliers, CROs and other service providers. Even if we are able to seek indemnity from them, they may not be able to indemnify us in a timely manner, or at all, for any costs that we incur as a result of such claims, disputes and legal proceedings.

Our reputation is important to our success. Negative publicity with respect to us, our management, employees, business partners, affiliates, or our industry, may materially and adversely affect our reputation, business, results of operations and prospect.

We believe that market awareness and recognition of our brand image, and the maintenance of a positive brand image, is crucial to the success of our business. However, our reputation is vulnerable to potential threats that can be difficult or impossible to control, and costly or impossible to remediate. While we will continue to promote our brands to remain competitive, we may not be successful in doing so. In addition, we may engage various third parties, such as CROs, CSOs and CDMOs to expand our commercialization network and increase market access for our drugs, which can make it increasingly difficult to effectively manage our brand reputation, as we have relatively limited control over these third parties.

Any regulatory inquiries or investigations or other actions against our management, any perceived unethical, fraudulent, or inappropriate business conduct by us or perceived wrongdoing by any key member of our management team or other employees, our business partners or our affiliates, could harm our reputation and materially and adversely affect our business. Regardless of the merits or final outcome of such regulatory inquiries, investigations or actions, our reputation may be substantially damaged, which may impede our ability to attract and retain talent and business partners and grow our business.

We may be exposed to risks of conducting our business and operations in international markets.

International markets are an important component of our growth strategy. We plan to explore market opportunities overseas, where we believe there is substantial demand for our drug candidates, and we intend to identify and collaborate with reputable local partners that have proven track record to maximize the global value of our drug candidates. We will also continue to seek licensing and co-development opportunities with global MNCs, and expand our global clinical programs. For more details, see "Business — Our Business Strategies."

However, such activities may subject us to additional risks that may materially adversely affect our ability to attain or sustain profitable operations, including but not limited to:

- efforts to enter into collaboration or licensing arrangements with third parties may increase our expenses or divert our management's attention from the development of drug candidates;
- changes in a specific country's or region's political and cultural climate or economic condition;
- differing regulatory requirements for drug approvals and marketing internationally;
- difficulty of effective enforcement of contractual provisions in local jurisdictions;
- potentially reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- compliance with tax, employment, immigration and labor laws for employees traveling abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters, including earthquakes, volcanoes, typhoons, floods, hurricanes and fires.

These and other risks may materially adversely affect our ability to attain or sustain revenue and profits from international markets.

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

Our operations depend in part on the skills and know-how of our employees. In recent years, the average labor cost in the global biopharmaceutical market, particularly for highly skilled and experienced personnel, has been steadily increasing as the competition for qualified employees has become more intense. We cannot assure you that there will be no further

increase in labor cost, which may adversely affect our operations and financial condition. In addition, share options and other share-based incentives granted under our existing or future share-based incentive arrangements and scheme could adversely affect our costs and our results of operations. See also "— Risks Relating to Our Financial Position and Need for Additional Capital — We have granted, and may continue to grant, certain awards under our share incentive plans, which may result in increased share-based compensation expenses."

Changes in international trade policies and political tensions may adversely impact our business and results of operations.

We are susceptible to constantly changing international economic, regulatory, social and political conditions, and local conditions in foreign countries and regions. Tensions and political concerns between China and other countries or regions may adversely affect our business, financial condition, results of operations, cash flows and prospects. China's political relationships with foreign countries and regions may affect the prospects of our relationship with third parties, such as business partners, suppliers and future customers. 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 between China and the relevant foreign countries or regions. Any tensions and political concerns between China and the relevant foreign countries or regions may cause a decline in the demand for our future products and adversely affect our business, financial condition, results of operations, cash flows and prospects. Rising trade and political tensions, as well as changes in relevant government policies could reduce levels of trades, investments, technological exchanges and other economic activities between China and other countries and regions. For example, on February 21, 2025, U.S. President Donald J. Trump issued a memo entitled the "America First Investment Policy" (the "**America First Memo**"), outlining the ongoing review and consideration of potential new or expanded restrictions on U.S. outbound investment in the PRC in sectors such as semiconductors, artificial intelligence, quantum, biotechnology, hypersonics, aerospace, advanced manufacturing, directed energy, and other areas implicated by the PRC's national military-civil fusion strategy. The America First Memo also contemplates potential restrictions on investments in publicly traded securities by pension funds, university endowments and other limited partner investors. Such political tensions and policy changes would have an adverse effect on global economic conditions, the stability of global financial markets, and international trade policies.

While we have not started commercialization of drug candidates, any rising trade and political tensions or unfavorable government policies on international trade, such as capital controls or tariffs, may affect the competitive position of our drug products. In addition, rising trade and political tensions, heightened government scrutiny or unfavorable government policies may also affect our existing and future relationships with shareholders and business partners, including our suppliers, CROs and CDMOs, the provision of research and development and other services, the supplies of materials and products, the hiring of scientists and other research and development personnel, and import or export of raw materials in relation to drug development, or prevent us from selling our drug products in certain countries. Any failure in confirming and continuing business relationships with our existing partners or any delay in identifying and entering into commercially reasonable business relationship with a new partner could harm our ability to develop, manufacture and distribute our drug

candidates as planned or within budget, which could materially adversely affect our business, financial condition and results of operations. In particular, if any new tariffs, legislation and/or regulations, including the recently proposed BIOSECURE Act aiming at discouraging federal funding to, and contracting with, entities that use biotechnology equipment or services provided by certain Chinese biotechnology companies, are implemented, or if existing trade agreements are renegotiated, such changes could limit our ability to expand into certain markets and have an adverse effect on our business, financial condition and results of operations. In addition, our results of operations could be adversely affected if any such tensions or unfavorable government trade policies harm the Chinese economy or the global economy in general.

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

Natural disasters, health epidemics, acts of war or terrorism or other factors beyond our control may adversely affect the economy, infrastructure and livelihood of the people in the regions where we conduct our business. Our operations may be under the threat of natural disasters, such as floods, earthquakes, sandstorms, snowstorms, fire or drought, the outbreak of a widespread health epidemic, such as swine flu, avian influenza, severe acute respiratory syndrome, or SARS, Ebola, Zika, COVID-19, other factors beyond our control, such as power, water or fuel shortages, failures, malfunction and breakdown of information management systems, unexpected maintenance or technical problems, or are susceptible to potential wars or terrorist attacks.

The occurrence of a disaster or a prolonged outbreak of an epidemic illness, including the COVID-19 pandemic, or other adverse public health developments in which we operate our business could materially disrupt our business and operations. These uncertain and unpredictable factors include, but are not limited to, adverse effects on the economy, potential delays of our ongoing and future clinical trials, and disruptions to the operations of our business partners and CROs.

Acts of war or terrorism may also injure our employees, cause loss of lives, disrupt our business network and destroy our markets. Any of the foregoing events and other events beyond our control could have an adverse effect on the overall business sentiment and environment, cause uncertainties in the regions where we conduct business, cause our business to suffer in ways that we cannot predict and materially and adversely impact our business, financial condition and results of 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.

We maintain industry-standard benefit plans in accordance with relevant laws and regulations, based on our assessment of our operational needs and industry practice. Although we maintain insurance coverage for adverse events in clinical trials, this coverage may prove to be inadequate or could cease to be available to us on acceptable terms, if at all. A claim brought against us that is uninsured or under-insured could harm our business, financial condition and results of operations.

In line with general market practice, we have elected not to maintain certain types of insurances, such as business interruption insurance or key man insurance. Our insurance coverage may be insufficient to cover any claim for product liability, damage to our fixed assets or employee injuries. 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.

We may be unable to detect, deter and prevent all instances of bribery, fraud or other misconduct committed by our employees or third parties.

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 and 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 by our employees or third parties. 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, results of operations and reputation.

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

Despite the implementation of security measures, our information technology systems and those of our CROs, consultants and other service providers are vulnerable to damage from computer viruses, unauthorized access, cyber-attacks, natural disasters, terrorism, war and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our research and development programs. For example, our data may not be backed up in a timely manner and the loss of clinical trial data from ongoing or future clinical trials for any of our drug candidates could result in delays in regulatory approval efforts and significantly increase costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our drug candidates could be delayed.

Our risk management and internal control systems may not be thorough or effective in all respects.

We seek to establish risk management and internal control systems consisting of an organizational framework, policies, procedures and risk management methods that are appropriate for our business operations, and seek to continue to improve these systems. See "Business — Risk Management and Internal Control" for further details. However, due to the

inherent limitations in the design and implementation of risk management and internal control systems, we cannot assure that our risk management and internal control systems will be able to identify, prevent and manage all risks. Our internal procedures are designed to monitor our operations and ensure their overall compliance. However, our internal control procedures may be unable to identify all non-compliance incidents in a timely manner or at all. It is not always possible to timely detect and prevent fraud and other misconduct committed by our employees or third parties, and the precautions we take to prevent and detect such activities may not be effective.

Furthermore, we cannot assure you that our risk management and internal control systems will be effectively implemented. 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, which may materially and adversely affect our business and results of operations. Moreover, as we are likely to offer a broader and more diverse range of services and solutions in the future, the expansion and diversification of our service offerings will require us to continue to enhance our risk management capabilities. If we fail to adapt our risk management policies and procedures to our evolving business in a timely manner, our business, financial condition and results of operations could be materially and adversely affected.

Our leased properties may be subject to non-compliances or challenges that could potentially affect our future use of them.

We have leased certain properties in China as our offices and R&D facilities. Pursuant to the Measures for Administration of Lease of Commodity Properties (《商品房屋租賃管理辦法》), which was promulgated by the Ministry of Housing and Urban-Rural Development of the PRC (中華人民共和國住房和城鄉建設部) on December 1, 2010 and became effective on February 1, 2011, both lessors and lessees are required to file the lease agreements for registration and obtain property leasing filing certificates for their leases.

As of the Latest Practicable Date, our lease agreements in China had not been registered. Although failure to register does not in itself invalidate the leases, we may be subject to fines if we fail to rectify such non-compliance within the prescribed time frame after receiving notice from the relevant PRC government authorities. The penalty ranges from RMB1,000 to RMB10,000 for each unregistered lease, at the discretion of the relevant authority. As of the Latest Practicable Date, we were not subject to any penalties arising from the non-registration of lease agreements. However, we cannot assure you that we would not be subject to any penalties and/or requests from local authorities to fulfill the registration requirements, which may increase our costs in the future. If any of our leases is terminated or becomes unenforceable as a result of challenges from third parties, we would need to seek alternative properties and incur relocation costs. Any relocation could lead to disruptions to our operations and adversely affect our business, financial conditions and results of operations.

As our leases expire, we may face difficulties renewing them, either on commercially acceptable terms or at all. 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.

You may experience difficulties in effecting service of process upon or enforcing foreign judgments against us or our Directors or officers.

Most of our assets are situated in the PRC and most of our directors and officers reside in the PRC. Therefore, there remains the possibility that it may be difficult to effect service of process outside the PRC upon most of our directors and officers, including with respect to matters arising under applicable securities laws. The PRC does not have treaties providing for the reciprocal recognition and enforcement of civil case judgments of courts with the United States and many other countries. Consequently, you may experience difficulties in enforcing against us or our directors or officers in the PRC any judgments obtained from courts outside of the PRC.

On July 14, 2006, Hong Kong and China 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 (《關於內地與香港特別行政區法院相互認可和執行當事人協議管轄的民商事案件判決的安排》), or the Arrangement, pursuant to which a party with a final court judgment rendered by a Hong Kong court requiring payment of money in a civil and commercial case according to a choice of court agreement in writing may apply for recognition and enforcement of the judgment in China. Similarly, a party with a final judgment rendered by a Chinese court requiring payment of money in a civil and commercial case pursuant to a choice of court agreement in writing may apply for recognition and enforcement of such judgment in Hong Kong. On January 18, 2019, the Supreme People's Court and the Hong Kong 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 (《關於內地與香港特別行政區法院相互認可和執行民商事案件判決的安排》), which has come into effect on January 29, 2024 and superseded the Arrangement, 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 and the mainland. The New Arrangement discontinued the requirement for a choice of court agreement for bilateral recognition and enforcement. After the New Arrangement became effective, a judgment rendered by a Hong Kong court can generally be recognized and enforced in the PRC even if the parties in the dispute do not enter into a choice of court agreement in writing. However, we cannot guarantee that all judgments made by Hong Kong courts will be recognized and enforced in the PRC, as whether a specific judgment will be recognized and enforced is still subject to a case-by-case examination by the relevant court in accordance with the New Arrangement.

RISKS RELATING TO THE [REDACTED]

There has been no prior [REDACTED] for our Shares prior to the [REDACTED]. An active [REDACTED] for our Shares may not develop or be sustained and the [REDACTED] and [REDACTED] of our Shares may be volatile.

Prior to the completion of the [**REDACTED**], there has been no [**REDACTED**] for our Shares. There can be no guarantee that an active [**REDACTED**] for our Shares will develop or be sustained after completion of the [**REDACTED**]. The [**REDACTED**] is the result of negotiations between our Company and the [**REDACTED**] (for themselves and on behalf of the [**REDACTED**]), which may not be indicative of the price at which our Shares will be traded following completion of the [**REDACTED**]. The [**REDACTED**] of our Shares may drop below the [**REDACTED**] at any time after completion of the [**REDACTED**]. We have applied to the Stock Exchange for the [**REDACTED**] of, and permission to [**REDACTED**] the Share. A [**REDACTED**] on the Stock Exchange, however, does not guarantee that an active and liquid [**REDACTED**] for our Shares will develop, 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**].

The [**REDACTED**] and [**REDACTED**] and of our Shares may be volatile and could fluctuate widely in response to factors beyond our control, including general market conditions of the securities markets in Hong Kong, China, the United States and elsewhere in the world. In particular, the performance and fluctuation of the [**REDACTED**] of other companies with business operations located mainly in China that have listed their securities in Hong Kong may affect the volatility in the price of and [**REDACTED**] for our Shares. A number of China-based companies have listed their securities, and some are in the process of preparing for listing their securities, in Hong Kong. Some of these companies have experienced significant volatility. The trading performances of the securities of these companies at the time of or after their offerings may affect the overall investor sentiment towards China-based companies listed in Hong Kong and consequently may impact the [**REDACTED**] performance of our Shares. These broad market and industry factors may significantly affect the [**REDACTED**] and volatility of our Shares, regardless of our actual operating performance, and may result in losses on your [**REDACTED**] in our Shares.

In addition to market and industry factors, the [**REDACTED**] and [**REDACTED**] for our Shares maybe highly volatile for specific business reasons. In particular, factors such as variations in our revenue, earnings, and cash flow could cause the [**REDACTED**] of our Shares to change substantially. Any of these factors may result in large and sudden change in the [**REDACTED**] and [**REDACTED**] of our Shares.

The actual or perceived sale or availability for sale of substantial amounts of our Shares, especially by our directors, executive officers and substantial Shareholders, could adversely affect the [REDACTED] of our Shares.

Future sales of a substantial number of our Shares, especially by our directors, executive officers and existing Shareholders, or the perception or anticipation of such sales, could negatively impact the [**REDACTED**] of our Shares in Hong Kong and our ability to raise equity capital in the future at a time and price that we deem appropriate.

The Shares held by our existing Shareholders are subject to certain lock-up periods. See "Structure of the [**REDACTED**]." While we currently are not aware of any intention of such persons to dispose of significant amounts of their Shares after the expiry of the lock-up periods, we cannot assure you that they will not dispose of any Shares they may own now or in the future. The effect of such disposal, if any, on the [**REDACTED**] of the Shares cannot be predicted.

You will incur immediate and substantial dilution and may experience further dilution in the future.

As the [**REDACTED**] of Shares is higher than the net tangible book value per share of our Shares immediately prior to the [**REDACTED**], [**REDACTED**] of our Shares in the [**REDACTED**] will experience an immediate dilution. If we issue additional Shares in the future, purchasers of our Shares in the [**REDACTED**] may experience further dilution in their shareholding percentage.

We cannot assure you that we will declare and distribute any amount of dividends in the future.

We currently intend to retain most, if not all, of our available funds and any future earnings to fund the development and growth of our business. As a result, we have not yet adopted a dividend policy with respect to future dividends. Therefore, you should not rely on an [**REDACTED**] in our Shares as a source for any future dividend income.

Our Board has discretion as to whether to distribute dividends, subject to certain restrictions under Cayman Islands law, namely that our Company may pay dividends out of profits or share premium, provided always that in no circumstances may a dividend be paid out of share premium if this would result in our Company being unable to pay its debts as they fall due in the ordinary course of business. In addition, our Shareholders may by ordinary resolution declare a dividend, but no dividend may exceed the amount recommended by our Board. Even if our Board decides to declare and pay dividends, the timing, amount and form of future dividends, if any, will depend on, among other things, our future results of operations and cash flow, our capital requirements and surplus, the amount of distributions, if any, received by us from our subsidiary, our financial condition, contractual restrictions and other factors deemed relevant by our board of directors. Accordingly, the return on your [**REDACTED**] in our Shares will likely depend entirely upon any future price appreciation of

our Shares. There is no guarantee that our Shares will appreciate in value or even maintain the price at which you [**REDACTED**] the Shares. You may not realize a return on your [**REDACTED**] in our Shares and you may even lose your entire [**REDACTED**] in our Shares.

We may allocate the [REDACTED] from this [REDACTED] in ways that you and other Shareholders may not agree.

Our management will have broad discretion in the application of the [**REDACTED**] from this [**REDACTED**], including for any of the purposes described in the section titled "Future Plans and [**REDACTED**]." Because of the number and variability of factors that will determine our use of the [**REDACTED**] from this [**REDACTED**], their ultimate use may vary substantially from their currently intended use. Our management might not apply the [**REDACTED**] in ways that ultimately increase the value of your [**REDACTED**], and the failure by our management to apply these funds effectively could harm our business. The failure by our management to apply these funds effectively could have a material adverse effect on our business, financial condition and results of operation. You will not have the opportunity, as part of your [**REDACTED**] decision, to assess whether [**REDACTED**] are being used appropriately. You must rely on the judgment of our management regarding the application of the [**REDACTED**] of this [**REDACTED**].

The industry facts, statistics and forecasts in this document that were obtained from various government publications and the industry report have not been independently verified.

This document, particularly the section headed "Industry Overview," contains information and statistics relating to the healthcare market. Such information and statistics have been derived from third-party reports, either commissioned by us or publicly accessible, and other publicly available sources. The information and statistics from such sources have not been independently verified by us, the Joint Sponsors, the [**REDACTED**], the [**REDACTED**], the [**REDACTED**], the [**REDACTED**], the [**REDACTED**], and other [**REDACTED**], any of our or their respective directors, officers or representatives or any other party, other than Frost & Sullivan, 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. You should therefore not place undue reliance on such information. In addition, we cannot assure you that such information is stated or compiled on the same basis or with the same degree of accuracy as similar statistics presented elsewhere. In any event, you should consider carefully the importance placed on such information or statistics.

You should read the entire document carefully and should not rely on any information contained in press articles or other media regarding us and the [REDACTED].

We strongly caution you not to rely on any information contained in press articles or other media regarding us and the [**REDACTED**]. Prior to the publication of this document, there has been press and media coverage regarding us. Such press and media coverage may include

references to certain information that does not appear in this document, including certain operating and financial information and projections, valuations and other information. We have not authorized the disclosure of any such information in the press or media and do not accept any responsibility for any such press or media coverage or the accuracy or completeness of any such information or publication. We make no representation as to the appropriateness, accuracy, completeness or reliability of any such information or publication. To the extent that any such information is inconsistent or conflicts with the information contained in this document, we disclaim responsibility for it and you should not rely on such information.

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

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

MANAGEMENT PRESENCE IN HONG KONG

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

Since all our business operations are not principally located, managed or conducted in Hong Kong, and our Directors consider that the relocation of our executive Directors to Hong Kong or the appointment of additional executive Directors who will be ordinarily resident in Hong Kong would not be beneficial to, or appropriate for, our Company and therefore would not be in the best interests of our Company and our Shareholders as a whole, our Company does not, and, for the foreseeable future, will not, have two executive Directors who are ordinarily resident 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], a waiver from strict compliance with the requirements under Rule 8.12 of the Listing Rules. We will ensure that there is a regular and effective communication between the Stock Exchange and us by way of the following arrangements:

(a) **Authorized representatives**: both of our Company's authorized representatives, Dr. ZHU Zhongyuan (朱忠遠), chairman of the Board, executive Director and our chief executive officer, and Ms. TSANG Wing Man (曾穎雯), a joint company secretary of our Company, will act as our Company's principal channels of communication with the Stock Exchange. Accordingly, the authorized representatives of our Company will be able to meet with the relevant members of the Stock Exchange on reasonable notice and will be readily contactable by telephone, facsimile (if any) and email. Each of the authorized representatives of our Company has means of contacting all Directors (including our independent non-executive Directors) promptly at all times as and when the Stock Exchange proposes to contact a Director with respect to any matter;

(b) **Directors**: each Director has provided his/her mobile phone number, office phone number, fax number (if any) and e-mail address to the authorized representatives of our Company and the Stock Exchange, and in the event that any Director expects to travel or otherwise be out of the office, he/she will provide the phone number of the place of his/her accommodation to the authorized representatives.

Each of our Directors not ordinarily residing in Hong Kong possesses or can apply for valid travel documents to visit Hong Kong and will be able to meet with the relevant members of the Stock Exchange within a reasonable period of time;

(c) **Compliance advisor**: we have appointed First Shanghai Capital Limited as our Compliance Advisor, in compliance with Rule 3A.19 of the Listing Rules, who will, among other things and in addition to the authorized representatives and our Directors, also act as an additional channel of communication with the Stock Exchange from the [**REDACTED**] to the date when our Company complies with Rule 13.46 of the Listing Rules in respect of its financial results for the first full financial year immediately following the [**REDACTED**]. Pursuant to the Note of Rule 3A.23, the Compliance Advisor will have access at all times to our authorized representatives, our Directors and other officers. We shall also ensure that our authorized representatives, Directors and other officers will promptly provide such information and assistance as the Compliance Advisor may need or may reasonably require in connection with the performance of the Compliance Advisor's duties as set forth in Chapter 3A of the Listing Rules. We shall ensure that there are adequate and efficient means of communication among our Company, our authorized representatives, our Directors, and other officers and the Compliance Advisor, and will keep the Compliance Advisor fully informed of all communications and dealings between the Stock Exchange and us.

Any meeting between the Stock Exchange and our Directors will be arranged through the authorized representatives or the Compliance Advisor or directly with our Directors within a reasonable time frame. We will inform the Stock Exchange promptly in respect of any changes in our authorized representatives and/or our Compliance Advisor; and

(d) **Legal advisors**: we will also retain legal advisors to advise on on-going compliance requirements as well as other issues arising under the Listing Rules and other applicable laws and regulations of Hong Kong after the [**REDACTED**].

JOINT COMPANY SECRETARIES

Pursuant to Rules 3.28 and 8.17 of the Listing Rules, the company secretary must be an individual who, by virtue of his/her academic or professional qualifications or relevant experience, is, in the opinion of the Stock Exchange, capable of discharging the functions of the company secretary. 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); and

(c) a certified public accountant (as defined in the Professional Accountants Ordinance).

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

(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 law and regulations including the Securities and Futures Ordinance, the Companies Ordinance, the Companies (Winding Up and Miscellaneous Provisions) Ordinance and the Takeovers Code;

(c) relevant training taken and/or to be taken in addition to the minimum requirement of taking not less than 15 hours of relevant professional training in each financial year 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 Listing Guide, 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 Listing Guide) nor Relevant Experience (as defined under paragraph 11 of Chapter 3.10 of the Listing Guide) 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 Listing Guide, 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.

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

Our Company considers that while it is important for the company secretary to be familiar with the relevant securities regulation in Hong Kong, he/she also needs to have experience relevant to our Company's operations, nexus to the Board and close working relationship with the management of our Company in order to perform the function of a company secretary and to take the necessary actions in the most effective and efficient manner. It is for the benefit of our Company to appoint a person who has been with the Company for a period of time and is familiar with our Company's business and affairs as company secretary.

We have appointed Ms. YUAN Jiali (袁佳麗) and Ms. TSANG Wing Man as our joint company secretaries. Ms. YUAN Jiali is our head of legal and compliance. Since Ms. YUAN Jiali does not possess a qualification stipulated in Rule 3.28 of the Listing Rules, she is not able to solely fulfill the requirements as a company secretary of a listed issuer stipulated under Rules 3.28 and 8.17 of the Listing Rules. In order to provide support to Ms. YUAN Jiali, we have appointed Ms. TSANG Wing Man, an associate member of The Chartered Governance Institute and The Hong Kong Chartered Governance Institute, who meets the requirements under Rules 3.28 and 8.17 of the Listing Rules, as a joint company secretary to provide assistance to Ms. YUAN Jiali, for a three-year period from the [**REDACTED**] so as to enable her to acquire the relevant experience (as required under Rule 3.28(2) of the Listing Rules) to duly discharge her duties.

Accordingly, 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 in relation to the appointment of Ms. YUAN Jiali as our joint company secretary. Pursuant to the Chapter 3.10 of the Listing Guide, such waiver has been granted on the conditions that:

(a) Ms. TSANG Wing Man is appointed as a joint company secretary to assist Ms. YUAN Jiali in discharging her functions as a company secretary and in gaining the relevant experience under Rule 3.28 of the Listing Rules;

(b) our Company will further ensure that Ms. YUAN Jiali has access to the relevant training and support to enable her to familiarize herself with the Listing Rules and the duties required of a company secretary of an issuer listed on the Stock Exchange. Our Hong Kong legal advisors have provided training to Ms. YUAN Jiali on the principal requirements of the Listing Rules and the Hong Kong laws and regulations applicable to our Company after the [**REDACTED**]. In addition, Ms. YUAN Jiali will endeavor to familiarize herself with the Listing Rules, including any updates thereto, during the three-year period from the [**REDACTED**];

(c) Ms. YUAN Jiali has confirmed that she will attend no less than 15 hours of training courses on the Listing Rules, corporate governance, information disclosure, investor relations as well as the functions and duties of a company secretary of a Hong Kong [**REDACTED**] issuer during each financial year as required under Rule 3.29 of the Listing Rules;

(d) before the expiry of Ms. YUAN Jiali's initial term of appointment as the company secretary of our Company, our Company will evaluate her experience in order to determine if she has acquired the qualifications required under Rule 3.28 of the Listing Rules; and

(e) this waiver will be revoked immediately if and when Ms. TSANG Wing Man ceases to provide such assistance during the three-year period, and we undertake to re-apply to the Stock Exchange for a waiver in the event that Ms. TSANG Wing Man ceases to meet the requirements under Rule 3.28 of the Listing Rules or otherwise ceases to serve as a joint company secretary of our Company. In addition, this waiver is subject to revocation in the event of any material breaches of the Listing Rules by our Company.

Prior to the end of the three-year period, we will demonstrate and seek the confirmation from the Stock Exchange that Ms. YUAN Jiali, having had the benefit of Ms. TSANG Wing Man during the three years, has attained the relevant experience and is capable of discharging the functions of our company secretary.

See the section headed "Directors and Senior Management" in this document for further information regarding the qualifications of Ms. YUAN Jiali and Ms. TSANG Wing Man.

EXEMPTION 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

According to section 342(1)(b) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance, this document shall include an accountant's report which contains the matters specified in the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance.

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

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

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

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

According to Rule 4.04(1) of the Listing Rules, the Accountant's Report contained in this document must include, inter alia, the results of our Company in respect of each of the three financial years immediately preceding the issue of this document or such shorter period as may be acceptable to the Stock Exchange.

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

Accordingly, we applied to the SFC for, and SFC [has granted] us, 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, and a certificate of exemption has been granted by the SFC under section 342A(1) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance, on the conditions that (i) the particulars of the exemption are set forth in this document, and (ii) this document must be issued on or before [**REDACTED**] on the following grounds:

(a) our Company is a global player in ADC innovation, dedicated to the development of next-generation therapeutics in this fast-growing drug modality to treat cancer, autoimmune diseases, and beyond, and falls within the scope of biotech company as defined under Chapter 18A of the Listing Rules;

(b) the Accountant's Report for the two years ended December 31, 2023 and [2024] has been disclosed in the document of our Company 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 set out in this document are only for the two years ended December 31, 2023 and [2024] in accordance with Chapter 18A of the Listing Rules, other information required to be disclosed under the Listing Rules and requirements under the Companies (Winding Up and Miscellaneous Provisions) Ordinance has been adequately disclosed in this document pursuant to the relevant requirements;

(d) furthermore, as Chapter 18A of the Listing Rules provides track record period of two years for biotech companies in terms of financial disclosure, strict compliance with the requirements of 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 would be unduly burdensome for our Company as this would require additional work to be performed by us and our reporting accountants; and

(e) our Directors are of the view that the Accountant's Report covering the two years ended December 31, 2023 and [2024], together with other disclosures in this document, has already provided the potential [**REDACTED**] with adequate and reasonably up-to-date information in the circumstances to form a view on the track record of our Company, and our Directors confirm that all information which is necessary for the [**REDACTED**] public to make an informed assessment of our Company's business, assets and liabilities, financial position, [**REDACTED**] position, management and prospects has been included in this document. Therefore, the exemption would not prejudice the interests of the [**REDACTED**] public.

THE PRE-[REDACTED] EQUITY INCENTIVE PLAN

Under Rule 17.02(1)(b) of, and paragraph 27 of Appendix D1A to, the Listing Rules, and paragraph 10(d) of Part I of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance, this document is required to include, among other things, details of the number, description and amount of any shares in or debentures of our Company which any person has, or is entitled to be given, an option to subscribe for, together with certain particulars of each option, namely the period during which it is exercisable, the price to be paid for shares or debentures subscribed for under it, the consideration (if any) given or to be given for it or for the right to it and the names and addresses of the persons to whom it was given.

Under section 342(1)(b) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance, the document must state the matters specified in Part I of the Third Schedule.

According to Chapter 3.6 of the Listing Guide, the Stock Exchange would normally grant waivers from disclosing the names and addresses of certain grantees if the issuer could demonstrate that such disclosures would be irrelevant and unduly burdensome, subject to certain conditions specified therein.

The maximum number of Shares that may be issued pursuant to the share awards under the Pre-[**REDACTED**] Equity Incentive Plan shall not exceed 22,287,582 Shares in the aggregate, representing [**REDACTED**]% of the total number of Shares in issue immediately after completion of the [**REDACTED**] (assuming the [**REDACTED**] is not exercised). As of

the Latest Practicable Date, our Company had granted options under the Pre-[**REDACTED**] Equity Incentive Plan to a total of 102 eligible grantees, including (i) three Directors and eight senior management members; (ii) three external consultants (all being key external consultants who serve on the Company's scientific advisory board); and (iii) 88 non-connected employees of our Company, to subscribe for an aggregate of 18,763,423 Shares, representing approximately [**REDACTED**]% of the total number of Shares in issue immediately after completion of the [**REDACTED**] (assuming the [**REDACTED**] is not exercised), with the remaining 3,524,159 options to be granted prior to the [**REDACTED**]. For details, please see the section headed "Statutory and General Information — D. Share Incentive Plans — 1. Pre-[**REDACTED**] Equity Incentive Plan" in Appendix IV to this document.

We have applied to the Stock Exchange and the SFC, respectively, for, (i) a waiver from strict compliance with the disclosure requirements under Rule 17.02(1)(b) of, and paragraph 27 of Appendix D1A to the Listing Rules; and (ii) a certificate of exemption under section 342A of the Companies (Winding Up and Miscellaneous Provisions) Ordinance exempting our Company from strict compliance with the disclosure requirements under paragraph 10(d) of Part I of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance, on the grounds that strict compliance with the above requirements would be unduly burdensome for our Company for the following reasons:

(a) given that 102 grantees are involved, setting out full details of all the grantees under the Pre-[**REDACTED**] Equity Incentive Plan in this document would be costly and unduly burdensome for our Company in light of a significant increase in cost and time for information compilation and document preparation. For example, we would need to collect and verify the addresses of 102 grantees to meet the disclosure requirement;

(b) we are a global player in ADC innovation, dedicated to the development of next-generation therapeutics in this fast-growing drug modality to treat cancer, autoimmune diseases, and beyond. The relevant market is very competitive. Given such nature of the industry in which our Company operates, it is extremely important for our Company to recruit and retain talents, and the success of our Company's long-term development will very much depend on the loyalty and contribution of the grantees. The information relating to the options granted to the grantees is highly sensitive and confidential to our Group, and full disclosure of the details of the grantees (including their addresses) and the options granted to each of them in the document which is readily accessible to the general public would provide our Group's competitors with our employees' compensation details and facilitate their soliciting activities which could adversely impact our Group's ability to recruit and retain valuable talents. The disclosure of such information in the document would also easily allow the employees of our Group to gain access to the others' compensation, which could negatively affect our employees' morale, giving rise to negative internal competitions and leading to an increase in the costs for recruitment and retention;

(c) as of the date of this document, except for 11 grantees who are Directors and senior management members of our Company, none of the grantees under the Pre-[**REDACTED**] Equity Incentive Plan is a Director, member of senior management or the connected person of our Company. Disclosing the names, addresses and entitlements on an individual basis in this document will require number of additional pages of disclosure that does not provide any material information to the [**REDACTED**] public;

(d) the grant and exercise in full of the options under the Pre-[**REDACTED**] Equity Incentive Plan will not cause any material adverse impact on the financial position of our Company;

(e) deviation from strict compliance with the disclosure requirements would not deprive potential [**REDACTED**] of information necessary for them to make an informed assessment of the activities, assets, liabilities, financial position, management and prospects of our Group; and

(f) material information relating to the options under the Pre-[**REDACTED**] Equity Incentive Plan will be disclosed in this document, including a summary of the major terms of the Pre-[**REDACTED**] Equity Incentive Plan, the total number of Shares to be issued subject to the Pre-[**REDACTED**] Equity Incentive Plan, the exercise price per Share, the exercise period, the potential dilution effect on shareholding and the impact on earnings per Share. Our Directors consider that the information that is reasonably necessary for the potential [**REDACTED**] to make an informed assessment of our Company in their [**REDACTED**] decision making process has been included in this document.

In light of the above, our Directors are of the view that the grant of the waiver and exemption sought under this application will not prejudice the interests of the [**REDACTED**] public.

The Stock Exchange [has granted] to us a waiver under the Listing Rules on the conditions that:

(a) on an individual basis, full details of the options granted under the Pre-[**REDACTED**] Equity Incentive Plan to each of the Directors, members of senior management, connected persons of our Company and external consultants, will be disclosed in "Statutory and General Information — D. Share Incentive Plans — 1. Pre-[**REDACTED**] Equity Incentive Plan" in Appendix IV to this document, as required under Rule 17.02(1)(b) of, and paragraph 27 of Appendix D1A to, the Listing Rules, and paragraph 10 of Part I of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance;

(b) in respect of the options granted by our Company under the Pre-[**REDACTED**] Equity Incentive Plan to the grantees other than those referred to in paragraph (a) above, disclosures are made of, on an aggregate basis, categorized into lots based on the number of Shares underlying each individual grantee, being (i) 5,000 to 49,999 Shares, (ii) 50,000 to 99,999 Shares, and (iii) 100,000 to 216,000 Shares, (1) the aggregate number of grantees and the number of Shares underlying the options granted to all the grantees under the Pre-[**REDACTED**] Equity Incentive Plan, (2) the consideration paid for the grant of the options under the Pre-[**REDACTED**] Equity Incentive Plan, and (3) the exercise period and the exercise price for the options granted under the Pre-[**REDACTED**] Equity Incentive Plan;

(c) there will be disclosure in this document for the aggregate number of Shares underlying the options under the Pre-[**REDACTED**] Equity Incentive Plan and the percentage of our Company's total issued share capital represented by such number of Shares as of the date of this document;

(d) the dilutive effect upon full exercise of the options under the Pre-[**REDACTED**] Equity Incentive Plan will be disclosed in "Statutory and General Information — D. Share Incentive Plans — 1. Pre-[**REDACTED**] Equity Incentive Plan" in Appendix IV to this document;

(e) a summary of the major terms of the Pre-[**REDACTED**] Equity Incentive Plan will be disclosed in "Statutory and General Information — D. Share Incentive Plans — 1. Pre-[**REDACTED**] Equity Incentive Plan" in Appendix IV to this document;

(f) the particulars of the waiver will be disclosed in this document;

(g) a full list of all the grantees under the Pre-[**REDACTED**] Equity Incentive Plan, containing all the particulars as required under Rule 17.02(1)(b) of, and paragraph 27 of Appendix D1A to, the Listing Rules, and paragraph 10 of Part I of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance, will be made available for public inspection in accordance with "Documents Delivered to the Registrar of Companies and Available on Display — Documents Available for Inspection" in Appendix V to this document; and

(h) the grant of a certificate of exemption under the Companies (Winding Up and Miscellaneous Provisions) Ordinance from the SFC exempting our Company from the disclosure requirements provided in paragraph 10(d) of Part I of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance.

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

The SFC [has agreed] to grant to our Company the certificate of exemption under Part I of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance on condition that:

(a) on an individual basis, full details of the options granted under the Pre-[**REDACTED**] Equity Incentive Plan to each of the Directors, members of senior management, connected persons of our Company and external consultants, will be disclosed in "Statutory and General Information — D. Share Incentive Plans — 1. Pre-[**REDACTED**] Equity Incentive Plan" in Appendix IV to this document, as required under paragraph 10 of Part I of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance;

(b) in respect of the options granted by our Company under the Pre-[**REDACTED**] Equity Incentive Plan to the grantees other than those referred to in paragraph (a) above, disclosures are made of, on an aggregate basis, categorized into lots based on the number of Shares underlying each individual grantee, being (i) 5,000 to 49,999 Shares, (ii) 50,000 to 99,999 Shares, and (iii) 100,000 to 216,000 Shares, (1) the aggregate number of grantees and the number of Shares underlying the options granted to all the grantees under the Pre-[**REDACTED**] Equity Incentive Plan, (2) the consideration paid for the grant of the options under the Pre-[**REDACTED**] Equity Incentive Plan, and (3) the exercise period and the exercise price for the options granted under the Pre-[**REDACTED**] Equity Incentive Plan;

(c) a full list of all the grantees under the Pre-[**REDACTED**] Equity Incentive Plan, containing all the particulars as required under Rule 17.02(1)(b) of, and paragraph 27 of Appendix D1A to, the Listing Rules, and paragraph 10 of Part I of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance, will be made available for public inspection in accordance with "Documents Delivered to the Registrar of Companies and Available on Display — Documents Available for Inspection" in Appendix V to this document;

(d) the particulars of the exemption will be disclosed in this document; and

(e) this document is issued on or before [**REDACTED**].

[REDACTED]

[**REDACTED**]

[**REDACTED**]

[REDACTED]

[**REDACTED**]

DIRECTORS

Name	Address	Nationality
Executive Directors		
Dr. ZHU Zhongyuan (朱忠遠)	Room 403, Building 10 Lane 1299, Dingxiang Road Pudong New Area Shanghai the PRC	Chinese
Mr. ZHANG Shaoren (張韶壬)	Rooms 201-203, Building 2 Lane 76, Nujiang Road Putuo District Shanghai the PRC	Chinese
Ms. SI Wen (司文)	Room 402, No. 44 Lane 438, Guzong Road Pudong New Area Shanghai the PRC	Chinese
Non-executive Directors		
Mr. CAI Zhiyang (蔡志洋)	Room 1601 No. 8, Lane 299, Yaohong Road Minhang District Shanghai the PRC	Chinese
Dr. YU Tao (余濤)	Room 601, Building 26 No. 139 Zhongshan Avenue West Tianhe District Guangzhou, Guangdong Province the PRC	Chinese

Name	Address	Nationality
Independent Non-executive Directors		
Mr. XIE Dong (謝東)	Flat E, 15/F 5-17 Western Street Sai Ying Pun Hong Kong	Chinese
Mr. GAO Fengyong (高鳳勇)	Room 302, No. 12 Lane 199, Baiyang Road Pudong New Area Shanghai the PRC	Chinese
Ms. CHUAI Shuyin (揣姝茵)	Room 1902, No. 110 Lane 2388, Chengshan Road Pudong New Area Shanghai the PRC	Chinese

See the section headed "Directors and Senior Management" in this document for further details.

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CITIC Securities (Hong Kong) Limited*
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(in no particular order)*

[**REDACTED**]

[**REDACTED**]

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Industry Consultant	**Frost & Sullivan (Beijing) Inc., Shanghai Branch Co.** Room 2504, Wheelock Square No. 1717 West Nanjing Road Jing'an District, Shanghai the PRC
Compliance Advisor	**First Shanghai Capital Limited** 19/F., Wing On House 71 Des Voeux Road Central Hong Kong

[**REDACTED**]

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Registered office in the Cayman Islands	The offices of Aequitas International Management Ltd. Grand Pavilion Commercial Centre Suite 24, 802 West Bay Road P.O. Box 10281 Grand Cayman KY1-1003 Cayman Islands
Company's Website	**www.dualitybiologics.com** *(Information contained in this website does not form part of this document)*
Joint Company Secretaries	**Ms. YUAN Jiali (袁佳麗)** Units 1103-1106, Building A No. 868 Yinghua Road Pudong New Area Shanghai the PRC **Ms. TSANG Wing Man (曾穎雯)** *(an associate member of The Hong Kong Chartered Governance Institute and The Chartered Governance Institute)* 40/F Dah Sing Financial Centre 248 Queen's Road East Wanchai Hong Kong

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	Mr. GAO Fengyong (高鳳勇)
	Ms. CHUAI Shuyin (揣姝茵)
Remuneration Committee	Ms. CHUAI Shuyin (揣姝茵) *(Chairperson)*
	Mr. GAO Fengyong (高鳳勇)
	Ms. SI Wen (司文)
Nomination Committee	Dr. ZHU Zhongyuan (朱忠遠) *(Chairperson)*
	Ms. CHUAI Shuyin (揣姝茵)
	Mr. XIE Dong (謝東)

[**REDACTED**]

[**REDACTED**]

Principal bank	**Industrial and Commercial Bank of China Limited, Suzhou Industrial Park Branch** No. 1 Suzhou Avenue West Suzhou Industrial Park Suzhou, Jiangsu Province the PRC

The information and statistics set out in this section and other sections of this document were extracted from different official government publications, available sources from public market research and other sources from independent suppliers, and from the independent industry report prepared by Frost & Sullivan in connection with the [**REDACTED**] *(the "**F&S Report**"). The information from official government sources has not been independently verified by us, the Joint Sponsors, the* [**REDACTED**]*, the* [**REDACTED**]*, the* [**REDACTED**]*, the* [**REDACTED**]*, any of the* [**REDACTED**]*, any of their respective directors and advisers, or any other persons or parties involved in the* [**REDACTED**]*, and no representation is given as to its accuracy.*

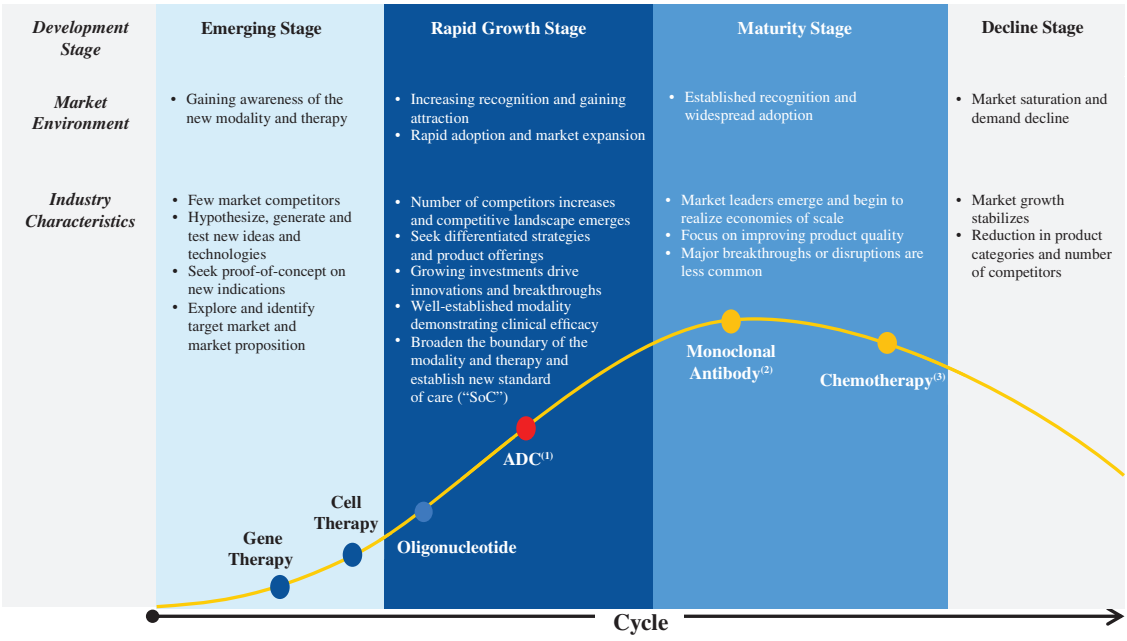
ANTIBODY-DRUG CONJUGATES: A PRECISION TREATMENT REVOLUTION

Evolution of Disease Treatment Paradigm

The treatment landscape of major diseases, such as cancer and autoimmune diseases, has undergone a dynamic transformation. For decades, systemic treatments, such as chemotherapy and radiotherapy, have been the mainstays in the standard of care for cancer and other diseases. While these treatments can be applied to a broad spectrum of cancer types, their indiscriminate nature can damage healthy cells and often causes serious side effects, prompting the revolutionary development of precision treatments and immunotherapies for cancer in recent years. Immunotherapies, such as programmed cell death protein 1/ligand 1 ("**PD-(L)1**") checkpoint inhibitors, have transformed the treatment landscape for cancer with improved efficacy and better tolerability. However, these treatments still face significant limitations, including a large population of unresponsive or resistant patients and treatment discontinuation due to side effects.

Antibody-drug conjugates ("**ADCs**") have emerged as one of the most promising and fastest-growing treatment modalities, with the ability to leverage the targeting and binding abilities of antibodies to precisely deliver cytotoxic payloads to cancer or other diseased cells. The first ADC was approved in 2000, and ten of the 15 marketed ADCs to date were approved after 2019, with five ADCs achieving blockbuster status (i.e., more than US$1.0 billion in annual sales).

Building upon earlier technologies and successes, ADCs have reached an inflection point with their full potential ready to be unleashed. Substantial research is being conducted to optimize each component of the ADC — the payload, linker and antibody — to explore new formats, targets and mechanisms. These efforts aim to improve efficacy and safety of ADCs to advance the modality towards first-line treatment and establish a new standard of care. Beyond oncology, ADCs are a promising modality in other underserved therapeutic areas, such as autoimmune, metabolic and cardiovascular diseases. These ongoing advancements are propelling ADCs to new frontiers, unlocking the promise of this innovative modality to benefit a much wider patient population.



Notes:

(1) The global ADC market grew rapidly from US$2.0 billion in 2018 to US$10.4 billion in 2023 with a CAGR of 38.6%, and is projected to continue its robust growth at a CAGR of 31.8% and 29.2% from 2023 to 2028 and from 2028 to 2032, respectively, and reach US$115.1 billion in 2032.

(2) The global market size of PD-(L)1 checkpoint inhibitors, being one of the major modalities of monoclonal antibody for oncology treatment, grew from US$16.3 billion in 2018 to US$47.6 billion in 2023 with a CAGR of 24.0%, and is expected to reach US$57.1 billion in 2032 with a CAGR of 2.0% from 2023 to 2032.

(3) The global market size of oncology chemotherapy grew from US$22.3 billion in 2018 to US$29.5 billion in 2023 with a CAGR of 5.7%, and is expected to reach US$33.2 billion in 2032 with a CAGR of 1.3% from 2023 to 2032.

Source: Literature review, Frost & Sullivan

Substantial Market Interest in ADCs

ADCs have attracted significant interest and investment in the pharmaceutical industry. Each of the global top ten multinational corporations ("**MNCs**") has established an ADC presence, through in-house development or external collaboration and investment. Since 2022, the global ADC industry has witnessed a record-breaking volume of over 20 licensing deals by global MNCs in aggregate, with a total deal value of over US$60 billion.

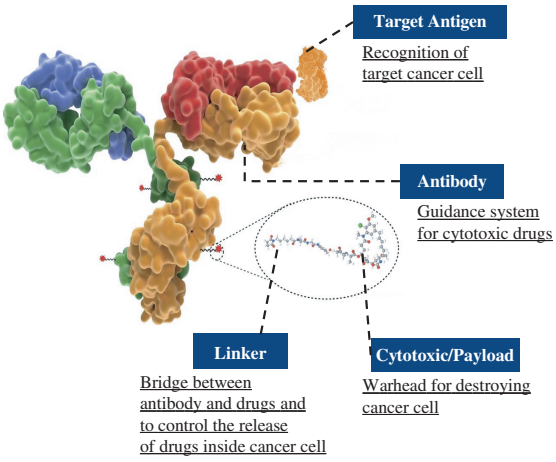
Notably, China-based biopharmaceutical companies have emerged as prominent players. As the licensors in a majority of these deals, China-based companies have exemplified strong ADC discovery and development capabilities. Since 2022, over 20 ADC assets have been licensed or acquired for a total deal value of over US$35 billion from China-based companies. China-based companies and institutions also ranked second in the world in terms of the number of ADC-related journal articles published and the number of patents granted in 2022. China's leading position is attributed to its robust interdisciplinary R&D capabilities. In addition, the

innovation-oriented regulatory framework, including expedited approval process, incentives to innovative R&D and promotion of international collaboration, also supports drug innovation and accelerates drug development in China.

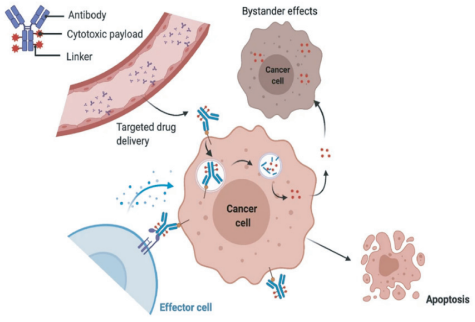
Introduction to ADC Structure and Mechanism

ADCs comprise three core components and require holistic and intricate design based on features of each component and characteristics of the target disease. Modifications to each component can have a substantial influence on the pharmacological properties and clinical profiles of the ADC. The following diagrams illustrate an ADC's structure and its mechanism of action:

Main Structure of ADC



Mechanism of Action of ADC



- Once antibody of ADC is bound to the target antigens that are specifically expressed on the cancer cells, the ADC is endocytosed/internalized by cells to form an early endosome, followed a maturation into late endosomes and finally fused with lysosomes.
- The cytotoxic payloads are eventually released via either chemical or enzyme mediated mechanism in the lysosomes, resulting in cell apoptosis or death via targeting DNA or microtubules.
- When the payload released is permeable or transmembrane, it may also induce bystander effect to enhance the efficacy of ADC.

Source: Literature review, Frost & Sullivan

As "guided missiles," ADCs combine the target selectivity of antibodies and the cancer-killing potency of cytotoxic drugs (payloads). This synergistic design potentially reduces off-target, systemic toxicity and allows the targeted delivery of highly potent cytotoxic drugs that would otherwise be intolerable in systemic therapies such as chemotherapies, thereby leading to a wider therapeutic window, improved efficacy, duration of response and overall survival in cancer patients. Notably, the achievement of bystander killing effects by topoisomerase-based ADCs in recent years has further enhanced efficacy by enabling killing of neighboring tumor cells that may not express the target antigen.

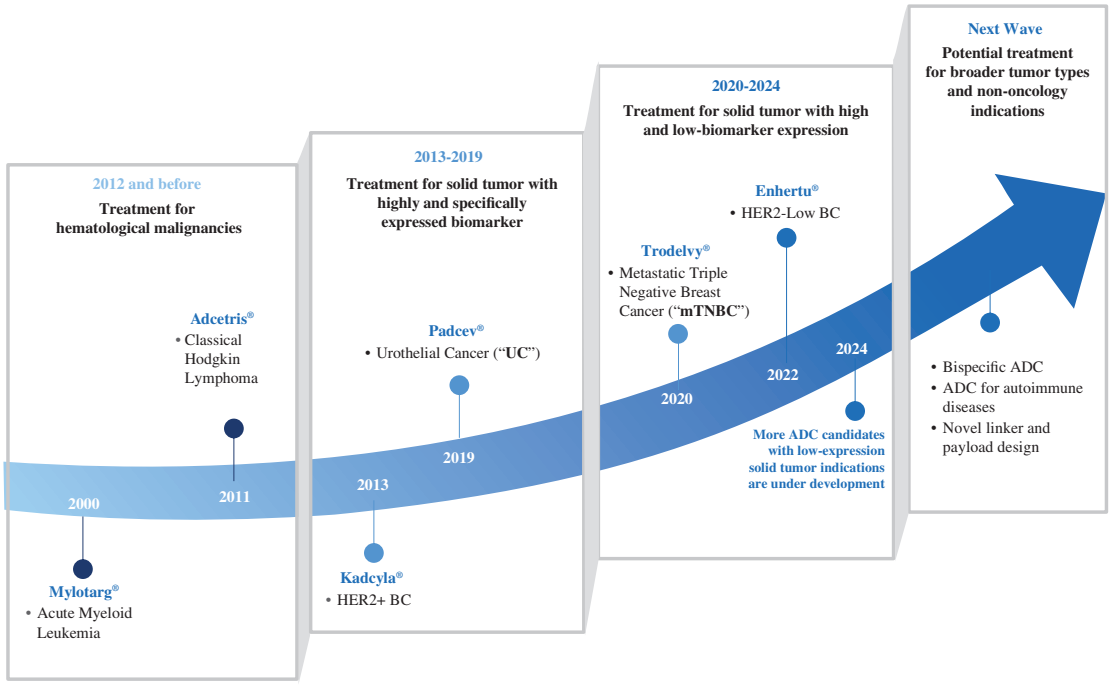
Evolution of ADCs

Despite their vast therapeutic potential, early generations of ADCs faced various challenges, including intolerable toxicity and suboptimal efficacy that stymied numerous ADC development programs from the 1980s to the 2000s. The first ADC, Mylotarg®, was approved

by the United States Food and Drug Administration (the "**FDA**") in 2000 for the treatment of acute myeloid leukemia. Since then, ADC technology has undergone continuous innovation, bringing substantial improvements in stability, tolerability and efficacy. Examples include the introduction of bystander killing effects through new payloads with better cross-cell permeability, the evolution from chimeric antibodies to humanized antibodies, cleavable linkers for payload release in the tumor microenvironment, and advancements in site-specific conjugation techniques to improve therapeutic window. These technological breakthroughs have expanded the application of ADCs from blood cancers only to a growing number of solid tumors. Significant efforts are being made to investigate new and emerging targets with no approved drugs, such as B7-H3 and HER3. There are also continuous efforts to optimize each of the three ADC components for difficult-to-treat tumors with low or ultralow protein expression, such as HER2-low breast cancer ("**BC**") and endometrial cancer ("**EC**").

The next wave ADCs are expected to leverage novel linkers and payloads, moving beyond traditional cytotoxic agents to employ innovative molecules such as immunomodulatory payloads. Other innovation fronts in ADC development include the exploration of novel bispecific and multi-specific formats, and potential combination therapies with other treatment modalities to create synergistic effects. All these advancements will pave the way for ADCs to expand towards earlier lines of treatment and therapeutic areas beyond oncology.

The table below sets forth the details of the evolution of ADCs and representative products and their treatment potential.



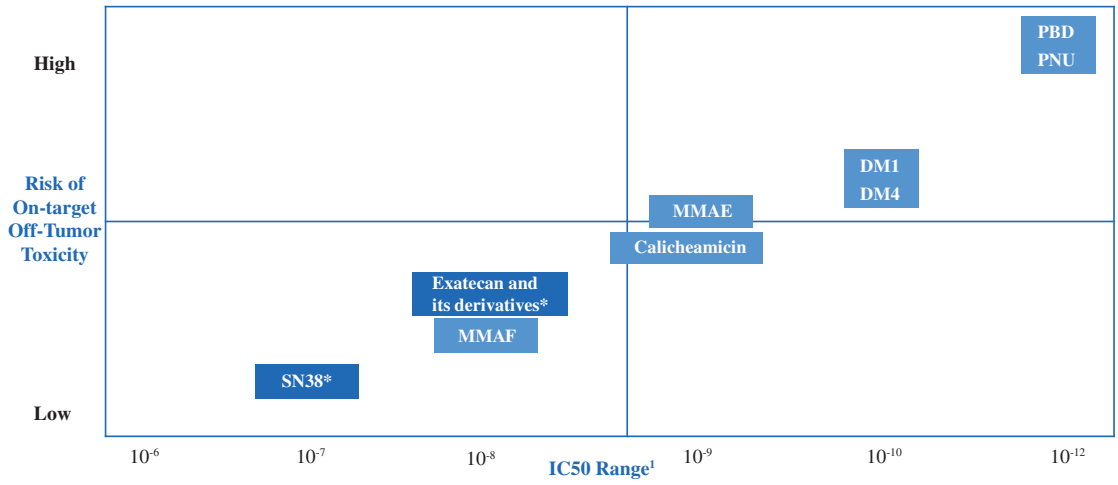
Source: FDA, NMPA, Frost & Sullivan

Major Considerations and Challenges in ADC Design and Development

Payload design is a crucial factor to the success of an ADC drug, and involves selecting a cytotoxic agent with the optimal potency and a mechanism of action suitable for the target tumor type. A well-designed payload typically possesses a small molecular weight to enable good tissue penetration, coupled with a short half-life to reduce systemic exposure and potential off-target toxicity, while maintaining a sufficient concentration within the tumor microenvironment to exert the desired cytotoxic effects. Payload design has been a key focus in ADC innovation with significant improvements over the years. While traditional payloads such as monomethyl auristatin E ("**MMAE**") have their advantages, topoisomerase-based inhibitors have revolutionized the ADC modality, with their ability to exert bystander killing, high potency, effective mechanism of action and accessibility for linker attachment.

The chart below sets forth the respective potency and on-target, off-tumor toxicity profiles of different payload designs. Topoisomerase-based payloads, such as exatecan and its derivatives, have exhibited a favorable balance between potency and off-tumor toxicity, delivering strong antitumor efficacy while minimizing adverse effects on healthy tissues.

Risk of Off-Tumor Toxicity as Function of Payload Potency



Note:

(1) IC50 range represents the span of concentrations at which a substance inhibits 50% of a specific biological or biochemical function. IC50 range is used here to measure and compare the potency of different payloads.

* Topoisomerase-based payload

Source: ENA 2022, Frost & Sullivan

Antibody selection requires careful consideration of the target antigen's expression profile, internalization rate, and potential for off-target toxicity, where the chosen antibody possesses the desired specificity and affinity to ensure efficient and targeted delivery of the payload to the tumor cells. However, challenges remain in identifying suitable antigens with limited expression in healthy tissues, developing antibodies with optimal pharmacokinetic and pharmacodynamic properties, and mitigating potential immunogenicity of the antibody. In addition, new targeting backbones, such as bispecific antibodies, are being developed to achieve synergistic anti-tumor effects and increase tumor specificity. The complexity of combining targets with different targeting moieties introduces new challenges in antibody selection and engineering.

Linker design focuses on selecting a linker that is stable in circulation to minimize premature payload release and systemic toxicity, while also enabling efficient release of the active drug within the target cells and tissues. Linkers can be broadly categorized into cleavable and non-cleavable linkers, chosen based on payload properties and the desired release mechanism. For example, cleavable linkers can achieve more targeted and precise delivery through their controlled release mechanism, whereas non-cleavable linkers are typically more stable in circulation. Other linker design considerations include ensuring consistent drug-to-antibody ratio ("**DAR**") through site-specific conjugation, and minimizing the impact of the linker on the ADC's pharmacokinetics and immunogenicity.

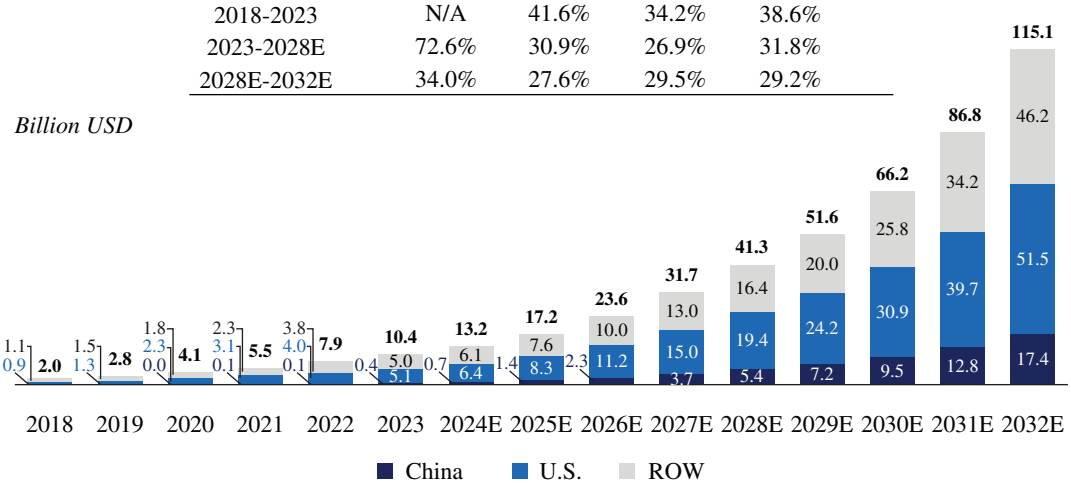
Global ADC Market Size

The global ADC market has witnessed rapid growth in recent years following the approval of novel ADCs that demonstrate enhanced safety and efficacy profiles. For example, Padcev®, a Nectin-4 targeted ADC, and Enhertu®, a HER2-targeted ADC, both of which received initial FDA approval in 2019, have experienced rapid uptake and commercial success in recent years. In 2023, Padcev® and Enhertu® generated global sales revenue of US$1,178.0 million and US$2,566.0 million, respectively.

The global ADC market grew rapidly from US$2.0 billion in 2018 to US$10.4 billion in 2023 at a CAGR of 38.6% and is projected to continue its robust growth at a CAGR of 31.8% and 29.2% from 2023 to 2028 and from 2028 to 2032, respectively, and reach US$115.1 billion in 2032. The U.S. and China are expected to remain the largest and fastest-growing markets for ADCs, with a CAGR of 30.9% and 72.6% from 2023 to 2028, respectively. In addition, with the exploration of this modality in non-oncology indications, ADCs for autoimmune diseases are expected to further enlarge the ADC market. The chart below illustrates the growth of the global ADC market with a breakdown by major regions.

Global ADC Market Size and Forecast, 2018-2032E

Period	CAGR			
	China[1]	U.S.	ROW	Global[2]
2018-2023	N/A	41.6%	34.2%	38.6%
2023-2028E	72.6%	30.9%	26.9%	31.8%
2028E-2032E	34.0%	27.6%	29.5%	29.2%



Notes:

(1) China's relatively small share in the global ADC market is primarily attributable to (i) the fewer number of approved ADCs to date (8 in China compared to 13 in the U.S.), (ii) later market entry (first approval in 2020 in China as compared to 2000 in the U.S.), and (iii) lower pricing compared to the U.S. and EU. Despite the above factors, China's share in the global ADC market is projected to grow from 3.4% in 2023 to 15.2% in 2032.

(2) As the global ADC market size expands, the expected growth of the global ADC market between 2023 and 2032 is projected to slow down compared to the period between 2018 and 2023. However, it is still expected to grow faster than other traditional treatment modalities, including chemotherapy and monoclonal antibodies.

Source: Annual Reports of Listed Medical Companies, NMPA, CDE, NRDL, MOHRSS, Frost & Sullivan

Entry Barriers

The major entry barriers for new entrants to the ADC market are set forth as follows:

- ***Sophisticated development process.*** ADC development is a challenging process involving significant uncertainties. Many ADCs have exhibited potential in preclinical research, but failed to perform well in clinical trials, with toxicity being one of the main factors contributing to these failures. The nature of ADCs requires robust and specialized data, such as drug-to-antibody ratio, in addition to a wide range of other parameters. Such a sophisticated development process also necessitates significant capital investment and substantial financial support, which also poses challenges to new entrants to the ADC market.

- ***Stringent and evolving regulatory oversight.*** The ADC market is subject to stringent and constantly evolving regulatory oversight, with the approval process for new ADCs often characterized by its lengthiness and high expenses. Regulatory authorities such as the FDA and the NMPA closely evaluate the safety, efficacy and

quality of ADCs and ADC candidates through rigorous preclinical and clinical review. The process requires substantial documentation, additional studies and regulatory communications, making ADC development and approval time-consuming and expensive for market players, especially new entrants.

Market Drivers and Future Trends

The growth of the ADC market is expected to be driven by the following factors:

- ***Expanding patient base with unmet needs.*** The global cancer incidence reached 20.8 million cases in 2023, and is projected to increase to 25.5 million cases in 2032. Incidence is growing in major tumor types currently covered by approved ADCs, including certain subtypes of BC and non-small cell lung cancer ("**NSCLC**"). Other cancers, such as EC, ovarian cancer (**"OC**"), small-cell lung cancer ("**SCLC**") and castration-resistant prostate cancer ("**CRPC**"), are also growing in global incidence. Due to the lack of effective treatments, as well as the occurrence of drug resistance and relapse, the five-year survival rate for cancer remains low, highlighting the demand for novel therapies to improve cancer prognosis and outcome. Notably, ADCs have emerged as a promising upgrade to chemotherapy in cancer treatment, as they combine the specificity of antibodies with the potent cell-killing ability of cytotoxic drugs, representing a significant market opportunity.

- ***Broadened application through technology advances.*** Significant investments are being devoted to cancer research and drug development, with the goal to further elucidate disease biology and discover targeted cancer treatments that improve patient outcomes. In particular, ongoing ADC research and development on novel payloads can potentially yield new designs that improve the therapeutic effects of this modality and reduce toxicity that limits the use of some marketed ADCs. To date, there are over 100 ADC candidates under clinical development globally targeting new indications not covered by approved ADCs. These efforts will drive ADCs towards becoming a backbone cancer therapy and their expansion into other therapeutic areas.

- ***Dynamic collaboration among market players.*** There has been a surge of collaboration and licensing deals in the ADC industry, with large MNCs increasing investments into this field and smaller biotechnology companies contributing significantly to the R&D of ADC candidates. Biotechnology companies often leverage their innovative capabilities and expertise to conduct initial exploratory work and proof-of-concept studies, while collaborating with MNCs provides substantial technical, financial and regulatory support to expedite further development and commercialization of promising ADC candidates. Meanwhile, in-licensing components for innovative drug development has emerged as a common practice, especially for complex therapeutics like ADCs. The enhanced collaboration among biotechnology companies to advance the R&D and commercialization of ADCs also contributes substantially to the growth of the ADC market. Overall, synergistic collaboration models have become increasingly instrumental in bringing novel candidates to the market.

The future development of ADCs is likely to witness the following trends:

- ***Novel payloads and linkers***. Although traditional payloads have been proven to be effective, there is a growing focus on exploring novel payloads to expand the range of treatable cancer types and overcome drug resistance, as more patients are treated with, and acquire resistance to, existing ADCs. In addition, beyond the site-specific conjugation methods of existing ADCs, researchers are exploring more sophisticated linker designs aimed to further improve payload delivery and release while reducing off-target toxicity.

- ***Wider coverage of targets and expression levels***. Expression level refers to the quantity of specific targets present on the surface of cells. Many solid tumors express low or heterogeneous levels of targets, limiting the applicability of existing ADCs that focus on tumors with high expression levels of targets. Research is underway to develop ADC candidates effective against solid tumors with low expression. For example, recent advancements in ADC design, including the development of topoisomerase-based payloads, have resulted in successful applications of HER2 ADCs for HER2-low BC patients. Novel targets such as HER3 and B7-H3 have also emerged, drawing significant industry attention. Research into these emerging targets aims to broaden the landscape of tumor antigens that can be leveraged for the selective delivery of cytotoxic payloads.

- ***Novel ADC formats.*** New formats such as bispecific and multi-specific ADCs are a rising trend in the development of next-generation ADCs. Compared to monospecific ADCs, BsADCs can potentially target and kill tumor cells more precisely by simultaneously targeting two different antigens to overcome tumor heterogenicity, and reduce the risk of off-target toxicity. Some BsADCs can also harness the patient's own immune system through simultaneous immune-modulation to achieve synergistic anti-tumor effects. Moreover, BsADCs can potentially overcome drug resistance to monospecific ADCs by blocking escape pathways, making them more promising for extended duration of response.

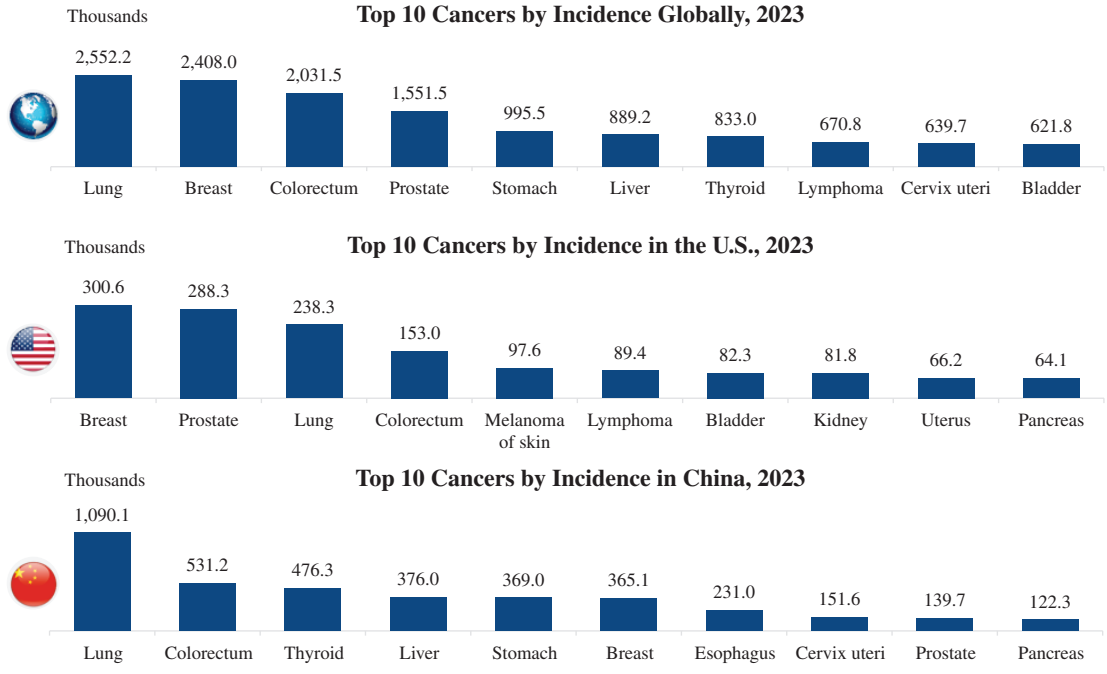
- ***Expansion to non-oncology therapeutic areas.*** With technological advances in progress, ADCs are expected to cover a wider range of cancer types as well as expand to non-oncology areas such as autoimmune, metabolic and cardiovascular diseases. With the ability to minimize off-target effects and systemic toxicity through targeting specificity, ADCs have become a promising option for these chronic, non-oncology conditions that require treatments with improved safety profiles. This expansion is likely to bring new market potential for ADCs in the near future.

- ***Combination with other treatment modalities and expansion of treatment lines.*** The mechanism of action of ADCs is highly synergistic with other treatment modalities to potentiate tumor cell killing. Combination strategies have shown to be crucial in improving efficacy and promising as first-line treatments for a broader

patient population. Notably, a strong biological rationale supports the investigation of combining ADCs with IO to overcome the occurrence of resistance and improve treatment outcomes for cancer patients. ADCs interact with cancer cells and immune cells through mechanisms such as immunogenic cell death, antibody-dependent cell mediated cytotoxicity and dendritic cell activation, leading to synergistic effects when combined with immunotherapies such as immune checkpoint inhibitors ("**ICIs**"). Combination therapies of ADCs with tyrosine kinase inhibitors ("**TKIs**") have also shown promise in clinical studies to enhance anti-tumor efficacy.

THE CANCER DRUG MARKET

Cancer is the leading cause of mortality worldwide, resulting in approximately 10 million deaths globally each year. Global cancer incidence reached 20.8 million in 2023 and is expected to reach 25.5 million in 2032. As illustrated in the charts below, lung cancer, BC and colorectal cancer ("**CRC**") were the top three cancers by global incidence in 2023, with 2,552 thousand cases, 2,408 thousand cases and 2,032 thousand cases, respectively.



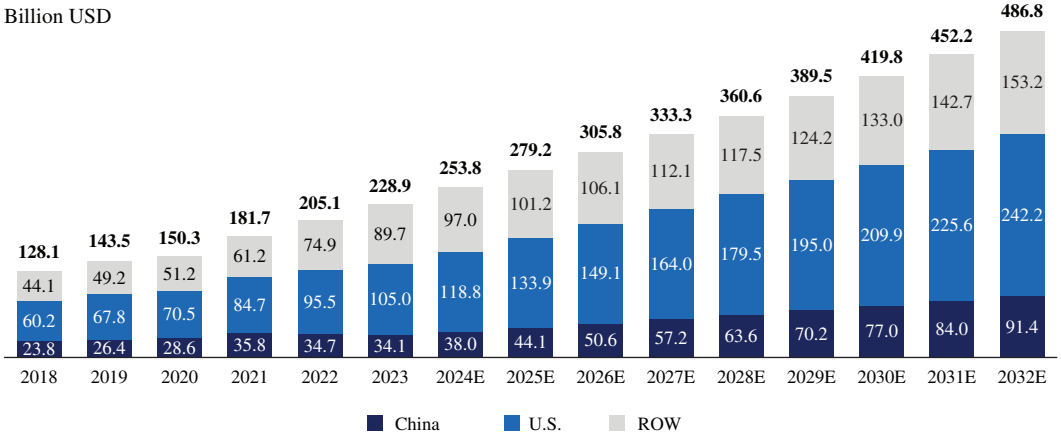
Source: Globocan, IARC, NCCR, Frost & Sullivan

Global Cancer Drug Market Size

In line with the continuous growth of cancer incidence, the global cancer drug market has expanded rapidly in recent years. The global cancer drug market grew from US$128.1 billion in 2018 to US$228.9 billion in 2023 at a CAGR of 12.3% and is expected to continue its growth at a CAGR of 9.5% and 7.8% from 2023 to 2028 and 2028 to 2032, respectively, and reach US$486.8 billion in 2032.

Global Cancer Drug Market, 2018-2032E

Period	CAGR			
	China	U.S.	ROW	Global
2018-2023	7.5%	11.8%	15.2%	12.3%
2023-2028E	13.2%	11.3%	5.5%	9.5%
2028E-2032E	9.5%	7.8%	6.9%	7.8%



Source: Frost & Sullivan

Despite the advancement of various cancer treatment modalities in recent years, there remains an unmet need for novel, differentiated therapies that can enhance the overall survival of cancer patients. These unmet needs have grown even more pressing as the patient population continues to expand.

GLOBAL HER2 ADC MARKET

Overview

HER2 is a cell surface receptor protein within the HER family that plays a key role in regulating cellular growth, division and survival. Upon activation by ligand binding or overexpression, HER2 dimerizes with other HER family members, leading to the activation of downstream signaling cascades such as the PI3K/AKT and MAPK/ERK pathways. These pathways promote cell proliferation, inhibit apoptosis, and enhance cell migration and invasion. HER2 is expressed in normal tissues at a low level, but its aberrant activation through overexpression in tumor cells promotes their growth and survival, thus driving the development of various types of cancers. HER2 has become a well-established cancer drug target with successful HER2-targeted therapies in different modalities, among which HER2 ADC represents one of the most successful strategies.

While HER2 is frequently overexpressed in tumor cells, expression levels can vary, requiring different therapeutic strategies. The table below sets forth the percentage of different tumor types with HER2+ and HER2 low expression levels.

Cancer	HER2+ (IHC 3+ or IHC 2+ /ISH +)	HER2 Low (IHC 2+/ISH- or IHC 1+)
Breast cancer	15–30%	45–55%
Endometrial cancer	17–30%	47–53%
Ovarian cancer	20–30%	60–70%
Colorectal cancer	5–6%	45–50%
Gastric cancer	9–38%	30–35%
Esophageal cancer	7–22%	N/A
Non-small cell lung cancer	7–23%	N/A

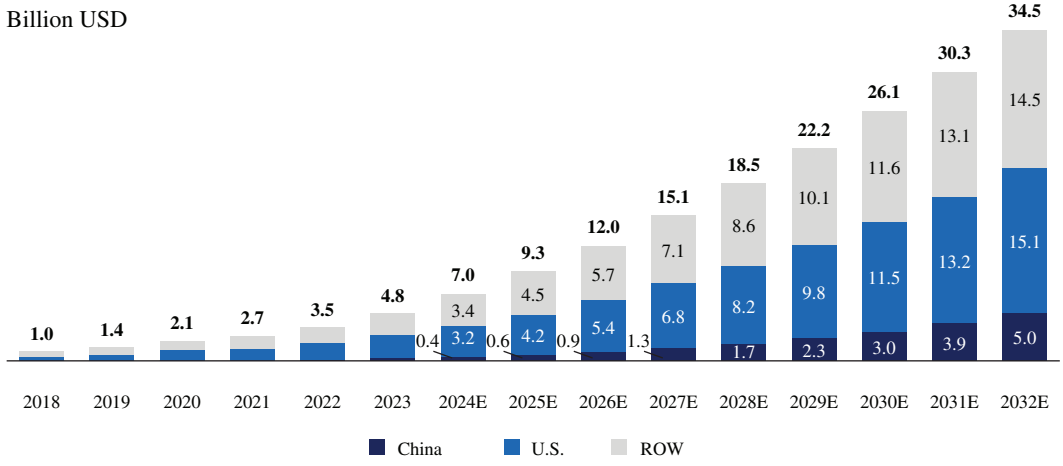
Sources: Literature review, Frost & Sullivan

Addressable Market Size

The first ADC targeting HER2 in the world, Kadcyla®, was approved in 2013. As shown in the chart below, the global HER2 ADC market increased to US$4.8 billion in 2023, representing a CAGR of 37.1% from 2018. The global HER2 ADC market is projected to increase at a CAGR of 30.8% and 16.8% from 2023 to 2028 and from 2028 to 2032, respectively, and reach US$34.5 billion in 2032. The chart below sets forth the growth of the global HER2 ADC market with a breakdown by major regions.

Global HER2 ADC Market Size, 2018-2032E

Period	CAGR			
	China	U.S.	ROW	Global
2018-2023	NA	44.5%	29.1%	37.1%
2023-2028E	46.0%	28.9%	30.4%	30.8%
2028E-2032E	30.7%	16.2%	14.0%	16.8%



Source: Frost & Sullivan

Market Opportunities of HER2 ADCs

Breast Cancer

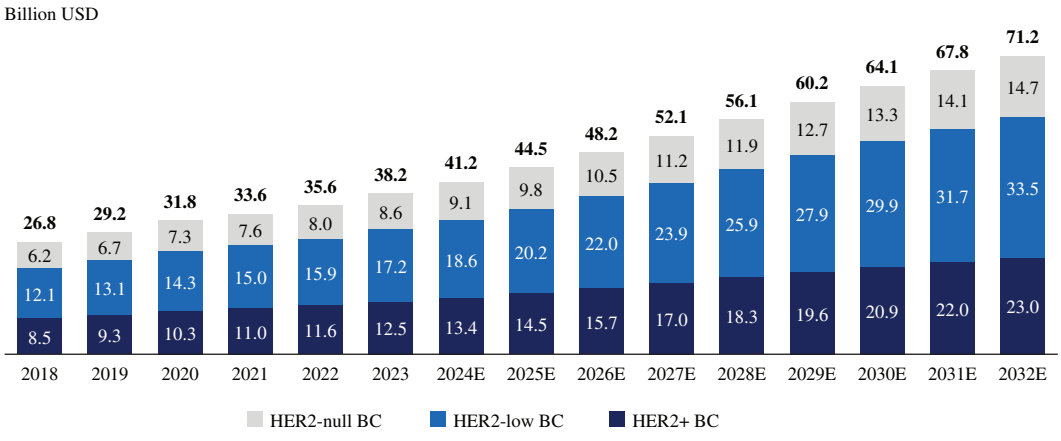
BC is the second largest cancer type in the world with incidence of approximately 2,408.0 thousand cases globally and 365.1 thousand cases in China in 2023. HER2 is expressed in approximately 70% of BC cases, with expression levels varying from high (IHC 3+ or IHC 2+/ISH+) to low (IHC 2+/ISH- or IHC 1+) to null (IHC 0). The table below sets forth the classification of HER2 expression by IHC scores and their respective percentages in total BC cases.

Classification of HER2 Expression in BC Patients	
HER2 Positive (IHC 3+ or IHC 2+/ISH+)	~15-30%
HER2 Low (IHC 2+/ISH- or IHC 1+)	~45-55%
HER2 Null (IHC 0)	~15-40%

The global BC drug market grew from US$26.8 billion in 2018 to US$38.2 billion in 2023 at a CAGR of 7.4%, and is expected to increase to US$56.1 billion and US$71.2 billion in 2028 and 2032, respectively, representing a CAGR of 8.0% from 2023 to 2028 and 6.1% from 2028 to 2032. The chart below sets forth the growth of the global BC drug market with a breakdown by HER2 expression level.

Global Breast Cancer Drug Market Size, 2018-2032E

Period	CAGR			
	HER2-null BC	HER2-low BC	HER2+ BC	Total
2018-2023	6.6%	7.3%	8.0%	7.4%
2023-2028E	6.9%	8.5%	8.0%	8.0%
2028E-2032E	5.4%	6.7%	5.9%	6.1%



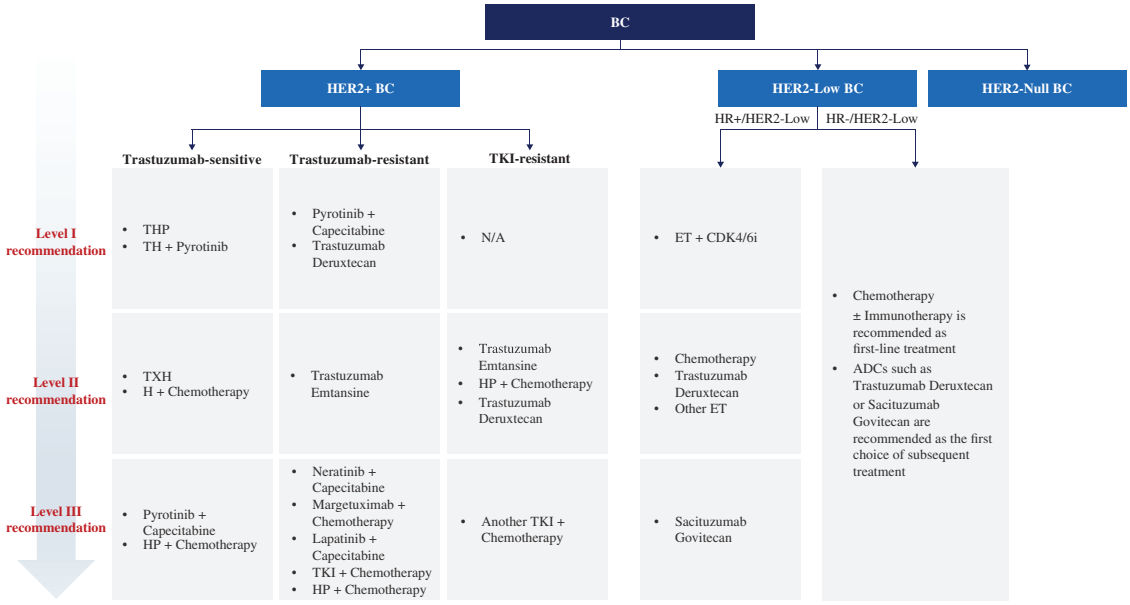
Source: Frost & Sullivan

The current treatment landscape of BC primarily consists of chemotherapy, monoclonal antibodies ("**mAbs**"), immune checkpoint inhibitors such as PD-(L)1 inhibitors and small molecule inhibitors such as CDK4/6 inhibitors, as well as ADCs which represent a novel treatment modality.

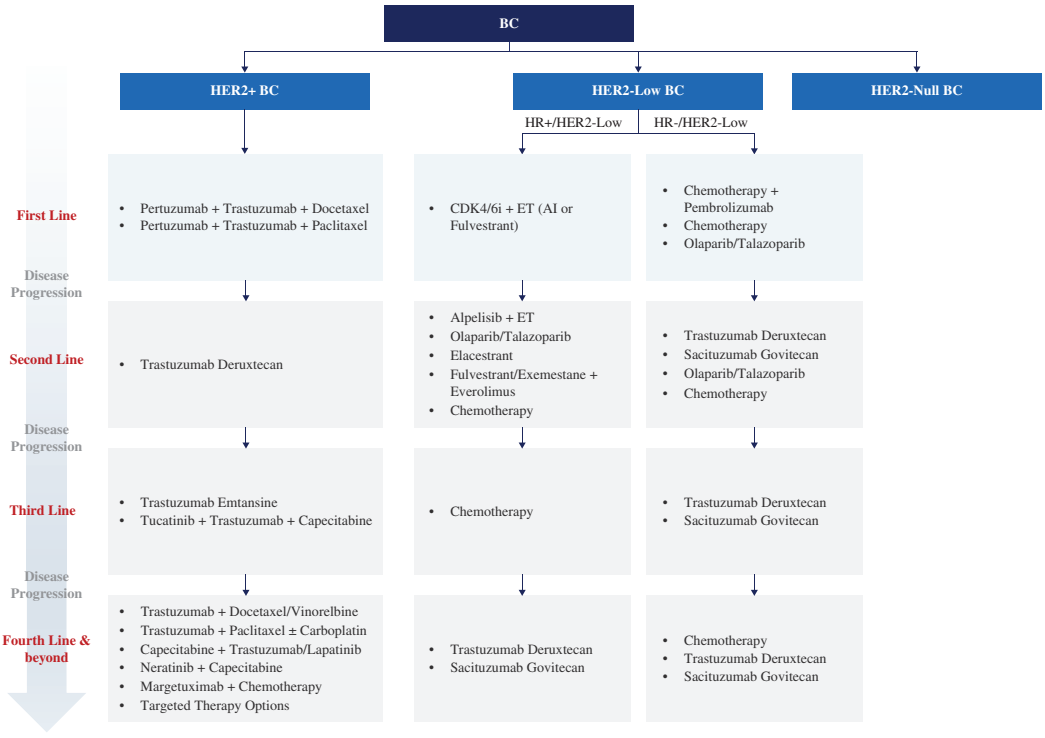
As of the Latest Practicable Date, Kadcyla® and Enhertu® were the only two HER2 ADCs indicated for BC approved both in the U.S and in China. Traditionally, HER2 ADCs were designed to target and were believed to be effective only against HER2+ BC. However, HER2+ BC patients account for less than one third of the total BC patient population, leaving the HER2-low and HER2-null population untreated. Recent advancements in ADC design, including the development of topoisomerase-based payloads, have resulted in successful applications of HER2 ADCs for HER2-low BC patients. As of the Latest Practicable Date, only one HER2 ADC, Enhertu®, was approved for HER2-low BC and only for patients who have received a prior chemotherapy in the metastatic setting or developed disease recurrence during or within six months of completing adjuvant chemotherapy, highlighting an unmet need among the large HER2-low or null patient population.

The charts below set forth the subsets of BC patients as well as the treatment paradigm for BC in China and the U.S.

Treatment Paradigm for BC in China



Treatment Paradigm for BC in the U.S.



Note: Our Group's DB-1303 is being investigated as (i) a potential second-line (or later) treatment for HER2+ BC, with first-line potential to treat this patient group in combination with pertuzumab, and (ii) a potential treatment for chemo naïve HER2-low BC patients; Our Group's DB-1310 is being investigated as a potential treatment for HER2+ BC patients with prior Enhertu treatments.

Source: *CSCO 2024, NCCN 2024, A review of treatment options in HER2-low breast cancer and proposed treatment sequencing algorithm, Frost & Sullivan*

HER2-low BC

HER2-low BC is the most prevalent subtype of BC, accounting for approximately 50% of total BC cases. Global incidence of HER2-low BC increased from 1,044.4 thousand cases in 2018 to 1,204.0 thousand cases in 2023, and is projected to reach 1,597.9 thousand cases by 2032. Our Group's DB-1303 is being investigated as a potential treatment for chemo naïve HER2-low BC patients. Global incidence of chemo naïve HER2-low BC patients increased from 241.9 thousand cases in 2018 to 293.9 thousand cases in 2023 and are projected to reach 437.1 thousand cases in 2032.

The global HER2-low BC drug market increased from US$12.1 billion in 2018 to US$17.2 billion in 2023 at a CAGR of 7.3%, and is expected to increase to US$25.9 billion and US$33.5 billion in 2028 and 2032, respectively, representing a CAGR of 8.5% from 2023 to 2028 and 6.7% from 2028 to 2032.

In China, for HR+/HER2-low BC patients who have not undergone CDK4/6 inhibitor treatment, endocrine therapies ("**ETs**") with CDK4/6 inhibitor are recommended as level I treatment option. For patients with prior CDK4/6 inhibitor treatment, trastuzumab deruxtecan (Enhertu®, HER2 ADC), chemotherapy and other ET-based therapies are recommended as level II treatment options. Sacituzumab govitecan (Trodelvy®, TROP2 ADC) is recommended as level III treatment. For HR-/HER2-low BC patients, chemotherapy with or without immunotherapy is recommended as first-line treatment. ADCs such as trastuzumab deruxtecan or sacituzumab govitecan are recommended as the first choice of subsequent treatment.

In the U.S., for hormone receptor positive ("**HR+**")/HER2-low BC patients, ET-based therapy with CDK4/6 inhibitors is recommended as first-line treatment. Second-line treatments include targeted therapies such as alpelisib, olaparib and talazoparib, and estrogen receptor degrader such as elacestrant, which are recommended based on driver mutations status. Chemotherapy is also used in second-line or later settings for patients with imminent organ failure or rapid progressive disease. Trastuzumab deruxtecan and sacituzumab govitecan are used in third-line or later settings. For hormone receptor negative ("**HR-**")/HER2-low BC patients, chemotherapy with or without pembrolizumab can be considered as first-line treatment. Trastuzumab deruxtecan and sacituzumab govitecan are recommended to be used in the second-line setting or later.

The current treatment paradigm for HER2-low BC has significant limitations. ETs, such as aromatase inhibitors and a selective estrogen receptor degrader, represent the cornerstone of standard first-line and second-line treatment options for advanced HER2-low BC in China and the U.S. However, the recurrence rate after using ETs is approximately 40-50%. Limited effective treatment options are available for recurrent patients, leaving a need for effective non-ET-based treatment.

HER2+ BC

HER2+ BC is an aggressive type of BC, representing approximately 15-30% of total BC cases. Up to 10% of HER2+ BC patients present with late-stage tumors that are challenging to treat at the time of diagnosis, and 20% of early-stage patients eventually develop advanced disease. The global incidence of HER2+ BC increased from 470.0 thousand cases in 2018 to 541.8 thousand cases in 2023 and is expected to reach 719.0 thousand cases in 2032. Our Group's DB-1303 is being investigated as a potential second-line (or later) treatment for HER2+ BC, with first-line potential to treat this patient group in combination with pertuzumab. Global incidence of HER2+ BC patients requiring first-line treatment increased from 172.8 thousand cases in 2018 to 200.4 thousand cases in 2023 and are projected to reach 264.8

thousand cases in 2032. Global incidence of HER2+ BC patients requiring second-line (or later) treatment increased from 124.4 thousand cases in 2018 to 147.3 thousand cases in 2023 and are projected to reach 201.8 thousand cases in 2032.

The global HER2+ BC drug market increased from US$8.5 billion in 2018 to US$12.5 billion in 2023 at a CAGR of 8.0%, and is expected to increase to US$18.3 billion and US$23.0 billion in 2028 and 2032, respectively, representing a CAGR of 8.0% from 2023 to 2028 and 5.9% from 2028 to 2032.

In China, treatments for HER2+ BC are generally categorized based on three patient types: trastuzumab-sensitive patients, trastuzumab-resistant patients and TKI-resistant patients. For trastuzumab-sensitive patients, level I recommended treatments include (i) combination therapy of docetaxel, trastuzumab and pertuzumab, (ii) combination therapy of docetaxel and trastuzumab plus pyrotinib. Level II recommended treatments include (i) combination therapy of docetaxel, capecitabine and trastuzumab, and (ii) trastuzumab with chemotherapy. Level III recommended treatments include (i) pyrotinib plus capecitabine, and (ii) combination therapy of trastuzumab and pertuzumab plus chemotherapy. For trastuzumab-resistant patients, trastuzumab deruxtecan (Enhertu®, HER2 ADC) is recommended as a level I treatment option, and trastuzumab emtansine (Kadcyla®, HER2 ADC) as a level II treatment option. For TKI-resistant patients, trastuzumab deruxtecan and trastuzumab emtansine are also recommended as level II treatment options.

In the U.S., for recurrent unresectable HER2+ BC eligible for HER2 mAb treatment, first-line treatments comprise taxane-based chemotherapy in combination with pertuzumab and trastuzumab (HER2 mAbs) and second-line options include trastuzumab deruxtecan. Combination therapies such as tucatinib and trastuzumab plus capecitabine, and trastuzumab emtansine (Kadcyla®, HER2 ADC) are recommended in third-line or later settings.

With the approval of effective treatments such as HER2 ADCs in recent years, HER2+ BC patients have experienced increased progression free survival ("**PFS**") and overall survival ("**OS**"). However, there is still a risk of acquired resistance and need for safer treatments for long-term use. Approved HER2 ADCs, Kadcyla®, for example, carry a black box warning issued by the FDA for hepatic, cardiac and embryo-fetal toxicities, indicating the need for future improvements in safety profiles of HER2 ADCs.

Endometrial Cancer

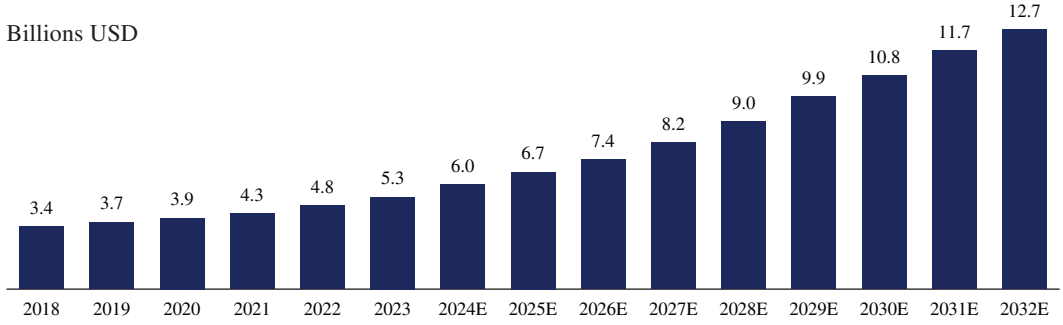
Endometrial cancer is one of the most common gynecological cancers in the world. As one of the fastest growing cancers in terms of incidence, new cases of EC increased from 343.9 thousand in 2018 to 401.7 thousand in 2023 and are projected to reach 494.1 thousand in 2032. While EC has traditionally been more prevalent in post-menopausal women, there is a growing incidence in younger women, indicating increasing medical needs. HER2 overexpression is reported in 17-30% of total EC cases and HER2 low-expression is reported in 47-53% of total EC cases. Our Group's DB-1303 is being investigated as a potential second-line (or later)

treatment for HER2-expressing EC patients. Global incidence of HER2-expressing EC patients requiring second-line (or later) treatment increased from 44.5 thousand cases in 2018 to 52.1 thousand cases in 2023 and are projected to reach 63.2 thousand cases in 2032.

The global EC drug market grew from US$3.4 billion in 2018 to US$5.3 billion in 2023 at a CAGR of 9.1%, and is expected to increase to US$9.0 billion and US$12.7 billion in 2028 and 2032, respectively, representing a CAGR of 11.2% from 2023 to 2028 and 8.9% from 2028 to 2032. The chart below sets forth the growth of the global EC drug market.

Global Endometrial Cancer Drug Market Size, 2018-2032E

Period	CAGR
2018-2023	9.1%
2023-2028E	11.2%
2028E-2032E	8.9%

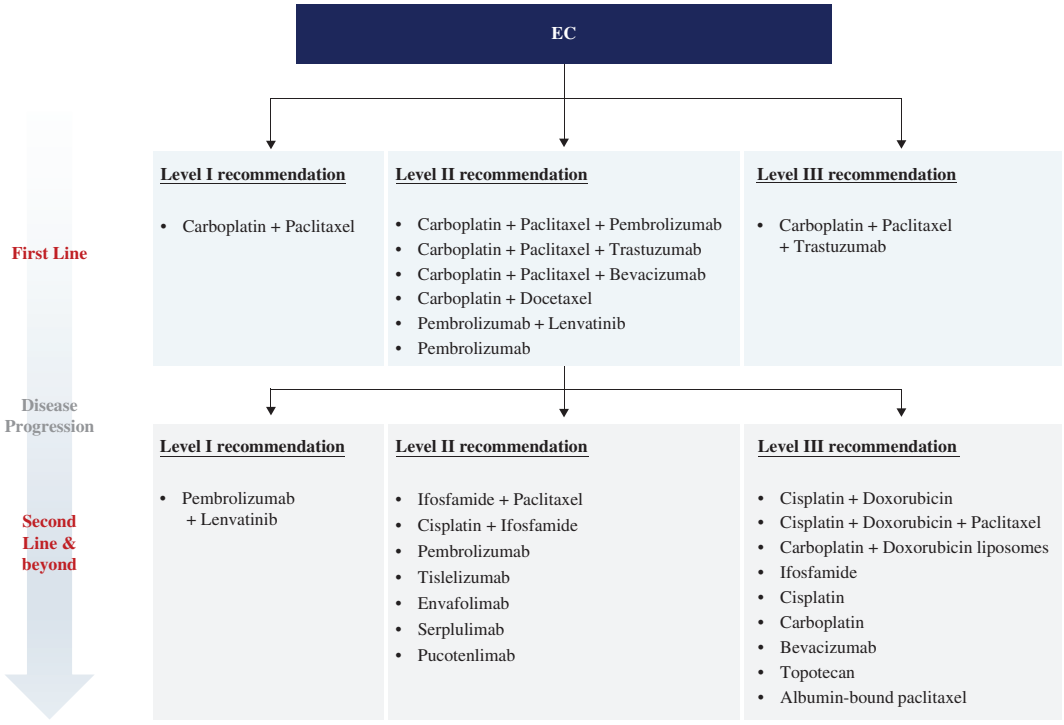


Source: Frost & Sullivan

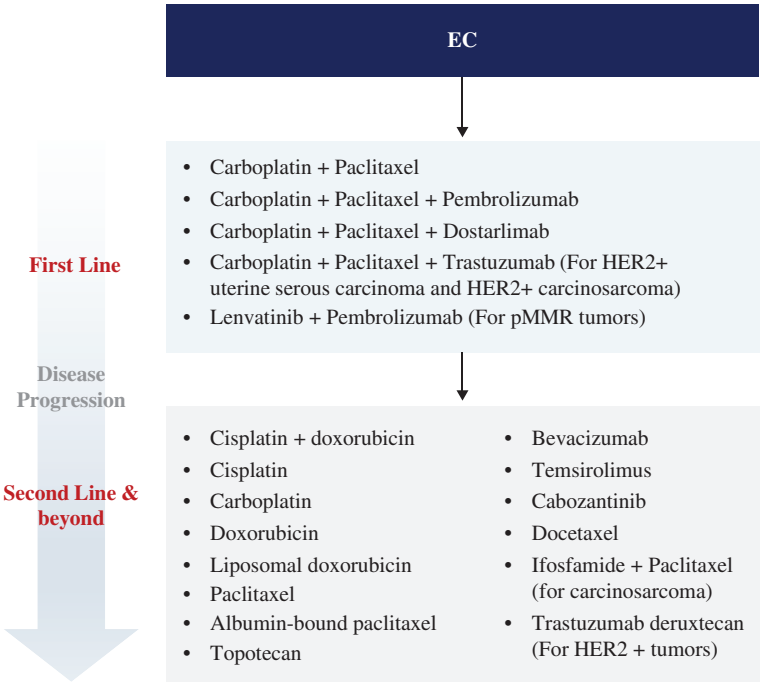
The current treatment landscape of EC primarily consists of chemotherapy, targeted therapies such as TKIs, hormone therapies, immune checkpoint inhibitors such as PD-(L)1 inhibitors, as well as ADCs which represent a novel treatment modality.

The charts below set forth the treatment paradigm for EC in China and the U.S.

Treatment Paradigm for EC in China



Treatment Paradigm for EC in the U.S.



Note: Our Group's DB-1303 is being investigated as a potential second-line (or later) treatment for HER2-expressing EC patients.

Source: CSCO 2024, NCCN 2024, Frost & Sullivan

In China, systemic therapy for recurrent and metastatic EC use carboplatin with paclitaxel as level I recommended treatment. Level II treatment options include (i) combination therapies of carboplatin with paclitaxel plus trastuzumab or bevacizumab, and (ii) combination therapy of carboplatin with docetaxel. In second-line setting, level I recommended treatment options include pembrolizumab plus lenvatinib.

In the U.S., first-line treatment options for recurrent disease include (i) combination therapy of carboplatin and paclitaxel with or without pembrolizumab or dostarlimab, (ii) combination therapy of carboplatin and paclitaxel with or without trastuzumab for HER2+ patients. Second-line treatment options include (i) combination therapy of cisplatin and doxorubicin with or without paclitaxel, (ii) combination therapy of cisplatin with gemcitabine, (iii) monotherapy of cisplatin, carboplatin or doxorubicin and others.

The current treatment paradigm for EC has significant limitations. For patients not suitable for total hysterectomy, traditional drug treatments have substantial side effects. In addition, a significant percentage of patients develop advanced and recurrent disease after first-line treatment, and have limited response to second- or third-line treatment.

As of the Latest Practicable Date, no HER2 ADC had been approved for EC across HER2-expression levels globally, and DB-1303 was the only HER2 ADC candidate in phase 3 clinical development or beyond for EC patients across HER2 expression levels.

Competitive Landscape

As of the Latest Practicable Date, there were two HER2 ADCs approved both in the U.S. and in China, namely Enhertu® and Kadcyla®, and one additional approved in China, Aidixi®. As of the same date, there were three HER2 ADCs (including Enhertu®) in phase 3 clinical development or beyond under global multi-regional clinical trials ("**MRCTs**"). The following tables illustrate the competitive landscape of marketed HER2 ADCs and HER2 ADC in phase 2 clinical development or beyond.

Marketed HER2 ADCs Globally

Brand Name (Chemical Name; Code Name)	Company	Indications	Treatment Line	FDA First Approval	NMPA First Approval	Price	NRDL Inclusion	U.S. Insurance/ Assistance Program Coverage	Patent Expiry Date	Global Sales in 2023
Kadcyla® (Ado-trastuzumab emtansine; T-DM1)	Roche	HER2+ BC	≥2L	2013.02	2021.06	US$4,148/ 100mg	Yes	100%	Not available	US$2,188.1 million
		HER2+ Early BC	Adjuvant	2019.05	2020.01					
Enhertu® (Trastuzumab deruxtecan; DS-8201)	Daiichi Sankyo Astra-Zeneca	HER2+ BC	≥3L	2019.12	N/A	US$2,967/ 100mg	No	100%	2033 (US) 2033-2035 (China and EU)	US$2,566.0 million
		HER2+ GC or GJA	≥2L	2021.01	2024.08					
		HER2+ BC		2022.05	2023.02					
		HER2-Low BC		2022.08	2023.07					
		HER2m NSCLC		2022.08	N/A					
		HER2+ Solid Tumors		2024.04	N/A					
		HR+/HER2-Low or HER2-Ultralow BC		2025.01	N/A					
Aidixi® (Disitamab vedotin; RC48)	RemeGen	HER2-Overexpressing GC	≥3L	N/A	2021.06	RMB3,800/ 60mg[1]	Yes	N/A	2034 (China) 2034 (US)	N/A[2]
		HER2-Overexpressing UC	≥2L		2022.01					

Notes:

(1) Represents price after medical insurance reimbursement.

(2) Sales revenue of Aidixi® is not publicly available.

Sources: FDA, NMPA, Drug.com, annual reports, Frost & Sullivan

HER2 ADCs under Global MRCTs (Phase 2 or beyond)

Drug Name	Company	Indications	Phase of Trial	First Post Date[3]	Location
DS-8201[1]	Daiichi Sankyo /AstraZeneca	NSCLC Harboring HER2 Exon 19 or 20 Mutations	Phase 3	2021-09	Global
		Biliary Tract Cancer	Phase 3	2024-06	Global
		HER2-Low or HER2- Null BC	Phase 3	2024-09	Global
		HER2+, pMMR EC	Phase 3	2024-11	Global
		HER2-Overexpressing CRC	Phase 2	2021-02	Global
		HER2-Expressing Tumors, incl. EC	Phase 2	2020-07	Global
DB-1303/BNT323[4]	Our Group /BioNTech	HR+/HER2-Low BC	Phase 3	2023-08	Global
		HER2-Expressing EC	Phase 3	2024-04	Global
SYD985	Byondis	HER2+ BC	NDA[2]	2022-07	Global
		HER2-Expressing EC	Phase 2	2019-12	Global
ARX788	Ambrx/Novo Codex	HER2+ BC	Phase 2	2021-04	Global
RC48	RemeGen /Seagen	HER2-Expressing UC	Phase 2	2021-05	Global
		HER2-Expressing Solid Tumors, incl. EC	Phase 2	2023-08	Global
DX126-262	DAC Biotech	HER2+ BC	Phase 2	2021-08	Global

Notes:

(1) DS-8201 (Enhertu®, trastuzumab deruxtecan), first approved by the FDA in December 2019 for HER2+ BC, is currently under clinical development for new indications.

(2) In May 2023, FDA issued a complete response letter to Byondis on SYD985, which requested additional information that will require additional time and resources that extend beyond the current evaluation period.

(3) First post date is the date on which the study record was first published on *ClinicalTrials.gov* or CDE's website, which may be different from the date on which a trial is initiated.

(4) DB-1303/BNT323 obtained Fast Track and Breakthrough Therapy Designations from the FDA in January and December 2023, respectively, and Breakthrough Therapy Designation from the NMPA in March 2024 for the treatment of advanced EC in patients who progressed on or after treatment with immune checkpoint inhibitors. For details on the requirements of Fast Track and Breakthrough Therapy Designations, please refer to "Regulatory Overview — PRC Regulation — Regulations on Pharmaceutical Product — Accelerated Approval for Clinical Trial and Registration" and "Regulatory Overview — Overview of Laws and Regulations in the United States — Laws and Regulations in Relation to New Drug — Expedited Development and Review Programs."

Other HER2 ADCs under Clinical Development (Phase 2 or beyond)

Drug Name	Company	Indications	Phase of Trial	First Post Date[1]	Location
A166	Kelun-Biotech	HER2+ BC	NDA	2023-05	China
DS-8201	Daiichi Sankyo/ AstraZeneca	GC	NDA	2023-12	China
		NSCLC	NDA	2024-02	China
		HER2-Overexpressing Solid Tumors	Phase 2	2024-03	China
DB-1303/BNT323	Our Group/BioNTech	HER2+ BC	Phase 3	2023-11	China
RC48	RemeGen	HER2-Low BC	Phase 3	2020-05	China
		HER2-Overexpressing GC	Phase 3	2021-01	China
		HER2-Expressing UC	Phase 3	2022-03	China
		HER2+ BC	Phase 2/3	2018-04	China
		HER2- UC	Phase 2	2019-08	China
		HER2-Overexpressing BTC	Phase 2	2020-04	China
		HER2-Expressing Gynecological Malignancies	Phase 2	2021-07	China
		Muscle-Invasive Bladder Cancer	Phase 2	2022-03	China
		Cervical Cancer	Phase 2	2023-12	China
SHR-A1811	Hengrui Pharmaceuticals	HER2+ BC	Phase 3	2022-06	China
		HER2-Low BC	Phase 3	2023-04	China
		HER2+ GC or GJA	Phase 3	2023-11	China
		CRC	Phase 3	2023-12	China
		HER2m NSCLC	Phase 3	2024-05	China
		Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer	Phase 3	2025-02	China
		HER2+ BTC	Phase 2	2025-02	China
MRG002	Miracogen	HER2+ UC	Phase 3	2023-01	China
		HER2+ BC	Phase 2/3	2021-05	China
		HER2-Low BC	Phase 2	2021-02	China
		HER2+/HER2-Low GC or GJA	Phase 2	2021-11	China
FS-1502	Fosun Pharma	HER2+ BC	Phase 3	2023-02	China
		NSCLC	Phase 2	2022-01	China
		RAS/BRAF Wild-Type HER2+ CRC	Phase 2	2022-01	China
		HER2-Expressing GC	Phase 2	2022-09	China
DP303c	CSPC Group	HER2+ BC	Phase 3	2023-06	China
		HER2-Expressing OC	Phase 2	2021-03	China
		HER2-Expressing GC	Phase 2	2021-04	China
JSKN003	Alphamab	HER2-Low BC	Phase 3	2023-10	China
		Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer	Phase 3	2024-12	China
		HER2+ BC	Phase 3	2025-02	China
BL-M07D1	Sichuan Biokin	HER2+ BC	Phase 3	2024-03	China
		HER2+ GC or GJA	Phase 2	2024-05	China
TQB2102	Chia Tai Tianqing	HER2-Low BC	Phase 3	2024-08	China
		HER2+ BC	Phase 2	2024-01	China
		HER2-IHC 0 BC	Phase 2	2024-03	China
		HER2- BC	Phase 2	2024-06	China
		HER2 Gene Abnormality NSCLC	Phase 2	2024-07	China
		HER2+ GEA	Phase 2	2024-10	China
		Gynecological Tumor	Phase 2	2025-02	China
ARX788	Ambrx/NovoCodex	HER2+ BC	Phase 2/3	2020-06	China
		HER2+ GC or GJA	Phase 2/3	2021-06	China
GQ1005	GeneQuantum	HER2+ BC	Phase 3	2024-12	China
IBI354	Innovent	Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer	Phase 3	2025-02	China
BB-1701	Eisai/Bliss Biopharmaceutical	HER2-Mutated NSCLC	Phase 2	2023-11	China
		HER2+ or HER2-low BC	Phase 2	2024-01	U.S., Japan
		HER2-Expressing or HER2-Mutated Solid Tumors	Phase 2	2024-09	China
FDA022-BB05	Shanghai Fudan-Zhangjiang	HER2-Expressing EC, HER2-Low BC and HER2-Overexpressing Solid Tumors	Phase 2	2024-04	China
SHR-4602	Hengrui Pharmaceuticals	HER2-Expressing or HER2-Mutated Solid Tumors	Phase 2	2024-07	China

Note:

(1) First post date is the date on which the study record was first published on *ClinicalTrials.gov* or CDE's website, which may be different from the date on which a trial is initiated.

Sources: Clinicaltrials.gov, CDE, Frost & Sullivan

The following table illustrates the key features of DB-1303 alongside Enhertu® (DS-8201), Kadcyla® and Aidixi®, the only three FDA and/or NMPA-approved HER2 ADCs as of the Latest Practicable Date.

ADC design of HER2 ADCs (DB-1303, Enhertu® (DS-8201), Kadcyla® and Aidixi®)

	DB-1303	Enhertu® (DS-8201)	Kadcyla®	Aidixi®
Antibody	Trastuzumab	Trastuzumab	Trastuzumab	Disitamab
Linker	Tetrapeptide-based cleavable linker	GGFG linker	MCC linker	Val-Cit linker
Payload	P1003, an exatecan derivative and a moderately potent TOPO I inhibitor	Dxd, an exatecan derivative and a moderately potent TOPO I inhibitor	DM1, a maytansine derivative and a highly potent tubulin inhibitor	MMAE, a highly potent tubulin inhibitor
DAR	8	8	3.5	4

Source: Literature review, Frost & Sullivan

GLOBAL B7-H3 ADC MARKET

Overview

B7-H3 is a prominent member of the B7 family that plays a critical role in promoting tumor progression and metastasis. B7-H3 can effectively inhibit the function of T cells and NK cells, and inhibit the production of cytokines, thus possibly promoting the immune escape of cancer cells. High expression of B7-H3 is widely observed in various solid tumors, including lung cancer, BC and prostate cancer. B7-H3 is an active area of research and a potential therapeutic target for its role in tumor immune evasion, making it a potential backbone treatment target for multiple cancer types. The table below sets forth the B7-H3 expression rate in different cancer types.

Cancer	B7-H3 Expression
Castration-resistant prostate cancer	93%
Hepatocellular carcinoma	92%
Non-small cell lung cancer	74%
Small-cell lung cancer	65%
Gastric cancer	58%
Breast cancer	57-74%

Sources: Literature review, Frost & Sullivan

As of the Latest Practicable Date, no B7-H3-targeting drug had been approved globally. Clinical development has been conducted to develop therapies leveraging B7-H3's role in inhibiting tumor growth and enhancing anti-tumor immunity in various cancers. Despite the current absence of approved B7-H3-targeted therapies, recent advancements in B7-H3 ADCs have demonstrated encouraging clinical efficacy, sparking substantial interest and high-profile licensing deals in the field. For example, in 2023, Merck & Co and GSK in-licensed B7-H3 ADC candidates from Daiichi Sankyo and Hansoh Pharma, respectively. In the same year, our Group entered into an out-license and collaboration agreement to grant BioNTech the rights to develop and commercialize DB-1311, also a B7-H3 ADC, outside Mainland China, Hong Kong and Macau.

Market Opportunities of B7-H3 ADCs

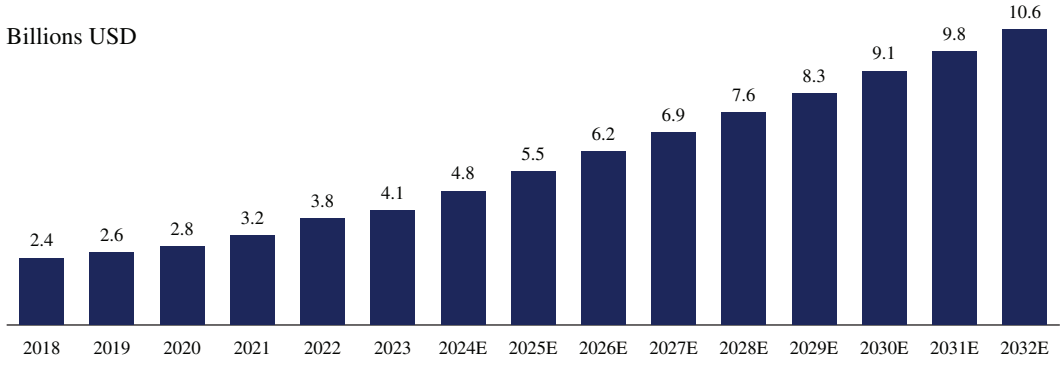
Small-cell Lung Cancer

Lung cancer is the most common cancer and the leading cause of cancer death worldwide. SCLC represents 10-15% of all lung cancer cases globally. The global incidence of SCLC increased from 332.9 thousand cases in 2018 to 382.8 thousand cases in 2023, and is projected to reach 484.1 thousand cases by 2032. In China, incidence of SCLC increased from 142.7 thousand cases in 2018 to 163.5 thousand cases in 2023, and is projected to reach 202.1 thousand cases by 2032. SCLC has two stages: limited stage, which is confined to one side of the chest, and extensive stage, which spreads beyond the chest to other body parts. As a highly aggressive cancer, the average five-year survival rate for SCLC patients in extensive stage is less than 5%. B7-H3 is expressed in approximately 65% of SCLC cases. The global incidence of B7-H3-overexpressing SCLC increased from 199.7 thousand cases in 2018 to 229.7 thousand cases in 2023, and is projected to reach 290.5 thousand cases by 2032. Our Group's DB-1311 is being investigated as a potential second-line (or later) treatment for SCLC patients, with combination potential to expand into earlier treatment lines. Global incidence of SCLC patients requiring first-line treatment increased from 243.6 thousand cases in 2018 to 284.9 thousand cases in 2023, and is projected to reach 368.2 thousand cases in 2032. Global incidence of SCLC patients requiring second-line (or later) treatment increased from 127.1 thousand cases in 2018 to 149.4 thousand cases in 2023, and is projected to reach 194.8 thousand cases in 2032.

The global SCLC drug market grew from US$2.4 billion in 2018 to US$4.1 billion in 2023 at a CAGR of 11.9%, and is expected to increase to US$7.6 billion and US$10.6 billion in 2028 and 2032, respectively, representing a CAGR of 13.0% from 2023 to 2028 and 8.7% from 2028 to 2032. The chart below sets forth the growth of the global SCLC drug market.

Global SCLC Drug Market Size, 2018-2032E

Period	CAGR
2018-2023	11.9%
2023-2028E	13.0%
2028E-2032E	8.7%

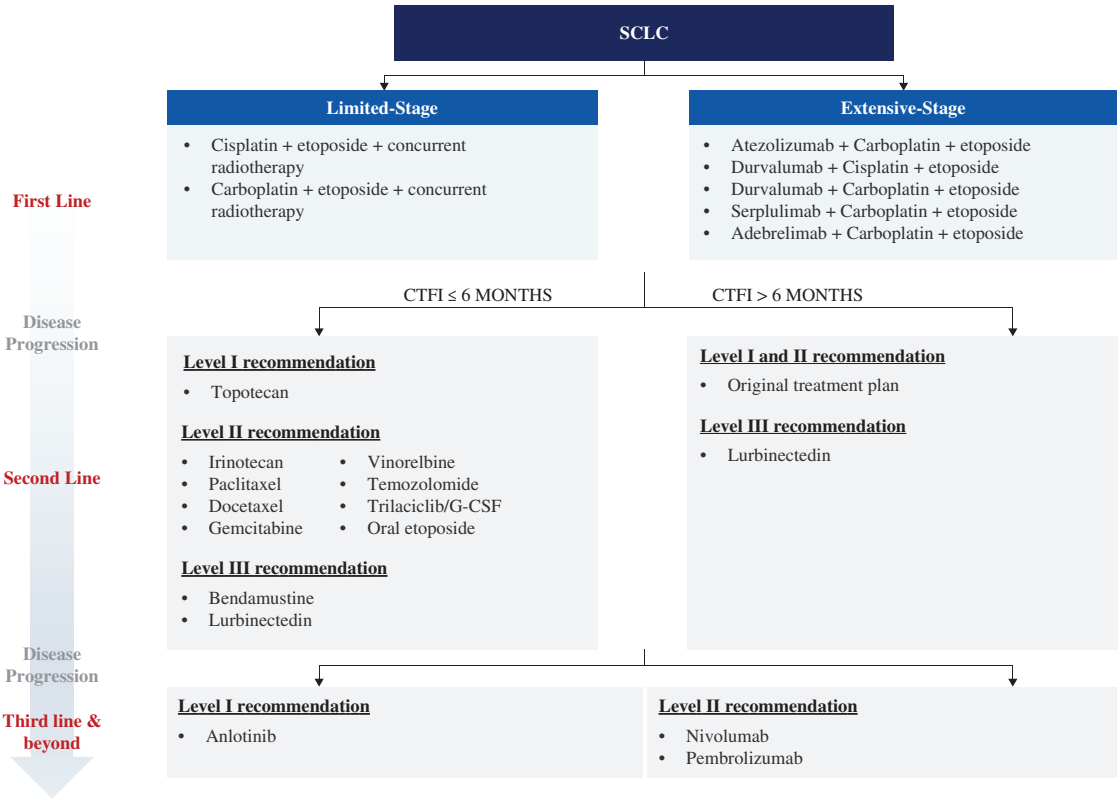


Sources: Frost & Sullivan

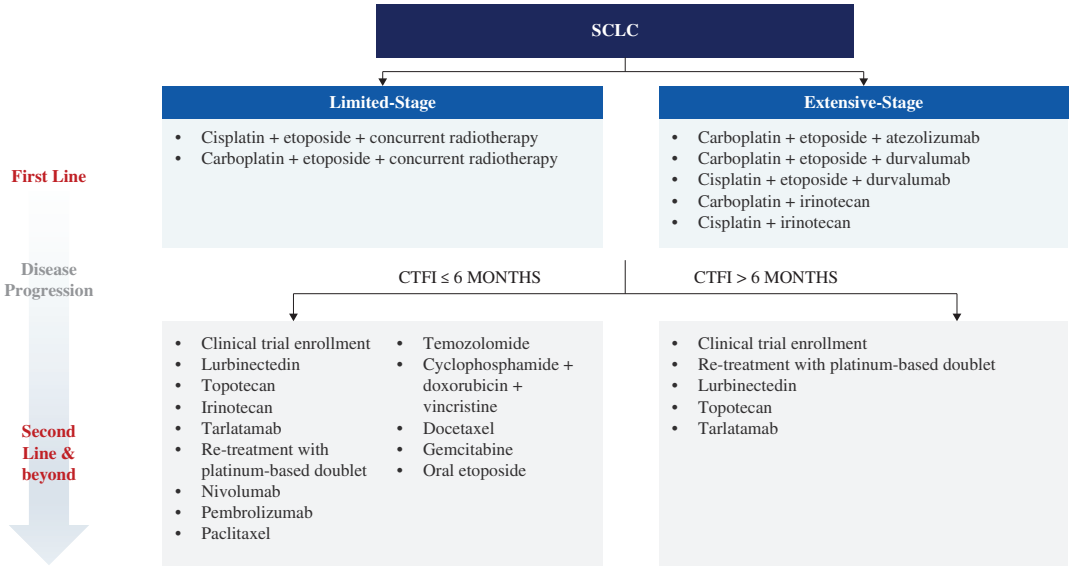
The current treatment landscape of SCLC primarily consists of platinum-based chemotherapy, radiotherapy and immune checkpoint inhibitors such as PD-(L)1 inhibitors. Novel treatment modalities, such as ADCs, are being investigated as a potential treatment for SCLC patients.

The charts below set forth the subsets of SCLC patients as well as the treatment paradigm for SCLC in China and the U.S.

Treatment Paradigm for SCLC in China



Treatment Paradigm for SCLC in the U.S.



Note: Our Group's DB-1311 is being investigated as a potential second-line (or later) treatment for SCLC patients, with combination potential to expand into earlier treatment lines.

Source: CSCO 2024, NCCN 2024, Frost & Sullivan

In China and the U.S., for limited stage SCLC patients, chemotherapy involving etoposide plus cisplatin with concurrent radiotherapy is recommended as first-line treatment.

For extensive stage SCLC patients in China, first-line treatment options include (i) chemotherapy of etoposide plus carboplatin, used in combination with atezolizumab or serplulimab or durvalumab or adebrelimab, and (ii) chemotherapy of etoposide plus cisplatin, used in combination with durvalumab. In second-line or later settings, topotecan, irinotecan and clinical trials enrollment are recommended.

For extensive stage SCLC patients in the U.S., first-line treatment options include (i) chemotherapy of etoposide plus carboplatin, used in combination with atezolizumab and durvalumab (PD-(L)1 inhibitors), and (ii) chemotherapy of etoposide plus cisplatin, used in combination with durvalumab (PD-(L)1 inhibitor). Subsequent lines of treatments include (i) platinum-based doublet chemotherapy, (ii) topotecan-based and taxane-based chemotherapy and other monotherapy such as lurbinectedin, and (iii) immunotherapies such as nivolumab and pembrolizumab (PD-(L)1 inhibitors).

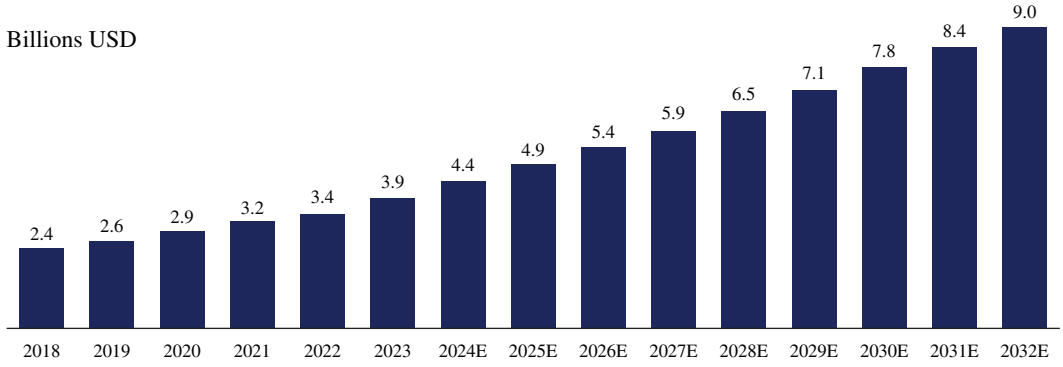
While chemotherapy is still the mainstay for SCLC treatment, SCLC patients often develop resistance to chemotherapy and the disease often relapses within one year. Relapsed SCLC patients often have worse prognosis, with limited treatment options available. While immunotherapies such as PD-(L)1 inhibitors are also recommended in frontline settings for extensive stage SCLC patients, there remains an unmet need for new and more effective treatments for SCLC patients. B7-H3 overexpression is reported in 65% of all SCLC cases, making it a promising target for novel treatments of SCLC.

Castration-resistant Prostate Cancer

CRPC is a severe form of prostate cancer that exhibits resistance to treatments aiming to reduce testosterone levels. B7-H3 is expressed in approximately 93% of CRPC cases. The global incidence of B7-H3-overexpressing CRPC increased from 158.8 thousand cases in 2018 to 183.5 thousand cases in 2023, and is projected to reach 220.3 thousand cases by 2032. The global CRPC drug market grew from US$2.4 billion in 2018 to US$3.9 billion in 2023 at a CAGR of 10.6%, and is expected to increase to US$6.5 billion and US$9.0 billion in 2028 and 2032, respectively, representing a CAGR of 10.9% from 2023 to 2028 and 8.4% from 2028 to 2032. The chart below sets forth the growth of the global CRPC drug market.

Global CRPC Drug Market Size, 2018-2032E

Period	CAGR
2018-2023	10.6%
2023-2028E	10.9%
2028E-2032E	8.4%



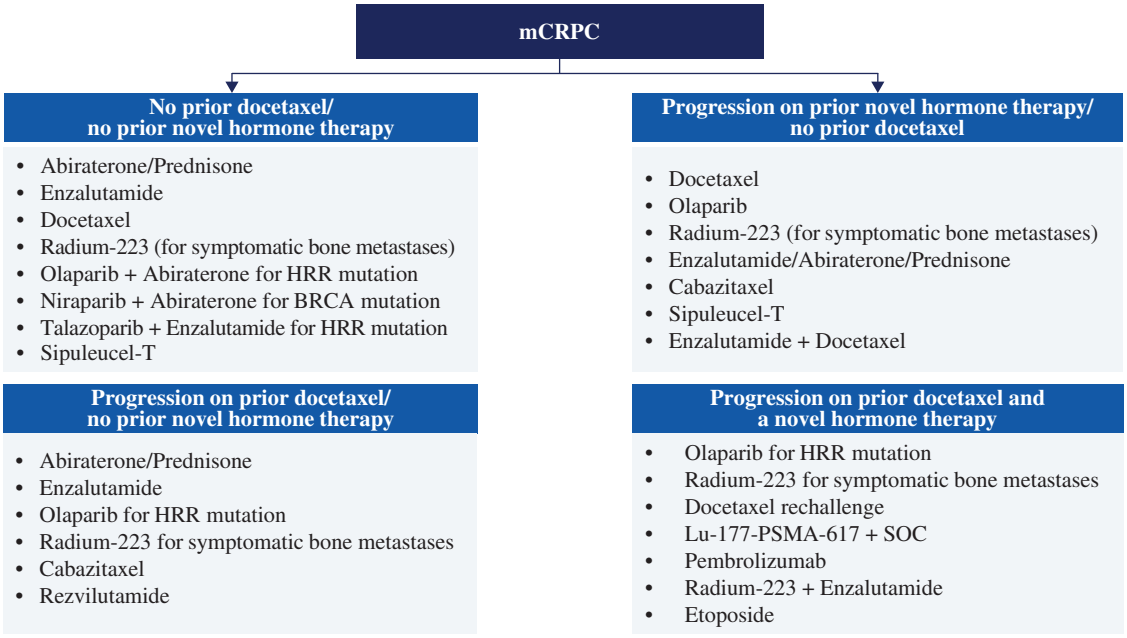
Sources: Frost & Sullivan

Among the subtypes of CRPC, metastatic CRPC ("**mCRPC**") is particularly advanced and challenging. The global incidence of mCRPC increased from 176.4 thousand cases in 2018 to 203.9 thousand cases in 2023 and is projected to reach 244.8 thousand cases by 2032. The incidence of mCRPC in China increased from 42.8 thousand cases in 2018 to 50.5 thousand cases in 2023, and is projected to reach 72.2 thousand cases by 2032. Our Group's DB-1311 is being investigated as a potential second-line (or later) treatment for mCRPC patients, with combination potential to expand into earlier treatment lines. Global incidence of mCRPC patients requiring first-line treatment increased from 162.3 thousand cases in 2018 to 189.6 thousand cases in 2023, and is projected to reach 232.1 thousand cases in 2032. Global incidence of mCRPC patients requiring second-line (or later) treatment increased from 108.7 thousand cases in 2018 to 127.5 thousand cases in 2023, and is projected to reach 157.1 thousand cases in 2032.

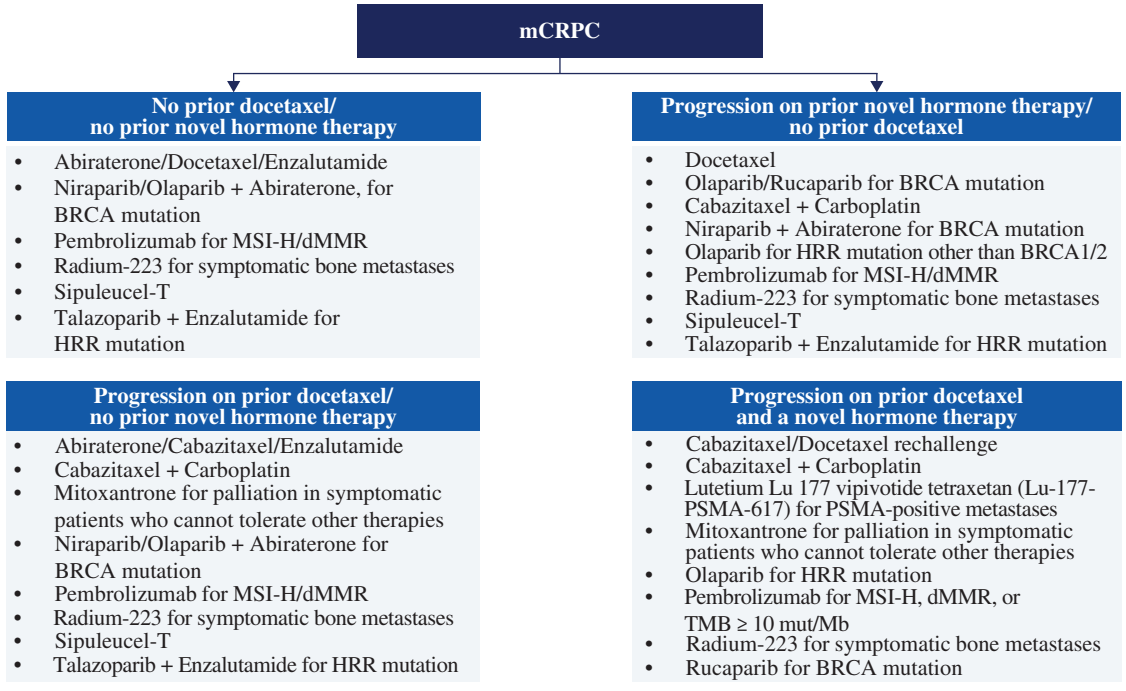
The current treatment landscape of mCRPC primarily consists of androgen deprivation therapy ("**ADT**"), chemotherapy, radiotherapy such as Radium-223, and PARP inhibitors. Novel treatment modalities, such as ADCs, are being investigated as a potential treatment for mCRPC patients.

The charts below set forth the treatment paradigm for mCRPC in China and the U.S.

Treatment Paradigm for mCRPC in China



Treatment Paradigm for mCRPC in the U.S.



Note: Our Group's DB-1311 is being investigated as a potential late-line treatment for CRPC patients, with combination potential to expand into earlier treatment lines.

Source: CSCO 2024, NCCN 2024, Frost & Sullivan

In China, for mCRPC patients without prior treatment of ADT and chemotherapy, level I recommended treatment options include (i) abiraterone or prednisone, (ii) olaparib plus abiraterone, (iii) enzalutamide, and (iv) docetaxel. For patients with ADT failure and without prior treatment of chemotherapy, docetaxel or olaparib is recommended as level I treatment. For patients with docetaxel treatment failure and without prior treatment of ADT, abiraterone, prednisone, enzalutamide or olaparib is recommended as level I treatment. For patients with docetaxel treatment failure and with prior treatment of chemotherapy, olaparib is recommended as level I treatment. Radium-223 is also recommended for patients with symptomatic bone metastases.

In the U.S., preferred regimens for mCRPC patients without prior docetaxel and novel hormone therapy consist of abiraterone, docetaxel and enzalutamide. For patients with disease progression after prior novel hormone therapy without prior docetaxel, preferred regimens consist of (i) docetaxel and (ii) olaparib or rucaparib. For patients with disease progression after prior docetaxel without prior novel hormone therapy, preferred regimens consist of abiraterone, cabazitaxel and enzalutamide. For patients with disease progression after prior docetaxel and novel hormone therapy, preferred regimens consist of cabazitaxel and docetaxel rechallenge. Other regimens include radium-223, niraparib and pembrolizumab, recommended based on metastases and mutation status.

The current treatment paradigm for mCRPC remains limited in its ability to provide durable and effective long-term control. Drug resistance remains a critical challenge in the treatment of mCRPC. While ADT like enzalutamide and abiraterone provides initial benefits, most patients eventually develop resistance, leading to disease progression, underscoring the potential of innovative targeted therapy to address this unmet need. With a B7-H3 expression rate as high as 93% in all CRPC cases, B7-H3 ADCs are a promising treatment option for CRPC.

Competitive Landscape

As of the Latest Practicable Date, there were no approved B7-H3 drugs, including ADCs, globally. As of the same date, there were six B7-H3 ADCs under global MRCTs. The following tables illustrate the global competitive landscape of B7-H3 ADCs under clinical development.

B7-H3 ADCs under Global MRCTs

Drug Name	Company	Indications	Phase of Trial	First Post Date[2]	Location
DS-7300	Daiichi Sankyo/ Merck Sharp & Dohme	SCLC	Phase 3	2024-01	Global
		ESCC	Phase 3	2025-02	Global
DB-1311/BNT324[3]	Our Group/BioNTech	Solid Tumors, incl. SCLC, CRPC and other cancer types	Phase 1/2a	2023-06	Global
YL201	MediLink	Solid Tumors	Phase 1	2022-09	U.S., China
HS-20093/ GSK5764227	Hansoh/GSK	Solid Tumors	Phase 1	2024-08	Global
BGB-C354	BeiGene	Solid Tumors	Phase 1	2024-10	Global
MGC018[1]	MacroGenics	mCRPC and Other Solid Tumors, incl. SCLC	Phase 2	2022-09	Global

Notes:

(1) The trial of MGC018 on mCRPC patients was suspended according to MacroGenics' announcement on July 30, 2024.

(2) First post date is the date on which the study record was first published on *ClinicalTrials.gov* or CDE's website, which may be different from the date on which a trial is initiated.

(3) In June 2024, DB-1311 was granted Fast Track Designation by the FDA for the treatment of patients with advanced/unresectable, or metastatic CRPC who have progressed on or after standard systemic regimens, in recognition of DB-1311's potential for the treatment of this challenging tumor type. For details on the requirements of Fast Track Designation, please refer to "Regulatory Overview — Overview of Laws and Regulations in the United States — Laws and Regulations in Relation to New Drug — Expedited Development and Review Programs."

Other B7-H3 ADCs under Clinical Development

Drug Name	Company	Indications	Phase of Trial	First Post Date[1]	Location
DS-7300	Daiichi Sankyo/ Merck Sharp & Dohme	Solid Tumors, incl. EC and CRC	Phase 2	2024-03	U.S.
		Solid Tumors, incl. SCLC and CRPC	Phase 1/2	2019-10	U.S., Japan
HS-20093/ GSK5 764227	Hansoh/GSK	Limited-Stage SCLC	Phase 3	2024-07	China
		Osteosarcoma and Other Sarcomas	Phase 2	2023-03	China
		mCRPC	Phase 2	2023-08	China
		HNSCC	Phase 2	2023-08	China
		Extensive-Stage SCLC	Phase 2	2023-09	China
		Esophageal Carcinoma	Phase 2	2023-11	China
		Solid Tumors	Phase 1	2022-03	China
		Bone and Soft Tissue Sarcomas	Phase 1	2024-12	China
YL201	MediLink	SCLC	Phase 3	2024-11	China
		mCRPC	Phase 2	2024-01	China
		Solid Tumors, incl. SCLC	Phase 1/2	2023-08	China
MHB088C	Minghui Pharmaceutical	Solid Tumors, incl. SCLC and CRPC	Phase 1/2	2022-12	Australia
7MW3711	Mabwell	Solid Tumors	Phase 1/2	2023-08	China
IBI129	Innovent	Solid Tumors, incl. SCLC	Phase 1/2	2023-08	Australia
ILB-3101	Innolake Biopharm	Solid Tumors, incl. SCLC	Phase 1/2	2024-05	China
MGC018	MacroGenics	Solid Tumors, incl. CRPC	Phase 1	2022-03	U.S.
BAT8009	Bio-Thera	Solid Tumors	Phase 1	2022-06	China
MGC026	MacroGenics	Solid Tumors, incl. SCLC	Phase 1	2024-02	U.S., Australia
BGB-C354	BeiGene	Solid Tumors	Phase 1	2024-05	U.S., Australia
SYS6043	CSPC Group	Solid Tumors, incl. SCLC	Phase 1	2024-12	China
BB-1712	Bliss Biopharmaceutical	Solid Tumors	Phase 1	2025-01	China

Note:

(1) First post date is the date on which the study record was first published on *ClinicalTrials.gov* or CDE's website, which may be different from the date on which a trial is initiated.

Sources: Clinicaltrials.gov, CDE, Frost & Sullivan

The following table illustrates the key features of DB-1311, DS-7300 and MGC018, the only three B7-H3 ADCs under global MRCTs in phase 1/2a clinical development or beyond.

ADC design of B7-H3 ADCs (DB-1311, DS-7300 and MGC018)

	DB-1311	DS-7300	MGC018
Antibody	Humanized anti-B7-H3 IgG1 mAb	Ifinatamab	Vobramitamab
Linker	Tetrapeptide-based cleavable linker	GGFG linker	Valine-citrulline linker
Payload	P1021, an exatecan derivative and a highly potent TOPO I inhibitor	Dxd, an exatecan derivative and a moderately potent TOPO I inhibitor	Seco-DUBA, a DNA alkylating agent
DAR	6	4	2.7

Source: Literature review, Frost & Sullivan

GLOBAL HER3 ADC MARKET

Overview

HER3 is a cell surface receptor that is a member of the HER family, playing crucial roles in tumor survival and growth. In contrast to other HER family members, HER3 is not oncogenic when overexpressed alone. However, ubiquitous HER3 expression is detected in various solid tumors, including breast, lung, colorectal, prostate, and head and neck cancers. The table below sets forth HER3 expression rate in different cancer types.

Cancer	HER3 Expression
Prostate cancer	90%
Non-small cell lung cancer	83%
Cervical cancer	55-74%
Colorectal cancer	51-75%
Ovarian cancer	41-68%
Pancreatic cancer	41%
Gastric cancer	34-59%
Breast cancer	30-75%

Sources: Literature review, Frost & Sullivan

Despite lacking intrinsic tyrosine kinase activity, HER3 is activated by dimerization with another receptor, with EGFR and HER2 being its preferred dimerization partners, ultimately promoting tumorigenesis, metastatic dissemination and drug resistance. Moreover, therapies targeting HER3 can mediate resistance to other targeted therapies, including resistance of NSCLC patients to EGFR targeted therapy.

Despite the growing research and clinical interest in HER3, its exploration is still limited and development of HER3-targeted drugs has been challenging due to the limited understanding of its complex signaling pathway, its lack of intrinsic kinase activity and limited internalization. As of the Latest Practicable Date, there were no approved HER3-targeting drugs globally. HER3 ADCs present significant potential with highly potent cytotoxic payloads that bypass the need for strong intrinsic kinase activity, the ability to exert bystander killing and improved antibody engineering to enhance internalization. The features of ADCs and characteristics of HER3 biology make HER3 ADCs a promising all-comer drug.

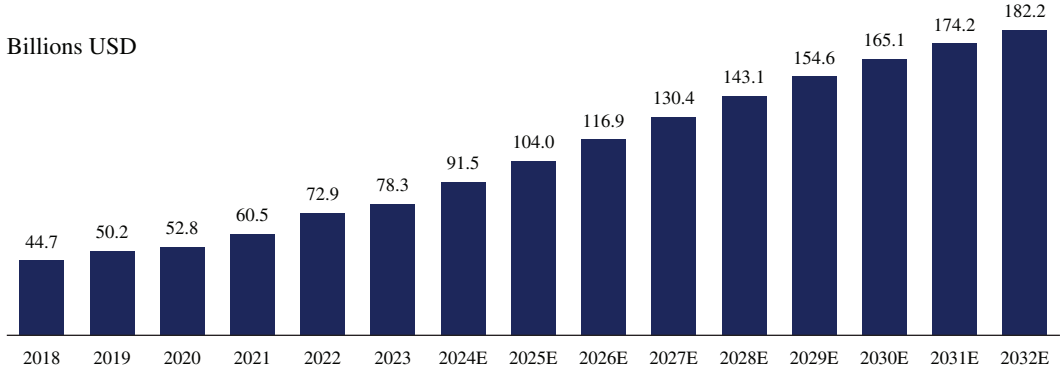
Market Opportunities of HER3 ADCs

Non-small Cell Lung Cancer

NSCLC is the most common subtype of lung cancer and represents approximately 85% of all lung cancer cases globally. Global incidence of NSCLC increased from 1,886.3 thousand cases in 2018 to 2,169.4 thousand cases in 2023 and is projected to reach 2,743.2 thousand cases by 2032. In China, NSCLC incidence increased from 808.7 thousand cases in 2018 to 926.6 thousand cases in 2023, and is projected to reach 1,145.4 thousand cases by 2032. The global NSCLC drug market grew from US$44.7 billion in 2018 to US$78.3 billion in 2023 at a CAGR of 11.9%, and is expected to increase to US$143.1 billion and US$182.2 billion in 2028 and 2032, respectively, representing a CAGR of 12.8% from 2023 to 2028 and 6.2% from 2028 to 2032. The chart below sets forth the growth of the global NSCLC drug market.

Global NSCLC Drug Market Size, 2018-2032E

Period	CAGR
2018-2023	11.9%
2023-2028E	12.8%
2028E-2032E	6.2%



Sources: Frost & Sullivan

A set of genetic abnormalities occurring in NSCLC have been identified as predictors for patients' responses to various targeted therapies, including EGFR mutations. Treatments developed specifically for different subtypes of NSCLC based on these genetic differences can be more effective for disease control.

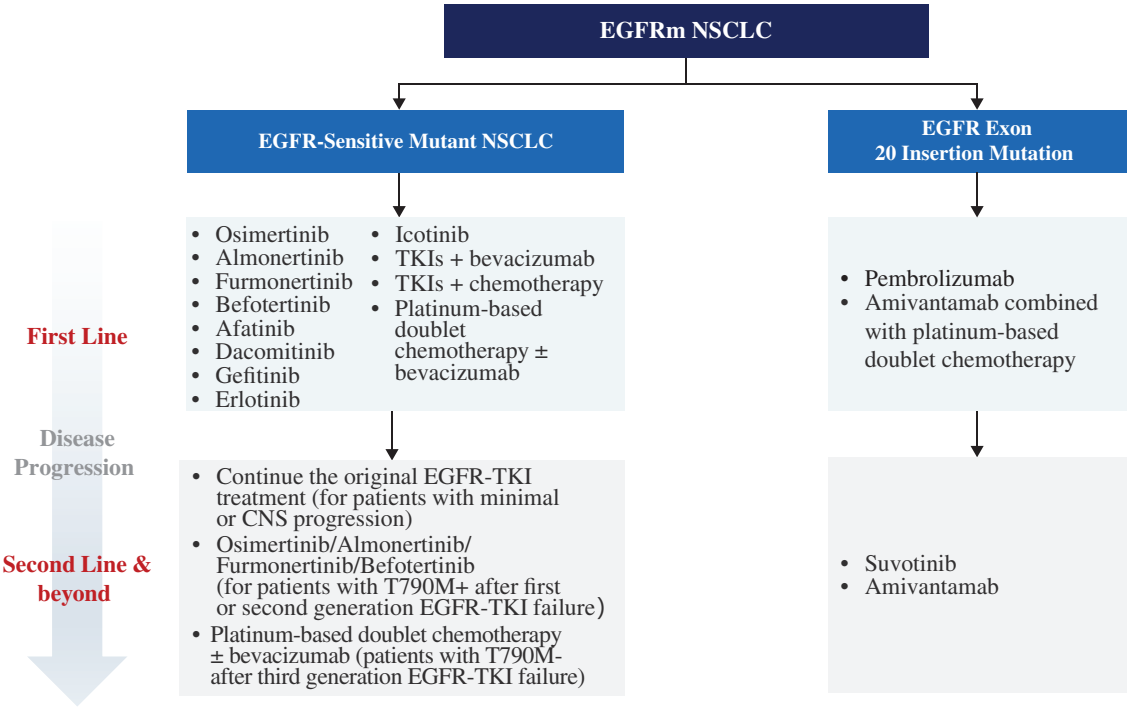
EGFR-mutant NSCLC

EGFR-mutant ("**EGFRm**") NSCLC is a prevalent subtype of NSCLC with approximately 700 thousand new cases each year globally. EGFR mutations are particularly prevalent in the Asian population, accounting for over 50% of all NSCLC cases in this demographic group.

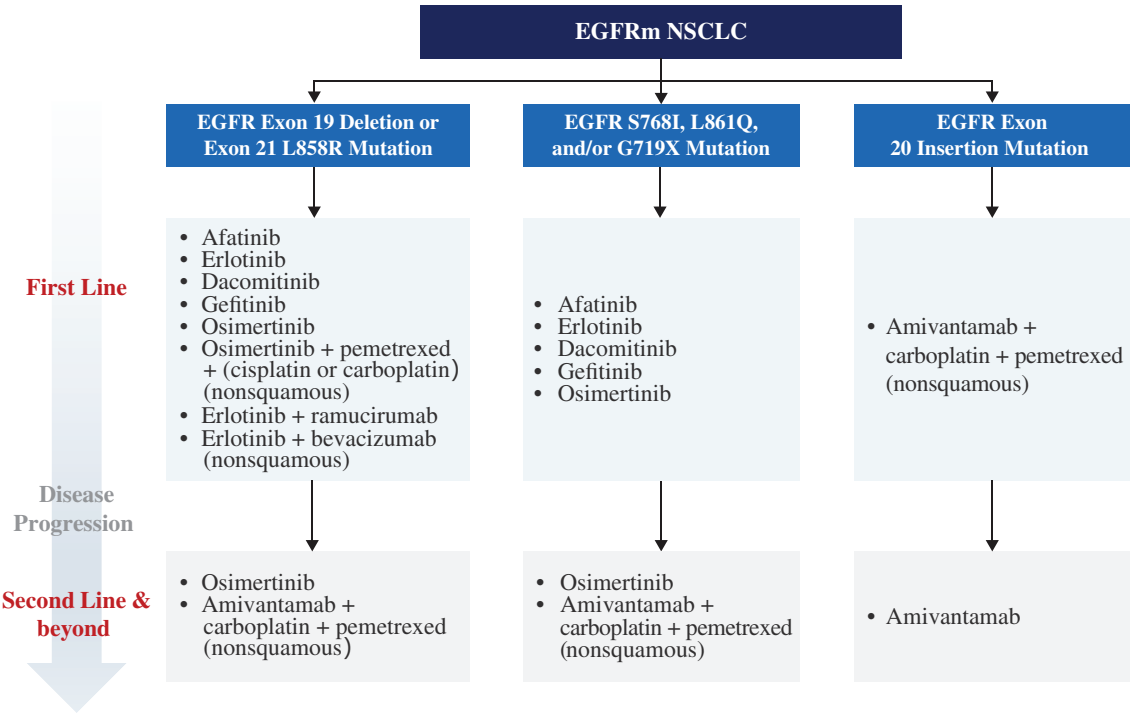
EGFR-TKIs are the major first-line therapies for EGFRm NSCLC, with chemotherapy and PD-(L)1 inhibitors also used in the first-line setting or in specific clinical scenarios. Novel treatment modalities, such as ADCs, are being investigated as a potential treatment for EGFRm NSCLC patients.

The charts below set forth the subsets of EGFRm NSCLC patients as well as the treatment paradigm for EGFRm NSCLC in China and the U.S.

Treatment Paradigm for EGFRm NSCLC in China



Treatment Paradigm for EGFRm NSCLC in the U.S.



Note: Our Group's DB-1310 is being investigated as a potential treatment for TKI-resistant EGFRm NSCLC patients in combination with osimertinib.

Source: CSCO 2024, NCCN 2024, Frost & Sullivan

In China, the first-line treatments for EGFRm NSCLC patients include (i) TKIs, such as osimertinib, almonertinib, furmonertinib, befotertinib, afatinib, dacomitinib, gefitinib, erlotinib, and icotinib, (ii) combination therapy of TKIs and mAbs, (iii) platinum-based doublet chemotherapy plus bevacizumab and (iv) combination therapy of TKIs and chemotherapy. Second and subsequent lines of treatments include (i) continuous original EGFR-TKI treatment in combination with local treatment, (ii) single-agent chemotherapy and (iii) anlotinib.

In the U.S., the first-line treatments for EGFRm NSCLC patients include (i) TKIs, such as afatinib, erlotinib, dacomitinib, gefitinib and osimertinib, (ii) combination therapy of TKIs and mAbs, such as erlotinib with ramucirumab or bevacizumab. In second-line or later settings, TKIs such as osimertinib and mobocertinib, and bispecific antibodies ("**bsAbs**") such as amivantamab are recommended.

TKIs are still the mainstay for EGFRm NSCLC treatment. However, most patients eventually acquire resistance with median relapse occurring approximately 9-14 months after treatment with TKIs. For patients who have failed TKIs, effective treatment options are limited. HER3 has become a validated target for EGFRm NSCLC, supported by promising efficacy data shown in pivotal trial. EGFR and HER3 can together form heterodimeric complexes, leading to the activation of downstream signaling pathways. HER3 is also shown to be an escape mechanism involved in resistance to EGFR TKI therapies.

Breast Cancer

The global incidence of BC increased from 2,088.8 thousand cases in 2018 to 2,408.0 thousand in 2023, and is projected to reach 3,195.7 thousand cases by 2032. While HER2 is a well-established target for BC treatments, approximately 15-40% of all BC cases are HER2-null, which show limited response to current HER2-targeted therapies. In addition, HER2-expressing BCs commonly exhibit co-expression and activation of HER3. Inhibition of HER2 can lead to a compensatory upregulation or activation of HER3, which can limit the efficacy of HER2-targeted therapies, including HER2 ADCs. This feedback loop between the two receptors highlights the importance of developing HER3-targeted therapies to overcome potential resistance to HER2-targeted therapies. For more details on the background and epidemiology of BC, see "— Global HER2 ADC Market — Market Opportunities for HER2 ADC — Breast Cancer."

Castration-resistant Prostate Cancer

HER3 is expressed in approximately 90% of prostate cancer cases and is commonly overexpressed, making it an actionable target in treating prostate cancer, including CRPC. The current treatment paradigm for CRPC remains limited in its ability to provide durable and effective long-term control, underscoring the potential of innovative targeted therapy to address this unmet need. For more details on the background and epidemiology of CRPC, see "— Global B7-H3 ADC Market — Market Opportunities for B7-H3 ADC — Castration-resistant Prostate Cancer."

Competitive Landscape

As of the Latest Practicable Date, there were no approved HER3-targeted therapies, including ADCs, globally. As of the same date, there were four HER3 ADCs under global MRCTs. The following tables illustrate the global competitive landscape of HER3 ADCs under clinical development.

HER3 ADCs under Global MRCTs

Drug Name	Company	Indications	Phase of Trial	First Post Date[1]	Location
U3-1402	Daiichi Sankyo/Merck Sharp & Dohme	EGFRm NSCLC	NDA	2023-12	Global
		Solid Tumors	Phase 2	2023-12	Global
		Gastrointestinal Cancers	Phase 1/2	2024-09	Global
		NSCLC	Phase 1	2017-08	Global
DB-1310	Our Group	Solid Tumors, incl. NSCLC and BC	Phase 1/2a	2023-03	Global
SHR-A2009	Hengrui Pharmaceuticals	Solid tumors	Phase 1	2021-11	Global
YL202/BNT326	MediLink/BioNTech	NSCLC and BC	Phase 1	2022-12	China, U.S.

Other HER3 ADCs under Clinical Development

Drug Name	Company	Indications	Phase of Trial	First Post Date[1]	Location
SHR-A2009	Hengrui Pharmaceuticals	EGFRm NSCLC	Phase 3	2024-11	China
		Solid Tumors	Phase 1b/2	2023-10	China
		BC	Phase 1/2	2024-01	China
U3-1402	Daiichi Sankyo/ Merck Sharp & Dohme	BC	Phase 2	2021-01	U.S.
		BC and NSCLC with Brain Metastases	Phase 2	2023-05	Austria, Spain
		HER3+ BC	Phase 1/2	2016-12	U.S., Japan
YL202/BNT 326	MediLink/BioNTech	Solid Tumors	Phase 2	2023-10	China
		mTNBC	Phase 2	2024-06	China
IBI133	Innovent	Solid Tumors	Phase 1/2	2023-12	Australia
AMT-562	Multitude Therapeutics	Solid Tumors	Phase 1	2024-01	Australia
SIBP-A13	Shanghai Institute Of Biological Products	Solid Tumors	Phase 1	2024-02	China
AK138D1	Akeso	Solid Tumors	Phase 1	2024-12	Australia

Note:

(1) First post date is the date on which the study record was first published on *ClinicalTrials.gov* or CDE's website, which may be different from the date on which a trial is initiated.

Sources: Clinicaltrials.gov, CDE, Frost & Sullivan

The following table illustrates the key features of DB-1310 and U3-1402, the only two HER3 ADCs under global MRCTs in phase 1/2a clinical development or beyond.

ADC design of HER3 ADCs (DB-1310 and U3-1402)

	DB-1310	U3-1402
Antibody	Humanized anti-HER3 IgG1 mAb	Patritumab
Linker	Tetrapeptide-based cleavable linker	GGFG linker
Payload	P1021, an exatecan derivative and a highly potent TOPO I inhibitor	Dxd, an exatecan derivative and a moderately potent TOPO I inhibitor
DAR	8	7-8

Source: Literature review, Frost & Sullivan

GLOBAL TROP2 ADC MARKET

Overview

TROP2 is a transmembrane protein that has essential functions in embryonic and organ development with low expression in normal tissues. TROP2 is a clinically valuable ADC target as it is overexpressed in a wide range of highly prevalent or hard-to-treat cancers, including advanced tumors with limited actionable targets. The table below sets forth the TROP2 expression rate in different cancer types.

Cancer	TROP2 Expression
Endometrial cancer	96%
Ovarian cancer	91%
Urothelial cancer	90%
Cervical cancer	89-98%
Castration-resistant prostate cancer	89%
Pancreatic cancer	87%
Breast cancer	80%
Gastric cancer	66%
Non-small cell lung cancer	64-75%

Sources: Literature review, Frost & Sullivan

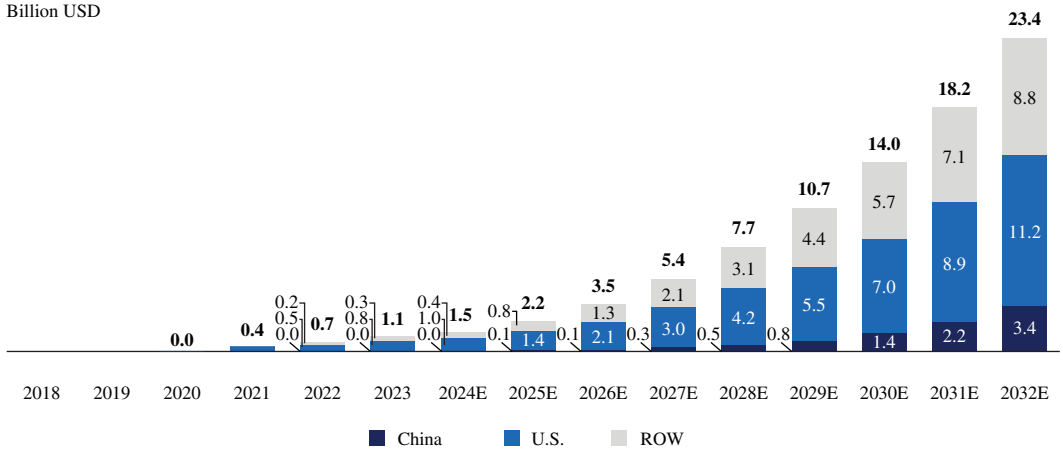
TROP2 ADCs have demonstrated synergistic anti-tumor activity in various preclinical and clinical studies as the backbone of potential combination therapies with other treatment modalities such as chemotherapy, targeted therapy and immunotherapy. Despite the encouraging therapeutic benefits shown by TROP2 ADCs, the global clinical development of TROP2 ADCs is currently heavily focused on triple-negative breast cancer ("**TNBC**"), HR+/HER2- BC, UC and NSCLC. This leaves unmet needs among patients with other prevalent or hard-to-treat cancers, such as OC.

Addressable Market Size

The first TROP2 ADC was approved by the FDA in 2020 and by the NMPA in 2022. Driven by TROP2 ADCs' proven success in indication expansion and the continued exploration of new clinical applications, the global TROP2 ADC market reached US$1.1 billion in 2023. It is expected to increase to US$7.7 billion in 2028, with a CAGR of 48.8% from 2023 and further increase to US$23.4 billion in 2032 at a CAGR of 31.8% from 2028. In China, the market size for TROP2 ADCs is projected to reach US$3.4 billion in 2032, representing a CAGR of 63.8% from 2028. The chart below sets forth the growth of the global TROP2 ADC market with a breakdown by major regions.

Global TROP2 ADC Market Size, 2018-2032E

Period	CAGR			
	China	U.S.	ROW	Global
2018-2023	NA	NA	NA	NA
2023-2028E	117.7%	39.8%	62.4%	48.8%
2028E-2032E	63.8%	28.2%	29.5%	31.8%



Source: Frost & Sullivan

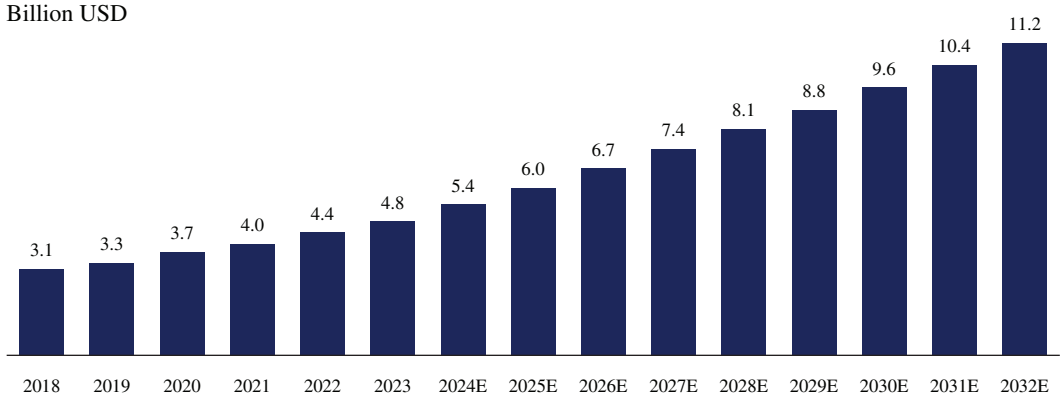
Market Opportunities of TROP2 ADCs

Ovarian Cancer

OC is the third most common cancer of the female reproductive system worldwide. High expression of TROP2 is reported in about 83% of OC patients. The global incidence of OC increased from 295.4 thousand cases in 2018 to 333.9 thousand cases in 2023, and is projected to further increase to 396.8 thousand cases by 2032. In China, incidence of OC increased from 57.8 thousand cases in 2018 to 61.6 thousand cases in 2023, and is projected to increase to 66.6 thousand cases by 2032. TROP2 is expressed in approximately 91% of OC cases. The global incidence of TROP2-overexpressing OC increased from 173.1 thousand cases in 2018 to 195.7 thousand cases in 2023, and is projected to reach 232.5 thousand cases by 2032. The global OC drug market grew from US$3.1 billion in 2018 to US$4.8 billion in 2023 at a CAGR of 9.2%, and is expected to increase to US$8.1 billion and US$11.2 billion in 2028 and 2032, respectively, representing a CAGR of 11.1% from 2023 to 2028 and 8.5% from 2028 to 2032. The chart below sets forth the growth of the global OC drug market.

Global Ovarian Cancer Drug Market Size, 2018-2032E

Period	CAGR
2018-2023	9.2%
2023-2028E	11.1%
2028E-2032E	8.5%

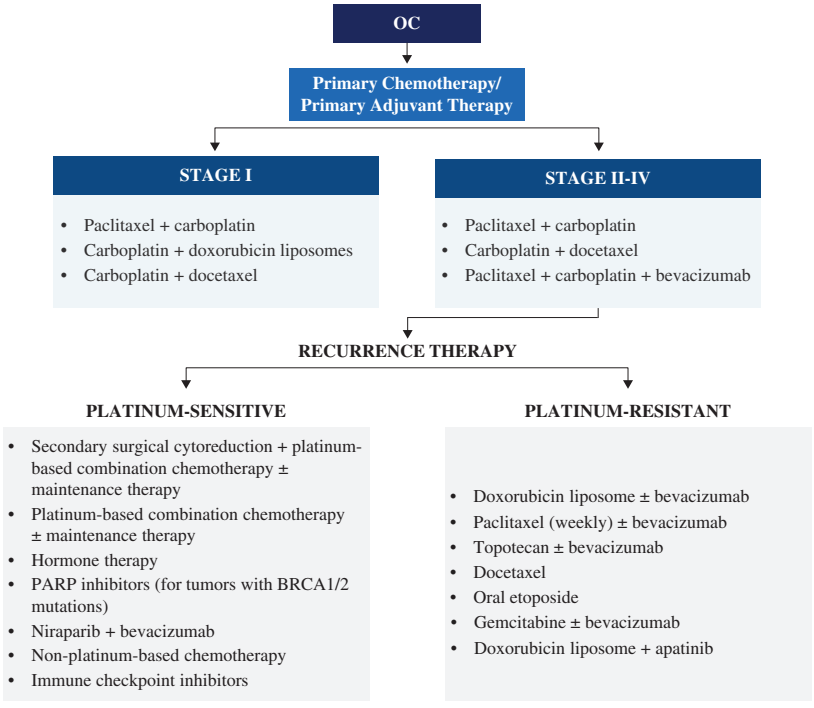


Sources: Frost & Sullivan

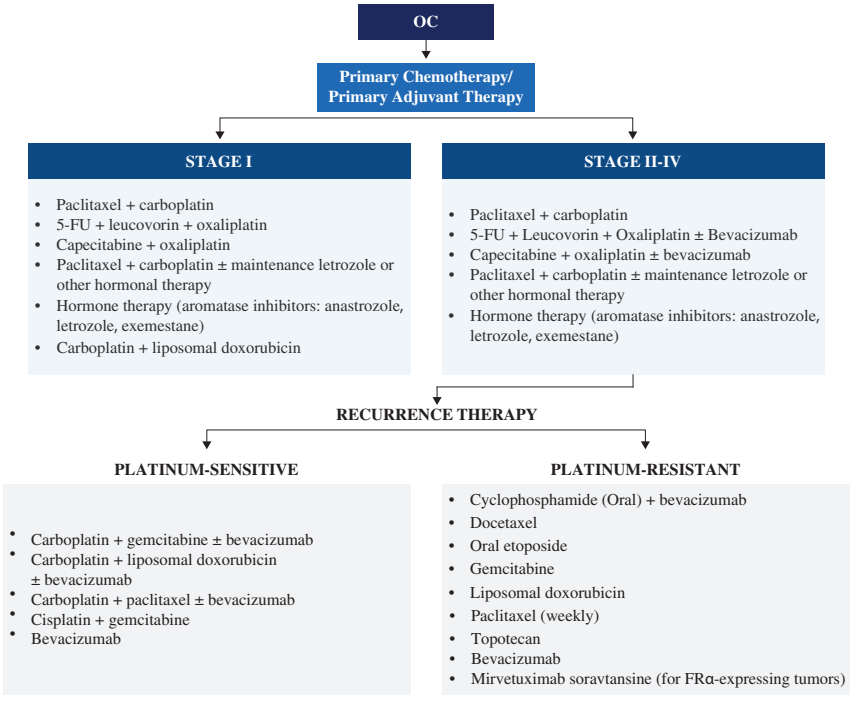
The current treatment landscape of OC primarily consists of platinum-based chemotherapy, targeted therapies such as PARP inhibitors and anti-VEGF mAbs, and immunotherapy such as ICIs. Novel treatment modalities, such as ADCs, are being investigated as a potential treatment for OC patients.

The charts below set forth the subsets of OC patients as well as the treatment paradigm for OC in China and the U.S.

Treatment Paradigm for OC in China



Treatment Paradigm for OC in the U.S.



Note: Our Group's DB-1305 is being investigated as (i) a potential second-line (or later) treatment for OC patients, and (ii) a potential early-line treatment for OC patients in combination with a PD-L1x VEGF bsAb.

Source: CSCO 2024, NCCN 2024, Frost & Sullivan

In China, first-line treatments for OC include (i) carboplatin and paclitaxel or docetaxel or doxorubicin liposome, (ii) paclitaxel and carboplatin with bevacizumab. For relapsed patients resistant to platinum-based chemotherapy, recommended treatments include (i) doxorubicin liposome with or without bevacizumab, (ii) docetaxel or etoposide or gemcitabine, (iii) topotecan hydrochloride with or without bevacizumab, (iv) doxorubicin liposome plus apatinib, and (v) PARP inhibitors.

In the U.S., preferred regimens for primary therapy of OC include (i) carboplatin and paclitaxel, (ii) 5-FU, leucovorin and oxaliplatin, (iii) capecitabine and oxaliplatin, and (iv) hormone therapy such as anastrozole, letrozole and exemestane. For platinum-sensitive patients, recurrence therapy includes (i) carboplatin and gemcitabine with or without bevacizumab, (ii) carboplatin and doxorubicin liposome with or without bevacizumab, (iii) carboplatin and paclitaxel with or without bevacizumab, and (iv) cisplatin and gemcitabine. For platinum-resistant patients, preferred regimens include (i) cyclophosphamide or bevacizumab, (ii) docetaxel, (iii) etoposide, (iv) gemcitabine, and (v) liposomal doxorubicin or paclitaxel or topotecan with or without bevacizumab.

Chemotherapy represents the mainstay of standard treatments for advanced OC in China and the U.S., which involves platinum-based and taxane-based chemotherapy with or without antiangiogenic mAb bevacizumab. However, the disease often recurs in a more resistant form even after initial successful treatment with surgery and chemotherapy. Immunotherapy, such as PD-(L)1 inhibitors, may be considered for patients with certain immunotherapy biomarkers who have no satisfactory alternative treatment options. However, immunotherapy, while promising, has shown limited effectiveness in OC when used as a monotherapy. This limited efficacy and high recurrence rate underscore the need for more effective and durable treatment options that can improve long-term survival outcomes for patients.

Traditionally, ADC development has focused on FRα-positive OC patients, who constitute a limited subset of the OC population. Given that TROP2 is overexpressed in the majority of OC patients and the under-exploration of OC as an indication for other TROP2 ADC candidates, TROP2 ADCs targeting OC patients represent a promising therapeutic strategy with vast potential. In addition, TROP2 ADCs can potentially provide a novel therapeutic option when standard platinum-based chemotherapy is no longer effective. They can also be used in combination with or as a complement to standard platinum-based chemotherapy, potentially enhancing treatment efficacy.

Non-small Cell Lung Cancer

TROP2 is broadly overexpressed in NSCLC, making TROP2 ADCs a promising modality for treating advanced NSCLC regardless of driver mutation status. Lung cancer is the most common cancer and the leading cause of cancer death worldwide, with NSCLC accounting for over 85% of all lung cancer cases. For more details on the background and epidemiology of NSCLC, see "— Global HER3 ADC Market — Market Opportunities for HER3 ADC — Non-small Cell Lung Cancer." TROP2 is expressed in approximately 64-75% of NSCLC cases. The global incidence of TROP2-overexpressing NSCLC increased from 997.9 thousand cases in 2018 to 1,147.6 thousand cases in 2023, and is projected to reach 1,451.2 thousand cases by 2032.

Competitive Landscape

As of the Latest Practicable Date, Trodelvy® was the only TROP2-targeted drug approved both in the U.S. and in China, indicated for mTNBC, metastatic UC ("**mUC**") and HR+/HER2- BC in the U.S., and for mTNBC in China. Despite its promising clinical activity, Trodelvy® is associated with severe neutropenia (i.e., a lower-than-normal number of neutrophils in the blood) and severe diarrhea, two serious adverse reactions for which Trodelvy® has black box warnings issued by the FDA. Consequently, there is a need for novel TROP2 ADCs that have limited toxicities while maintaining robust anti-tumor activity. As of the same date, there were one additional TROP2-targeted drug approved in China, SKB264 (brand name: 佳泰萊®), indicated for mTNBC, and one approved in the U.S., Datroway®, indicated for HR+/HER2- BC.

The following tables illustrate the global competitive landscape of marketed TROP2 ADCs, TROP2 ADCs indicated for OC under clinical development, and TROP2 ADCs in combination with immunotherapies in phase 1/2 clinical development or beyond.

Marketed TROP2 ADCs Globally

Brand Name (Chemical Name; Code Name)	Company	Indications	Treatment Line	FDA First Approval	NMPA First Approval	Price	NRDL Inclusion	U.S. Insurance/ Assistance Program Coverage	Patent Expiry Date	Global Sales in 2023
Trodelvy® (Sacituzumab govitecan; IMMU-132)	Gilead	mTNBC	≥3L	2020.04	2022.06	US$2,604/ 180mg	No	100%	2028 (U.S.) 2029 (EU)	US$1,063.0 million
		mUC	≥3L	2021.04	N/A					
		HR+/HER2- BC	≥2L	2023.02	N/A					
佳泰萊® (Sacituzumab Tirumotecan; SKB264)	Kelun-Biotech/ Merck Sharp & Dohme	mTNBC	≥3L	N/A	2024.11	RMB9,399/ 200mg	No	N/A	2038 (China)	N/A
Datroway® (datopotamab deruxtecan-dlnk)	Daiichi Sankyo/ AstraZeneca	HR+/HER2- BC	≥2L	2025.01	N/A	US$4,891/ 100mg	N/A	100%	2034 (U.S.) 2034 (EU)	N/A

Sources: Clinicaltrials.gov, CDE, Frost & Sullivan

TROP2 ADCs Indicated for OC under Clinical Development

Drug Name	Company	Indications	Phase of Trial	First Post Date[1]	Location
SKB264/ MK-2870	Kelun-Biotech/Merck Sharp & Dohme	Platinum-sensitive OC	Phase 3	2025-02	Global
		Solid Tumors, incl. OC	Phase 2	2022-12	Global
DS-1062	Daiichi Sankyo /AstraZeneca	Solid Tumors, incl. OC	Phase 2	2022-08	Global
DB-1305/ BNT325[2]	Our Group/BioNTech	Solid Tumors, incl. OC	Phase 1/2a	2022-06	Global
SHR-A1921	Hengrui Pharmaceuticals	OC	Phase 3	2024-05	China
XYD-9668-198	Xinyunda Biotechnology	Solid Tumors, incl. OC	Phase 1/2	2023-04	China
BHV1510/ GQ1010	GeneQuantum/Pyramid Biosciences	Solid Tumors, incl. OC	Phase 1/2	2024-05	China
FDA018	Fudan-Zhangjiang Bio-Pharmaceutical	Solid Tumors, incl. OC	Phase 1	2022-01	China
DXC1002	DAC Biotech	Solid Tumors, incl. OC	Phase 1	2023-12	China

TROP2 ADCs in Combination with Immunotherapies under Clinical Development (Phase 1/2 or beyond)

Drug Name	Company	Indications	Combo IO Drug	Phase of Trial	First Post Date[1]	Location
DS-1062	Daiichi Sankyo /AstraZeneca	NSCLC	PD-1 mAb	Phase 3	2022-01	Global
		TNBC	PD-1 mAb	Phase 3	2022-11	Global
		TNBC or HR-Low/ HER2- BC	PD-L1 mAb+chemo	Phase 3	2023-11	Global
Sacituzumab Govitecan	Gilead	TNBC	PD-1 mAb	Phase 3	2022-05	Global
		NSCLC	PD-1 mAb+chemo	Phase 2	2022-01	Global
SKB264/MK-2870	Kelun-Biotech/ Merck Sharp & Dohme	HR+/HER2- BC	PD-1 mAb	Phase 3	2024-03	Global
		TNBC	PD-1 mAb	Phase 3	2024-05	Global
		Non sq-NSCLC	PD-1 mAb	Phase 3	2024-09	China
		NSCLC	PD-L1 mAb+chemo	Phase 2	2022-04	China
		HER2- BC	PD-L1 mAb	Phase 2	2022-07	China
		Solid Tumors	PD-1 mAb	Phase 2	2022-12	Global
		UC	PD-1 mAb+chemo	Phase 1/2	2024-07	Global
DB-1305/BNT325[2]	Our Group/ BioNTech	OC	PD-L1× VEGF bsAb	Phase 1/2a	2022-06	Global
		NSCLC		Phase 1/2a	2022-06	Global
		TNBC		Phase 1/2a	2022-06	Global
		CC		Phase 1/2a	2022-06	Global
SHR-1921	Hengrui Pharmaceuticals	NSCLC	CTLA-4 mAb+PD-L1 mAb	Phase 1/2	2024-05	China
BIO-106	BiOneCure Therapeutics	Solid Tumors	PD-1 mAb	Phase 1/2	2022-04	U.S.
LCB84	LegoChem Biosciences	Solid Tumors	PD-1 mAb	Phase 1/2	2023-07	U.S., Canada
BAT8008	Bio-Thera	Solid Tumors	PD-1 mAb	Phase 1/2	2024-04	China

Note:

(1) First post date is the date on which the study record was first published on *ClinicalTrials.gov* or CDE's website, which may be different from the date on which a trial is initiated.

(2) In January 2024, DB-1305 was granted Fast Track Designation by the FDA for patients with platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, acknowledging its potential to address unmet medical needs. For details on the requirements of Fast Track Designation, please refer to "Regulatory Overview — Overview of Laws and Regulations in the United States — Laws and Regulations in Relation to New Drug — Expedited Development and Review Programs."

Sources: Clinicaltrials.gov, CDE, Frost & Sullivan

The following table illustrates the key features of DB-1305 alongside Trodelvy®, the only TROP2 ADC approved both by the FDA and the NMPA as of the Latest Practicable Date, as well as DS-1062 and SKB264/MK-2870, the only two TROP2 ADCs indicated for OC under global MRCTs in phase 1/2a clinical development or beyond other than DB-1305.

ADC design of TROP2 ADCs (DB-1305, Trodelvy®, DS-1062 and SKB264/MK-2870)

	DB-1305	Trodelvy®	DS-1062	SKB264/MK-2870
Antibody	Sacituzumab	Sacituzumab	Datopotamab	Sacituzumab
Linker	Tetrapeptide-based cleavable linker	Maleimide-containing CL2A linker	GGFG linker	2-methylsulfonyl pyrimidine containing CL2A linker
Payload	P1021, an exatecan derivative and a highly potent TOPO I inhibitor	SN38, a metabolite of the camptothecin derivative and a moderately potent TOPO I inhibitor	Dxd, an exatecan derivative and a moderately potent TOPO I inhibitor	T030, a belotecan-derivative TOP I inhibitor
DAR	4	7.6	4	7.4

Source: Literature review, Frost & Sullivan

OVERVIEW OF BISPECIFIC ADCS

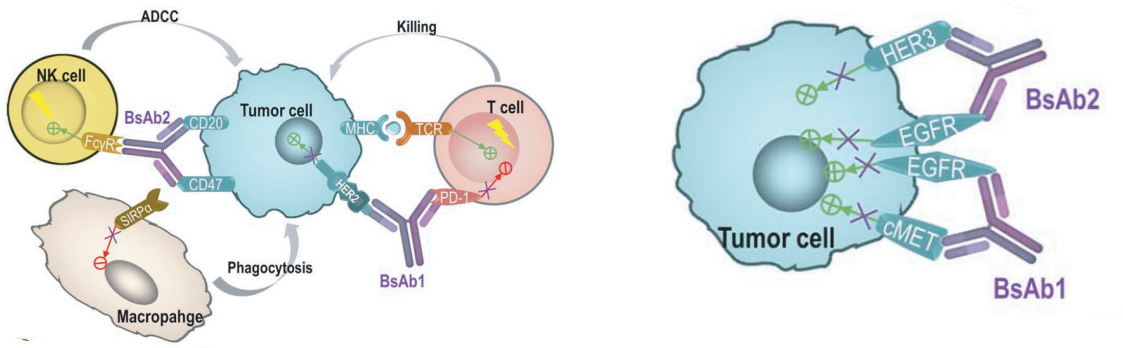
Bispecific ADCs ("**BsADCs**") are next-generation therapeutics that combine the targeting precision of bsAbs with the potent cytotoxicity of ADCs. By incorporating two distinct binding moieties in a single therapeutic entity, BsADCs can potentially offer meaningful advantages over traditional monospecific ADCs and their combination therapies. While promising, the complexity of BsADCs introduces new challenges in antibody engineering, stability and manufacturing, setting a high entry barrier.

BsADCs employ various design strategies to enhance therapeutic efficacy and safety, represented by the tumor-associated antigen ("**TAA**") + immunotherapy ("**IO**") approach and the dual-TAA approach. The TAA + IO strategy utilizes dual-function antibodies that simultaneously target TAAs on cancer cells to induce direct tumor cell death while engaging IO targets to activate the immune system, promoting more potent and durable anti-tumor responses.

By comparison, the dual-TAA approach targets two distinct, carefully selected TAAs co-expressed on cancer cells, enhancing binding specificity, reducing off-tumor toxicity, and potentially overcoming tumor heterogeneity and antigen escape mechanisms.

The mechanisms of actions of the TAA+IO approach and the dual-TAA approach are illustrated below.

TAA+IO Approach **Dual-TAA Approach**



Source: Development of bispecific antibodies in China: overview and prospects, Frost & Sullivan

Both strategies aim to improve the therapeutic index of ADCs by increasing tumor-specific targeting while minimizing off-target effects, with the choice between approaches depending on the specific cancer type, target availability, and desired mechanism of action. In recent years, BsADC has attracted growing interest and development as a new modality, with over ten BsADCs under current clinical development across a broad range of solid tumors and hematological malignancies.

TAA+IO Approach: B7-H3xPD-L1 BsADCs

BsADCs that can simultaneously block both PD-L1 and B7-H3 pathways are developed under the TAA+IO approach to synergistically enhance T cell activity and cancer cell killing. B7-H3's pan-cancer expression coupled with PD-L1's immune-modulating function may offer enhanced anti-tumor effects across broad indications. Studies have shown that B7-H3xPD-L1 BsADCs may have strong binding and neutralizing capabilities and can potentially achieve better anti-tumor activity than using PD-L1 or B7-H3 antibodies alone or in combination. B7-H3xPD-L1 BsADCs have treatment potential across various solid tumors, including SCLC, hepatocellular carcinoma ("**HCC**"), NSCLC, melanoma, ESCC and TNBC.

Dual-TAA Approach: EGFRxHER3 BsADCs

BsADCs that target EGFR and HER3 are a representative therapy of the dual-TAA BsADC approach. EGFR is a cell surface receptor with key roles in multiple signaling pathways that promote cell proliferation and survival. Aberrant activation of EGFR, such as overexpression or mutation, is widely established as an oncogenic driver in a wide range of cancers, such as CRC, HNSCC and NSCLC. HER3 belongs to the same family as EGFR and preferentially forms heterodimers with EGFR to activate downstream oncogenic pathways. Due to target synergies, EGFRxHER3 BsADCs have demonstrated enhanced efficacy and ability to overcome resistance to EGFR-directed treatments in clinical studies. Potential indications for EGFRxHER3 BsADCs include ESCC, HNSCC, CRC, nonmelanoma skin cancer, NSCLC, gastric cancer ("**GC**"), pancreatic adenocarcinoma, nasopharyngeal cancer, bladder cancer and BC.

THE AUTOIMMUNE DISEASE TREATMENT MARKET

Overview

Autoimmune diseases are caused by the abnormal functioning of the immune system, where the body's immune system mistakenly attacks its normal cells and tissues. Many autoimmune diseases are chronic conditions that require lifelong treatment. Major types of autoimmune disease include systemic lupus erythematosus ("**SLE**"), cutaneous lupus erythematosus ("**CLE**"), rheumatoid arthritis and psoriasis.

ADC as An Emerging Modality for Autoimmune Disease Treatment

For decades, a considerable number of autoimmune disease patients have suffered from drug-related side effects and emerging challenges from novel therapies such as paradoxical effects of biologics and immune-related adverse events ("**AEs**"). Anti-inflammatory agents, such as non-steroidal anti-inflammatory drugs ("**NSAIDs**"), glucocorticoids and disease-modifying anti-rheumatic drugs, are commonly used treatment options for patients with autoimmune diseases, particularly during the initial stages of disease. While they are effective in alleviating pain, reducing fever and mitigating inflammatory responses, they are limited to easing symptoms instead of treating the cause of disease. Moreover, many of these anti-inflammatory agents are systemic treatments, and as a result, may globally impair the immune system with long-term use and result in serious side effects, such as increased susceptibility to infections, metabolic disturbances and cardiovascular complications.

In recent years, targeted treatments such as biologics have been developed and marketed with better safety profiles. However, current drawbacks of biologic therapies prevent their wider use as first-line treatments for autoimmune diseases, which include paradoxical effects, side effects on normal immune functions and responses, narrow therapeutic window due to drug resistance, and poor patient compliance resulting from the inconvenience of intravenous administration. While cell therapies such as CAR-T cell therapy have emerged as a promising approach for treating certain autoimmune diseases, the B-cell depletion associated with this

therapy can subsequently jeopardize the overall integrity of patients' immune systems, presenting a significant clinical challenge. The table below sets forth the current treatment landscape for autoimmune diseases.

Type	Subtype	Mechanism of Action	Representative Drugs	Dates of Market Launch	Drawbacks
Anti-inflammatory Agents	NSAIDs	Exert an anti-inflammatory effect by inhibiting the activity of cyclooxygenase (COX)	Aspirin	1899	• Traditional non-selective NSAIDs inhibit platelet aggregation and cause significant gastrointestinal disorders such as bleeding, ulcers, and perforation
			Ibuprofen	1969	
	SAIDs (Glucocorticoids)	Prevent the formation of both PGs and LTs by causing the release of lipocortin, which by inhibition of phospholipase A2 reduces arachidonic acid release	Prednisone	1955	• Long-term GC use should be individualized based on patient characteristics and minimized due to their potential AEs
			Dexamethasone	1958	
Targeted Biologics	Anti-TNF Antibodies	Bind to TNF-α to prevent its association with receptors on the cell surface, thereby blocking the signaling pathways mediated by TNF-α	Infliximab	1998	• May affect the normal immune function and its response, leading to the development of many autoimmune phenomena and diseases • May affect the normal immune function and its response, leading to the development of many autoimmune phenomena and diseases • Long-term use of targeted biologics can easily lead to the drug resistance, thereby reducing the therapeutic effect • Inconvenience of intravenous administration, leading to poor patient compliance
			Adalimumab	2002	
			Etanercept	1998	
	Interleukin Related Drugs	Target and inhibit interleukins involved in inflammation	Rilonacept	2008	
			Anakinra	2001	
			Secukinumab	2015	
	Other Monoclonal Antibodies	Target specific antigens on cells (e.g., CD20, CD22), leading to cell lysis or inhibition of cell proliferation	Rituximab	1997	
			Ocrelizumab	2017	
Other Novel Therapy	CAR-T	Modify the patients' T-cells to recognize and attack abnormal B-cells	Under development	N.A.	• Side effects are potentially severe or even life-threatening immune-related toxicities, specifically cytokine release syndrome (CRS) and immune effector cell-associated neurotoxicity syndrome (ICANS) • Long manufacturing time and high treatment costs

* CAR-T cell therapy has not been approved for autoimmune diseases.

ADCs represent a promising new frontier and an area of growing interest for autoimmune and inflammatory conditions given their high specificity for target cells, enabling potent payloads (anti-inflammatory agents) to be delivered with minimal impact to healthy cells. As a result, ADCs may enable durable treatment response and improved patient outcomes compared to existing therapies.

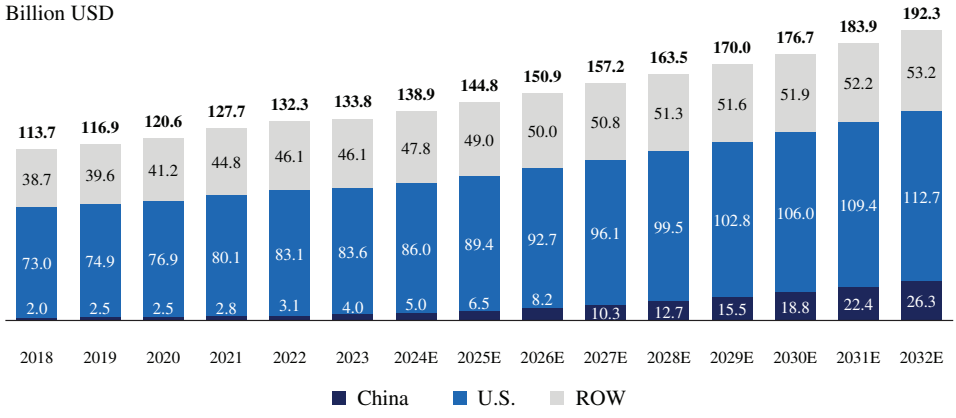
While no autoimmune ADCs have been approved, the advantages and potential of ADCs indicated for autoimmune diseases have attracted significant research interest and investment. With the continuous advancements in this field, next-generation ADCs are expected to maximize therapeutic efficacy while reducing the risk of off-target toxicities that have hampered some earlier autoimmune ADC candidates.

Global Autoimmune Diseases Drug Market Size

The global autoimmune disease drug market size increased from US$113.7 billion in 2018 to US$133.8 billion in 2023 at a CAGR of 3.3%. Targeted biologics have become the mainstay treatment of autoimmune diseases. The global autoimmune disease drug market is expected to continue its growth at a CAGR of 4.1% and 4.1% from 2023 to 2028 and from 2028 to 2032, respectively, and reach US$192.3 billion in 2032.

Global Autoimmune Disease Drug Market, 2018-2032E

Period	CAGR			
	China	U.S.	ROW	Global
2018-2023	13.4%	2.8%	3.7%	3.3%
2023-2028E	27.3%	3.5%	2.1%	4.1%
2028E-2032E	20.0%	3.2%	0.9%	4.1%



Source: Frost & Sullivan

GLOBAL BDCA2 ADC MARKET

Overview

Blood dendritic cell antigen 2 ("**BDCA2**") is a transmembrane protein uniquely expressed on the surface of plasmacytoid dendritic cells ("**pDCs**"). pDCs play a crucial role in the innate immune response and BDCA2 acts as an inhibitory receptor on pDCs, modulating their activation and function. Targeting BDCA2 can inhibit pDC activation and the subsequent production of type I interferons, which are known to play a key pathogenic role in various autoimmune conditions. As a result, BDCA2 has been explored as a potential therapeutic target for autoimmune and inflammatory disorders, such as SLE and CLE.

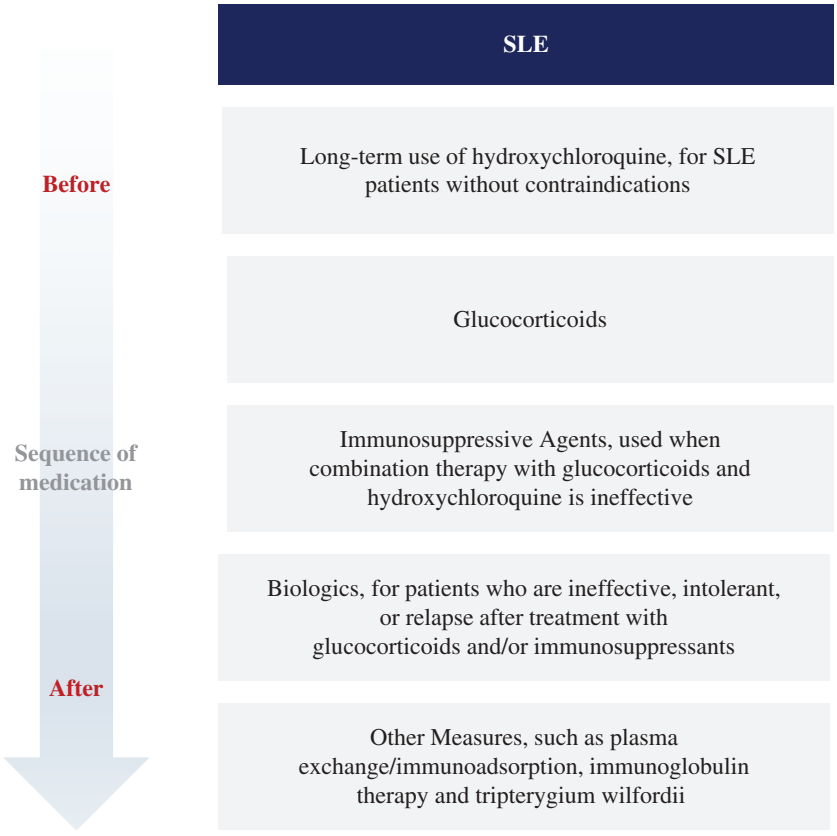
Market Opportunities of BDCA2 ADCs

Systemic Lupus Erythematosus

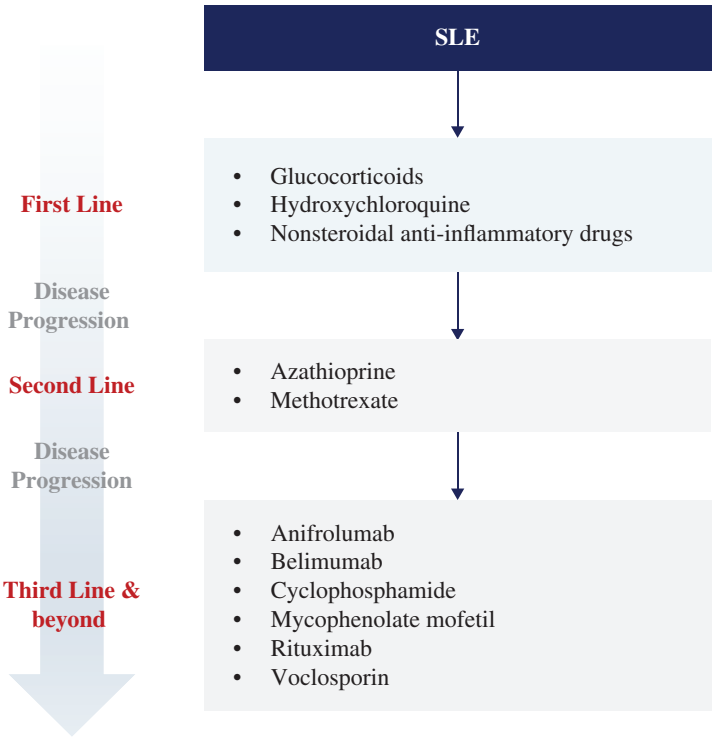
Systemic lupus erythematosus is an autoimmune disease characterized by the production of autoantibodies that target the body's own tissues and cells. It is the most common type of lupus, causing widespread inflammation and tissue damage in the affected organs. The global prevalence of SLE grew from 7,632.8 thousand cases in 2018 to 8,048.8 thousand cases in 2023. It is projected to increase to 8,800.3 thousand cases by 2032. In China, the prevalence of SLE grew from 1,015.6 thousand cases in 2018 to 1,048.3 thousand cases in 2023. It is projected to increase to 1,078.3 thousand cases by 2032.

The charts below set forth the treatment paradigm for SLE in China and the U.S.

Treatment Paradigm for SLE in China



Treatment Paradigm for SLE in the U.S.



Source: Guidelines for Diagnosis and Treatment of Systemic Lupus Erythematosus, Systemic Lupus Erythematosus: Diagnosis and Treatment, Frost & Sullivan

In China, long-term use of hydroxychloroquine is the primary treatment for SLE patients without contraindications, followed by glucocorticoids. Immunosuppressive agents are used in second-line setting when combination therapy with glucocorticoids and hydroxychloroquine is ineffective. For patients who are ineffective, intolerant, or relapse after treatment with glucocorticoids and/or immunosuppressants, biologics are recommended.

In the U.S. first-line treatment options for SLE mainly include (i) glucocorticoids, (ii) hydroxychloroquine, and (iii) NSAIDs. Azathioprine and methotrexate are recommended as second-line treatments. Third-line treatments include anifrolumab, belimumab, cyclophosphamide, mycophenolate mofetil, rituximab and voclosporin.

With advancements in diagnostic tools and treatment options, the prognosis for individuals with SLE has improved significantly over the past few decades. However, SLE remains a chronic and potentially life-threatening condition, and calls for innovative treatment options with improved efficacy. A major shortcoming of mainstay treatments for SLE, such as glucocorticoids and immunosuppressants, is their inability to address the high heterogeneity of pathogenesis in these complex diseases, which often result in limited efficacy and serious side effects, especially when used long term for chronic disease management. Given the complex and heterogeneous nature of SLE, an ideal treatment modality for SLE should be able to achieve optimal disease control and minimize long-term side effects, calling for the

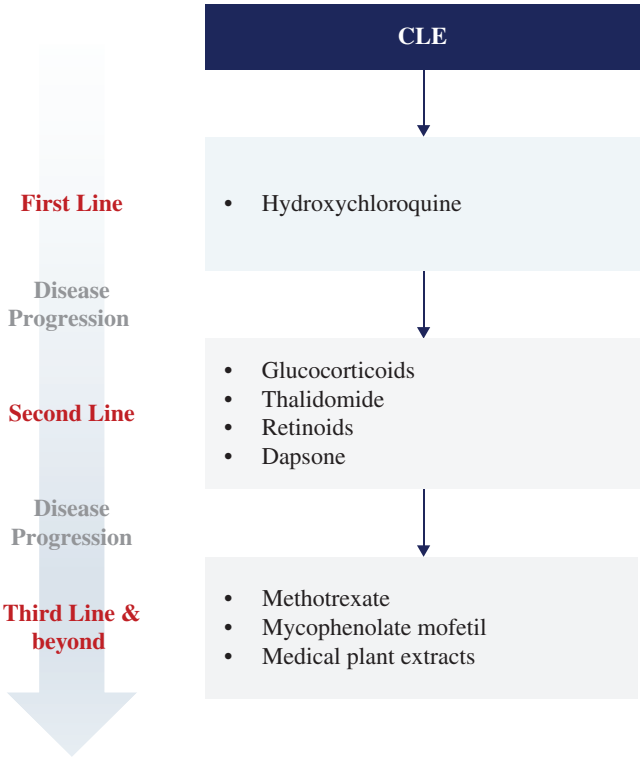
development of targeted therapies such as ADCs. As a validated target that is specifically expressed on pDCs, BDCA2 and its over-production of type I interferon ("**IFN-I**") are crucial in SLE pathogenesis, making BDCA2-targeted ADCs promising for the treatment of SLE.

Cutaneous Lupus Erythematosus

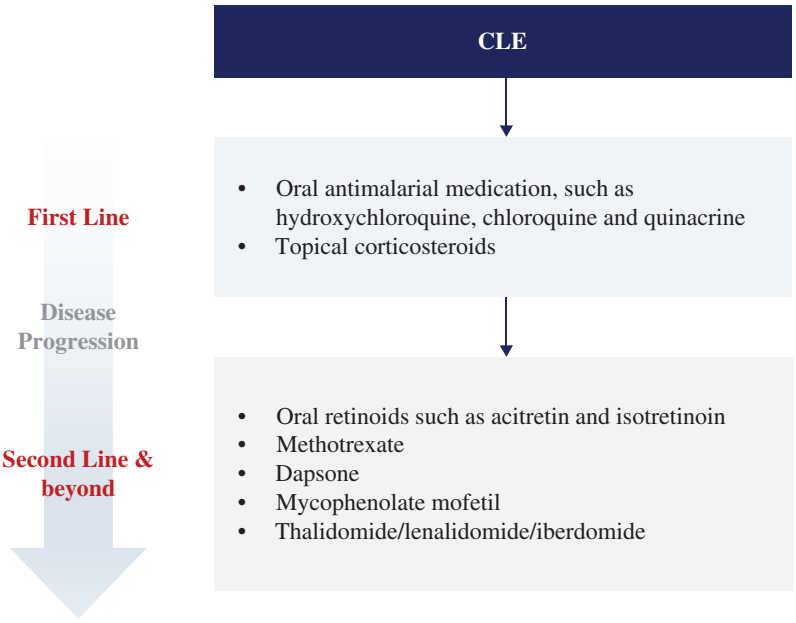
CLE is an autoimmune disorder that primarily affects the skin. CLE is characterized by a range of inflammatory skin lesions and rashes that can appear on various parts of the body, including the face, scalp, arms, and trunk. The global annual incidence of CLE remained relatively stable at approximately 330 thousand cases from 2018 to 2023, and is projected to reach 363.4 thousand cases in 2032. In China, the incidence of CLE grew from 55.8 thousand cases in 2018 to 57.2 thousand cases in 2023, and is projected to remain at an annual incidence of approximately 58 thousand cases from 2023 to 2032.

The charts below set forth the treatment paradigm for CLE in China and the U.S.

Treatment Paradigm for CLE in China



Treatment Paradigm for CLE in the U.S.



Source: An Update on the Management of Refractory Cutaneous Lupus Erythematosus, Guidelines for Diagnosis and Treatment of Cutaneous Lupus Erythematosus, Frost & Sullivan

In China, first-line systematic therapy for CLE patients is hydroxychloroquine. Glucocorticoids, thalidomide, retinoids and dapsone are used as second-line treatments. Third-line treatments include methotrexate, mycophenolate mofetil. In the U.S., first-line systemic therapy for CLE patients is the use of an oral antimalarial medication. In second-line settings, oral retinoids such as acitretin and isotretinoin, immunosuppressants such as methotrexate are recommended.

Despite the available treatment options, many patients continue to experience suboptimal disease control, highlighting the need for more effective and targeted therapies such as ADCs to improve outcomes for individuals living with this debilitating autoimmune skin condition. As a validated target that is specifically expressed on pDCs, BDCA2 and its over-production of IFN-I are crucial in CLE pathogenesis, making BDCA2-targeted ADCs promising for the treatment of CLE.

Competitive Landscape

As of the Latest Practicable Date, there were no approved BDCA2 ADCs and no BDCA2 ADCs under clinical development globally.

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 major markets for which our drug candidates are positioned. Frost & Sullivan is an independent global market research and consulting company which was founded in 1961 and is based in the United States. We have agreed to pay Frost & Sullivan a total fee of approximately RMB0.6 million for the preparation of the F&S Report, and we believe that such fees are consistent with the market rate. The payment of such amount is 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**].

The market projections in the F&S Report were based on the following key assumptions: (i) the overall social, economic and political environment globally and in China is expected to remain stable during the forecast period; (ii) the economic and industrial development globally and in China is likely to maintain a steady growth trend over the next decade; (iii) related key industry drivers are likely to continue driving the growth of the market during the forecast period; and (iv) there is no extreme force majeure or industry regulation in which the market may be affected dramatically or fundamentally. The reliability of the F&S Report may be affected by the accuracy of the foregoing key assumptions.

The Directors and Joint Sponsors have exercised reasonable care in selecting and identifying the named information sources, compiling, extracting and reproducing the information, and in ensuring that there is no material omission of the information.

PRC REGULATION

We are subject to a variety of PRC laws, rules and regulations across a number of aspects of our business. This section sets forth a summary of the most significant laws and regulations that are applicable to our current business activities within the territory of the PRC.

REGULATIONS ON FOREIGN INVESTMENT

Investment activities in the PRC by foreign investors are principally governed by the *Catalog of Encouraged Industries for Foreign Investment* (《鼓勵外商投資產業目錄》) (the "**Encouraged Catalog**"), and the *Special Administrative Measures (Negative List) for Foreign Investment Access* (《外商投資准入特別管理措施(負面清單)》) (the "**Negative List**"), which are promulgated and amended from time to time by the MOFCOM and the National Development and Reform Commission (the "**NDRC**"), and together with the *Foreign Investment Law of PRC* (《中華人民共和國外商投資法》) (the "**FIL**") and its respective implementation rules and ancillary regulations.

In March 2019, the FIL was promulgated by National People's Congress (the "**NPC**") and came into effect on January 1, 2020, which replaced three then existing laws on foreign investments in China, namely, the *Sino-Foreign Equity Joint Venture Enterprise Law of PRC* (《中華人民共和國中外合資經營企業法》), the *Sino-Foreign Cooperative Joint Venture Enterprise Law of PRC* (《中華人民共和國中外合作經營企業法》) and the *Wholly Foreign-owned Enterprise Law of PRC* (《中華人民共和國外資企業法》). The FIL, by means of legislation, establishes the basic framework for the access, promotion, protection and administration of foreign investment in view of investment protection and fair competition. According to the FIL, foreign investment shall enjoy pre-entry national treatment, except for those foreign invested entities that operate in industries deemed to be either "restricted" or "prohibited" in the "negative list", and the State Council shall promulgate or approve a list of special administrative measures for access of foreign investments. To ensure the effective implementation of the FIL, the *Regulations on Implementing the Foreign Investment Law of the PRC* (《中華人民共和國外商投資法實施條例》) (the "**Implementation Regulations**"), was promulgated by State Council in December 2019 and came into effect on January 1, 2020, which further clarified that the state encourages and promotes foreign investment, protects the lawful rights and interests of foreign investors, regulates foreign investment administration, continues to optimize foreign investment environment, and advances a higher-level opening.

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

According to the *Measures for the Security Review of Foreign Investment* (《外商投資安全審查辦法》) promulgated by the NDRC and the MOFCOM on December 19, 2020 and became effective on January 18, 2021, any foreign investment that has or possibly has an impact on state security shall be subject to security review in accordance with the provisions hereof. A foreign investor or a party concerned in China shall take the initiative to make a declaration to the working mechanism office prior to making the investment in any important infrastructure, important transportation services and other important fields that concern state security while obtaining the actual control over the enterprises invested in.

REGULATIONS ON PHARMACEUTICAL PRODUCT

Drug Regulatory Regime

The *Drug Administration Law of the PRC* (《中華人民共和國藥品管理法》) (the "**Drug Administration Law**") was promulgated by the Standing Committee of the NPC (the "**SCNPC**"), in September 1984, last amended on August 26, 2019 and became effective on December 1, 2019. The *Implementation Regulations of the Drug Administration Law of the PRC* (《中華人民共和國藥品管理法實施條例》) (the "**Implementation Regulations**") was promulgated by the State Council in August 2002, and was last amended in December 2024, and became effective on January 2025. The Drug Administration Law and the Implementation Regulations have jointly established the legal framework for the administration of pharmaceutical products in the PRC, including the research, development and manufacturing of drugs. The Drug Administration Law applies to entities and individuals engaged in the development, production, trade, application, supervision and administration of pharmaceutical products, which regulates and provides for a framework for the administration of pharmaceutical manufacturers, pharmaceutical trading companies and medicinal preparations of medical institutions, and the development, research, manufacturing, distribution, packaging, pricing and advertisements of pharmaceutical products. The Implementation Regulations, at the same time, provides the detailed implementation regulations on the Drug Administration Law.

In 2017, the drug regulatory system entered a new and significant period of reform. The General Office of the State Council and the General Committee of China Communist Party jointly issued an Opinions on Deepening the Reform of the Evaluation and Approval Systems and Encouraging Innovation on Drugs and Medical Devices (《關於深化審評審批制度改革鼓勵藥品醫療器械創新的意見》) (the "**Innovation Opinions**") in October 2017. According to the Innovation Opinions, institutions for drug clinical trials should establish an independent ethics committee and the clinical trial schemes are subject to examination, approval and signing with approval opinions by the ethics committee before implementation, in order to protect the rights and interests of human subjects in clinical trials. For a multi-center clinical trial conducted in the PRC, after ethical review by the leader unit of clinical trial, other member units should recognize the review results of the leader unit and may not conduct repeated review. In addition, the expedited programs, the record-filing system, the prioritized review mechanism, the acceptance of foreign clinical data under the Innovation Opinions and other recent reforms encourage drug marketing authorization holders to seek marketing approval in China first for the development of drugs in highly prioritized therapeutic areas such as oncology or rare disease areas.

To implement the regulatory reform introduced by Innovation Opinions, the SCNPC and the NMPA as well as other authorities, are currently responsible for revising the laws, regulations and rules regulating the pharmaceutical products and the industry.

Application for Clinical Trial

According to the *Decision on Adjusting the Approval Procedures of Certain Administrative Approval Items for Drugs* (《關於調整部分藥品行政審批事項審批程序的決定》) promulgated by the China Food and Drug Administration (currently known as the NMPA) on March 17, 2017, the decision on the approval of clinical trials of drugs shall be made by the Center for Drug Evaluation ("**CDE**") from May 1, 2017. According to the *Administrative Measures for Drug Registration* (《藥品註冊管理辦法》) (the "**Registration Measures**"), which was promulgated on January 22, 2020 and took effect on July 1, 2020, drug clinical trials shall be divided into Phase 1 clinical trial, Phase 2 clinical trial, Phase 3 clinical trial, Phase 4 clinical trial, and bioequivalence trial. After the completion of the pharmaceutical, pharmacological and toxicological research of the drug clinical trial, the applicant may submit relevant research materials to CDE for applying for the approval to conduct drug clinical trial. The CDE will organize pharmaceutical, medical and other technicians to review the application and to decide whether to approve the drug clinical trial within 60 days of the date of acceptance of the application. Once the decision is made, the result will be notified to the applicant through the website of the CDE and if no notice of decision is issued within the aforementioned time limit, the application of clinical trial shall be deemed as approval. In accordance with Registration Measures and the *Announcement on Adjusting Evaluation and Approval Procedures for Clinical Trials for Drugs* (《關於調整藥物臨床試驗審評審批程序的公告》) issued in July 2018, if a clinical trial applicant does not receive any negative or questioned opinions from the CDE within 60 days after the date when the trial application is accepted and the fees are paid, the applicant can proceed with the clinical trial in accordance with the trial protocol submitted to the CDE.

The Registration Measures further requires that the applicant shall, prior to conducting the drug clinical trial, register the information of the drug clinical trial plan, etc. on the Drug Clinical Trial Information Platform. After obtaining the approval of clinical trial, the applicant must complete the clinical trial registration at the Drug Clinical Trial Information Platform for public disclosure in accordance with the *Circular on Drug Clinical Trial Information Platform* (《關於藥物臨床試驗信息平台的公告》), which came into effect in September 2013. The applicant shall complete the trial pre-registration within one month after obtaining the approval of the clinical trial application in order to obtain the trial's unique registration number and complete registration of certain follow-up information before the first subject's enrollment in the trial. If the registration is not completed within one year after the approval, the applicant shall submit an explanation, and if the first submission is not completed within three years, the approval of the clinical trial application shall automatically expire. During the drug clinical trials, the applicant shall update registration information continuously, and register information of the outcome of the drug clinical trial upon completion.

Accelerated Approval for Clinical Trial and Registration

The *Opinions on the Reform of Evaluation and Approval System for Drugs and Medical Devices* (《關於改革藥品醫療器械審評審批制度的意見》) issued by the State Council on August, 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 drug registration, accelerating the evaluation and approval process for innovative drugs, and improving the approval for clinical trials of drugs, etc.

The China Food and Drug Administration (currently known as the NMPA) released the *Circular Concerning Several Policies on Drug Registration Review and Approval* (《關於藥品註冊審評審批若干政策的公告》) in November 2015, which clarified the measures and policies regarding simplifying and accelerating the approval process of clinical trials, including but not limited to an one-time approval procedure allowing the overall approval of all phases of a drug's clinical trials, replacing the phase-by-phase application and approval.

The Innovation Opinions established a framework for reforming the evaluation and approval system for drugs, medical devices and equipment. The Innovation Opinions indicated enhancing the standard of approval for drug marketing registration and accelerating the evaluation and approval process for innovative drugs as well as improving the approval of drug clinical trials.

According to the *Announcement on Matters Concerning the Optimization of Drug Registration Review and Approval* (《關於優化藥品註冊審評審批有關事宜的公告》) jointly issued by the NMPA and the NHC in May 2018, the CDE will prioritize the allocation of resources for review, inspection, examination and approval of registration applications that have been included in the scope of fast track clinical trial approval.

In July 2020, the NMPA issued the *Review and Approval Procedures for Conditional Approval of Drug Marketing Applications (Trial Implementation)* (《藥品附條件批准上市申請審評審批工作程序(試行)》), pursuant to which and the Registration Measures, an applicant may submit, during the stage of clinical trials, an application for conditional approval, for pharmaceuticals which fall under the following circumstances: (i) drugs for treatment of life-threatening illnesses for which there is no effective treatment, whose clinical trial has data to prove efficacy and to forecast the clinical value thereof; (ii) drugs urgently needed for public health, whose clinical trial has data to prove efficacy and to forecast the clinical value thereof; and (iii) other vaccines urgently needed for major public health emergencies or deemed by the NHC to be urgently needed, which has been concluded upon evaluation that the benefits outweigh the risks. For applications for a conditional approval, the applicant shall communicate with the CDE on the conditional approval criteria for marketing and the post-marketing research work to be continued and completed, and apply for drug marketing authorization upon communication and confirmation. If it is concluded that the conditional approval requirements are complied with, the drug registration certificate shall state the validity period of the drug registration with conditional approval, the post-marketing research work to be continued and completed and the deadline to complete such work, etc. For the drug

which is granted with conditional approval, the holder shall adopt the appropriate risk management measures following marketing of the drug, and complete the drug clinical trial and relevant post-marketing research within the stipulated period, and declare so to the CDE via a supplementary application.

In July 2020, NMPA issued the *Priority Review and Approval Procedures for Drug Marketing Authorizations (Trial Implementation)* (《藥品上市許可優先審評審批工作程序(試行)》), at the time of application for drug marketing authorization, the following drugs which have obvious clinical value may apply for prioritized review and approval procedures: (i) clinically and urgently needed but insufficient drugs, innovative drugs and improved new drugs for prevention and treatment of major contagious diseases and rare diseases; (ii) new pediatric use pharmaceutical products, dosage form and specifications which comply with pediatric physiological characteristics; (iii) vaccines and innovative vaccines urgently needed for prevention and control of diseases; (iv) drugs included in the procedures for breakthrough therapy designation; (v) drugs which comply with conditional approval criteria; and (vi) other circumstances entitled to prioritized review as stipulated by the NMPA. Upon communication and confirmation with the CDE, when the applicant submits the application for drug marketing authorization, the applicant shall simultaneously submit an application for prioritized review and approval. If an application satisfies one of the foregoing criteria, the CDE shall announce so and admit the application in the prioritized review and approval procedures. The following policy support shall be granted to an application for drug marketing authorization admitted in the prioritized review and approval procedures: (i) the review period shall be limited to no more than 130 days; (ii) for clinically and urgently needed imported drugs for rare diseases which are not yet marketed in the PRC, the review period shall be limited to no more than 70 days; (iii) priority shall be granted to examination, inspection and approval of the commonly used name of drugs (if applicable); and (iv) upon communication and confirmation, supplementary supporting materials may be required.

Conduct of Clinical Trial

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

The applicant filing an application for clinical drug trial after completing the pharmaceutical research, pharmacological and toxicological research, and other researches supporting clinical drug trial shall submit relevant research materials according to the requirements for the application materials. The applicant who intends to carry out a bioequivalence test shall, after undergoing the recordation formalities for bioequivalence test at the website of the CDE as required, carry out relevant research work according to the plan recorded. The applicant who is approved to carry out clinical drug trial shall, before carrying out subsequent clinical drug trial by stages, develop corresponding plan for clinical drug trial, carry out clinical drug trial upon examination and with consent of the ethics committee, and submit corresponding plan for clinical drug trial and supporting materials on the website of the Center for Drug Evaluation. Where indications (or functions) are intended to be added for a drug approved for clinical drug trial and the use of a drug in combination with other drugs is added, the applicant shall file a new application for clinical drug trial, and may only carry out new clinical drug trial with approval.

The *Announcement on Issuing the Guidelines for General Considerations for Clinical Trials on Drugs* (《關於發佈藥物臨床試驗的一般考慮指導原則的通告》) promulgated by the NMPA in January 2017 provides technical guidelines for applicants and investigators in formulating overall research and development plan of drugs and separate clinical trial and provides references for evaluation of the technical standards of the drugs.

According to the *Announcement on Adjusting Evaluation and Approval Procedures for Clinical Trials for Drugs* (《關於調整藥物臨床試驗審評審批程序的公告》), where the application for clinical trial of new investigational drug has been approved, upon the completion of Phases 1 and 2 clinical trials and prior to Phase 3 clinical trial, the applicant shall submit the application for communication meetings to CDE to discuss with CDE the key technical questions including the design of Phase 3 clinical trial protocol. According to the *Administrative Measures for Communication on the Research, Development and Technical Evaluation of Drugs* (《藥物研發與技術審評溝通交流管理辦法》), revised by the NMPA on December 10, 2020, during the research and development periods and in the registration applications of, among others, the innovative new drugs, the applicants may propose to conduct communication meetings with the CDE. The communication meetings can be classified into three types. Type I meetings are convened to address key safety issues in clinical trials of drugs and key technical issues in the research and development of breakthrough therapeutic drugs. Type II meetings are held during the key research and development stages of drugs, mainly including meetings before submitting the clinical trial application, meetings upon the completion of Phase 2 trials and prior to Phase 3 trials, meetings before submitting the marketing application for a new drug, and meetings for risk evaluation and control. Type III meetings refer to other meetings not classified as Type I or Type II.

Good Clinical Practices

Clinical trials must be conducted in accordance with the *Good Clinical Practice for Drug Trials* (《藥物臨床試驗質量管理規範》) (the "**GCP Rules**") promulgated by NMPA and NHC on April 23, 2020 and effective on July 1, 2020, which stipulates the requirements for the procedures of conducting clinical trials, including preclinical trial preparation, trial protocols, protection of testees' rights and interests, duties of researchers, sponsors and monitors, as well as data management and statistical analysis. According to the GCP Rules, clinical trial means systematical investigation of drugs conducted on human subjects (patients or healthy volunteers) to prove or reveal the clinical, pharmacological and other pharmacodynamic effects, adverse reactions or absorption, distribution, metabolism and excretion of the drug being investigated. In order to ensure the quality of clinical trials and the safety of human subjects, the GCP Rules provides comprehensive and substantive requirements on the design and conduct of clinical trials in the PRC. In particular, the GCP Rules enhances the protection for study subjects and tightens the control over bio-samples collected under clinical trials.

The GCP Rules stipulated that the sponsor shall bear the expenses for medical treatment and the corresponding compensation for any human subject who is harmed or dies due to reasons connected with the clinical trial. The sponsor and investigator shall pay the human subject the compensation or indemnification in a timely manner. However, the GCP Rules promulgated in 2020 abolishes the compulsory insurance the sponsor provides to human subjects participating in a clinical trial compared with the GCP Rules promulgated in 2003.

The GCP Rules also set out the qualifications and requirements for the investigators and centers participating in clinical trial, including: (i) professional certification at a clinical trial center, professional knowledge, training experience and capability of clinical trial, and being able to provide the latest resume and relevant qualification documents per request; (ii) being familiar with the trial protocol, investigator's brochure and relevant information of the trial drug provided by the applicant; (iii) being familiar with and comply with the Revised GCP Rules and relevant laws and regulations relating to clinical trials; (iv) keeping a copy of the authorization form on work allocation signed by investigators; (v) investigators and clinical trial centers shall accept supervision and inspection organized by the applicant and inspection by the drug regulatory authorities; and (vi) in the case of investigators and clinical trial centers authorizing other individual or institution to undertake certain responsibilities and functions relating to clinical trial, they shall ensure such individual or institution are qualified and establish complete procedures to ensure the responsibilities and functions are fully performed and generate reliable data.

The GCP Rules also summarizes the role of ethic committee in clinical trial process. An ethic committee shall consist of experts working in the medical, pharmaceutical and other fields. The clinical trial protocol may not be executed unless approved by the ethic committee. Pursuant to the *Announcement on Issuing the Guidelines for Ethical Review Work of Drug Clinical Trials* (《關於印發藥物臨床試驗倫理審查工作指導原則的通知》) promulgated by State Food and Drug Administration (currently known as the NMPA) in November 2010, the ethics committee shall carry out a review on the project of clinical trial on the drug to decide

if it is rational in terms of science and ethics, and shall be subject to guidance and supervision under the drug supervisory and administrative departments. The Regulations for the Administration of Drug Clinical Trial Institutions also stipulates that each clinical trial institution shall maintain an ethic committee responsible for the ethical review of drug clinical trial.

Non-clinical Research

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

Trial Exemptions and Acceptance of Foreign Data

The NMPA issued the *Technical Guidance Principles on Accepting Foreign Drug Clinical Trial Data* (《接受藥品境外臨床試驗數據的技術指導原則》) in July 2018, as one of the implementing rules for the Innovation Opinions, which provides that overseas clinical data can be submitted for the drug marketing registration applications in China. Such applications can be in the form of waivers to China-based clinical trials, bridging trials and direct drug marketing registration. According to the Technical Guidance Principles on Accepting Foreign Drug Clinical Trial Data, sponsors may use the data of foreign clinical trials to support drug marketing registration in China, provided that sponsors must ensure the authenticity, integrity, accuracy and traceability of foreign clinical trial data and such data must be obtained consistent with the relevant requirements under the Good Clinical Practice of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (the "**ICH**"). Moreover, sponsors shall ensure the scientific design of overseas clinical trials, the compliance of clinical trial quality management system requirements, and the accuracy and integrity of statistical analysis of data. To ensure that the clinical trial design and statistical analysis of the data are scientific and reasonable, for the drugs with simultaneous R&D at home and abroad and forthcoming clinical trials in China, the sponsors may, prior to implementing registrational clinical trials, contact the CDE to ensure the compliance of registrational clinical trials' design with the essential technical requirements for drug registration in China. Sponsors must also comply with other relevant sections of the Registration Measures when applying for drug marketing registrations in China using foreign clinical trial data.

The NMPA now officially permits, and its predecessor agencies have permitted on a case-by-case basis in the past, drugs approved outside of China to be approved in China on a conditional basis without pre-approval clinical trials being conducted in China. Specifically,

the NMPA and the NHC released the *Procedures for Reviewing and Approval of Clinical Urgently Needed Overseas New Drugs* (《關於臨床急需境外新藥審評審批相關事宜的公告》) in October 2018, permitting drugs that have been approved within the last ten years in the United States, the European Union or Japan and that prevent or treat orphan diseases or prevent, or treat serious life-threatening illnesses for which there is either no effective therapy in China, or for which the foreign-approved drug would have clear clinical advantages. Applicants will be required to establish a risk mitigation plan and may be required to complete trials in China after the drug has been marketed. The CDE has developed a list of qualifying drugs that meet the foregoing criteria.

On November 15, 2021, the CDE introduced the Guiding Principles for Clinical Research and Development of Anti-tumor Drugs Oriented by Clinical Value (《以臨床價值為導向的抗腫瘤藥物臨床研發指導原則》), for anti-tumor drugs, which states that the fundamental purpose of the drug market is to address the needs of patients, and emphasizes that drug R&D should be based on patient needs and clinical value.

New drug registration

Pursuant to the Registration Measures, upon completion of clinical trials, determination of quality standards, completion of validation of commercial-scale production processes and completion of other related preparation works, the applicant may apply with the NMPA for the marketing authorization. The NMPA then determines whether to approve the application according to applicable laws and regulations. The applicant must obtain the marketing authorization for a new drag before the drug can be manufactured and sold in the China market.

Marketing Authorization Holder Mechanism

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

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

The drug marketing authorization holder shall establish a drug quality assurance system and be equipped with special personnel to take charge of quality management on drugs independently. The drug marketing authorization holder shall regularly review the quality management system of the drug manufacturer and the drug distributor, and supervise its continuous quality assurance and control capabilities. Where the marketing authorization holder is an overseas enterprise, its designated domestic enterprise shall perform the obligations of the marketing authorization holder and jointly assume responsibilities of the marketing authorization holder with the overseas enterprise.

Approval or Filing of Human Genetic Resources

The Ministry of Science and Technology (the "**MST**") promulgated the *Service Guide for Administrative Licensing Items concerning Examination and Approval of Sampling, Collecting, Trading or Exporting Human Genetic Resources, or Taking Such Resources out of the PRC* (《人類遺傳資源採集、收集、買賣、出口、出境審批行政許可事項服務指南》) in July 2015, according to which, the sampling, collection or research activities of human genetic resources by a foreign-invested sponsor fall within the scope of international cooperation, and the cooperating organization of China shall apply for approval of the Human Genetic Resources Management Office of the PRC through the online system. The MST and the Human Genetic Resources Management Office of the PRC further respectively promulgated the *Circular on Optimizing the Administrative Examination and Approval of Human Genetic Resources* (《關於優化人類遺傳資源行政審批流程的通知》) in October 2017 and the *Circular on Further Optimizing the Administrative Examination and Approval of Human Genetic Resources* (《關於進一步優化人類遺傳資源行政審批流程的通知》) in October 2020, which simplify the approval of sampling and collecting human genetic resources for the purpose of listing a drug in the PRC.

The *Regulations on the Administration of Human Genetic Resources of the PRC* (《中華人民共和國人類遺傳資源管理條例》), promulgated by the State Council in May 2019, latest amended in March 2024 and came into effect in May 2024, further stipulates that in order to obtain marketing authorization for relevant drugs and medical devices in China, no approval is required in international clinical trial cooperation using China's human genetic resources at clinical institutions without export of human genetic resource materials. However, the type, quantity and usage of the human genetic resources to be used shall be filed with the administrative department of health under the State Council before clinical trials. In May 2023, the MST issued the *Implementation Rules for the Administrative Regulation on Human Genetic Resources* (《人類遺傳資源管理條例實施細則》), which came into effect on July 1, 2023, optimizing the scope of administrative licensing and record-keeping, enhancing the operability of the human genetic resources administration system, and implementing the registration and reporting system for the management of human genetic resources.

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 and latest amended on April 26, 2024, establishing a comprehensive legislative framework on the current regulations in the areas including prevention and control of outbreak of major

newly-emerged infectious diseases, animal and plant epidemics, security of biotechnology research, development and application, biosafety management of pathogenic microbiology laboratories, security management of human genetic resources and biological resources, prevention of the invasion of alien species and protection of biodiversity, 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 administrative department of health 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 administrative department of health under the State Council.

REGULATIONS ON INFORMATION SECURITY AND DATA PROTECTION

According to the *PRC Civil Code* (《中華人民共和國民法典》), the personal information of an individual shall be protected by the law. Any organization or individual that needs to obtain personal information of others shall obtain such information legally and ensure the safety of such information, and shall not illegally collect, use, process or transmit personal information of others, or illegally purchase or sell, provide or make public personal information of others. In addition, the processing of personal information shall follow the principles of lawfulness, legitimacy and necessity.

On August 20, 2021, the SCNPC promulgated the *Personal Information Protection Law of the PRC* (《中華人民共和國個人信息保護法》), or the Personal Information Protection Law, which became effective on November 1, 2021. The Personal Information Protection Law requires, among others, that the processing of personal information should have a clear and reasonable purpose and should be limited to the minimum scope necessary to achieve the processing purpose, adopt a method that has the least impact on personal rights and interests, and shall not process personal information that is not directly related to the processing purpose.

The *Interpretations of the Supreme People's Court and the Supreme People's Procuratorate on Several Issues Concerning the Application of Law in the Handling of Criminal Cases Involving Infringement of Citizens' Personal Information* (《最高人民法院、最高人民檢察院關於辦理侵犯公民個人信息刑事案件適用法律若干問題的解釋》), or the Interpretations were promulgated on May 8, 2017 and became effective on June 1, 2017. The Interpretations clarify several concepts regarding the crime of "infringement of citizens' personal information" stipulated by Article 253A of the *Criminal Law of the PRC* (《中華人民共和國刑法》), including "citizens' personal information", "violation of relevant national

provisions", "provision of citizens' personal information" and "illegally obtaining any citizen's personal information by other methods". In addition, the Interpretations specify the standards for determining "serious circumstances" and "extraordinary serious circumstances" of this crime.

On June 10, 2021, the SCNPC promulgated the *Data Security Law of PRC* (《中華人民共和國數據安全法》), or the Data Security Law, which became effective on September 1, 2021. The Data Security Law mainly sets forth specific provisions regarding establishing basic systems for data security management, including data classification and hierarchical protection system, risk assessment system, monitoring and early warning system and emergency disposal system. In addition, it clarifies the data security protection obligations of organizations and individuals carrying out data activities and implementing data security protection responsibility. The Data Security Law stipulates the measures to support and promote data security and development, to establish and optimize the national data security management system and to clarify organizations' and individuals' responsibilities in data security.

On November 7, 2016, the SCNPC promulgated *the Cybersecurity Law of the PRC* (《中華人民共和國網絡安全法》), which became effective on June 1, 2017, according to which, network operators shall fulfill their obligations to safeguard the security of the network when conducting business and providing services. Those who build, operate or provide services through networks shall take technical measures and other necessary measures according to laws, regulations and compulsory national standards to safeguard the safe and stable operation of the networks, respond to network security incidents effectively, prevent illegal and criminal activities, and maintain the integrity, confidentiality and usability of network data. The network operator shall not collect personal information irrelevant to the services it provides or collect or use the personal information in violation of the provisions of laws and regulations or agreements concluded with its users.

On December 28, 2021, the Cyberspace Administration of China, or the CAC, jointly with 12 other administrative authorities, promulgated the *revised Measures for Cybersecurity Review* (《網絡安全審查辦法》), or the MCR, which became effective on February 15, 2022. According to the MCR, (i) CIIO that the purchase of cyber products and services or network platform operators that engage in data processing activities that affects or may affect national security shall be subject to the cybersecurity review by the Cybersecurity Review Office, the department which is responsible for the implementation of cybersecurity review under the CAC; (ii) network platform operators with personal information of more than one million users that seek for listing in a foreign country are obliged to apply for a cybersecurity review by the Cybersecurity Review Office; and (iii) the relevant regulatory authorities may initiate cybersecurity review if such regulatory authorities determine that the issuer's network products or services, or data processing activities affect or may affect national security. On November 14, 2021, the CAC published the *Administration Regulations on Cyber Data Security (Draft for Comments)* (《網絡數據安全管理條例(徵求意見稿)》), which stipulated that data processing entities should apply for cybersecurity review in the event that, among others, its listing in Hong Kong affects or may affect national security. On September 30, 2024, the State Council promulgated the *Administration Regulations on Cyber Data Security* (《網絡數據安全管理條

例》) (the "**Data Security Regulations**"), which came into effect on January 1, 2025. The Data Security Regulations reiterate and refine the general regulations for cyber data processing activities, rules of personal information protection, important data security protection, cyber data cross-border transfer management, and the responsibilities of online platform service providers. In addition, the officially promulgated Data Security Regulations do not specifically include the requirement that cyber data processing entities seeking a listing in Hong Kong that affects or may affect national security should apply for a cybersecurity review, as the requirement originally set forth in the draft regulations published on November 14, 2021. Instead, the officially promulgated regulations generally provide that cyber data processors whose cyber data processing activities affect or may affect national security shall be subject to national security review in accordance with the relevant regulations.

On July 7, 2022, the CAC promulgated the *Measures for the Security Assessment of Cross-border Data Transfer* (《數據出境安全評估辦法》), or the Security Assessment Measures, which became effective on September 1, 2022. The Security Assessment Measures provides four circumstances, under any of which data processors shall, through the local cyberspace administration at the provincial-level, apply to the national cyberspace administration for security assessment of cross-border data transfer. These circumstances include: (i) where the important data are transferred to an overseas recipient; (ii) where the personal information is transferred to an overseas recipient by a CIIO or a data processor that has processed personal information of more than one million individuals; (iii) where a data processor provides personal information to an overseas recipient if such data processor has already provided overseas the personal information of 100,000 individuals or sensitive personal information of 10,000 individuals in total since January 1 of the preceding year; or (iv) other circumstances under which security assessment of outbound data transfer is required as prescribed by the national cyberspace administration. In addition, on February 22, 2023, the *Measures for the Administration of Standard Contractual Clauses for the Cross-Border Transfer of Personal Information* (《個人信息出境標準合同辦法》), or the SCC Measures, were promulgated by the CAC, which took effect on June 1, 2023. The SCC Measures attach the prescribed template for the standard contract on the outbound transfer of personal information that could be used as an available option to satisfy the condition for cross-border transfer of personal information under Article 38 of the Personal Information Protection Law.

On March 22, 2024, the CAC promulgated the *Provisions on Promoting and Regulating Cross-Border Data Flows* (《促進和規範數據跨境流動規定》), effective on the date of promulgation. The provisions provide several exemptions from undergoing data security assessment, obtaining personal information protection certification or entering into standard contract for outbound transfer of personal information for businesses. These exemptions include, among others, the scenario where a data processor, other than a CIIO, has cumulatively transferred overseas personal information, excluding sensitive personal information, of fewer than 100,000 individuals since January 1 of the current year. A data processor, other than a CIIO, shall enter into a standard contract with overseas recipients for the cross-border transfer of personal information or obtain certification for personal information protection if since January 1 of the current year, the data processor has cumulatively transferred to overseas recipients (a) personal information of more than 100,000

but less than 1,000,000 individuals, excluding sensitive personal information, or (b) sensitive personal information of less than 10,000 individuals. The provisions also explicitly state that data processors are not required to conduct data security assessment for cross-border transfer of important data if the data has not been notified or published as important data by relevant departments or regions.

REGULATIONS ON INTELLECTUAL PROPERTY

In terms of international conventions, the PRC has entered into (including but not limited to) the *Agreement on Trade-Related Aspects of Intellectual Property Rights* (《與貿易有關的知識財產權協定》), the *Paris Convention for the Protection of Industrial Property* (《保護工業產權巴黎公約》), the *Madrid Agreement Concerning the International Registration of Marks* (《商標國際註冊馬德里協定》) and the *Patent Cooperation Treaty* (《專利合作條約》).

Patent

In accordance with the *Patent Law of the PRC* (《中華人民共和國專利法》), promulgated by the SCNPC, which was latest amended in October 2020 and became effective on June 1, 2021, and the *Implementation Rules of the Patent Law of the PRC* (《中華人民共和國專利法實施細則》), which were promulgated by the State Council on June 15, 2001 and last amended on December 11, 2023 and became effective on January 20, 2024, patent is divided in to 3 categories, i.e., invention patent, design patent and utility model patent. The duration of invention patent right, design patent right and utility model patent right shall be 20 years, 15 years and 10 years, respectively, which all calculated from the date of application. Implementation of a patent without the authorization of the patent holder shall constitute an infringement of patent rights, and shall be held liable for compensation to the patent holder and may be imposed a fine, or even subject to criminal liabilities.

Specifically, for the purpose of compensating for the time taken to evaluate and approve a new drug to be put on market, the patent administrative department under the State Council shall grant compensation for duration of patent rights for invention of a new drug approved to be put on market in China upon request of the patentee. The compensation period shall not exceed five years, and the total validity period of patent rights for a new drug after being approved for marketing shall not exceed 14 years.

Patent Transfer and License

Patent transfer (patent assignment) and patent license are two different ways of transferring or granting rights of a patent. Patent assignment refers to the transfer of ownership of a patent from one party (assignor) to another (assignee). The party who receives the assignment (assignee) becomes the new owner of the patent, has the entire right to enforce it and collect any damages for infringement. In countries like the PRC, patent assignment needs to be recorded with the patent office and announced to public, before it takes effect. On the other hand, patent license grants permission to another party (licensee) to use a patent, but

ownership of the patent remains with the original owner (licensor). The licensee is allowed to use the patent subject to the terms of the license agreement, which may specify limitations on territory, field, scope and/or duration of use. In the PRC, the recordal of a patent license agreement is not mandatory.

Patent Enforcement

Unauthorized use of patents without consent from owners of patents, forgery of the patents belonging to other persons, or engagement in other patent infringement acts, will subject the infringers to infringement liability. Serious offences such as forgery of patents may be subject to criminal penalties.

A patent owner, or an interested party who believes the patent is being infringed, may either file a civil legal suit or file an administrative complaint with the relevant patent administration authority. A PRC court may issue a preliminary injunction upon the patent holder's or an interested party's request before instituting any legal proceedings or during the proceedings. Damages for infringement are calculated as the loss suffered by the patent holder arising from the infringement or the benefit gained by the infringer from the infringement. If it is difficult to ascertain damages in this manner, damages may be determined by using a reasonable multiple of the license fee under a contractual license. If willful patent infringement is found with serious circumstances, the damages may be increased to an amount between one and five times the amount determined as per the aforementioned calculation method. Statutory damages may be awarded in the circumstances where the damages cannot be determined by the above-mentioned calculation standards. The damage calculation methods shall be applied in the aforementioned order.

Trade Secrets

According to the Anti-Unfair Competition Law, the term "trade secrets" refers to technical and business information that is unknown to the public, has utility, may create business interests or profits for its legal owners or holders, and is maintained as a secret by its legal owners or holders. Under the PRC Anti-Unfair Competition Law, business persons are prohibited from infringing others' trade secrets by: (i) obtaining the trade secrets from the legal owners or holders by any unfair methods such as theft, bribery, fraud, coercion, electronic intrusion, or any other illicit means; (ii) disclosing, using or permitting others to use the trade secrets obtained illegally under item (i) above; (iii) disclosing, using or permitting others to use the trade secrets, in violation of any contractual agreements or any requirements of the legal owners or holders to keep such trade secrets in confidence; or (iv) instigating, inducing or assisting others to violate confidentiality obligation or to violate a rights holder's requirements on keeping confidentiality of trade secrets, disclosing, using or permitting others to use the trade secrets of the rights holder. If a third party knows or should have known of the above-mentioned illegal conduct but nevertheless obtains, uses or discloses trade secrets of

others, the third party may be deemed to have committed a misappropriation of the others' trade secrets. The parties whose trade secrets are being misappropriated may petition for administrative corrections, and regulatory authorities may stop any illegal activities and fine infringing parties.

Trademark

According to the *Trademark Law of the PRC* (《中華人民共和國商標法》) promulgated by SCNPC on August 23, 1982, most recently amended on April 23, 2019 and effective from November 1, 2019, and the *Implementation Regulation of the Trademark Law of the PRC* (《中華人民共和國商標法實施條例》) promulgated by the State Council on August 3, 2002, later amended on April 29, 2014 and effective from May 1, 2014, registered trademarks are granted a term of ten years which may be renewed for consecutive ten-year periods upon request by the trademark owner. Trademark license agreements must be filed with the Trademark Office for record, and the Trademark Law of the PRC has adopted a "first-to-file" principle with respect to trademark registration. Conducts that shall constitute an infringement of the exclusive right to use a registered trademark include but not limited to using a trademark that is identical with or similar to a registered trademark on the same or similar goods without the permission of the trademark registrant, and the infringing party will be ordered to stop the infringement act immediately and may be imposed a fine. The infringing party may also be held liable for the right holder's damages, which will be equal to gains obtained by the infringing party or the losses suffered by the right holder as a result of the infringement, including reasonable expenses incurred by the right holder for stopping the infringement.

Copyright

According to the *Copyright Law of the PRC* (《中華人民共和國著作權法》) promulgated by the SCNPC, which was latest amended in November 2020, and its related Implementing Regulations, Chinese citizens, legal persons, or other organizations shall, whether published or not, own copyright in their works, which include, among others, works of literature, art, natural science, social science, engineering technology and computer software. Copyright owners of protected works enjoy personal rights and property rights with respect to publication, authorship, alteration, integrity, reproduction, distribution, lease, exhibition, performance, projection, broadcasting, dissemination via information network, production, adaptation, translation, compilation, and other rights shall be enjoyed by the copyright owners.

Domain Names

The *Measures on Administration of Internet Domain Names* (《互聯網域名管理辦法》) was promulgated by the MIIT in 2017, which adopts "first to file" rule to allocate domain names to applicants, and provide that the MIIT shall supervise the domain names services nationwide and publicize the PRC domain name system. After completion of the registration procedures, the applicant will become the holder of the relevant domain name.

REGULATIONS ON LEASING

According to the Civil Code, an owner of immovable or movable property is entitled to possession, use, earnings, and disposal of such property in accordance with the law. Subject to the consent of the lessor, the lessee may sublease the leased premises to a third party. Where a lessee subleases the premises, the lease contract between the lessee and the lessor remains valid. The lessor is entitled to terminate the lease if the lessee subleases the premises without the consent of the lessor. In addition, if the ownership of the leased premises changes during the lessee's possession in accordance with the terms of the lease contract, the validity of the lease contract shall not be affected. Moreover, pursuant to the Civil Code, if the mortgaged property has been leased and transferred for occupation prior to the establishment of the mortgage right, the original tenancy shall not be affected by such mortgage right.

On December 1, 2010, the Ministry of Housing and Urban-Rural Development promulgated the *Administrative Measures on Leasing of Commodity Housing* (《商品房屋租賃管理辦法》), which became effective on February 1, 2011. According to such measures, the lessor and the lessee are required to complete property leasing registration and filing formalities within 30 days from execution of the property lease contract with the development authorities or real estate authorities of the municipality or county where the leased property is located. If a company fails to do as aforesaid, it may be ordered to rectify within a stipulated period, and if such company fails to rectify, a fine ranging from RMB1,000 to RMB10,000 may be imposed on each lease agreement.

According to the *Interpretation of the Supreme People's Court on Several Issues concerning the Application of Law in the Trial of Cases about Disputes Over Lease Contracts on Urban Buildings (2020 version)* (《最高人民法院關於審理城鎮房屋租賃合同糾紛案件具體應用法律若干問題的解釋(2020修正)》), which took effect on January 1, 2021, if the ownership of the leased premises changes during lessee's possession in accordance with the terms of the lease contract, and the lessee requests the assignee to continue to perform the original lease contract, the PRC court shall support it, except that the mortgage right has been established before the lease of the leased premises and the ownership changes due to the mortgagee's realization of the mortgage right.

REGULATIONS ON FIRE PROTECTION AND ENVIRONMENTAL PROTECTION

Fire Control

Pursuant to the *Fire Control Law of the PRC* (《中華人民共和國消防法》) promulgated by the SCNPC on April 29, 1998, and last amended on April 29, 2021 and effective therefrom, the Department of Emergency Management under the State Council and the local people's governments at or above county level shall supervise and administer the matters of fire protection, while the fire control and rescue institutions of such people's governments shall be responsible for implementation. The design of fire control of the construction projects must comply with the national technical standards of fire control. If the design of fire control of a construction project has not been examined pursuant to the relevant laws or failed to pass the

examination, the construction of such project is not allowed. If a completed construction project has not gone through the fire safety inspection or failed to satisfy the requirements of fire safety upon inspection, such project is not allowed to be put to use or business. According to *Interim Regulations on Administration of Examination and Acceptance of Fire Control Design of Construction Projects* (《建設工程消防設計審查驗收管理暫行規定》) issued by the Ministry of Housing and Urban-Rural Development on April 1, 2020 and latest amended on 21 August, 2023, an examination system for fire control design and acceptance only applies to special construction projects, and for other projects, a record-filing and spot check system would be applied.

Environmental Protection

The *Environmental Protection Law of the PRC* (《中華人民共和國環境保護法》) was promulgated and effective on 26 December 1989, and most recently amended on 24 April 2014. The Environmental Protection Law has been formulated for the purpose of protecting and improving both the living and the ecological environment, preventing and controlling pollution and other public hazards and safeguarding people's health. According to the provisions of the Environmental Protection Law, in addition to other relevant laws and regulations of the PRC, the Ministry of Environmental Protection and its local counterparts are responsible for administering and supervising environmental protection matters. Pursuant to the Environmental Protection Law, construction projects that have environmental impact shall be subject to environmental impact assessment.

Environment Impact Assessment

On 28 October 2002, the SCNPC promulgated the *Environmental Impact Assessment Law of PRC* (《中華人民共和國環境影響評價法》), which was latest amended on 29 December 2018. According to the Environmental Impact Assessment Law, the State Council implemented the environmental impact assessment to classify construction projects according to the impact of the construction projects on the environment.

Pursuant to the *Interim Measures for Environmental Protection Acceptance of Completed Construction Projects* (《建設項目竣工環境保護驗收暫行辦法》) effective as of 20 November, 2017 and the *Regulations on the Administration Construction Project Environmental Protection* (《建設項目環境保護管理條例》), which was revised on 16 July 2017 and implemented on October 1, 2017, after the completion of a construction project for which an environmental impact report or an environmental impact report form is required, the construction entity shall, according to standards and procedures prescribed by the environmental protection administrative authorities, conduct environmental protection completion acceptance check and compile an acceptance check report. A construction project for which an environmental impact report or an environmental impact report form is required shall not be put into production or use until the environmental protection completion acceptance check has been passed.

On 30 November 2020, Ministry of Ecology and Environment of the PRC promulgated the *Classified Administration Catalogue of Environmental Impact Assessments for Construction Project (2021 version)* (《建設項目環境影響評價分類管理名錄(2021年版)》), which became effective on 1 January 2021. According to the Environmental Impact Assessment Law, where a construction entity commenced construction prior to submission of the environmental impact report and environmental impact statement of the construction project or prior to resubmission of the environmental impact report and environmental impact statement, the ecological environment authorities at the county level or above shall order it to stop the construction, impose a fine of not less than 1% but not more than 5% of the overall investment amount for such construction project according to the seriousness and consequences of such violations, and order it to restore to the original status; and the person-in-charge and responsible personnel of the construction project shall be liable to administrative sanctions in accordance with laws.

Pollutant Discharges Permitting Administration

Pursuant to the provisions of the *Regulation on the Administration of Permitting of Pollutant Discharges* (《排污許可管理條例》) promulgated on 24 January 2021, and the *Measures for Pollutant Discharge Permitting Administration* (《排污許可管理辦法》) promulgated on April 1, 2024 and became effective on July 1, 2024, the PRC implements the classified pollutant discharge permit management (i.e., key management, simplified management and registration management) on pollutant discharges of enterprises based on factors such as the volume of pollutants generated, the amount of pollutant discharged and the degree of impact on the environment. Enterprises and other producers that are included in the *Classification Administration List of Pollutant Discharge Permits for Fixed Pollution Sources* (《固定污染源排污許可分類管理名錄》) shall apply for and obtain a pollutant discharge permit or fill in a pollutant discharge registration form within the prescribed time limit, and shall not discharge pollutants without a pollutant discharge permit or filling in a pollutant discharge registration form.

For any violation of the Regulation on the Administration of Permitting of Pollutant Discharges and the Measures for Pollutant Discharge Permitting Administration, in accordance with the Environmental Protection Law of the PRC, the Atmospheric Pollution Prevention and Control Law of the PRC, the Water Pollution Prevention and Control Law of the PRC and other laws and regulations, the environmental protection authorities have the right to order to make corrections, restrict production, suspend production for rectification, and suspend business and close down, and impose a fine. If a violation of the public security provisions is constituted, it shall be punished for public security violation in accordance with the law. If a crime is constituted, it shall be investigated for criminal liabilities in accordance with the law.

Disposal of Hazardous Waste

Pursuant to the *Law on the Prevention and Control of Environmental Pollution Caused by Solid Waste of the PRC* (《中華人民共和國固體廢物污染環境防治法》), which was promulgated by the SCNPC in 1995 and was latest amended on 29 April 2020, entities

generating hazardous waste shall store, utilise and dispose hazardous waste according to the relevant requirements of the state and environmental protection standards, and shall not dump or pile up hazardous waste without authorisation. Furthermore, it is forbidden to entrust hazardous waste to entities without a permit for disposal, or else the competent ecological and environmental authorities shall order it to make rectification, impose fines, confiscate illegal gains, and in serious circumstance, order it to suspend business or close down upon the approval of the government authorities.

REGULATIONS ON EMPLOYMENT AND SOCIAL WELFARE

Employment

The major PRC laws and regulations that govern employment relationship are the *Labor Law of the PRC* (《中華人民共和國勞動法》), the *Labor Contract Law of the PRC* (《中華人民共和國勞動合同法》) (the "**Labor Contract Law**") and its implementation, which impose stringent requirements on the employers in relation to entering into fixed-term employment contracts, hiring of temporary employees and dismissal of employees.

The Labor Contract Law, which became effective on January 1, 2008, primarily aims at regulating rights and obligations of employment relationships, including the establishment, performance, and termination of labor contracts. Pursuant to the Labor Contract Law, labor contracts must be executed in writing if labor relationships are to be or have been established between employers and employees. Employers are prohibited from forcing employees to work above certain time limits and employers must pay employees for overtime work in accordance with national regulations. In addition, employee wages must not be lower than local standards on minimum wages and must be paid to employees in a timely manner.

In December 2012, the Labor Contract Law was amended to impose more stringent requirements on the use of employees of temp agencies, who are known in China as "dispatched workers". Dispatched workers are entitled to equal pay with full-time employees for equal work. Employers are only allowed to use dispatched workers for temporary, auxiliary or substitutive positions. According to the *Interim Provisions on Labor Dispatch* (《劳務派遣暫行規定》) promulgated by the Ministry of Human Resources and Social Security and came into effect on March 1, 2014, the number of dispatched workers hired by an employer may not exceed 10% of the total number of its employees. Where rectification is not made within the stipulated period, the employers may be subject to a penalty ranging from RMB5,000 to RMB10,000 per dispatched worker exceeding the 10% threshold.

Social Insurance

The Social Insurance Law of the PRC (《中華人民共和國社會保險法》) (the "**Social Insurance Law**") issued by the SCNPC in 2010 and latest amended on December 29, 2018, has established social insurance systems of basic pension insurance, basic medical insurance, work-related injury insurance, unemployment insurance and maternity insurance and has elaborated in detail the legal obligations and liabilities of employers who fail to comply with relevant laws and regulations on social insurance. According to the Social Insurance Law and the *Provisional Regulations on Collection and Payment of Social Insurance Premiums* (《社

會保險費徵繳暫行條例》) promulgated by the State Council on January 22, 1999 and most recently amended on March 24, 2019 and effective from the same date, enterprises shall register social insurance with local social insurance and pay or withhold relevant social insurance for or on behalf of its employees. Any employer that fails to make social insurance contributions may be ordered to rectify the non-compliance and pay the required contributions within a prescribed time limit and be subject to a late fee. If the employer still fails to rectify the failure to make the relevant contributions within the prescribed time, it may be subject to a fine ranging from one to three times the amount overdue.

Housing Provident Fund

In accordance with the Regulations on the Administration of Housing Provident Funds (《住房公積金管理條例》) promulgated by the State Council on April 3, 1999, and amended on March 24, 2002, and March 24, 2019, enterprises must register at the designated administrative centers and open bank accounts for depositing employees' housing provident funds. Employers and employees are also required to pay and deposit housing provident funds, with an amount no less than 5% of the monthly average salary of the employee in the preceding year in full and on time. In case of overdue payment or underpayment by employers, orders for payment within a specified period will be made by the housing fund management center. Where employers fail to make payment within such period, enforcement by the people's court will be applied.

In case of failure to register and open accounts for depositing employees' housing provident funds, the housing fund management center shall order employers to go through the formalities within a specified period, where employers fail to do such formalities within the prescribed time, a fine of not less than RMB10,000 nor more than RMB50,000 shall be imposed.

REGULATIONS ON FOREIGN EXCHANGE

Regulations relating to Foreign Currency Exchange

The principal regulations governing foreign currency exchange in China are the *Foreign Exchange Administration Regulations of the PRC* (《中華人民共和國外匯管理條例》), most recently amended in August 2008. Under the PRC foreign exchange regulations, payments of current account items, such as profit distributions, interest payments and trade and service-related foreign exchange transactions, can be made in foreign currencies without prior approval from the SAFE, by complying with certain procedural requirements. By contrast, approval from or registration with appropriate government authorities is required where Renminbi is to be converted into foreign currency and remitted out of China to pay capital account items, such as direct investments, repayment of foreign currency-denominated loans, repatriation of investments and investments in securities outside of China.

The SAFE issued the *Circular on Reforming of the Management Method of the Settlement of Foreign Currency Capital of Foreign-Invested Enterprises* (《國家外匯管理局關於改革外商投資企業外匯資本金結匯管理方式的通知》) (the "**SAFE Circular 19**") on March 30, 2015, and it became effective on June 1, 2015, which was partially repealed on December 30, 2019, and latest amended on March 23, 2023. The SAFE Circular 19 expands a pilot reform of the administration of the settlement of the foreign exchange capitals of foreign-invested enterprises nationwide. In June 2016, SAFE further promulgated the *Circular on the State Administration of Foreign Exchange on Reforming and Standardizing the Foreign Exchange Settlement Management Policy of Capital Account* (《國家外匯管理局關於改革和規範資本項目結匯管理政策的通知》) (the "**SAFE Circular 16**"), which, among other things, amends certain provisions of SAFE Circular 19. Pursuant to SAFE Circular 19 and SAFE Circular 16, the flow and use of the Renminbi capital converted from foreign currency denominated registered capital of a foreign-invested company is regulated such that Renminbi capital may not be used for business beyond its business scope or to provide loans to persons other than affiliates unless otherwise permitted under its business scope.

In October 2019, SAFE issued the *Circular on Further Facilitating Cross-border 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》) (the "**SAFE Circular 28**"), which cancels the restrictions on domestic equity investments by capital fund of non-investment foreign invested enterprises and allows non-investment foreign invested enterprises to use their capital funds to lawfully make equity investments in China, provided that such investments do not violate the Negative List and the target investment projects are genuine and in compliance with laws. According to the *Circular on Optimizing Administration of Foreign Exchange to Support the Development of Foreign-related Business* (《國家外匯管理局關於優化外匯管理支持涉外業務發展的通知》) (the "**SAFE Circular 8**"), issued by SAFE in April 2020, under the prerequisite of ensuring true and compliant use of funds and compliance with the prevailing administrative provisions on use of income under the capital account, 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 prior provision of the evidentiary materials concerning authenticity to the bank for each transaction. The handling banks shall conduct spot checks afterwards in accordance with the relevant requirements. The interpretation and implementation in practice of SAFE Circular 28 and SAFE Circular 8 are still subject to substantial uncertainties given they are newly issued regulations.

Foreign Exchange Registration of Offshore Investment by PRC Residents

The 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* (《國家外匯管理局關於境內居民通過特殊目的公司境外投融資及返程投資外匯管理有關問題的通知》) (the "**SAFE Circular 37**") in July 2014. The SAFE Circular 37 requires PRC residents (including PRC institutions and individuals) must register with local branches of SAFE in connection with their direct or indirect offshore investment in an overseas special purpose vehicle (the "**SPV**") directly established or indirectly controlled by PRC residents for the purposes of offshore investment and financing with their

legally owned assets or interests in domestic enterprises, or their legally owned offshore assets or interests. Such PRC residents are also required to amend their registrations with SAFE when there is a change to the basic information of the SPV, such as changes of a PRC resident individual shareholder, the name or operating period of the SPV, or when there is a significant change to the SPV, such as changes of the PRC individual resident's increase or decrease of its capital contribution in the SPV, or any share transfer or exchange, merger, division of the SPV.

Failure to comply with the registration procedures set forth in the SAFE Circular 37 may result in restrictions being imposed on the foreign exchange activities of the relevant onshore company, including the payment of dividends and other distributions to its offshore parent or affiliate, the capital inflow from the offshore entities and settlement of foreign exchange capital, and may also subject relevant onshore company or PRC residents to penalties under PRC foreign exchange administration regulations.

Regulations relating to Stock Incentive Plans

Pursuant to the *Circular on Issues Concerning the Foreign Exchange Administration for Domestic Individuals Participating in Stock Incentive Plan of Overseas Publicly Listed Company* (《國家外匯管理局關於境內個人參與境外上市公司股權激勵計劃外匯管理有關問題的通知》) (the "**SAFE Circular 7**"), promulgated by SAFE in February 2012, employees, directors, supervisors, and other senior management participating in any share incentive plan of an overseas publicly-listed company who are PRC citizens or who are non-PRC citizens residing in China for a continuous period of not less than one year, subject to a few exceptions, are required to register with SAFE through a domestic agency. Moreover, an overseas-entrusted institution must be retained to handle matters in connection with the exercise or sale of stock options and the purchase or sale of shares and interests.

The income of foreign exchange PRC residents by selling out the shares according to the equity incentive plan and the dividend distributed by the overseas-listed company shall be distributed to the PRC residents after being remitted to the bank account in China opened by the domestic institutions.

REGULATIONS ON TAXATION

Enterprise Income Tax

According to the CIT Law, which was promulgated by the SCNPC and was latest amended on December 29, 2018, and the *Regulation on the Implementation of the CIT Law*, which was promulgated by the State Council and was latest amended in April 2019, a uniform 25% enterprise income tax rate is imposed to both foreign invested enterprises and domestic enterprises, except where tax incentives are granted to special industries and projects. The enterprise income tax rate is reduced to 20% for qualifying small low-profit enterprises. The high-tech enterprises that need full support from the PRC's government will enjoy a reduced tax rate of 15% for enterprise income tax.

Value-added Tax

Pursuant to the *Provisional Regulations of the PRC on Value-added Tax* (《中華人民共和國增值税暫行條例》), which was promulgated by the State Council and was latest amended on November 19, 2017, and the Implementation Rules for the *Provisional Regulations the PRC on Value-added Tax* (《中華人民共和國增值税暫行條例實施細則》), which was promulgated by the Ministry of Finance and was latest amended on October 28, 2011 and effective from November 1, 2011, entities and individuals engaging in selling goods, providing processing, repairing or replacement services or importing goods within the territory of the PRC are taxpayers of the value-added tax ("**VAT**").

According to the *Notice of the Ministry of Finance and the State Taxation Administration on the Adjusting Value-added Tax Rates* (《財政部　税務總局關於調整增值税税率的通知》) effective in May 2018, the VAT rates of 17% and 11% on sales, imported goods shall be adjusted to 16% and 10%, respectively.

According to the *Announcement of the Ministry of Finance, the State Taxation Administration and the General Administration of Customs on Relevant Policies for Deepening the Value-Added Tax Reform* (《財政部　税務總局　海關總署關於深化增值税改革有關政策的公告》) promulgated on March 20, 2019 and effective from April 1, 2019, the VAT rates of 16% and 10% on sales, imported goods shall be adjusted to 13% and 9%, respectively.

Dividends Distribution

The principal laws, rules and regulations governing dividend distributions by foreign-invested enterprises in the PRC are the Company Law, promulgated in 1993 and latest amended in 2023, and the FIL and its Implementing Regulations. Under these requirements, foreign-invested enterprises may pay dividends only out of their accumulated profit, if any, as determined in accordance with PRC accounting standards and regulations. A PRC company is required to allocate at least 10% of their respective accumulated after-tax profits each year, if any, to fund certain capital reserve funds until the aggregate amount of these reserve funds have reached 50% of the registered capital of the enterprises. A PRC company is not permitted to distribute any profits until any losses from prior fiscal years have been offset. Profits retained from prior fiscal years may be distributed together with distributable profits from the current fiscal year.

REGULATIONS ON OVERSEAS LISTINGS

Overseas Listings

On February 17, 2023, the CSRC released several regulations regarding the management of filings for overseas offerings and listings by domestic companies, including the *Trial Measures for the Administration on Overseas Securities Offering and Listing by Domestic Companies* (《境內企業境外發行證券和上市管理試行辦法》) (the "**Overseas Listing Trial Measures**") together with 5 supporting guidelines (together with the Overseas Listing Trial Measures, collectively referred to as the "**Overseas Listing Regulations**"). Under Overseas Listing Regulations, PRC domestic companies that seek to offer and list securities in overseas markets, either in direct or indirect means, are required to file the required documents with the CSRC within three working days after its application for overseas listing is submitted.

Under the Overseas Listing Trial Measures, an issuer shall be deemed to have filed with the CSRC for indirect overseas issuance and listing if the issuer meets the following circumstances: (i) the operating revenues, total profits, total assets or net assets of the domestic enterprise in the most recent fiscal year, with any one of the indicators accounting for more than 50% of the relevant data in the issuer's audited consolidated financial statements for the same period; (ii) the major aspects of the operating activities are carried out in the territory or the principal place of business is located in the territory, or the majority of the senior management in charge of the operation and management are Chinese citizens or have their usual place of residence in the territory. If an issuer submits an application for an initial public offering to a foreign regulatory body, it shall file the application with the CSRC within three working days after the application is made.

The Overseas Listing Regulations provides that no overseas offering and listing shall be made under any of the following circumstances: (i) such securities offering and listing is explicitly prohibited by provisions in laws, administrative regulations and relevant state rules; (ii) the intended securities offering and listing may endanger national security as reviewed and determined by competent authorities under the State Council in accordance with law; (iii) the domestic company intending to make the securities offering and listing, or its controlling shareholders 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 make the securities offering and listing is suspected of committing crimes or major violations of laws and regulations, and is under investigation according to law 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 or by other shareholders that are controlled by the controlling shareholder and/or actual controller. Additionally, the Overseas Listing Regulations stipulates that after an issuer has offering and listing securities in an overseas market, the issuer shall submit a report to the CSRC within three working days after the occurrence and public disclosure of (i) a change of control thereof, (ii) investigations of or sanctions imposed on the issuer by overseas securities regulators or relevant competent authorities, (iii) changes of listing status or transfers of listing segment, and (iv) a voluntary or mandatory delisting.

Overseas offering and listing by domestic companies shall be made in strict compliance with relevant laws, administrative regulations and rules concerning national security in spheres of foreign investment, cybersecurity, data security and etc., and duly fulfill their obligations to protect national security.

On February 24, 2023, the CSRC and three other relevant government authorities jointly promulgated the *Provisions on Strengthening the Confidentiality and Archives Administration Related to the Overseas Securities Offering 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**"). Pursuant to the Provision on Confidentiality, where a domestic enterprise provides or publicly discloses any document or material that involving state secrets and working secrets of state agencies to the relevant securities companies, securities service institutions, overseas regulatory authorities and other entities and individuals, it shall report to the competent department with the examination and approval authority for approval in accordance with the law, and submit to the secrecy administration department of the same level for filing. The working papers formed within the territory of the PRC by the securities companies and securities service agencies that provide corresponding services for the overseas issuance and listing of domestic enterprises shall be kept within the territory of the PRC, and cross-border transfer shall go through the examination and approval formalities in accordance with the relevant provisions of the State.

As advised by our PRC Legal Advisor, we are required to submit filings with the CSRC within three business days after we submit application for this [**REDACTED**]. As confirmed by our Directors and our PRC Legal Advisor, we have submitted the filing with the CSRC within the specific time limit as required by the Overseas Listing Regulations after our submission of the application for this [**REDACTED**] to the Stock Exchange.

OVERVIEW OF LAWS AND REGULATIONS IN THE UNITED STATES

This section summarizes the principal laws and regulations in the United States that are relevant to our business.

Laws and Regulations in Relation to New Drug

U.S. Government Regulation of Drug and Biological Products

In the United States, the FDA regulates drugs under the FDCA and its implementing regulations, and biologics under the FDCA and the Public Health Service Act and their implementing regulations. Both drugs and biologics also are subject to other federal, state and local statutes and regulations, such as those related to competition. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, and local statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or following approval may subject an applicant to administrative actions or judicial sanctions. These actions and sanctions could include, among

other actions, the FDA's refusal to approve pending applications, withdrawal of an approval, license revocation, a clinical hold, untitled or warning letters, voluntary or mandatory product recalls or market withdrawals, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement and civil or criminal fines or penalties. Any agency or judicial enforcement action could have a material adverse effect on our business, the market acceptance of our products and our reputation.

Once a product candidate is identified for development, it enters preclinical testing, which includes laboratory evaluations of product chemistry, toxicity, formulation and stability, as well as animal studies. Preclinical testing is conducted in accordance with FDA's Good Laboratory Practice regulations. A sponsor of an IND must submit the results of the preclinical tests, manufacturing information, analytical data, the clinical trial protocol, and any available clinical data or literature to the FDA. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions and places the trial on a clinical hold within that 30-day period. FDA may also impose clinical holds or partial clinical holds at any time during clinical trials due to safety concerns or non-compliance.

All clinical trials, which involve the administration of the investigational product to humans, must be conducted under the supervision of one or more qualified investigators in accordance with Good Clinical Practice regulations, including the requirement that all research subjects provide informed consent in writing before their participation in any clinical trial. Further, an Institutional Review Board (the "**IRB**"), must review and approve the plan for any clinical trial before it commences at any institution, and the IRB must conduct continuing review and reapprove the study at least annually. Each new clinical protocol and any amendments to the protocol must be submitted for FDA review, and to the IRBs for approval. An IRB can suspend or terminate approval of a clinical trial at its institution if the trial is not being conducted in accordance with the IRB's requirements or if the product has been associated with unexpected serious harm to subjects.

Clinical trials generally are conducted in three sequential phases, known as phase 1, phase 2 and phase 3, and may overlap.

- phase 1 clinical trials generally involve a small number of healthy volunteers or disease-affected patients who are initially exposed to a single dose and then multiple doses of the product candidate. The primary purpose of these clinical trials is to assess the metabolism, pharmacologic action, side effect tolerability and safety of the product candidate.

- phase 2 clinical trials involve studies in disease-affected patients to evaluate proof of concept and/or determine the dose required to produce the desired benefits. At the same time, safety and further PK and PD information is collected, possible adverse effects and safety risks are identified and a preliminary evaluation of efficacy is conducted.

- phase 3 clinical trials generally involve a large number of patients at multiple sites and are designed to provide the data necessary to demonstrate the effectiveness of the product for its intended use, its safety in use and to establish the overall benefit/risk relationship of the product and provide an adequate basis for product labeling.

Specifically for oncology drugs and biologics, in August 2018, the FDA, together with other US competent authorities, introduced a draft guidance paper "Expansion Cohorts: Use in First-In-Human Clinical Trials to Expedite Development of Oncology Drugs and Biologics Guidance for Industry", which was formally adopted in March 2022. This guidance paper acknowledges a new clinical trial design, which the FDA calls the first-in-human multiple expansion cohort trial. These are trial designs that have a single protocol with an initial dose escalation phase for the initial determination of a tolerated dose and multiple concurrently accruing expansion cohorts with assessments that are more typical of phase 2 trials (i.e., to assess anti-tumor activity). The new trial design is intended to efficiently expedite the clinical development of oncology drugs, including biological products, through multiple expansion cohort trial designs.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA. Safety reports must be submitted to the FDA and the investigators 15 calendar days after the trial sponsor determines that the information qualifies for reporting. The sponsor also must notify FDA of any unexpected fatal or life-threatening suspected adverse reaction as soon as possible but in no case later than 7 calendar days after the sponsor's initial receipt of the information. Sponsors of clinical trials of FDA-regulated products, including drugs, are required to register and disclose certain clinical trial information, which is publicly available at **www.clinicaltrials.gov**.

Concurrent with clinical trials, companies usually complete additional animal studies and must also finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The process of obtaining regulatory approvals and compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements may subject an applicant to administrative or judicial sanctions.

U.S. Review and Approval Processes

The results of product development, preclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the product, proposed labeling and other relevant information, are submitted to the FDA as part of an NDA or a BLA. Unless deferred or waived, NDAs or BLAs, or supplements must contain data adequate to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The submission of an NDA or a BLA is subject to the payment of a substantial user fee and an annual prescription drug product program fee.

Within 60 days of its receipt, the FDA reviews the NDA/BLA to ensure that it is sufficiently complete for substantive review before it accepts the NDA/BLA for filing. After accepting the NDA/BLA filing, the FDA begins an in-depth substantive review to determine, among other things, whether a product is safe and effective for its intended use. The FDA also evaluates whether the product's manufacturing is cGMP-compliant to assure the product's identity, strength, quality and purity. Before approving the NDA/BLA, the FDA typically will inspect whether the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. The FDA may refer the NDA/BLA to an advisory committee, a panel of experts, for review whether the application should be approved and under what conditions and considers such recommendations when making decisions.

The FDA may refuse to approve the NDA/BLA if the applicable regulatory criteria are not satisfied or may require additional clinical data or other data and information. The FDA will issue a complete response ("**CR**") letter describing all of the specific deficiencies that the FDA identified in the NDA/BLA that must be satisfactorily addressed before it can be approved. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the CR letter may include recommended actions that the applicant might take to place the application in a condition for approval. The applicant may either resubmit the NDA/BLA, addressing all of the deficiencies identified in the letter, or withdraw the application or request an opportunity for a hearing.

The regulatory approval may be limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. In addition, the FDA may require post-approval studies, including phase 4 clinical trials, to further assess a product's safety and effectiveness after NDA/BLA approval and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized.

In the United States, products composed of components that would normally be regulated by different centers at the FDA are known as combination products. Typically, the FDA's Office of Combination Products assigns a combination product to a specific Agency Center as the lead reviewer. The FDA determines which Center will lead a product's review based upon the product's primary mode of action. Depending on the type of combination product, its approval, clearance or licensure may usually be obtained through the submission of a single marketing application. However, the FDA sometimes will require separate marketing applications for individual constituent parts of the combination product which may require additional time, effort, and information. Even when a single marketing application is required for a combination product, the relevant Centers may participate in the review. An applicant will also need to discuss with the Agency how to apply certain premarket requirements and post-marketing regulatory requirements, including conduct of clinical trials, adverse event reporting and good manufacturing practices, to their combination product.

Expedited Development and Review Programs

The FDA has various programs that are intended to expedite or streamline the process for the development and FDA review of drugs that are intended for the treatment of serious or life-threatening diseases or conditions and demonstrate the potential to address unmet medical needs. The purpose of these programs is to provide important new drugs to patients earlier than under standard FDA review procedures. The programs include fast track designation, breakthrough therapy designation, accelerated approval, priority review and orphan drug designation, among others.

Fast Track Designation

To be eligible for a fast track designation, the FDA must determine, based on the request of a sponsor, that a drug is intended to treat a serious or life-threatening disease or condition for which there is no effective treatment and demonstrates the potential to address an unmet medical need for the disease or condition. Under the fast-track program, the sponsor of a drug candidate may request FDA to designate the product for a specific indication as a fast-track product concurrent with or after the filing of the IND for the drug candidate. The FDA must make a fast-track designation determination within 60 days after receipt of the sponsor's request.

In addition to other benefits, such as the ability to use surrogate endpoints and have more interactions with FDA, FDA may initiate review of sections of a fast-track product's NDA before the application is complete. This rolling review is available if the applicant provides, and FDA approves, a schedule for the submission of the remaining information and the applicant pays applicable user fees. However, FDA's time period goal for reviewing a fast-track application does not begin until the last section of the NDA is submitted. In addition, the fast-track designation may be withdrawn by FDA if FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

Breakthrough Therapy Designation

Another program available for sponsors is the breakthrough therapy designation. A drug or biologic may be eligible for designation as a breakthrough therapy if the product is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. A sponsor may request that a product be designated as a breakthrough therapy concurrently with, or at any time after, the submission of an IND, and the FDA must determine if the candidate qualifies for such designation within 60 days of receipt of the request. If so designated, the FDA shall act to expedite the development and review of the product's marketing application, including by meeting with the sponsor throughout the product's development, providing timely advice to the sponsor to ensure that the development program to gather preclinical and clinical data is as efficient as practicable.

Accelerated Approval

Under FDA's accelerated approval regulations, the FDA may approve a drug or biologic candidate for a serious or life-threatening illness that provides meaningful therapeutic benefit to patients over existing treatments and demonstrates an effect on either a surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality ("**IMM**"), that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity, or prevalence of the disease or condition and the availability or lack of alternative treatments. For drugs under accelerated approval, the FDA grants priority review status, which aims to shorten the review time to six months from the submission of a complete application. A product candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of post-approval clinical trial to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or to confirm a clinical benefit during post-marketing studies, will allow the FDA to withdraw the product from the market on an expedited basis. All promotional materials for product candidates approved under accelerated regulations are subject to prior review by the FDA.

Priority Review

The FDA may give a priority review designation to drugs that offer major advances in treatment or provide a treatment where no adequate therapy exists. A priority review means that the goal for the FDA to review an application is six months, rather than the standard review of ten months under the Prescription Drug User Fee Act guidelines. These six and ten month review periods are measured from the "filing" date rather than the receipt date for NDAs for new molecular entities, which typically adds approximately two months to the timeline for review and decision from the date of submission. Most products that are eligible for fast-track designation are also likely to be considered appropriate to receive a priority review.

Orphan Drug Designation

Under The Orphan Drug Act of 1983, the FDA may grant orphan drug designation to drugs or biologic candidates intended to treat a rare disease or condition generally affecting fewer than 200,000 individuals in the U.S. or for which a manufacturer has no reasonable expectation of recovering drug treatment research and development costs. The first applicant to receive FDA approval for the disease or indication for which it has orphan drug designation is entitled to a seven year exclusive marketing period. During the exclusivity period, the FDA may not approve any other applications to market the same product for the same disease or condition except in limited circumstances.

Post-Marketing Requirements

Following the approval of a new product, the manufacturer and the approved product are subject to continuing regulation by the FDA, including, among other things, monitoring and record-keeping activities, reporting of adverse experiences, complying with promotion and advertising requirements, which include restrictions on promoting products for unapproved uses or patient populations (known as "off-label use") and limitations on industry-sponsored scientific and educational activities. Although physicians may prescribe legally available products for off-label uses, manufacturers may not market or promote such uses. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including investigation by federal and state authorities. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use or first publication. 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 NDA/BLA or NDA/BLA supplement, which may require the development of additional data or preclinical studies and clinical trials. The FDA may also place other conditions on approvals including the requirement for a risk evaluation and mitigation strategy ("**REMS**"), to assure the safe use of the product. If the FDA concludes a REMS is needed, the sponsor of the NDA/BLA must submit a proposed REMS. The FDA will not approve the NDA/BLA without an approved REMS, if required. A REMS 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. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing.

FDA regulations require that products be manufactured in specific approved facilities and in accordance with cGMP regulations. These manufacturers must comply with cGMP regulations that require, among other things, quality control and quality assurance, the maintenance of records and documentation, and the obligation to investigate and correct any deviations from cGMP.

Manufacturers and other entities involved in the manufacture and distribution of approved drugs or biologics are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP requirements and other laws. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance. The discovery of violative conditions, including failure to conform to cGMP regulations, could result in enforcement actions, and the discovery of problems with a product after approval may result in restrictions on a product, manufacturer or holder of an approved NDA/BLA, including recall.

Once an approval is granted, the FDA may issue enforcement letters or withdraw the approval of the product if compliance with regulatory requirements and standards is not maintained or if problems occur after the drug or biologic reaches the market. Corrective action could delay drug or biologic distribution and require significant time and financial expenditures. Later discovery of previously unknown problems with a drug or biologic, 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 trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the drug or biologic, suspension of the approval, complete withdrawal of the drug from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve applications or supplements to approved applications, or suspension or revocation of drug or biologic approvals; drug or biologic seizure or detention, or refusal to permit the import or export of drugs; or
- injunctions or the imposition of civil or criminal penalties.

Patent Term Restoration and Marketing Exclusivity

After approval, owners of relevant drug or biological product patents may apply for up to a five-year patent extension to restore a portion of patent term lost during product development and FDA review of an NDA or a BLA if approval of the application is the first permitted commercial marketing or use of a biologic containing the active ingredient under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Act. The allowable patent term extension is calculated as one-half of the product's testing phase, which is the time between IND and NDA/BLA submission, and all of the review phase, which is the time between NDA/BLA submission and approval, up to a maximum of five years. The time can be shortened if the FDA determines that the applicant did not pursue approval with due diligence. The total patent term after the extension may not exceed more than 14 years from the date of FDA approval of the product. Only one patent claiming each approved product is eligible for restoration, only those claims covering the approved product, a method for using it, or a method for manufacturing it may be extended, and the patent holder must apply for restoration within 60 days of approval. The USPTO, in consultation with the FDA, reviews and approves the application for patent term restoration. For patents that might expire during the application phase, the patent owner may request an interim patent extension. An interim patent extension increases the patent term by one year and may be renewed up to four times. For each interim patent extension granted, the post-approval patent extension is reduced by one year. The director of the USPTO must determine that approval of the drug candidate covered by the patent for which a patent extension is being sought is likely. Interim patent extensions are not available for a drug candidate for which an NDA or a BLA has not been submitted.

Proposed BIOSECURE Act

On December 20, 2023, members of the U.S. Senate introduced legislation to prohibit federal contracting with certain biotechnology providers connected to foreign adversaries. On March 6, 2024, the version of the legislation introduced in the U.S. Senate was advanced by the Homeland Security and Governmental Affairs Committee for consideration by the full U.S. Senate. On January 24, 2024, the U.S. House of Representatives proposed a similar version of such legislation titled the BIOSECURE Act (the "**BIOSECURE Act**"). On May 15, 2024, the BIOSECURE Act was advanced by the Committee on Oversight to the full U.S. House of Representatives. On September 9, 2024, the U.S. House of Representatives voted in favor of the BIOSECURE Act, which is currently now pending a vote in the full U.S. Senate.

The BIOSECURE Act, if enacted in its current form, would prohibit the U.S. government from procuring biotechnology equipment or services from designated "biotechnology companies of concern," and would prohibit government contracts, loans and grants to any entity that uses biotechnology equipment or services from a designated "biotechnology company of concern." The most recent House version of the legislation names five specific Chinese companies as "biotechnology companies of concern," namely BGI Group, MGI Tech Co., Ltd., Complete Genomics, Inc., WuXi AppTec Co., Ltd., and WuXi Biologics (Cayman) Inc., and any of their subsidiary, parent, affiliate, or successor. The U.S. government has the authority to identify additional entities for inclusion as "biotechnology companies of concern," specifically any entity that is subject to the administrative governance structure, direction, control, or operates on behalf of the government of a foreign adversary (defined by law to be China, Iran, North Korea, and Russia), is involved in the manufacturing, distribution, provision, or procurement of a biotechnology equipment or service, and poses a risk to the national security of the U.S., based on (i) engaging in joint research with, being supported by, or being affiliated with a foreign adversary's military, internal security forces, or intelligence agencies; (ii) providing multiomic data obtained via biotechnology equipment or services to the government of a foreign adversary; or (iii) obtaining human multiomic data via the biotechnology equipment or services without express and informed consent. In 2022, we entered into a license agreement with WuXi Biologics Ireland Limited, an indirect wholly owned subsidiary of WuXi Biologics (Cayman) Inc. (HKEX: 2269), in relation to the in-license of a B7-H3 mAb. During the Track Record Period, we also procured CRO services from WuXi Biologics (Cayman) Inc. through its subsidiaries.

The most recent House version of the legislation would delay the application of the BIOSECURE Act's provisions (i) until January 1, 2032, with respect to biotechnology equipment or services provided or produced by one of the named biotechnology companies of concern under a contract or agreement entered before the effective date of the legislation; and (ii) for a period of five years after the identification of new biotechnology companies of concern, with respect to biotechnology equipment and services provided or produced by an entity that the government identifies in the future as a biotechnology company of concern.

OVERVIEW

We are a global player in ADC innovation, dedicated to the development of next-generation therapeutics in this fast-growing drug modality to treat cancer, autoimmune diseases, and beyond. Our Company was established in July 2019 by our founder, Dr. ZHU Zhongyuan, who has extensive entrepreneurial and managerial experience in the pharmaceutical industry across China and the United States. With over 20 years of experience spanning biotech entrepreneurship and venture investment, Dr. ZHU has cultivated extensive relationships with founders, scientists, and industry experts across the biotech sector. His network and industry expertise were instrumental in assembling our Company's current management team and advisory board. For the biographical information of Dr. ZHU, please refer to the section headed "Directors and Senior Management" in this document.

MILESTONES

The following table summarizes various key milestones in our corporate and business development.

Year	Milestone
2019	The Company was incorporated under the laws of the Cayman Islands.
2020	We commenced our operations in China.
	We completed the Series Seed Financing.
	We completed the Series A-1 Financing and the Series A-2 Financing.
	We initiated our first ADC program DB-1303 (HER2 ADC).
2021	We commenced our operations in the U.S.
	We received IND approval from FDA to launch the first-in-human study of DB-1303 in the U.S.
2022	We completed the Series B Financing.
	We received IND approval from NMPA to launch the first-in-human study of DB-1303 in China.
	We initiated the phase 1/2a global trial of DB-1303.
	We received IND approvals from the FDA and NMPA for DB-1305 (TROP2 ADC) and initiated the first-in-human phase 1/2a global trial of DB-1305.

Year	Milestone
	We entered into an out-license and collaboration agreement with Adcendo* on December 23, 2022 on ADC assets utilizing our proprietary payload-linkers derived from DITAC platform.
2023	We completed the Series B+ Financing.
	We received IND approvals from the FDA and NMPA for DB-1311 (B7-H3 ADC) and initiated the first-in-human phase 1/2a global trial of DB-1311.
	We received IND approvals from the FDA and NMPA for DB-1310 (HER3 ADC) and initiated the first-in-human phase 1/2a global trial of DB-1310.
	We entered into a global strategic partnership with BioNTech* on DB-1303, DB-1311 and DB-1305 on March 16, 2023, March 31, 2023 and August 4, 2023, respectively.
	We entered into an out-license and collaboration agreement with BeiGene* on July 9, 2023 on DB-1312 (B7-H4 ADC).
	We and BioNTech* initiated a global potential registrational study of DB-1303 in HER2-expressing EC.
	DB-1303 obtained Fast Track and Breakthrough Therapy Designations from the FDA for the treatment of advanced EC in patients who progressed on or after treatment with immune checkpoint inhibitors.
2024	We and BioNTech* initiated a phase 3 global registrational trial for DB-1303 in chemo-naïve HR+/HER2-low metastatic BC.
	We initiated a phase 3 registrational trial of DB-1303 in HER2+ BC in China.
	DB-1303 obtained Breakthrough Therapy Designation by the NMPA for the treatment of advanced EC in patients who progressed on or after treatment with immune checkpoint inhibitors.
	DB-1305 was granted Fast Track Designation by the FDA for patients with platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer.
	DB-1311 received FDA Fast Track Designation for the treatment of patients with advanced/unresectable, or metastatic CRPC and Orphan Drug Designations for the treatment of ESCC and SCLC.

Year	Milestone
	We received IND approval from the FDA to launch the phase 1/2a clinical trial of DB-1419.
	We initiated a phase 1 study in healthy adults for DB-2304 in Australia.
	We entered into an exclusive option agreement with GSK for DB-1324, a preclinical asset developed with our DITAC platform.
	We entered into a collaboration and license agreement with Avenzo, pursuant to which we granted Avenzo an exclusive license to develop, manufacture and commercialize DB-1418/AVZO-1418, our EGFR/HER3 BsADC, globally excluding Greater China.
2025	We entered into a collaboration agreement with 3SBio Inc. (HKEX: 1530, "**3SBio**") through its subsidiaries, pursuant to which we have appointed 3SBio as our strategic partner in Mainland China, Hong Kong, and Macau to promote DB-1303 for certain indications.

* Throughout its business development history, the Company has established strategic collaborations with several biopharmaceutical companies, leveraging existing professional networks and industry events to initiate discussions. These collaborations, including those with Adcendo, BioNTech, and BeiGene, were formed through business development efforts.

CORPORATE HISTORY

Establishment and Major Shareholding Changes of Our Company

Our Company was incorporated as an exempted company with limited liability in the Cayman Islands on July 3, 2019. The initial authorized share capital of the Company was US$20,000 divided into 200,000,000 Ordinary Shares of par value of US$0.0001 each. Upon incorporation of the Company, one subscriber share was allotted and issued at par value to Mourant Nominees (Cayman) Limited, which was subsequently transferred at par value to Founder Holdco on February 19, 2020. On the same date, 5,999,999 Ordinary Shares were allotted and issued at par value to Founder Holdco.

Since our incorporation, we have completed several rounds of pre-[**REDACTED**] financing. See "— Pre-[**REDACTED**] Investments" below for more information.

Series Seed Financing

On April 24, 2020, a series seed preferred share purchase agreement was entered into by and among the Company, DualityBio HK, Dr. ZHU Zhongyuan and the Series Seed Investors, pursuant to which (i) 2,000,000 Ordinary Shares were issued and allotted to 6D (as defined below) at par value in consideration of and in recognition of 6D's provision of backing and endorsement to Dr. ZHU, who was a partner of 6D, during the early development phase of the company, and (ii) 5,000,000 Series Seed Preferred Shares were issued and allotted to the Series Seed Investors (the "**Series Seed Financing**") for a consideration of US$5,000,000, which was determined after arm's length negotiations with reference to our business prospects and the research and development of our drug candidates at the time of the investment. The total consideration of US$5,000,200 for the Series Seed Financing was fully settled on May 14, 2020.

Details of the Series Seed Financing are set forth below:

Investors	Number of Shares	Description of Shares	Consideration
			(US$)
Founder Holdco	500,000	Series Seed Preferred Shares	500,000
6 Dimensions Capital, L.P. ("**6D Capital**")	1,900,000	Ordinary Shares	190
	1,900,000	Series Seed Preferred Shares	1,900,000
6 Dimensions Affiliates Fund, L.P. ("**6D Affiliates**", together with 6D Capital, "**6D**")	100,000	Ordinary Shares	10
	100,000	Series Seed Preferred Shares	100,000
APHN Limited ("**APHN**")	1,500,000	Series Seed Preferred Shares	1,500,000
King Star Med LP ("**King Star Med**")	1,000,000	Series Seed Preferred Shares	1,000,000

Upon completion of the Series Seed Financing, the issued share capital of the Company was increased to US$1,300. The shareholding structure of our Company immediately following completion of the Series Seed Financing is set forth below:

Shareholders	Number of Shares	Description of Shares	Approximately shareholding
Founder Holdco	6,000,000	Ordinary Shares	46.15%
	500,000	Series Seed Preferred Shares	3.85%
6D Capital	1,900,000	Ordinary Shares	14.62%
	1,900,000	Series Seed Preferred Shares	14.62%
6D Affiliates	100,000	Ordinary Shares	0.77%
	100,000	Series Seed Preferred Shares	0.77%
APHN	1,500,000	Series Seed Preferred Shares	11.54%
King Star Med	1,000,000	Series Seed Preferred Shares	7.69%
Total	**13,000,000**		**100%**

Series A Financing

On July 20, 2020, a series A-1 preferred share purchase agreement was entered into by and among the Company, DualityBio HK, Duality Suzhou, Duality Shanghai, Dr. ZHU Zhongyuan, Founder Holdco and the Series A-1 Investors, pursuant to which 12,333,333 Series A-1 Preferred Shares were issued and allotted to the Series A-1 Investors (the "**Series A-1 Financing**").

On August 10, 2020, a series A-2 preferred share purchase agreement was entered into by and among, the Company, DualityBio HK, Duality Suzhou, Duality Shanghai, Dr. ZHU Zhongyuan, Founder Holdco and WuXi Biologics HealthCare Venture ("**WuXi Venture**"), pursuant to which 2,666,667 Series A-2 Preferred Shares were issued and allotted to WuXi Venture at the same purchase price as the Series A-1 Financing (the "**Series A-2 Financing**", together with the Series A-1 Financing, the "**Series A Financing**").

The total consideration for each of the Series A-1 Financing and the Series A-2 Financing is US$18,500,000 and US$4,000,000, respectively, which was determined after arm's length negotiations with reference to our business prospects and the research and development of our drug candidates at the time of the investment and was fully settled on August 13, 2020 and August 14, 2020, respectively.

Details of the Series A Financing are set forth below:

Investors	Number of Shares	Description of Shares	Consideration
			(US$)
Series A-1 Investors			
APHN	1,000,000	Series A-1 Preferred Shares	1,500,000
GOLDEN SWORD VENTURES LIMITED ("**Golden Sword**")	3,333,333	Series A-1 Preferred Shares	5,000,000
King Star Med	8,000,000	Series A-1 Preferred Shares	12,000,000
Series A-2 Investor			
WuXi Venture	2,666,667	Series A-2 Preferred Shares	4,000,000

Upon completion of the Series A Financing, the issued share capital of the Company was increased to US$2,800. The shareholding structure of our Company immediately following completion of the Series A Financing is set forth below:

Shareholders	Number of Shares	Description of Shares	Approximately shareholding
Founder Holdco	6,000,000	Ordinary Shares	21.43%
	500,000	Series Seed Preferred Shares	1.79%
6D Capital	1,900,000	Ordinary Shares	6.79%
	1,900,000	Series Seed Preferred Shares	6.79%
6D Affiliates	100,000	Ordinary Shares	0.36%
	100,000	Series Seed Preferred Shares	0.36%
APHN	1,500,000	Series Seed Preferred Shares	5.36%
	1,000,000	Series A-1 Preferred Shares	3.57%
King Star Med	1,000,000	Series Seed Preferred Shares	3.57%
	8,000,000	Series A-1 Preferred Shares	28.57%
Golden Sword	3,333,333	Series A-1 Preferred Shares	11.90%
WuXi Venture	2,666,667	Series A-2 Preferred Shares	9.52%
Total	**28,000,000**		**100%**

Series B and Series B+ Financing

Series B Financing

On April 16, 2021, a series B-1 and series B-2 preferred share purchase agreement was entered into by and among, the Company, DualityBio HK, Duality Suzhou, Duality Shanghai, Dr. ZHU Zhongyuan, Founder Holdco and the Series B Investors (the "**Series B Investment Agreement**"), pursuant to which 16,666,666 Series B-1 Preferred Shares and 13,392,857 Series B-2 Preferred Shares were issued and allotted to the Series B Investors (the "**Series B Financing**").

The total consideration for the Series B Financing was US$80,000,000, which was determined after arm's length negotiations with reference to our business prospects and the research and development of our drug candidates at the time of the investment. The consideration for the Series B-1 Preferred Shares and the Series B-2 Preferred Shares was fully settled on September 22, 2021 and June 10, 2022, respectively.

Series B+ First Tranche Financing

On April 13, 2022, the Company, DualityBio HK, Duality Suzhou, Duality Shanghai, Dr. ZHU Zhongyuan, Founder Holdco and each of the Series B+ First Tranche Investors entered into a series B-2 preferred share purchase agreement, pursuant to which a total of 4,185,267 Series B-2 Preferred Shares were issued and allotted to the Series B+ First Tranche Investors (the "**Series B+ First Tranche Financing**").

The total consideration for the Series B+ First Tranche Financing was US$12,500,000, which was determined based on the same purchase price of Series B-2 Preferred Shares as the Series B Financing. The consideration for the Series B+ First Tranche Financing was fully settled on April 13, 2023.

Series B+ Second Tranche Financing

On September 19, 2022, the Company, DualityBio HK, Duality Suzhou, Duality Shanghai, Dr. ZHU Zhongyuan, Founder Holdco and each of the Series B+ Second Tranche Investors entered into a series B-2 preferred share purchase agreement, pursuant to which a total of 5,859,374 Series B-2 Preferred Shares were issued and allotted to the Series B+ Second Tranche Investors (the "**Series B+ Second Tranche Financing**", together with the Series B+ First Tranche Financing, the "**Series B+ Financing**", and together with the Series B Financing and the Series B+ First Tranche Financing, the "**Series B and Series B+ Financing**").

The total consideration for the Series B+ Second Tranche Financing was US$17,500,000, which was determined based on the same purchase price of Series B-2 Preferred Shares as the Series B Financing. The consideration for the Series B+ Second Tranche Financing was fully settled on March 29, 2023.

Details of the Series B and Series B+ Financing are set forth below:

Investors	Number of Shares	Description of Shares	Consideration
			(US$)
Series B Investors			
WuXi Venture	833,333	Series B-1 Preferred Shares	2,000,000
	669,643	Series B-2 Preferred Shares	2,000,000
LAV Fund VI, L.P. ("**LAV Fund VI**")	6,250,000	Series B-1 Preferred Shares	15,000,000
	5,022,321	Series B-2 Preferred Shares	15,000,000
Green Pine Growth Fund I LP ("**Green Pine**")	1,041,667	Series B-1 Preferred Shares	2,500,000
	837,054	Series B-2 Preferred Shares	2,500,000
Orchids Limited ("**Orchids**")	2,083,333	Series B-1 Preferred Shares	5,000,000
	1,674,107	Series B-2 Preferred Shares	5,000,000
Shanghai Yingjia Enterprise Management Partnership (Limited Partnership) (上海楹伽企業管理合夥企業(有限合夥)) ("**Shanghai Yingjia**")	3,541,667	Series B-1 Preferred Shares	8,500,000
	2,845,982	Series B-2 Preferred Shares	8,500,000
Huagai Sunshine Investment Fund LP ("**Huagai USD**")	583,333	Series B-1 Preferred Shares	1,400,000
Shenzhen Huagai Qianhai Kekong Angel Venture Capital Partnership (Limited Partnership) (深圳華蓋前海科控天使創業投資合夥企業(有限合夥)) ("**Shenzhen Huagai**")	625,000	Series B-1 Preferred Shares	1,500,000
Suzhou Huagai Yizhen Equity Investment Partnership (Limited Partnership) (蘇州華蓋一臻股權投資合夥企業(有限合夥)) ("**Suzhou Huagai**")	41,667	Series B-1 Preferred Shares	100,000
	1,674,107	Series B-2 Preferred Shares	5,000,000

Investors	Number of Shares	Description of Shares	Consideration
			(US$)
Tianjin Huagai Zeyuan Equity Investment Partnership (Limited Partnership) (天津華蓋澤遠股權投資合夥企業(有限合夥)) ("**Tianjin Huagai**" together with Shenzhen Huagai and Suzhou Huagai, collectively "**Huagai RMB**")	833,333	Series B-1 Preferred Shares	2,000,000
China Singapore Suzhou Industrial Park Ventures (中新蘇州工業園區創業投資有限公司) ("**CSVC**") . . .	833,333	Series B-1 Preferred Shares	2,000,000
	669,643	Series B-2 Preferred Shares	2,000,000
Series B+ First Tranche Investors			
SW BIOTECH I LPF (七晟醫藥一號有限合夥基金) ("**SW Biotech**")	1,674,107	Series B-2 Preferred Shares	5,000,000
CSVC	1,004,464	Series B-2 Preferred Shares	3,000,000
Suzhou Taikuntong Start-up Investments Partnership (Limited Partnership) (蘇州泰鯤通創業投資合夥企業(有限合夥)) ("**Tai Kun**") . .	1,506,696	Series B-2 Preferred Shares	4,500,000
Series B+ Second Tranche Investors			
Hangzhou AstraZeneca CICC venture capital partnership (L.P.) (杭州阿斯利康中金創業投資合夥企業(有限合夥)) ("**AZ-CICC Fund I**")	1,674,107	Series B-2 Preferred Shares	5,000,000
Wuxi AstraZeneca CICC No. 1 Venture Capital Partnership (L.P.) (無錫阿斯利康中金壹號創業投資合夥企業(有限合夥)) ("**AZ-CICC Fund II**", together with AZ-CICC Fund I, "**AZ-CICC Fund**")	1,674,107	Series B-2 Preferred Shares	5,000,000

Investors	Number of Shares	Description of Shares	Consideration
			(US$)
Xiamen Shenglianzhiyuan Equity Investment Limited Partnership (廈門市晟聯致遠股權投資合夥企業(有限合夥)) ("**Shenglian**")	1,506,696	Series B-2 Preferred Shares	4,500,000
Tasly International Capital Limited (天士力國際資本有限公司) ("**Tasly International Capital**")*(Note)*	1,004,464	Series B-2 Preferred Shares	3,000,000

Note: On June 26, 2023, Tasly International Capital transferred all of its Shares (the "**Tasly Shares**") in the Company to Yue Cheng International Capital Limited ("**Yue Cheng Capital**") pursuant to a share purchase agreement entered into between Tasly International Capital and Yue Cheng Capital (the "**Share Purchase Agreement**"). Following further commercial discussions between the parties, the Share Purchase Agreement was terminated on June 29, 2024. Subsequently, the Tasly Shares were transferred back to Tasly International Capital and Tasly International Capital restored its shareholding in the Company on June 30, 2024.

As transitional arrangements before the completion of the ODI registration of certain investors on the same date of RMB CB Investors' (as defined below) respective share purchase agreements, (i) each of Orchids, Huagai RMB, CSVC, Tau Kun, and AZ-CICC Fund (collectively, the "**RMB CB Investors**") and their respective affiliates entered into a convertible loan agreement with Duality Suzhou, the Company, Duality Shanghai, and DualityBio HK, pursuant to which (a) the respective offshore affiliates of each RMB CB Investor agreed to provide convertible loans to Duality Suzhou in a total principal amount equal to the consideration for the respective purchase of the Series B-1 Preferred Shares and/or the Series B-2 Preferred Shares by the RMB CB Investors (the "**Convertible Loans**"); and (b) Duality Suzhou agreed to repay the Convertible Loans upon receipt of notification from each RMB CB Investor of the completion of its ODI registration for its respective purchase; and (ii) each of Shanghai Yingjia and Shenglian (collectively, the "**RMB Advance Investors**") and their respective affiliates entered into an advance payment agreement with Duality Suzhou, the Company, Duality Shanghai, and DualityBio HK, pursuant to which (a) the respective offshore affiliates of each RMB Advance Investor agreed to make advance payments to Duality Suzhou in a total principal amount equal to the consideration for their purchase of the Series B-2 Preferred Shares (the "**Advance Payments**"); and (b) Duality Suzhou agreed to repay the Advance Payments upon receipt of notification from each RMB Advance Investor of the completion of its ODI registration for its respective purchase. As of the Latest Practicable Date, all Convertible Loans and Advance Payments have been fully repaid.

Upon completion of the Series B and Series B+ Financing, the issued share capital of the Company increased to US$6,810.4164. The shareholding structure of our Company immediately following completion of the Series B and Series B+ Financing is set forth below:

Shareholders	Number of Shares	Description of Shares	Approximately shareholding
Founder Holdco	6,000,000	Ordinary Shares	8.81%
	500,000	Series Seed Preferred Shares	0.73%
6D Capital	1,900,000	Ordinary Shares	2.79%
	1,900,000	Series Seed Preferred Shares	2.79%
6D Affiliates	100,000	Ordinary Shares	0.15%
	100,000	Series Seed Preferred Shares	0.15%
APHN	1,500,000	Series Seed Preferred Shares	2.20%
	1,000,000	Series A-1 Preferred Shares	1.47%
King Star Med	1,000,000	Series Seed Preferred Shares	1.47%
	8,000,000	Series A-1 Preferred Shares	11.75%
Golden Sword	3,333,333	Series A-1 Preferred Shares	4.89%
WuXi Venture	2,666,667	Series A-2 Preferred Shares	3.92%
	833,333	Series B-1 Preferred Shares	1.22%
	669,643	Series B-2 Preferred Shares	0.98%
LAV Fund VI	6,250,000	Series B-1 Preferred Shares	9.18%
	5,022,321	Series B-2 Preferred Shares	7.37%
Green Pine	1,041,667	Series B-1 Preferred Shares	1.53%
	837,054	Series B-2 Preferred Shares	1.23%
Orchids	2,083,333	Series B-1 Preferred Shares	3.06%
	1,674,107	Series B-2 Preferred Shares	2.46%

Shareholders	Number of Shares	Description of Shares	Approximately shareholding
Shanghai Yingjia	3,541,667	Series B-1 Preferred Shares	5.20%
	2,845,982	Series B-2 Preferred Shares	4.18%
Huagai USD	583,333	Series B-1 Preferred Shares	0.86%
Shenzhen Huagai	625,000	Series B-1 Preferred Shares	0.92%
Suzhou Huagai	41,667	Series B-1 Preferred Shares	0.06%
	1,674,107	Series B-2 Preferred Shares	2.46%
Tianjin Huagai	833,333	Series B-1 Preferred Shares	1.22%
CSVC	833,333	Series B-1 Preferred Shares	1.22%
	1,674,107	Series B-2 Preferred Shares	2.46%
SW Biotech	1,674,107	Series B-2 Preferred Shares	2.46%
Tai Kun	1,506,696	Series B-2 Preferred Shares	2.21%
AZ-CICC Fund I	1,674,107	Series B-2 Preferred Shares	2.46%
AZ-CICC Fund II	1,674,107	Series B-2 Preferred Shares	2.46%
Shenglian	1,506,696	Series B-2 Preferred Shares	2.21%
Tasly International Capital	1,004,464	Series B-2 Preferred Shares	1.47%
Total	**68,104,164**		**100%**

Share Transfer from 6D and APHN to LAV USD

On October 15, 2024, LAV Fund VI Opportunities, L.P. ("**LAV Opportunities**", together with LAV Fund VI, "**LAV USD**") entered into instruments of transfer with each of APHN, 6D Capital and 6D Affiliates, pursuant to which (i) APHN transferred 1,000,000 Series A-1 Preferred Shares to LAV Opportunities for a consideration of US$3,584,000; (ii) 6D Capital transferred 1,900,000 Ordinary Shares and 1,900,000 Series Seed Preferred Shares to LAV Opportunities for an aggregate consideration of US$13,619,200; and (iii) 6D Affiliates transferred 100,000 Ordinary Shares and 100,000 Series Seed Preferred Shares to LAV Opportunities for a consideration of US$716,800 (collectively, the "**Share Transfer to LAV**

USD"). The considerations for the Share Transfer to LAV USD were determined through arm's length negotiations between the transferors and transferee, taking into account our business prospects, research and development progress of our drug candidates, and the commercial considerations of the relevant parties at the time of the transfer. The relevant considerations were fully settled on December 6, 2024. Upon completion of the Share Transfer to LAV USD, (i) LAV Opportunities held 2,000,000 Ordinary Shares, 2,000,000 Series Seed Preferred Shares and 1,000,000 Series A-1 Preferred Shares; (ii) APHN held 1,500,000 Series Seed Preferred Shares; and (iii) 6D ceased to be a Shareholder of the Company.

Share Transfer from King Star Med to Hoi Pok

On November 21, 2024, Hoi Pok (Hong Kong) Trading Company ("**Hoi Pok**") entered into an instrument of transfer with King Star Med, pursuant to which King Star Med transferred 1,205,223 Series A-1 Preferred Shares to Hoi Pok for a consideration of US$6,000,000 (the "**Share Transfer to Hoi Pok**"). The consideration for the Share Transfer to Hoi Pok was determined through arm's length negotiations between the transferor and transferee, taking into account our business prospects, research and development progress of our drug candidates, and the commercial considerations of the relevant parties at the time of the transfer. The consideration was fully settled on November 27, 2024. Upon completion of the Share Transfer to Hoi Pok, (i) Hoi Pok held 1,205,223 Series A-1 Preferred Shares; and (ii) King Star Med held 1,000,000 Series Seed Preferred Shares and 6,794,777 Series A-1 Preferred Shares.

Share Transfer from King Star Med to Hankang

On December 12, 2024, each of Hankang Biotech Fund III, L.P. and Splendid Biotech Fund L.P. (collectively, "**Hankang**") entered into an instrument of transfer with King Star Med, pursuant to which (i) King Star Med transferred 803,482 Series A-1 Preferred Shares to Hankang Biotech Fund III, L.P. for a consideration of US$4,000,000; and (ii) King Star Med transferred 401,741 Series A-1 Preferred Shares to Splendid Biotech Fund L.P. for a consideration of US$2,000,000 (collectively, the "**Share Transfer to Hankang**"). The considerations for the Share Transfer to Hankang were determined through arm's length negotiations between the transferor and transferees, taking into account our business prospects, research and development progress of our drug candidates, and the commercial considerations of the relevant parties at the time of the transfer. The relevant considerations were fully settled on December 13, 2024. Upon completion of the Share Transfer to Hankang, (i) Hankang Biotech Fund III, L.P. held 803,482 Series A-1 Preferred Shares; (ii) Splendid Biotech Fund L.P. held 401,741 Series A-1 Preferred Shares; and (iii) King Star Med held 1,000,000 Series Seed Preferred Shares and 5,589,554 Series A-1 Preferred Shares.

VOTING RIGHTS PROXY AGREEMENT

In order to maintain an appropriate balance of voting influence between the Company's single largest shareholder (i.e., LAV USD) and its founder (i.e., Dr. ZHU Zhongyuan) during the Company's private company phase following completion of the Share Transfer to LAV USD, on October 15, 2024, LAV Opportunities and Founder Holdco entered into a voting rights proxy agreement (the "**Voting Rights Proxy Agreement**"), pursuant to which LAV Opportunities irrevocably and unconditionally appointed Founder Holdco as its true and lawful attorney and proxy with respect to the exercise of voting rights of the 2,000,000 Ordinary Shares (representing approximately 2.94% of our Company's total issued Shares as of the Latest Practicable Date) held by LAV Opportunities (the "**Subject Shares**") in connection with all matters upon which the Subject Shares are entitled to vote. The Voting Rights Proxy Agreement shall effect from October 15, 2024 through the earlier of (a) the completion of the [**REDACTED**] or any deemed liquidation event as prescribed under the seventh amended and restated articles of association of our Company, and (b) the date when LAV Opportunities no longer holds any Subject Shares and such Subject Shares have been transferred to any third party by LAV Opportunities (other than any affiliate of LAV Opportunities).

Upon the [**REDACTED**], the Voting Rights Proxy Agreement will automatically terminate. The Company believes such arrangement can foster clarity and transparency within the Company's governance structure during its transition from a private company to a publicly [**REDACTED**] company as:

(a) it ensures that the Company will have a straightforward and transparent shareholding structure [**REDACTED**], enabling public [**REDACTED**] to easily comprehend the voting dynamics among the Company's shareholders by simply examining the shareholding structure table, which eliminates the necessity to refer to additional arrangements such as a voting proxy arrangement; and

(b) it aligns with the prevailing market practices and general corporate governance expectation for [**REDACTED**] companies where the institutional [**REDACTED**] typically maintain direct control over their voting rights, and various mechanisms exist to balance stakeholder interests.

PRE-[REDACTED] INVESTMENTS

Principal Terms of the Pre-[REDACTED] Investments

Our Company concluded several rounds of investments with the Pre-[**REDACTED**] Investors. The basis of determination for the consideration of the Pre-[**REDACTED**] Investments were from arm's length negotiations after taking into consideration the timing of the investments and the status of our business operation and product development between (i)

our Company and the Pre-[**REDACTED**] Investors in respect of the equity financings, and (ii) the relevant transferors and transferees in respect of the share transfers. The following tables summarize the key terms of the Pre-[**REDACTED**] Investments to our Company made by the Pre-[**REDACTED**] Investors:

Equity Financings of the Company

	Series Seed Financing	**Series A Financing**	**Series B Financing**	**Series B+ Financing**
Date of agreement(s)	April 24, 2020	July 20, 2020 and August 10, 2020	April 16, 2021	April 13, 2022 and September 19, 2022
Date of payment of full consideration	May 14, 2020	August 13, 2020 and August 14, 2020	September 22, 2021 and June 10, 2022	April 13, 2023 and March 29, 2023
Approximate cost per Share (US$)	US$0.0001 per Ordinary Shares; US$1.00 per Series Seed Preferred Shares	US$1.50 per Series A-1 Preferred Shares; US$1.50 per Series A-2 Preferred Shares	US$2.40 per Series B-1 Preferred Shares; US$2.9867 per Series B-2 Preferred Shares	US$2.9867 per Series B-2 Preferred Shares
Amount of Shares subscribed	2,000,000 Ordinary Shares; 5,000,000 Series Seed Preferred Shares	12,333,333 Series A-1 Preferred Shares; 2,666,667 Series A-2 Preferred Shares	16,666,666 Series B-1 Preferred Shares; 13,392,857 Series B-2 Preferred Shares	10,044,641 Series B-2 Preferred Shares
Amount of consideration paid for Shares subscription	US$200 for Ordinary Shares; US$5.0 million for Series Seed Shares	US$18.5 million for Series A-1 Preferred Shares; US$4.0 million for Series A-2 Preferred Shares	US$40.0 million for Series B-1 Preferred Shares; US$40.0 million for Series B-2 Preferred Shares;	US$30.0 million
Discount to the [REDACTED][(1)]	[REDACTED]% for per Ordinary Share and [REDACTED]% for per Series Seed Preferred Share	[REDACTED]% for per Series A-1 Preferred Share and per Series A-2 Preferred Share	[REDACTED]% for per Series B-1 Preferred Share and [REDACTED]% for Series B-2 Preferred Shares	[REDACTED]% for Series B-2 Preferred Shares

	Series Seed Financing	Series A Financing	Series B Financing	Series B+ Financing
Post-money valuation of our Company (undiluted)[2]	US$13.00 million	US$42.00 million[3]	US$173.41 million[4]	US$203.41 million[5][6]
Post-money valuation of our Company (fully diluted)[2]	US$14.50 million	US$56.25 million	US$208.52 million	US$269.97 million

Use of proceeds We utilized the proceeds to finance our ADC platform development activities, R&D activities of pipeline products, as well as to support the working capital needs of our Group. As of the Latest Practicable Date, all the net proceeds from the Pre-[**REDACTED**] Investments had been utilized for the aforementioned purposes.

Lock-up period It is expected that lock-up undertakings will be given by the Pre-[**REDACTED**] Investors to the Joint Sponsors, pursuant to which each Pre-[**REDACTED**] Investor will agree that, subject to the terms of such lock-up undertakings, it will not, whether directly or indirectly, at any time during the period agreed by such Pre-[**REDACTED**] Investor and the Joint Sponsors dispose of any of the Shares held by such Pre-[**REDACTED**] Investor.

Strategic benefits Our Group would benefit from the additional capital injected by the Pre-[**REDACTED**] Investors in our Group, their business resources, knowledge and experience, potential business opportunities and benefits that may be provided by them. Our Pre-[**REDACTED**] Investors include private equity funds and other professional investment companies, many of which are highly experienced in investing in the healthcare and biopharmaceutical industry. Our Directors believed that our Company could benefit from their industry insights and guidance. Our Directors were also of the view that the Pre-[**REDACTED**] Investments demonstrate the Pre-[**REDACTED**] Investors' commitment and confidence in the business performance and operations, strengths and long-term prospects of our Group.

Notes:

(1) The discount to the [**REDACTED**] is calculated based on the foreign exchange rate as of the Latest Practicable Date and the assumption that the [**REDACTED**] is HK$[**REDACTED**] per Share (being the [**REDACTED**] of the indicative [**REDACTED**] range).

(2) Post-money valuation (undiluted) is calculated as (a) cost per Share multiplied by (b) total number of Shares in issue upon completion of the relevant Pre-[**REDACTED**] Investment round. Post-money valuation (fully diluted) is calculated in accordance with the relevant shareholders agreement as (a) cost per Share multiplied by (b) total number of (i) Shares in issue and (ii) Shares to be issued pursuant to the Pre-[**REDACTED**] Equity Incentive Plan (on a fully-diluted and as-exercised basis), upon completion of the relevant Pre-[**REDACTED**] Investment round. The valuation of our Company was determined based on, among other things, arm's length negotiations between the relevant parties primarily taking into consideration the status and continuous development of our business and the progress in the R&D of our pipeline.

(3) The increase of our Company's valuation during the period between the Series Seed Financing and the Series A Financing reflects the investors' recognition of our initial blueprint for the next generation of ADC products. This growth is supported by key achievements on our DITAC platform, through which we successfully identified suitable linker payload molecules and conducted preliminary IP free-to-operate analyses, ensuring unrestricted implementation of our technology. Furthermore, we validated the anti-tumor activity of molecules in early preclinical models for DB-1303, both in vivo and in vitro, leading to the significant milestone of designating a preclinical candidate.

(4) The increase of our Company's valuation during the period between the Series A Financing and the Series B Financing is primarily due to the preliminary preclinical validation on the DITAC platform, and the related patent applications having been filed for priority. Specifically, DB-1303 advanced to the IND-enabling stage, demonstrating a better tolerable dose in monkey toxicity studies compared to other products. Additionally, DB-1305 achieved preclinical candidate designation and also entered the IND-enabling stage, demonstrating superior anti-tumor activity in multiple preclinical models relative to benchmark products. Furthermore, our autoimmune platform DIMAC made significant progress, identifying suitable linker payloads and initiating the development of DB-2304, a first-in-class drug targeting autoimmune diseases.

(5) The increase of our Company's valuation during the period between the Series B Financing and the Series B+ Financing is primarily due to (i) the establishment of our senior management team, (ii) the filing and approval of an IND application for DB-1303, marking its crucial transition from preclinical research to clinical development, (iii) our other products, including DB-1310, DB-1311, DB-1312 and DB-2304, obtaining preclinical candidate molecules, and (iv) early research results on our DIBAC platform. The purchase price of Series B-2 Preferred Shares remained unchanged between the Series B Financing and the Series B+ Financing, because the share purchase agreements for the Series B+ Financing were entered into around the time of the closing of the Series B Financing for the Series B-2 Preferred Shares.

(6) The increase of our Company's valuation upon [**REDACTED**] from Series B+ Financing is primarily due to the R&D progress we made in our drug candidates and platforms, alongside achieving key business milestones subsequent to Series B+ financing including, among others, (i) the R&D progress of our Core Product - DB-1303: initiating a global potential registrational study in HER2-expressing endometrial cancer (EC) and a phase 3 global registrational trial in chemo-naïve HR+/HER2-low metastatic BC and receiving Breakthrough Therapy Designations from both the FDA and the NMPA for certain indications; (ii) the R&D progress of our Core Product-DB-1311: receiving Fast Track Designation from the FDA; (iii) the R&D progress of our key products - DB-1305: receiving Fast Track Designation from the FDA; (iv) the R&D progress of our key products - DB-1419: receiving IND approval; and (v) entering into global partnerships with several world-class pharmaceutical companies with a total deal value of over US$5.0 billion, including a collaboration with BioNTech on DB-1303, DB-1311 and DB-1305 and a collaboration with GSK on DB-1324.

Transfers of Existing Shares

	Share Transfer to LAV USD	Share Transfer to Hoi Pok	Share Transfer to Hankang
Date of agreement(s)	October 15, 2024	November 21, 2024	December 12, 2024
Date of payment of full consideration	December 6, 2024	November 27, 2024	December 13, 2024
Approximate cost per Share (US$)[(1)]	US$3.584 per Ordinary Share; US$3.584 per Series Seed Preferred Shares; US$3.584 per Series A-1 Preferred Share	US$4.978 per Series A-1 Preferred Share	US$4.978 per Series A-1 Preferred Share

	Share Transfer to LAV USD	Share Transfer to Hoi Pok	Share Transfer to Hankang
Amount of Shares transferred	2,000,000 Ordinary Shares; 2,000,000 Series Seed Preferred Shares; 1,000,000 Series A-1 Preferred Shares	1,205,223 Series A-1 Preferred Shares	1,205,223 Series A-1 Preferred Shares
Amount of consideration paid for Shares transfers	US$17,920,000	US$6,000,000	US$6,000,000
Discount to the [REDACTED][(2)]	[**REDACTED**]%	[**REDACTED**]%	[**REDACTED**]%
Lock-up period	It is expected that lock-up undertakings will be given by LAV USD, Hoi Pok and Hankang to the Joint Sponsors, pursuant to which each of them will agree that, subject to the terms of such lock-up undertakings, it will not, whether directly or indirectly, at any time during the period agreed by it and the Joint Sponsors dispose of any of the Shares held by it.		

Notes:

(1) The transfer price was independently negotiated between the relevant transferor and transferee, both of which are professional investors.

(2) The discount to the [**REDACTED**] is calculated based on the foreign exchange rate as of the Latest Practicable Date and the assumption that the [**REDACTED**] is HK$[**REDACTED**] per Share (being the [**REDACTED**] of the indicative [**REDACTED**] range).

Information regarding the Pre-[REDACTED] Investors

Our Pre-[**REDACTED**] Investors include certain Sophisticated Investors, such as LAV USD, King Star Med, Shanghai Yingjia, Orchids and Golden Sword. Each Sophisticated Investor has made meaningful investment in the Company at least six months before the [**REDACTED**], holding approximately [**REDACTED**]%, [**REDACTED**]%, [**REDACTED**]%, [**REDACTED**]% and [**REDACTED**]% of the total issued Shares immediately following the completion of the [**REDACTED**], assuming the [**REDACTED**] is not exercised, respectively. Upon [**REDACTED**], LAV USD and Founder Holdco will be connected persons of the Company as (i) LAV USD will be a substantial shareholder of the Company, and (ii) Founder Holdco is wholly owned by Dr. ZHU Zhongyuan, who is a Director and chief executive officer of the Company. To the best of the Company's knowledge, information and belief having made all reasonable enquiries, all other Pre-[**REDACTED**] Investors are Independent Third Parties. The background information of the Pre-[**REDACTED**] Investors is set out below.

Pre-[REDACTED] Investors	Background
LAV USD	LAV Fund VI is a Cayman Islands exempted limited partnership and none of the limited partners of LAV Fund VI holds more than 30% interest. The general partner of LAV Fund VI is LAV GP VI, L.P. The general partner of LAV GP VI, L.P. is LAV Corporate VI GP, Ltd. LAV Opportunities is a Cayman Islands exempted limited partnership and none of the limited partners in LAV Opportunities holds more than 30% interest. The general partner of LAV Opportunities is LAV GP VI Opportunities, L.P. The general partner of LAV GP VI Opportunities, L.P. is LAV Corporate VI GP Opportunities, Ltd. Each of LAV Corporate VI GP, Ltd. and LAV Corporate VI GP Opportunities, Ltd. is a Cayman Islands exempted company wholly owned by Dr. SHI Yi. LAV USD is within a group of offshore investment vehicles, the investments of which are denominated in U.S. dollar, controlled by Dr. SHI Yi ("LAV USD Group"). As of the Latest Practicable Date, LAV USD Group had assets under management of approximately US$3.5 billion] and invested in over one hundred portfolios covering all major sectors of the biomedical and healthcare industry including biopharmaceuticals, medical devices, diagnostics and healthcare services, examples including ArriVent BioPharma, Inc., a company listed on the NASDAQ (symbol: AVBP), Abbisko Cayman Limited, a company listed on the Stock Exchange (stock code: 2256) and Jacobio Pharmaceuticals Group Co., Ltd., a company listed on the Stock Exchange (stock code: 1167).
APHN	APHN is a company with limited liability incorporated under the laws of the BVI and is ultimately owned by the personal representative of the estate of the late Dr. ZHAO Ning, Dr. LI Ge, an Independent Third Party. APHN's principal business is investment. As of the Latest Practicable Date, APHN's investment portfolio consists solely of its investment in the Company.

Pre-[REDACTED] Investors	Background
King Star Med.	King Star Med is an investment fund organized under the laws of the Cayman Islands, specializing in investments with a primary focus on healthcare and biotech with a fund size of approximately US$100 million. The general partner and manager of King Star Med, namely King Star Med Management Limited and King Star Consulting Limited, are both indirectly held by Ace Treasure Trust and Superb Outcome Trust (the "**Trusts**") as to 40.0% and 30.0%, respectively. Dr. LIN Xianghong is the settlor, the protector and one of the beneficiaries of the Trusts. The voting and investment power of shares held by King Star Med is exercised by the two directors, Dr. LIN Xianghong and Ms. YU Bin, of King Star Med Management Limited, no one of whom may act alone to vote or dispose of the shares. To the best knowledge of our Company, two limited partners of King Star Med, namely Hwa-An International Limited and Max Bloom Group Limited with economic interests of 42.65% and 19.47% in King Star Med respectively, have the same ultimate beneficial owner, namely Mr. SHI Jiangang, an Independent Third Party. Other than that, no limited partners of King Star Med hold more than 30% economic interests. The management team of King Star Med has been specializing in private equity and venture capital investment, and accumulated experience in financing for the development of biotech companies. The portfolio of King Star Med in biotech or healthcare sectors includes Gracell Biotechnologies, a company previously listed on the Nasdaq (stock code: GRCL) and acquired by AstraZeneca PLC, a company listed the Nasdaq and London Stock Exchange (symbol: AZN) in 2023, Adagene Inc., a company listed on the Nasdaq (stock code: ADAG), CStone Pharmaceuticals, a company listed on the Stock Exchange (stock code: 2616), JW (Cayman) Therapeutics Co. Ltd, a company listed on the Stock Exchange (stock code: 2126).
Golden Sword	Golden Sword is an investment holding wholly owned by Sino Biopharmaceutical Limited, a limited liability company incorporated in the Cayman Islands and was listed on the Stock Exchange (stock code: 1177) in 2003 and became a constituent stock of the Hang Seng Index in 2018. Sino Biopharmaceutical Limited principally engages in the research and development as well as the manufacture and sales of pharmaceutical products. Its products have gained a competitive foothold in various therapeutic categories with promising potentials, comprising a variety of biopharmaceutical and chemical medicines for tumors, surgery/analgesia, liver diseases, respiratory system diseases and others. Sino Biopharmaceutical Limited is an Independent Third Party.

Pre-[REDACTED] Investors	Background
WuXi Venture	WuXi Venture is a limited liability partnership incorporated in Hong Kong which is principally engaged in investment activities. WuXi Venture is wholly owned and ultimately controlled by WuXi Biologics (Cayman) Inc., a company listed on the Stock Exchange (stock code: 2269) and is a global contract research, development and manufacturing organization offering end-to-end solutions that enable partners to discover, develop and manufacture biologics from concept to commercialization for the benefit of patients worldwide. WuXi Biologics (Cayman) Inc. is an Independent Third Party, whose investment portfolio includes, among others, I-Mab (天境生物科技有限公司), a company listed on the Nasdaq (ticker: IMAB) and Zenas BioPharma, a company listed on the Nasdaq (ticker: ZBIO).
Green Pine	Green Pine is an exempted limited partnership incorporated under the laws of the Cayman Islands, with its general partner being Green Pine International Capital Partners ("**GPCP**") which is ultimately owned by LUO Fei (羅飛) and LI Wei (厲偉). GPCP principally invests in artificial intelligence, healthcare and new material industries. The limited partners of Green Pine are (i) Lilac International Investment Company Limited which is interested in 26.53% of its equity interests; (ii) Mizuho Bank, Ltd which is interested in 13.53% of its equity interests; (iii) Bondwa Enterprise Limited which is interested in 10.61% of its equity interests; (iv) JU Xiongwei who is interested in 10.61% of its equity interests; (v) Avant Sports Industrial Co., Limited which is interested in 5.31% of its equity interests; (vi) Sidereal Group Limited which is interested in 6.37% of its equity interests; (vii) KAV Invest Holding AG which is interested in 3.71% of its equity interests; and (viii) five individuals each of whom is interested in no more than 10% of its equity interests. Each of Green Pine, GPCP, LUO Fei and LI Wei and the aforesaid limited partners is an Independent Third Party. As of the Latest Practicable Date, Green Pine had assets under management of approximately US$18.9 million. Its investment portfolio includes, among others, HighTide Therapeutics, Inc., a company listed on the Stock Exchange (stock code: 2511), Analytical Biosciences Ltd., and Huahui Healthcare, Inc.

Pre-[REDACTED] Investors	Background
Orchids	Orchids is a limited liability company established under the laws of BVI. Orchids and is a subsidiary of Shanghai Lihao Biotech, L.P. (上海禮灝生物科技合夥企業(有限合夥)) ("**Shanghai Lihao**"), which is a limited partnership established under the laws of the PRC. The general partner of Shanghai Lihao is Shanghai Liyi Investment Management Partnership (Limited Partnership) (上海禮頤投資管理合夥企業(有限合夥)) ("**Liyi Investment I**"). The general partner of Liyi Investment I is Shanghai Liyao Investment Management Co., Ltd. (上海禮曜投資管理有限公司) ("**Shanghai Liyao**"), which is in turn wholly owned by Dr. CHEN Fei, an Independent Third Party. The sole limited partner of Shanghai Lihao is Suzhou Likang Equity Investment Centre (LP) (蘇州禮康股權投資中心(有限合夥) ("**Suzhou Likang**"). The general partner of Suzhou Likang is Shanghai Liyi Investment Management Partnership (Limited Partnership) (上海禮貽投資管理合夥企業(有限合夥)) ("**Liyi Investment II**"). The general partner of Liyi Investment II is Shanghai Liyao. As of the Latest Practicable Date, Liyi Investment I, Liyi Investment II, and their respective affiliates, all controlled by Dr. CHEN Fei (together, "**Liyi Investment Group**"), had assets under management of approximately US$1.7 billion. Liyi Investment Group dedicated its investments primarily to healthcare and biotech companies including Sichuan Kelun-Biotech Biopharmaceutical Co., Ltd. (四川科倫博泰生物醫藥股份有限公司), a company listed on the Stock Exchange (stock code: 6990), and Terns Pharmaceuticals, Inc., a company listed on the NASDAQ (ticker : TERN). As confirmed by LAV USD, which is ultimately controlled by Dr. SHI Yi, and Orchids, which is ultimately controlled by Dr. CHEN Fei, each of LAV USD and Orchids makes its investment decisions independently and there is no concert party arrangement or voting arrangement between them with respect to their interests in the Company.

Pre-[REDACTED] Investors	Background
Shanghai Yingjia . . .	Shanghai Yingjia is a limited partnership incorporated in the PRC. Shanghai Yingjia is held as to 0.01% by Xiamen Yinglian Health Industry Management Partnership (Limited Partnership) (廈門楹聯健康產業管理合夥企業(有限合夥)) ("**Yinglian Management**"), its general partner. The remaining 99.99% interest in Shanghai Yingjia is held by its limited partner, Xiamen Yinglian Health Industry Investment Partnership (Limited Partnership) (廈門楹聯健康產業投資合夥企業(有限合夥)) ("**Yinglian Investment**"). Each of Yinglian Management and Yinglian Investment is controlled by Xiamen Yinglian Health Industry Investment Management Co. Ltd. (廈門楹聯健康產業投資管理有限公司) ("**Xiamen Yinglian**"), which is ultimate beneficially owned by LUO Jing, an Independent Third Party. As of the Latest Practicable Date, Xiamen Yinglian had assets under management of over US$200 million. Its investment portfolio includes, among others, Hinova Pharmaceuticals Inc. (海創藥業股份有限公司), a company listed on Shanghai Stock Exchange (stock code: 688302), BioNova Pharmaceuticals (燁輝醫藥), Full-Life Technologies (輻聯科技), YolTech (Shanghai) Therapeutics Co., Ltd. (堯唐(上海)生物科技有限公司), Innovac Therapeutics (因諾維克生物科技), and Reistone Biopharma (瑞石醫藥).
Huagai RMB	Suzhou Huagai is a limited partnership incorporated in the PRC, whose general partner is Huagai Shangzhen Medical Investment Management (Suzhou) Co., Ltd. (華蓋尚臻醫療投資管理(蘇州)有限公司), which is controlled by Huagai Capital Co., Ltd. (華蓋資本有限責任公司) ("**Huagai Capital**"). Shenzhen Huagai is a limited partnership incorporated in the PRC, whose general partner is HuaGai Southern Investment Management (Shenzhen) Co., Ltd. (華蓋南方投資管理(深圳)), which is controlled by Huagai Capital. Tianjin Huagai is a limited partnership incorporated in the PRC, whose general partner is Beijing HuaGai Healthcare Investment Management Co., Ltd. (華蓋醫療投資管理(北京)有限公司), which is controlled by Huagai Capital.

Pre-[REDACTED] Investors	Background
	Huagai Capital is a company established in the PRC with assets under management of approximately RMB20 billion as of June 30, 2024, and is held as to 30% and controlled by Liaoning Chengda Co., Ltd. (遼寧成大股份有限公司), a company listed on the Shanghai Stock Exchange (stock code: 600739), an Independent Third Party which has invested in several healthcare and biotech companies, including Shenzhen Kangtai Biological Products Co., Ltd. (深圳康泰生物製品股份有限公司), a company listed on the Shenzhen Stock Exchange (stock code: 300601), Hygeia Healthcare Holding Co., Ltd. (海吉亞醫療控股有限公司), a company listed on the Stock Exchange (stock code: 6078) and Shanghai Micurx Pharmaceutical Co., Ltd. (上海盟科藥業股份有限公司),a company listed on the Shanghai Stock Exchange (stock code: 688373).
Huagai USD	Huagai USD is an exempted limited partnership registered in the Cayman Islands. The general partner of Huagai USD is Huagai Healthcare Investment Company Limited, an exempted company incorporated in the Cayman Islands and ultimately controlled by XU Xiaolin (許小林), an Independent Third Party. Huagai USD primarily focuses on early stage investment in biotech and medtech companies with cutting edge technology and has invested in several healthcare and biotech companies, including PAQ Therapeutics.
CSVC	CSVC is an investment services flagship which is directly and wholly-owned by Suzhou Oriza Holdings Co., Ltd (蘇州元禾控股股份有限公司). ("**Oriza Holdings**"). Oriza Holdings' primary investment focus is early-stage and growth-stage enterprises and Oriza Holdings has previously invested in healthcare companies such as Innovent Biologics, Inc., a company listed on the Stock Exchange (stock code: 1801), JW (Cayman) Therapeutics, a company listed on the Stock Exchange (stock code: 2126), Ascentage Pharma, a company listed on the Stock Exchange (stock code: 6855). Oriza Holdings is ultimately controlled by Suzhou Industrial Park Administrative Committee (蘇州工業園區管理委員會), which is an Independent Third Party.

Pre-[REDACTED] Investors	Background
Tai Kun	Tai Kun is a limited partnership incorporated in the PRC, which is held as to 1% by its general partner, Hangzhou Tailong Venture Capital Partnership Enterprise (Limited partnership) (杭州泰瓏創業投資合夥企業(有限合夥)) ("**Hangzhou Tailong**"), and 99% by its limited partner, Hangzhou Taikun Equity Investment Fund Partnership (Limited Partnership) (杭州泰鯤股權投資基金合夥企業(有限合夥)) ("**Hangzhou Taikun**"). Hangzhou Taikun is a limited liability partnership established in the PRC on August 10, 2021 and is an investment fund registered under the Asset Management Association of China with an aggregate amount of assets under management of approximately RMB20.0 billion. Hangzhou Taikun primarily focuses on investment opportunities in companies which engage in development of innovative medical devices and medicine, medical services, etc. Hangzhou Taikun has three limited partners, with the largest limited partner holding approximately 49.00% in Hangzhou Taikun and the general partner and fund manager of Hangzhou Taikun is Hangzhou Tailong. The general partner of Hangzhou Tailong is Zhaotai (Zibo) Venture Capital Management Partnership (Limited Partnership) (昭泰(淄博)創業投資管理合夥企業(有限合夥)), the general partner of which is Mr. LIU Chunguang (劉春光), an Independent Third Party, holding approximately 99% partnership interest therein. Mr. LIU Chunguang, the ultimate beneficial owner of Tai Kun, is a private investor with interest and experience in the biopharmaceutical industry. As of the Latest Practicable Date, approximately 49% and 99% of the respective interest in Hangzhou Taikun and Hangzhou Tailong was held by their respective largest limited partner, Hangzhou Tigermed Equity Investment Partnership (Limited Partnership) (杭州泰格股權投資合夥企業(有限合夥)), which is a wholly-owned subsidiary of Tigermed Consulting Co., Ltd. (杭州泰格醫藥科技股份有限公司), a biopharmaceutical company dually listed on the Stock Exchange (stock code: 3347) and the Shenzhen Stock Exchange (stock code: 300347). Tai Kun and its general partner and limited partners are all Independent Third Parties.

Pre-[REDACTED] Investors	Background
AZ-CICC.	AZ-CICC Fund I is a limited partnership incorporated in the PRC, the general partners of which are AstraZeneca Investment Consulting (Wuxi) Co., Ltd. (阿斯利康商務諮詢(無錫)有限公司) ("**AstraZeneca Investment Consulting**") and CICC Private Equity Management Co., Ltd. (中金私募股權投資管理有限公司) ("**CICC Capital Management**"). The limited partners of AZ-CICC Fund I are Independent Third Parties. AZ-CICC Fund II is a limited partnership incorporated in the PRC, the general partners of which are AstraZeneca Investment Consulting and CICC Capital Management. The limited partners of AZ-CICC Fund II are Independent Third Parties. CICC Capital Management is a wholly-owned subsidiary of China International Capital Corporation Limited (中國國際金融股份有限公司), a company listed on the Stock Exchange (stock code: 3908) and Shanghai Stock Exchange (stock code: 601995). AstraZeneca Investment Consulting is a wholly-owned subsidiary of AstraZeneca Investment (China) Co., Ltd. (阿斯利康投資(中國)有限公司) and these entities are indirectly wholly-owned subsidiaries of the parent company AstraZeneca PLC (the "**AstraZeneca**"), a public limited company with the principal markets for trading on the London Stock Exchange, Nasdaq Stockholm and Nasdaq Global Select Market (symbol: AZN) and an Independent Third Party. AstraZeneca is a global, science-led biopharmaceutical company that focuses on the discovery, development, and commercialisation of prescription medicines in oncology, rare diseases, and biopharmaceuticals, including cardiovascular, renal & metabolism, and respiratory & immunology. Based in Cambridge, UK, AstraZeneca's innovative medicines are sold in more than 125 countries and used by millions of patients worldwide. AstraZeneca has invested in a number of healthcare and biotech companies including Abbisko Cayman Limited (和譽開曼有限責任公司), a company listed on the Stock Exchange (stock code: 2256) and Dizal Pharmaceutical Co., Ltd. (迪哲(江蘇)醫藥股份有限公司), a company listed on the Shanghai Stock Exchange (stock code: 688192). Therefore, each of AZ-CICC Fund I and AZ-CICC Fund II is ultimately beneficially owned by each of CICC and AstraZeneca.

Pre-[REDACTED] Investors	Background
Shenglian	Shenglian is a limited partnership incorporated in the PRC. The general partner of Shenglian is Xiamen Qisheng Venture Capital Co., Ltd. (廈門市七晟創業投資有限公司) ("**Qisheng Venture Capital**"), which is controlled by Septwolves Group Holding CO., LTD. (七匹狼控股集團股份有限公司) ("**Septwolves Group**"). Septwolves Group is ultimately controlled by Zhou Yongwei, Zhou Shaoxiong and Zhou Shaoming, each of whom is an Independent Third Party. As of the Latest Practicable Date, Qisheng Venture Capital had assets under management of approximately RMB2 billion. Its investment portfolio includes, among others, Pyrotech (Beijing) Biotechnology Co., Ltd (北京炎明生物科技有限公司), XpectVision Technology Co., Ltd (深圳幀觀德芯科技有限公司) and Bluepha Co., Ltd (北京藍晶微生物科技有限公司).
SW Biotech	SW Biotech is a limited partnership fund registered in Hong Kong. The general partner of SW Biotech is Hong Kong Wang Yick Investment Limited, a company registered in Hong Kong and wholly owned by TSAI Yan Yan (蔡茵茵), an Independent Third Party. SW Biotech is primarily engaged in investments. As of the Latest Practicable Date, SW Biotech's investment portfolio consists solely of its investment in the Company.
Tasly International Capital	Tasly International Capital is a company incorporated under the laws of the BVI with limited liability on February 28, 2014 which is indirectly wholly owned by Tasly Bio-Medicine Industry Group Co., Ltd. (天士力生物醫藥產業集團有限公司) ("**Tasly Group**") and mainly focuses on overseas equity investment. Tasly Group business covers biopharmaceuticals, health care management, medical services, and investment in the healthcare industry which is ultimately controlled by Mr. YAN Kaijing (閆凱境), an Independent Third Party. Tasly Group has invested in a number of healthcare and biotech companies including Tasly Pharmaceutical Group Co., Ltd. (天士力醫藥集團股份有限公司), a company listed on the Shanghai Stock Exchange (stock code: 600535), Dingdang Health Technology Group Ltd. (叮噹健康科技集團有限公司), a company listed on the Stock Exchange (stock code: 9886), and ClouDr Group Limited (智雲健康科技集團), a company listed on the Stock Exchange (stock code: 9955).

Pre-[REDACTED] Investors	Background
Hoi Pok	Hoi Pok is a sole proprietorship registered in Hong Kong in accordance with the Business Registration Ordinance (Chapter 310 of the Laws of Hong Kong) and is wholly controlled by Ms. Chau Nga Chun, an Independent Third Party. Hoi Pok is principally engaged in investment holding activities.
Hankang	Hankang Biotech Fund III, L.P. is a limited partnership established in the Cayman Islands and is managed by Hankang Biotech III, LLC, which is ultimately owned by Ms. Meichai Zhang. Splendid Biotech Fund L.P. is a limited partnership established in the Cayman Islands and is managed by Pole Star Biotech LLC, which is ultimately owned by Mr. Quanhong Yuan, the spouse of Ms. Meichai Zhang. Both Ms. Meichai Zhang and Mr. Quanhong Yuan are Independent Third Parties. Each of Hankang Biotech Fund III, L.P., Splendid Biotech Fund L.P., Hankang Biotech III, LLC and Pole Star Biotech LLC is operated under Hankang Capital. Hankang Capital is a venture capital fund committed to the pharmaceutical and biotechnology industry with the mission to empower biomedical innovation and safeguard life wellness. Hankang Capital has established strong partnership with pioneering scientists and top-notch entrepreneurs to develop breakthrough new drugs for treatment of major diseases with great unmet clinical needs. Hankang Capital is based in China and with a global vision, many of Hankang Capital's portfolio companies have become industry-leading enterprises, such as Akeso, Inc., a company listed on the Stock Exchange (stock code: 9926), InnoCare Pharma Limited, a company dually listed on the Shanghai Stock Exchange (stock code: 688428) and the Stock Exchange (stock code: 9969), Keymed Biosciences Inc., a company listed on the Stock Exchange (stock code: 2162), Shenzhen Chipscreen Biosciences Co., Ltd., a company listed on the Shanghai Stock Exchange (stock code: 688321), Abbisko Cayman Limited, a company listed on the Stock Exchange (stock code: 2256) and Shanghai Opm Biosciences Co., Ltd., a company listed on the Shanghai Stock Exchange (stock code: 688293). As of the Latest Practicable Date, Hankang Capital has assets under management of approximately USD700 million.

Special Rights of the Pre-[REDACTED] Investors

All Preferred Shares will be converted into Shares of our Company on a one to one basis immediately prior to the completion of the [**REDACTED**]. All Shareholders (including our Pre-[**REDACTED**] Investors) are bound by (i) the terms of the existing memorandum and articles of association of our Company which will be replaced by our Articles effective upon the [**REDACTED**], (ii) the shareholders' agreement dated September 19, 2022 entered into by, among others, the Company and our Shareholders (the "**Shareholders' Agreement**"), and (iii) the agreement in respect of certain rights entered into by, among others, the Company and our Shareholders (the "**Agreement in respect of Certain Rights**") dated August 25, 2024.

Pursuant to the Shareholders' Agreement, the Pre-[**REDACTED**] Investors were granted certain special rights, including, among other rights, (i) information and inspection rights; (ii) pre-emptive rights; (iii) rights of first refusal; (iv) co-sale rights; (v) Board representation; (vi) liquidation preferences; (vii) registration rights; (viii) redemption rights; and (ix) prohibitions on transfers.

Pursuant to the Agreement in respect of Certain Rights, (i) the redemption rights of the Pre-[**REDACTED**] Investors will be terminated immediately upon the first filing of the [**REDACTED**] application by the Company with the Stock Exchange (the "**First Submission Date**"), but shall again become exercisable upon the earliest of (a) the withdrawal of the [**REDACTED**] application by the Company; (b) the rejection of the [**REDACTED**] application by the Stock Exchange; or (c) the expiration of eighteen (18) months after the First Submission Date, and (ii) all other special rights of the Pre-[**REDACTED**] Investors will be automatically terminated upon the completion of the [**REDACTED**]. No special rights granted to the Pre-[**REDACTED**] Investors will survive after the [**REDACTED**].

Compliance with the Listing Guide

On the basis that (i) the [**REDACTED**] will take place more than 120 clear days after the completion of the Pre-[**REDACTED**] Investments, and (ii) the termination of special rights granted to the Pre-[**REDACTED**] Investors as disclosed in "— Special Rights of the Pre-[**REDACTED**] Investors" above, the Joint Sponsors confirm that the Pre-[**REDACTED**] Investments are in compliance with Chapter 4.2 of the Listing Guide.

Public Float

The Shares held by LAV USD and Founder Holdco will not be considered as part of the public float for the purpose of Rule 8.08 of the Listing Rules as (i) LAV USD will be a substantial shareholder of the Company and thus a core connected person of the Company; and (ii) Founder Holdco is a company wholly owned by Dr. ZHU Zhongyuan, who is a Director and thus a core connected person of the Company.

Therefore, a total of [**REDACTED**] Shares, representing approximately [**REDACTED**]% of our Company's total issued Shares immediately following the completion of the [**REDACTED**], assuming the [**REDACTED**] is not exercised, will not be considered as part of the public float upon the [**REDACTED**] for the purpose of Rule 8.08 of the Listing Rules after the [**REDACTED**].

To our Directors' best knowledge, each of the other Pre-[**REDACTED**] Investors is an Independent Third Party. Accordingly, Shares held by them will be counted towards the public float for the purpose of Rule 8.08 of the Listing Rules after the [**REDACTED**].

Save as disclosed above, to the best of our Directors' knowledge, all other Shareholders of our Company are not core connected persons of the Company. As a result, over 25% of the Company's total issued Shares will be held by the public upon completion of the [**REDACTED**] as required under Rule 8.08(1)(a) of the Listing Rules. In addition, the [**REDACTED**] of the portion of the total number of the Company's issued Shares held by the public pursuant to the requirements under Rule 18A.07 of the Listing Rules (based on the [**REDACTED**] of HK$[**REDACTED**], being the [**REDACTED**] of the indicative [**REDACTED**] range) would be over HK$375 million at the time of the [**REDACTED**].

SHARE INCENTIVE PLANS OF THE COMPANY

As of the Latest Practicable Date, we had one share incentive scheme, namely the Pre-[**REDACTED**] Equity Incentive Plan, the terms of which are not subject to the provisions of Chapter 17 of the Listing Rules.

For the purpose of the [**REDACTED**], our Company [adopted] the Post-[**REDACTED**] Share Incentive Plan on [●], 2025, the terms of which comply with the requirements of Chapter 17 of the Listing Rules. The Post-[**REDACTED**] Share Incentive Plan will take effect upon the [**REDACTED**]. Upon the effectiveness of the Post-[**REDACTED**] Share Incentive Plan, no new awards can be granted under the Pre-[**REDACTED**] Equity Incentive Plan while the awards previously granted under the Pre-[**REDACTED**] Equity Incentive Plan will continue to be valid and governed by the Pre-[**REDACTED**] Equity Incentive Plan. We will comply with the requirements under Chapter 17 of the Listing Rules regarding the operation and administration of the Post-[**REDACTED**] Share Incentive Plan. For further details of the share incentive schemes, please see "Statutory and General Information — D. Share Incentive Plans" in Appendix IV to this document.

ACQUISITIONS AND DISPOSALS

Acquisition during the Track Record Period

In order to streamline our operations and mitigate potential competition, in November 2024, our Group acquired the entire equity interests from the then shareholders of Duality Beijing, namely Dr. ZHU Zhongyuan (our Director and chief executive officer, a connected person of our Company), Mr. ZHU Fuyuan (the brother of Dr. ZHU Zhongyuan, a connected

person of our Company) and LO' HK LIMITED (an Independent Third Party) for nil consideration, which was determined on an arm' length basis with reference to the valuation report prepared by an independent qualified professional valuer, taking into account that Duality Beijing was a holding company and had no actual business operations. At the time of completion of the acquisition, Duality Beijing did not have any outstanding liabilities.

Major Acquisitions and Disposals

We did not conduct any material acquisitions, mergers or disposals during the Track Record Period and up to the Latest Practicable Date that we consider significant to our business.

OUR SUBSIDIARIES

As of the Latest Practicable Date, we have five subsidiaries, detailed information of which is set out below:

Name	Date of establishment/ incorporation	Place of establishment/ incorporation	Principal business activities
DualityBio HK	January 21, 2020	Hong Kong	Investment holding
Duality Suzhou	March 23, 2020	PRC	Investment holding and pharmaceuticals research, development and production
Duality Shanghai	April 26, 2020	PRC	Pharmaceuticals research, development and production
Duality US	May 3, 2021	Delaware, the United States	Pharmaceuticals research and development
Duality Beijing	January 9, 2020	PRC	No material business activities

REASON FOR THE [REDACTED]

Our Company is seeking a [**REDACTED**] of its Shares on the Stock Exchange in order to primarily provide further capital for (i) research, development and commercialization of our Core Products; (ii) research and development of our key products; and (iii) continued development of our ADC technology platforms, advancement of our other pipeline assets, and exploration and development of new drug assets, as described in more details in "Future Plans and [**REDACTED**]" in this document.

SHAREHOLDING STRUCTURE OF OUR COMPANY AS OF THE [REDACTED]

The shareholding structure of our Company as of the Latest Practicable Date and immediately upon completion of the [**REDACTED**], assuming the [**REDACTED**] is not exercised is set forth below:

							As of the Latest Practicable Date		Immediately upon completion of the [REDACTED], assuming the [REDACTED] is not exercised	
Shareholders	**Ordinary Shares**	**Series Seed Preferred Shares**	**Series A-1 Preferred Shares**	**Series A-2 Preferred Shares**	**Series B-1 Preferred Shares**	**Series B-2 Preferred Shares**	**Aggregate number of Shares**	**Aggregate ownership percentage**	**Number of Shares**	**Ownership percentage**
Founder Holdco	6,000,000	500,000	–	–	–	–	6,500,000[(1)]	9.54%	6,500,000	[REDACTED]%
APHN	–	1,500,000	–	–	–	–	1,500,000	2.20%	1,500,000	[REDACTED]%
King Star Med	–	1,000,000	5,589,554	–	–	–	6,589,554	9.68%	6,589,554	[REDACTED]%
Golden Sword	–	–	3,333,333	3,333,333	–	–	3,333,333	4.89%	3,333,333	[REDACTED]%
WuXi Venture	–	–	–	2,666,667	833,333	669,643	4,169,643	6.12%	4,169,643	[REDACTED]%
LAV Fund VI	–	–	–	–	6,250,000	5,022,321	11,272,321	16.55%	11,272,321	[REDACTED]%
LAV Opportunities	2,000,000	2,000,000	1,000,000	–	–	–	5,000,000[(1)]	7.34%	5,000,000	[REDACTED]%
Green Pine	–	–	–	–	1,041,667	837,054	1,878,721	2.76%	1,878,721	[REDACTED]%
Huagai USD	–	–	–	–	583,333	–	583,333	0.86%	583,333	[REDACTED]%
Orchids	–	–	–	–	2,083,333	1,674,107	3,757,440	5.52%	3,757,440	[REDACTED]%
Shenzhen Huagai	–	–	–	–	625,000	–	625,000	0.92%	625,000	[REDACTED]%
Suzhou Huagai	–	–	–	–	41,667	1,674,107	1,715,774	2.52%	1,715,774	[REDACTED]%
Tianjin Huagai	–	–	–	–	833,333	–	833,333	1.22%	833,333	[REDACTED]%
Shanghai Yingjia	–	–	–	–	3,541,667	2,845,982	6,387,649	9.38%	6,387,649	[REDACTED]%
CSVC	–	–	–	–	833,333	1,674,107	2,507,440	3.68%	2,507,440	[REDACTED]%

Shareholders	Ordinary Shares	Series Seed Preferred Shares	Series A-1 Preferred Shares	Series A-2 Preferred Shares	Series B-1 Preferred Shares	Series B-2 Preferred Shares	As of the Latest Practicable Date		Immediately upon completion of the [REDACTED], assuming the [REDACTED] is not exercised	
							Aggregate number of Shares	Aggregate ownership percentage	Number of Shares	Ownership percentage
SW Biotech	–	–	–	–	–	1,674,107	1,674,107	2.46%	1,674,107	[REDACTED]%
Shenglian	–	–	–	–	–	1,506,696	1,506,696	2.21%	1,506,696	[REDACTED]%
AZ-CICC Fund I	–	–	–	–	–	1,674,107	1,674,107	2.46%	1,674,107	[REDACTED]%
AZ-CICC Fund II	–	–	–	–	–	1,674,107	1,674,107	2.46%	1,674,107	[REDACTED]%
Tai Kun	–	–	–	–	–	1,506,696	1,506,696	2.21%	1,506,696	[REDACTED]%
Tasly International Capital	–	–	–	–	–	1,004,464	1,004,464	1.47%	1,004,464	[REDACTED]%
Hoi Pok	–	–	1,205,223	–	–	–	1,205,223	1.77%	1,205,223	[REDACTED]%
Hankang Biotech Fund III, L.P.	–	–	803,482	–	–	–	803,482	1.18%	803,482	[REDACTED]%
Splendid Biotech Fund L.P.	–	–	401,741	–	–	–	401,741	0.59%	401,741	[REDACTED]%
[REDACTED]	–	–	–	–	–	–	–	–	[REDACTED]	[REDACTED]%
Total	**8,000,000**	**5,000,000**	**12,333,333**	**2,666,667**	**16,666,666**	**23,437,498**	**68,104,164**	**100.00%**	[REDACTED]	**100.00%**

Note:

Founder Holdco is entitled to exercise the voting rights attached to 2,000,000 Ordinary Shares held by LAV Opportunities pursuant to the Voting Rights Proxy Agreement, which will terminate upon completion of the [**REDACTED**]. For details, see "— Voting Rights Proxy Agreement".

PRC LEGAL COMPLIANCE

Our PRC Legal Advisor has confirmed that each of the capital increase and incorporation of our PRC subsidiaries have been legally completed and the requisite government approvals or filings in all material respects, as applicable, have been obtained in accordance with PRC laws and regulations.

M&A RULES

The M&A Rules require that foreign investors acquiring domestic companies by means of asset acquisition or equity acquisition shall comply with relevant foreign investment industry policies and shall be subject to approval by the relevant commerce authorities. Article 11 of the M&A Rules stipulates that an offshore special purpose vehicle, or a SPV, established or controlled by a PRC company or individual shall obtain approval from MOFCOM prior to the acquisition of any domestic enterprise related to such company or individual. The M&A Rules, among others, also require that an offshore SPV 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 SPV's securities on an overseas stock exchange.

As advised by our PRC Legal Advisor, the MOFCOM approvals or CSRC approvals under the M&A Rules are not required because Duality Suzhou was established at the beginning as a foreign-invested enterprise in the PRC, rather than become foreign-invested enterprises through merger or acquisition under the M&A Rules. However, there is uncertainty as to how the M&A Rules will be interpreted or implemented and whether the MOFCOM and other related government authorities would promulgate future PRC laws, regulations or rules contrary to the M&A Rules.

SAFE Registration

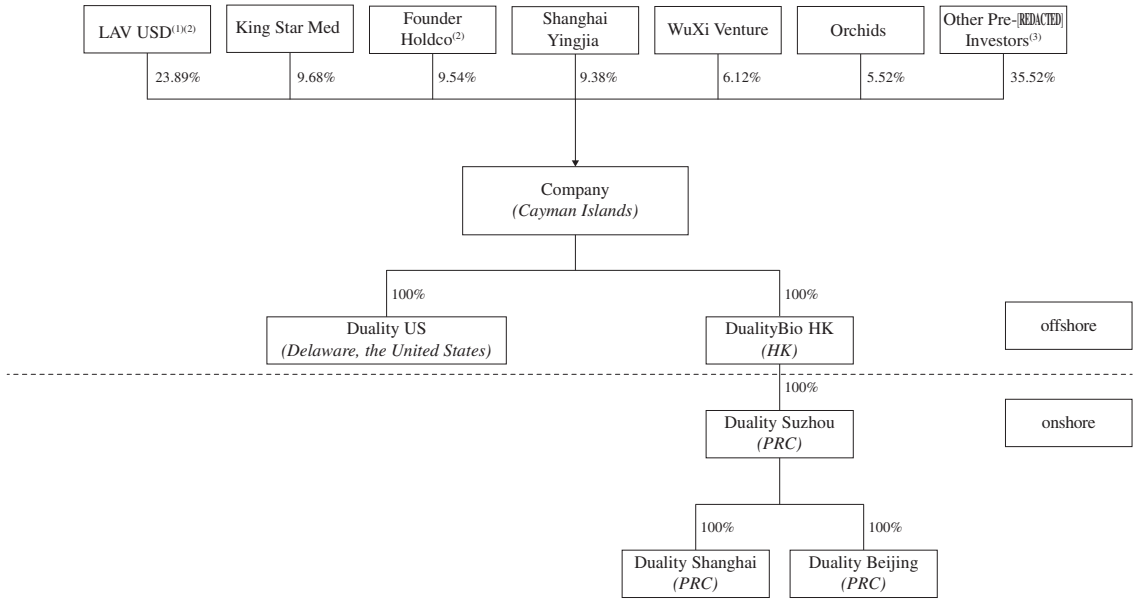
Pursuant to the SAFE Circular 37 which became effective on July 4, 2014, PRC residents are required to register with SAFE or its local branch in connection with their establishment or control of an offshore SPV established for the purpose of overseas investment or financing. Pursuant to the *Circular on Further Simplifying and Improving the Foreign Exchange Management Policies for Direct Investment (Hui Fa [2015] No. 13)* (《關於進一步簡化和完善直接投資外匯管理政策的通知》(匯發[2015]13號)) (the "**SAFE Circular 13**"), promulgated by SAFE in February 2015 and amended on December 30, 2019, banks are required to review and carry out foreign exchange registration under offshore direct investment directly. The SAFE and its branches shall implement indirect supervision over foreign exchange registration of direct investment via the banks.

As advised by our PRC Legal Advisor, Dr. ZHU, who is required to complete the registration under SAFE Circular 37 and SAFE Circular 13, has completed the foreign exchange initial registration in January 2020 in relation to his offshore investments as a PRC resident.

OUR SHAREHOLDING AND CORPORATE STRUCTURE

Immediately Prior to the [REDACTED]

Our corporate and shareholding structure immediately prior to the completion of the [**REDACTED**] is as follows:



Notes:

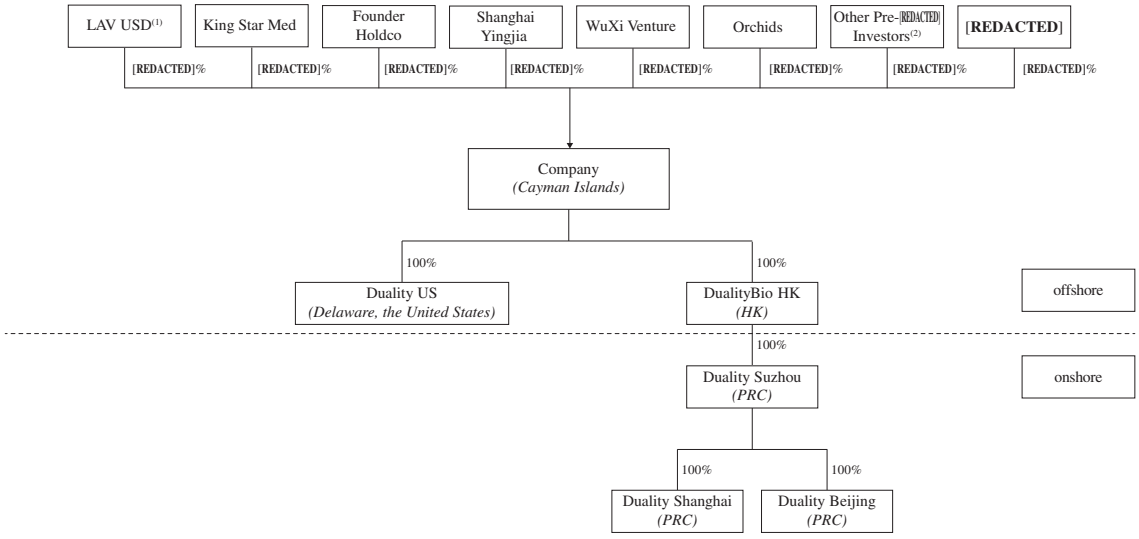
(1) As of the Latest Practicable Date, 2,000,000 Ordinary Shares, 2,000,000 Series Seed Preferred Shares, 1,000,000 Series A-1 Preferred, 6,250,000 Series B-1 Preferred Shares and 5,022,321 Series B-2 Preferred Shares were held by LAV USD, among which (i) 6,250,000 Series B-1 Preferred Shares and 5,022,321 Series B-2 Preferred Shares were held by LAV Fund VI; and (ii) 2,000,000 Ordinary Shares, 2,000,000 Series Seed Preferred Shares and 1,000,000 Series A-1 Preferred Shares were held by LAV Opportunities.

(2) Founder Holdco is entitled to exercise the voting rights attached to 2,000,000 Ordinary Shares held by LAV Opportunities pursuant to the Voting Rights Proxy Agreement, which will terminate upon completion of the [**REDACTED**]. For details, see "— Voting Rights Proxy Agreement".

(3) As of the Latest Practicable Date, other Pre-[**REDACTED**] Investors includes APHN (1,500,000 Preferred Shares), Golden Sword (3,333,333 Preferred Shares), Green Pine (1,878,721 Preferred Shares), Huagai USD (583,333 Preferred Shares), Shenzhen Huagai (625,000 Preferred Shares), Suzhou Huagai (1,715,774 Preferred Shares), Tianjin Huagai (833,333 Preferred Shares), CSVC (2,507,440 Preferred Shares), SW Biotech (1,674,107 Preferred Shares), Shenglian (1,506,696 Preferred Shares), AZ-CICC Fund I (1,674,107 Preferred Shares), AZ-CICC Fund II (1,674,107 Preferred Shares), Tai Kun (1,506,696 Preferred Shares), Tasly International Capital (1,004,464 Preferred Shares), Hoi Pok (1,205,223 Preferred Shares), Hankang Biotech Fund III, L.P. (803,482 Preferred Shares), and Splendid Biotech Fund L.P. (401,741 Preferred Shares).

Immediately Following the [REDACTED]

The following chart sets forth our corporate and shareholding structure upon the completion of the [**REDACTED**], assuming the [**REDACTED**] is not exercised:



Notes:

(1) Immediately following the [**REDACTED**], 16,272,321 Shares will be held by LAV USD, among which (i) 11,272,321 Shares will be held by LAV Fund VI; and (ii) 5,000,000 Shares will be held by LAV Opportunities.

(2) Immediately following the [**REDACTED**], other Pre-[**REDACTED**] Investors includes APHN (1,500,000 Shares), Golden Sword (3,333,333 Shares), Green Pine (1,878,721 Shares), Huagai USD (583,333 Shares), Shenzhen Huagai (625,000 Shares), Suzhou Huagai (1,715,774 Shares), Tianjin Huagai (833,333 Shares), CSVC (2,507,440 Shares), SW Biotech (1,674,107 Shares), Shenglian (1,506,696 Shares), AZ-CICC Fund I (1,674,107 Shares), AZ-CICC Fund II (1,674,107 Shares), Tai Kun (1,506,696 Shares), Tasly International Capital (1,004,464 Shares), Hoi Pok (1,205,223 Shares), Hankang Biotech Fund III, L.P. (803,482 Shares), and Splendid Biotech Fund L.P. (401,741 Shares).

OVERVIEW

Who we are. We are a global player in antibody-drug conjugate ("**ADC**") innovation, dedicated to the development of next-generation therapeutics in this fast-growing drug modality to treat cancer, autoimmune diseases, and beyond. Leveraging our technology platforms and a differentiated, clinically advanced pipeline, we aim to deliver transformative treatments that improve patient outcomes.

Since our inception, we have focused primarily on the independent discovery and development of ADC assets. We have assembled a highly experienced team of experts in all facets of ADC drug development. Leveraging our experienced R&D team, insights into ADC design, and strong execution capabilities, we have established four cutting-edge ADC technology platforms to push the boundaries of ADC treatment and a pipeline of 12 internally discovered ADC candidates covering a diverse range of indications. As recognition of the clinical and commercial value of our platforms and pipeline, we have forged several global partnerships to date with a total deal value of over US$6.0 billion, enabling us to accelerate the delivery of our ADC drugs to patients around the world.

We know how to create differentiated ADCs. From target selection, ADC design to clinical development, we build on the extensive experience of major players in the ADC space and have accumulated deep knowledge in this rising modality. This expertise has allowed us to stand out among the pioneers in this domain, harnessing proprietary next-generation ADC platform technologies and address unmet medical needs worldwide, according to Frost & Sullivan.

We strive to be at the forefront of ADC technologies and development strategies. Our pipeline of 12 in-house discovered ADC candidates is a testament to our prowess in ADC innovation, comprising: (i) seven clinical-stage ADCs with potential in a broad range of indications, each ranking among the most clinically advanced globally in terms of overall or lead indication development progress, according to Frost & Sullivan; (ii) two next-generation bispecific ADCs ("**BsADCs**") that are expected to enter into clinical stage from 2025 to 2026; and (iii) multiple other preclinical ADCs. Three of our clinical-stage assets, including our Core Products DB-1303/BNT323 and DB-1311/BNT324 and key product DB-1305/BNT325, have received Fast Track Designation from the United States Food and Drug Administration (the "**FDA**"), and DB-1303 has received Breakthrough Therapy Designations from both the FDA and the National Medical Products Administration (the "**NMPA**"), for certain indications. DB-1303 is a late clinical-stage HER2 ADC candidate with two ongoing registrational trials (one global trial and one in China) and one potential global registrational study, with the first indication (HER2-expressing endometrial cancer ("**EC**")) projected to file for accelerated approval with the FDA as early as 2025.

We have set our sights on the global market and aspire to treat patients worldwide. We have designed our ADC drug candidates to be competitive with, or differentiated from, those of the leading global ADC players. Five of our clinical-stage assets had obtained investigational new drug ("**IND**") approvals from both the FDA and the NMPA as of the Latest

Practicable Date. We have seven ongoing global multi-regional clinical trials ("**MRCTs**") across 17 countries and over 230 trial sites, with over 2,000 patients (more than 50% located in the U.S., EU and Australia) enrolled as of the Latest Practicable Date. Our innovative ADC assets have attracted global biopharmaceutical companies, culminating in several global partnerships to date, including with BioNTech SE ("**BioNTech**"), BeiGene, Ltd. ("**BeiGene**"), Adcendo ApS ("**Adcendo**"), GSK plc ("**GSK**"), and Avenzo Therapeutics, Inc. ("**Avenzo**"), with over US$6.0 billion in total deal value (of which approximately US$400 million had been received as of the Latest Practicable Date).

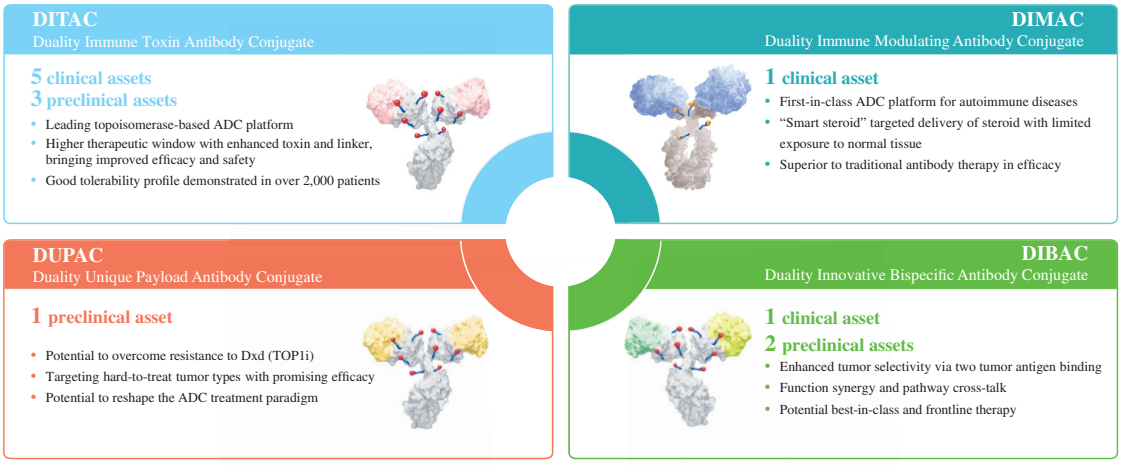
We implement our strategies with industry-leading clinical development and execution capabilities. Within just four years since our inception, seven of our ADC candidates have advanced from program initiation to IND approval. DB-1303 advanced from first-patient-in to end-of-phase 2 ("**EOP2**") meeting with the FDA in just 20 months and is projected to file for accelerated approval with the FDA as early as 2025, within four years after the first patient was dosed. We strive to achieve breakthroughs in ADC technology and execute our global drug development strategies at a pace that keeps us at the forefront of the industry.

ADC = CP^2 — Our Development Formula

CP^2 embodies our formula for compounded success and growth. "C" represents our Clinical development strategy, emphasizing our systematic approach in key aspects of clinical development and operations. The first "P" stands for our in-house developed ADC technology Platforms, which underscore our innovative prowess, and the second "P" stands for our robust Pipeline, which showcases our strategic target selection and clinical development capabilities.

Our In-house Developed ADC Platforms

Leveraging our experienced R&D team, insights into ADC design, and strong execution capabilities, we have established four cutting-edge ADC technology platforms: DITAC, DIBAC, DIMAC, and DUPAC, to push the boundaries of ADC treatment. Our technology platforms serve as the foundation for continuous and sustained innovation and value creation, whose value and versatility have been validated by our pipeline assets and recognized by global multinational corporation ("**MNC**") partners.



Notes:

Topoisomerase: An enzyme that plays an essential role in DNA replication and transcription. By targeting topoisomerase, ADCs derived from our DITAC platform can potentially treat various solid tumors by inhibiting DNA replication and inducing DNA damage in cancer cells.

Payload: Therapeutic agents delivered to the target area.

Linker: Molecule that connects the payload to the antibody of an ADC to deliver the therapeutic agent to target cells.

- *Duality Immune Toxin Antibody Conjugate (DITAC)*, our proprietary topoisomerase inhibitor-based ADC platform, is validated by the global clinical data from over 2,000 patients across the U.S., China, Europe, Australia and other major markets. Compared to non-topoisomerase ADCs, Topoisomerase-based ADCs have demonstrated a wide therapeutic window which potentially translates into improved efficacy and safety in the clinical setting. This platform is developed by screening and optimizing a library of proprietary ADC components, including our proprietary payloads P1003 and P1021, through meaningful technological improvements. As such, DITAC provides critical flexibility to design our ADCs with improved systemic stability, tumor-specific payload release, bystander-killing effects, and rapid payload clearance.

- *Duality Innovative Bispecific Antibody Conjugate (DIBAC)*, one of the few BsADC platforms in the world, is leading a new wave of ADC innovation. BsADCs can potentially offer improved efficacy over traditional monospecific ADCs and their combination therapies, by incorporating two distinct binding moieties in a single therapeutic entity. While promising, the complexity of BsADCs introduces new challenges in antibody engineering, stability and manufacturing, setting a high entry barrier. Our innovative DIBAC platform features our understanding of disease and target biology, rich experience in bispecific antibody engineering, and artificial intelligence-empowered target selection and antibody design.

- *Duality Immune-Modulating Antibody Conjugate (DIMAC)*, empowered by our proprietary immune-modulating payload, holds the potential to open the ADC modality to a significant white-space market in autoimmune and other therapeutic areas. DIMAC is one of the very few ADC platforms in the world that targets major autoimmune diseases. Many patients with chronic autoimmune diseases, such as SLE and CLE, are currently treated with therapies that often lead to severe side effects. Long term use of glucocorticoids, for example, are commonly associated with increased risks of bone fractures, weight gain, diabetes, immune system suppression, and other chronic conditions. We believe ADCs can reshape the treatment paradigm of autoimmune diseases by offering a targeted treatment with low systemic exposure, enhanced efficacy and reduced side effects. Molecules designed under our DIMAC platform have demonstrated potent and broad anti-inflammatory activity, long duration of action, sustained stability, and low systemic exposure in preclinical studies.

- *Duality Unique Payload Antibody Conjugate (DUPAC)* reflects our foresight into the future landscape of ADC innovation. DUPAC is one of the few ADC platforms globally dedicated to the development of linker-payload complexes with novel mechanisms of action, beyond traditional cytotoxic agents, to combat growing drug resistance and hard-to-treat tumors. We have made promising progress in a number of unique payload mechanisms and have obtained prototypes with broad-spectrum anti-tumor activity across multiple solid tumors, and potent direct and bystander killing effects in preclinical studies.

Our Pipeline of Innovative ADCs

We have built a pipeline of 12 in-house discovered ADC candidates, comprising: (i) seven clinical-stage ADCs with potential in a broad range of indications; (ii) two next-generation BsADCs that are expected to enter into clinical stage from 2025 to 2026; and (iii) multiple other preclinical ADCs. We take a tiered strategy in ADC development, leading the waves of technology iteration that place us at the forefront of ADC innovation:

- *First wave of assets*, empowered by DITAC and serving as proof of concept of our leading ADC technology, includes (i) ADC candidates with clinically validated targets strategically developed for differentiated indications, represented by our Core Product DB-1303, a HER2 ADC, and our key product DB-1305, a TROP2 ADC; and (ii) ADC candidates under global development for high-potential targets and under-explored indications, represented by our Core Product DB-1311, a B7-H3 ADC, and our key product DB-1310, a HER3 ADC;

- *Second wave of assets*, leveraging DIBAC and DIMAC, is represented by next-generation ADCs with novel formats and components that open ADCs to front-line or difficult-to-treat settings and new therapeutic areas, such as BsADCs, including DB-1419 (B7-H3xPD-L1 BsADC), DB-1418/AVZO-1418 (EGFRxHER3 BsADC) and DB-1421, and immune-modulating ADCs for autoimmune diseases, including DB-2304 (BDCA2 ADC), and others; and

- *Third wave of assets*, enabled by DUPAC, is the driving force behind our novel ADC payload and linker technologies that potentially disrupt the ADC modality, opening the possibility to reach hard-to-treat tumors and staying ahead of the growing need to overcome acquired resistance to existing ADCs.

The pipeline chart below summarizes the development status of our clinical-stage drug candidates and selected preclinical assets, all of which are in-house discovered.

	Program	Target	Indications (lines of treatment)	Mono/Combo	Preclinical/ IND-Enabling	Phase 1	Phase 2a/ Phase 2	Phase 3	Key Regulatory Authorities	Trial Location	NCT Number	Upcoming Milestone	Commercial Rights	Partners
Oncology	**DITAC – Leading TOP1i ADC Platform**													
	★ DB-1303 /BNT323	HER2	HER2-expressing EC (2L+)	Mono		Single-arm, Potential Registrational Study			FDA, NMPA	Global	NCT05150691	Trial completion: 2027	Mainland China, Hong Kong, Macau	BIONTECH
				Mono		Planned Phase 3 Confirmatory Trial		*	FDA, NMPA	Global	NCT06340568	Trial completion: 2029		
			HR+/HER2-low BC (chemo naïve)	Mono					FDA, NMPA	Global	NCT06018337	Trial completion: 2028		
			HER2+ BC (2L+)	Mono					NMPA	China	NCT06265428	Trial completion: 2026		
			HER2+ BC (1L)	+ Pertuzumab					FDA, NMPA	Global	NCT05150691	Trial completion: 2027		
			Solid Tumors (OC, CRC, esophageal cancer, etc.)	Mono					FDA, NMPA	Global				
	★ DB-1311 /BNT324	B7-H3	SCLC (2L+)	Mono					FDA, NMPA	Global	NCT05914116	Trial completion: 2026	Mainland China, Hong Kong, Macau (U.S.: Option to Co-develop and Co-commercialize)	BIONTECH
			CRPC (late line)	Mono					FDA, NMPA	Global				
			ESCC (2L+)	Mono					FDA, NMPA	Global				
			NSCLC (2L+)	Mono					FDA, NMPA	Global				
			Solid Tumors (HNSCC, HCC, CC, melanoma, etc)	Mono					FDA, NMPA	Global				
	☆ DB-1310	HER3	EGFRm NSCLC (TKI-resistant)	+ Osimertinib					FDA, NMPA	Global	NCT05785741	Trial completion: 2026	Global	
			KRASm NSCLC (2L+)	Mono					FDA, NMPA	Global				
			HER2+ BC (Post-Enhertu)	+ Trastuzumab					FDA, NMPA	Global				
			Solid Tumors	Mono					FDA, NMPA	Global				
	☆ DB-1305 /BNT325	TROP2	OC (2L+)	Mono					FDA, NMPA	Global	NCT05438329	Trial completion: 2025	Mainland China, Hong Kong, Macau	BIONTECH
			NSCLC (2L+)	Mono					FDA, NMPA	Global				
			NSCLC, OC, CC, TNBC (multiple lines)	+PD-L1xVEGF bsAb					FDA, NMPA	Global				
			Solid Tumors (CC, TNBC, etc.)	Mono					FDA, NMPA	Global				
	DB-1312 /BG-C9074	B7-H4	Solid Tumors	Mono/ + Tislelizumab		**			FDA, NMPA	Global	NCT06233942	Trial completion: 2027	/	BeiGene
	DB-1314	Undisclosed	Solid Tumors	Mono					N.A.	/	/	IND submission: 2026	Global	
	DB-1317	Undisclosed	Solid Tumors	Mono					N.A.	/	/	IND submission: 2025	Global	
	DB-1324	Undisclosed	Solid Tumors	Mono					N.A.	/	/		Mainland China, Hong Kong, Macau	GSK
	DIBAC – Leading Bispecific ADC Platform													
	☆ DB-1419	B7-H3 x PD-L1	Solid Tumors	Mono					FDA, NMPA	Global	NCT06554795	Trial completion: 2027	Global	
	DB-1418 /AVZO-1418	EGFR x HER3	Solid Tumors	Mono					N.A.	/	/	IND submission: 2025	Greater China	AVENZO THERAPEUTICS
	DB-1421	Undisclosed	Solid Tumors	Mono					N.A.	/	/	IND submission: 2026	Global	
	DUPAC – Unique Novel MOA Payload ADC Platform													
	DB-1316	Undisclosed	Solid Tumors	Mono					N.A.	/	/	IND submission: 2026	Global	
Autoimmune	**DIMAC – Leading Immune-modulating ADC Platform**													
	☆ DB-2304	BDCA2	SLE, CLE	Mono					FDA, NMPA	Global	NCT06625671	Trial completion: 2026	Global	

★ Core Products ☆ Key Products FDA Breakthrough Therapy Designation NMPA Breakthrough Therapy Designation FDA Fast Track Designation FDA Orphan Drug Designation

Notes: (1) Abbreviations: Mono = Monotherapy, Combo = Combination Therapy, IND = Investigational New Drug, NCT = National Clinical Trial, ADC = Antibody-drug Conjugate, HER2 = Human Epidermal Growth Factor Receptor 2, HER2-expressing = HER2 Status of Tumor Cells Identified with a Test Score of IHC 1+ or Above, EC = Endometrial Cancer, HR+ = Hormone Receptor Positive, HER2-low=HER2 Status of Tumor Cells Identified with a Test Score of IHC 1+ or IHC 2+/ISH-, BC = Breast Cancer, Chemo = Chemotherapy, HER2+ = HER2 Status of Tumor Cells Identified with a Test Score of Either IHC 3+ or IHC 2+/ISH+, OC = Ovarian Cancer, CRC = Colorectal Cancer, SCLC = Small Cell Lung Cancer, CRPC = Castration-resistant Prostate Cancer, ESCC = Esophageal Squamous Cell Carcinoma, NSCLC = Non-small Cell Lung Cancer, HNSCC = Head and Neck Squamous Cell Carcinoma, HCC= Hepatocellular Carcinoma, CC = Cervical Cancer, HER3 = Human Epidermal Growth Factor Receptor 3, EGFRm = EGFR Mutant, TKI = Tyrosine Kinase Inhibitor, KRASm = Kirsten Rat Sarcoma Virus Mutant, BTC = Biliary Tract Cancer, TROP2 = Human Trophoblast Cell-surface Antigen 2, TNBC = Triple-negative Breast Cancer, PD-L1 = PD-1 Ligand 1, VEGF = Vascular Endothelial Growth Factor, bsAb = Bispecific Antibody, EGFR = Epidermal Growth Factor Receptor, BDCA2 = Blood Dendritic Cell Antigen 2, MOA = Mechanism of Action, SLE = Systemic Lupus Erythematosus, CLE = Cutaneous Lupus Erythematosus, FDA = U.S. Food and Drug Administration, NMPA = National Medical Products Administration of the PRC, 1L: first-line treatment, 2L+: second-line or later treatment

(2) For each drug candidate, our clinical development typically begins with a combined phase 1/2a trial, where multiple patient groups across different tumor types or indications are enrolled to assess both safety and efficacy of the drug candidate. Based on the results from these phase 1/2 trials, we determine which indications to prioritize for advancement into later-stage clinical development. All ongoing clinical trials are subject to regulatory oversight by both the FDA and NMPA, except for DB-1303's phase 3 trial in HER2+ BC patients, which is conducted solely in China and regulated by the NMPA.

* BioNTech was the sponsor of this global trial as of the Latest Practicable Date.

** BeiGene was serving as the sponsor of this trial as of the Latest Practicable Date.

Core Products

- DB-1303/BNT323 is a late clinical-stage HER2 ADC candidate with two ongoing registrational trials (one global trial and one in China) and one potential global registrational study, with the first indication (HER2-expressing EC) projected to file for accelerated approval with the FDA as early as 2025. DB-1303 is designed with a stable, cleavable linker and proprietary topoisomerase-based payload that aim to lower off-target toxicity and enhance anti-tumor activity, including bystander killing effects. These features may enable DB-1303 to potentially serve as a new therapeutic option for patients with HER2-expressing advanced solid tumors, including both patients with high and low expression levels of HER2. The global HER2 ADC market is expected to increase from US$4.8 billion in 2023 to US$18.5 billion by 2028, representing a CAGR of 30.8%, according to Frost & Sullivan.

  DB-1303 is the most clinically advanced HER2 ADC candidate globally that targets EC across HER2-expression levels and a candidate in advanced clinical development for HER2 low-expressing breast cancer ("**BC**"), according to Frost & Sullivan, with potential for extension to other underserved cancer indications. DB-1303 has obtained Fast Track and Breakthrough Therapy Designations from the FDA and Breakthrough Therapy Designation from the NMPA for the treatment of advanced EC in patients who progressed on or after treatment with immune checkpoint inhibitors, demonstrating DB-1303's potential to treat advanced EC patients who currently have low survival rates and a strong medical need for new and more effective treatments. Moreover, DB-1303's antitumor activity has been observed in a range of tumors, including BC, EC, ovarian cancer ("**OC**"), colorectal cancer ("**CRC**") and esophageal cancer, supported by global clinical data from patients across the U.S., China and Australia to date. To further advance DB-1303, we formed a global strategic partnership with BioNTech in 2023 to accelerate its development and maximize its global value.

- DB-1311/BNT324 is a clinically advanced B7-H3 ADC candidate under global development. B7-H3 is a prominent member of the B7 family that plays a critical role in promoting tumor progression and metastasis. DB-1311 is designed to harness the potential of B7-H3 as a therapeutic target, leveraging its widespread overexpression in a broad range of tumor types, including small-cell lung cancer ("**SCLC**"), non-small cell lung cancer ("**NSCLC**"), BC, castration-resistant prostate cancer ("**CRPC**"), esophageal squamous cell carcinoma ("**ESCC**") and head and neck squamous cell carcinoma ("**HNSCC**"). Notably, DB-1311 demonstrates strong selectivity by targeting a specific isoform predominantly found on B7-H3-overexpressing tumor cells, which, combined with its potent payload, stable linker-payload and fragment crystallizable region silenced ("**Fc-silenced**") mAb, potentially translates into a favorable safety profile and a wide therapeutic window.

  In collaboration with BioNTech, we are actively pursuing a comprehensive clinical development plan to unlock the full potential of DB-1311, both as monotherapy and in combination with immunotherapy. DB-1311 has shown encouraging antitumor

activity and a manageable safety profile in its ongoing phase 1/2a trial, including in patients with advanced SCLC, CRPC and multiple other solid tumors. Preliminary data from this trial were presented in an oral session at the 2024 European Society of Medical Oncology Asia Annual Meeting ("**ESMO Asia**"). As of September 27, 2024, the data cut-off date for 2024 ESMO Asia, among all evaluable patients with at least one post-baseline tumor assessment (n=238), the overall unconfirmed ORR ("**uORR**") was 32.4%, and the DCR was 82.4%. As of the same date, among patients with SCLC (n=73), the uORR was 56.2%, and the DCR was 89.0%. Among patients with CRPC (n=32), DB-1311 demonstrated early antitumor activity with a uORR of 28.0% and a DCR of 92.0%; radiographic progression-free survival ("**rPFS**") data were not yet mature, with a median rPFS of 7.2 months and a 6-month rPFS rate of 94.7%.

Besides SCLC and CRPC, we are also investigating DB-1311's treatment potential in HNSCC, HCC, CC, and melanoma. In 2024, the FDA granted DB-1311 Fast Track Designation for the treatment of patients with advanced/unresectable, or metastatic CRPC and Orphan Drug Designations for the treatment of ESCC and SCLC.

Key Products

- DB-1310 is one of the world's most clinically advanced HER3 ADC candidates, according to Frost & Sullivan, for which we hold global rights. HER3, along with EGFR and HER2, are growth factor receptors in the HER family that play crucial roles in tumor survival and growth. Despite the growing research and clinical interest in HER3, it remains under-explored and has faced two decades of drug development challenges due to the complexity in achieving signaling inhibition and the potential for escape pathway activation. Guided by our team of leading experts in HER3 research, we have built a deep knowledge base in HER3 biology, including its dimerization patterns and intricate interactions with EGFR and HER2, and its involvement in resistance mechanisms. These insights have informed DB-1310's innovative design and equipped it with a high internalization capability to deliver payloads directly into HER3-expressing cancer cells, which leads to targeted tumor killing and improved therapeutic outcomes.

  We believe HER3 ADCs present opportunities to cover a broad patient population with limited reliance on biomarker-based patient selection and overcome resistance to standard of care. We have developed a rational and differentiated clinical development strategy focused on carefully selected indications that maximize its commercial potential. For EGFR-mutant ("**EGFRm**") NSCLC, while our peers explore HER3 ADCs as a second-line or later monotherapy, we have taken a differentiated strategy to investigate DB-1310's combination potential with osimertinib in EGFRm NSCLC patients resistant to osimertinib or other third-generation tyrosine kinase inhibitor ("**TKI**") therapy, with opportunity to be a first-line treatment covering a broader patient population. DB-1310 is also one of

the few global clinical-stage HER3 ADCs being investigated as a potential treatment for KRAS-mutant ("**KRASm**") NSCLC. We are also exploring the efficacy signals of DB-1310 in various other solid tumors, including BC, CRPC, HNSCC, ESCC and BTC.

- DB-1305/BNT325 is a TROP2 ADC candidate with a global development strategy. TROP2, a validated and highly expressed ADC target across a wide spectrum of cancers, plays a pivotal role in tumor progression. To date, there is only one TROP2 ADC approved globally, indicated for advanced triple-negative breast cancer ("**TNBC**"), urothelial cancer ("**UC**") and HR+/HER2- BC, according to Frost & Sullivan. The global TROP2 ADC market is expected to increase from US$1.1 billion in 2023 to US$7.7 billion by 2028, representing a CAGR of 48.8%.

  DB-1305 targets indications currently under-explored by other TROP2 ADC candidates, such as OC. DB-1305 also has combination potential as a backbone therapy in earlier lines of treatment, starting from NSCLC, OC, CC and TNBC. We believe this well-rounded strategy may position DB-1305 as a potential backbone therapy in the TROP2 ADC landscape. In collaboration with BioNTech, we are advancing DB-1305's global clinical development, including an ongoing phase 1/2a global trial in patients with advanced solid tumors, where encouraging preliminary efficacy signals in NSCLC and multiple other solid tumors have been observed.

- DB-1419 is a potential first-in-class B7-H3xPD-L1 BsADC candidate with a DNA topoisomerase I inhibitor, being the only B7-H3xPD-L1 BsADC currently under clinical development globally, according to Frost & Sullivan. The simultaneous action of delivering the toxin to tumor cell and modulate T cell activation provides potential synergistic anti-tumor effect. Combining payload mediated cytotoxicity with antibody mediated immunotherapy activity, DB-1419 provides an innovative approach for cancer treatment. We have obtained IND approval from the FDA for DB-1419 and we initiated DB-1419's phase 1/2a global trial in September 2024.

- DB-2304 is a potential first-in-class BDCA2 ADC candidate for systemic lupus erythematosus ("**SLE**") and cutaneous lupus erythematosus ("**CLE**"), being one of the most advanced BDCA2 ADCs in terms of development progress, according to Frost & Sullivan. DB-2304 offers a selective therapeutic approach specifically targeting the upstream signaling pathways of SLE/CLE pathogenesis, differentiating it from existing lupus treatments that often have broader effects on the immune system. We believe DB-2304 holds promise to substantially improve upon the standard of care for SLE and CLE, such as glucocorticoids and immunosuppressants, and represents a major step in the innovation of autoimmune ADCs. We initiated a phase 1 study in healthy adults for DB-2304 in Australia in October 2024. We have submitted IND applications to both the FDA and NMPA for DB-2304 and, subject to regulatory approval, expect to complete DB-2304's phase 1 global trial in 2026.

Our Clinical Development Strategy

We take a differentiated clinical development strategy to accelerate the global expansion of our drug programs and maximize their impact on patients worldwide, taking into account our unique features in ADC design, acumen in indication selection and understanding of unmet clinical needs and the market landscape. Our development strategies are carefully tailored by drug and target indication, following the general principles below:

- *First-to-market approach*. To maximize the global competitiveness of our pipeline, we will select and address initial target indications that are commercially attractive and often underserved, which enable us to demonstrate key asset differentiation, and rapidly enter and establish a strong presence in the global market. For example, DB-1303 is the most clinically advanced HER2 ADC candidate globally that targets EC across HER2-expression levels, according to Frost & Sullivan. We and BioNTech have completed patient enrollment for DB-1303's potential registrational cohort in HER2-expressing advanced/recurrent EC patients and plan to commence a confirmatory phase 3 trial in this patient population in 2025.

- *Fast-to-commercial approach*. Complementing our first-to-market strategy, we utilize a fast-to-commercial approach to accelerate access to our differentiated assets for a wider addressable population of patients in need. For instance, DB-1303 is a leading candidate for HER2 low-expressing BC, according to Frost & Sullivan, with potential for extension to other underserved cancer indications. DB-1303 is undergoing a phase 3 global registrational trial in HR+/HER2-low metastatic BC patients who are chemo-naïve (i.e., who have not previously received chemotherapy) with first patient dosed in January 2024. Furthermore, DB-1311 is currently one of the top three B7-H3 ADCs undergoing global MRCTs in terms of clinical development progress for advanced SCLC, according to Frost & Sullivan.

- *Combination and indication expansion strategy*. We adopt combination therapy strategies to unlock the frontline and backbone potential for our assets and offer improved clinical benefits to patients. For instance, DB-1310 is a global clinical-stage HER3 ADC candidate being developed for EGFRm NSCLC patients resistant to osimertinib or other third-generation TKI treatments through combination with osimertinib. Together with BioNTech, we are actively exploring DB-1305's combination potential as a backbone therapy in early lines of treatment, starting from NSCLC, OC, CC and TNBC. In June 2024, the first patient was dosed in a combination cohort of DB-1305's ongoing phase 1/2a global trial to evaluate the combination of DB-1305 and BNT327, a bispecific antibody ("**bsAb**") targeting PD-L1 and vascular endothelial growth factor ("**VEGF**"), aiming to harness the potent anti-tumor activity of ADCs along with the sustained benefit of immunomodulators. In October 2024, we received IND approval from the NMPA to initiate a phase 1/2a trial for DB-1305 in combination with BNT327 in patients with late-stage/metastatic solid tumors.

OUR COMPETITIVE STRENGTHS

Global ADC powerhouse with insights and strong execution capabilities to lead ADC innovation

We are a global player in ADC innovation, dedicated to the development of next-generation therapeutics in this fast-growing drug modality to treat cancer, autoimmune diseases, and beyond. ADCs are revolutionizing oncology treatment as the new backbone therapy, moving towards early-line treatment to replace existing standard of care and broadening coverage to pan-tumors and pan-expression. Beyond oncology, ADCs hold promise as the optimal modality in white-space therapeutic areas, such as autoimmune, metabolic and cardiovascular diseases.

We are a key player in the global ADC landscape, empowered by innovative research, clinical and regulatory insights and execution capability, according to Frost & Sullivan. In just four years, we have established four globally innovative ADC technology platforms for next-generation ADC research. We have designed and executed development strategies for our ADC drug candidates to be competitive with, or differentiated from, those of the leading global ADC players. Leveraging comprehensive global R&D capabilities, we have seven ongoing global MRCTs across 17 countries and over 230 trial sites, with over 2,000 patients (more than 50% located in the U.S., EU and Australia) enrolled as of the Latest Practicable Date.

With our insights and know-how supported by four leading technology platforms and strong global clinical development experience, we have accomplished these feats with industry-leading speed and quality. Our Core Product DB-1303 reached FDA EOP2 meeting in just 20 months after first-patient-in and is projected to file for accelerated approval with the FDA within four years after the first patient was dosed. By comparison, the average time for an innovative drug to advance from IND filing to NDA approval by the FDA is over eight years, according to Frost & Sullivan. Our ADC candidates have obtained three FDA Fast Track Designations, two Breakthrough Therapy Designations from the FDA and NMPA, and two FDA Orphan Drug Designations since our inception. As recognition of the clinical and commercial value of our platforms and pipeline, we have forged several global partnerships to date with a total deal value of over US$6.0 billion, enabling us to accelerate the delivery of our ADC drugs to patients around the world.

We strive to remain at the innovation forefront of this rising modality to unlock its full potential. Meaningful advancements are being made to enhance and innovate all three ADC components — the payload, linker and antibody — to improve efficacy and reduce toxicity, and potentially extend ADCs to front-line or difficult-to-treat settings, including relapsed patients with drug resistance to current standard-of-care treatments. In addition to cancer treatment, innovative ADCs are also being developed for a broader spectrum of non-oncology indications. Driven by continued innovation, the global ADC market is expected to surpass US$110 billion by 2032. In the pursuit of next-generation ADCs, China has emerged as a global innovation center, where over 45% of the world's clinical trials conducted for ADCs since 2023 took place. With growing global competency in drug discovery, biotech companies in China are leading the

research of novel targets such as HER3 and B7-H3 and new modalities like BsADCs, achieving a record-breaking US$35 billion in ADC deals with global MNCs since 2022. Guided by our "CP^2" formula, we aim to continue to achieve breakthroughs in ADC technology and drug development that propel us to the forefront of the industry.

Clinically advanced ADC assets with promising global data as validation of our DITAC platform

We have developed a pipeline of novel ADCs led by seven clinical-stage assets each ranking among the most clinically advanced globally in terms of overall or lead indication development progress, according to Frost & Sullivan. These assets leverage both well-validated targets, such as HER2 and TROP2, and emerging targets, such as B7-H3 and HER3, with broad indication opportunities. As we rapidly advance these assets towards regulatory approval and commercialization, we have established a global leading position in addressable markets with vast clinical and commercial potential.

Our clinical-stage assets have shared roots in DITAC, our proprietary topoisomerase-based ADC platform. DITAC is validated by the global clinical data from over 2,000 patients across the U.S., China, Europe, Australia and other major markets. Compared to ADCs with earlier-generation payloads such as monomethyl auristatin E ("**MMAE**"), topoisomerase-based ADCs are distinguished for their ability to target a broader range of tumor types. Notably, the bystander effect of topoisomerase-based ADCs enhances efficacy by allowing the cytotoxic payload to affect neighboring tumor cells that may not express the target antigen.

DITAC takes a holistic approach to ADC design, demonstrating improved systemic stability, tumor-specific payload release, bystander-killing effects, and rapid payload clearance, which potentially translates to a significantly improved therapeutic window. We have developed a library of proprietary linkers and payloads with meaningful technological improvements, giving us critical optionality in optimizing each ADC component for a broad range of target indications.

DB-1303/BNT323, a late clinical-stage HER2 ADC candidate, our Core Product

Our Core Product DB-1303 is a late clinical-stage HER2 ADC candidate with two ongoing registrational trials (one global trial and one in China) and one potential global registrational study, with the first indication (HER2-expressing EC) projected to file for accelerated approval with the FDA as early as 2025. DB-1303 is designed with a stable, cleavable linker and proprietary topoisomerase-based payload that aim to lower off-target toxicity and enhance anti-tumor activity, including bystander killing effects. These features may enable DB-1303 to potentially serve as a new therapeutic option for patients with HER2-expressing advanced solid tumors, including both patients with high and low expression levels of HER2. The global HER2 ADC market is expected to increase from US$4.8 billion in 2023 to US$18.5 billion by 2028, representing a CAGR of 30.8%, according to Frost & Sullivan.

DB-1303 is the most clinically advanced HER2 ADC candidate globally that targets EC across HER2-expression levels and a candidate in advanced clinical development for HER2 low-expressing BC, according to Frost & Sullivan, with potential for extension to other underserved cancer indications. DB-1303 has obtained Fast Track and Breakthrough Therapy Designations from the FDA and Breakthrough Therapy Designation from the NMPA for the treatment of advanced EC in patients who progressed on or after treatment with immune checkpoint inhibitors, demonstrating DB-1303's potential to treat advanced EC patients who currently have low survival rates and a strong medical need for new and more effective treatments. Moreover, DB-1303's antitumor activity has been observed in a range of tumors, including BC, EC, OC, CRC and esophageal cancer, supported by global clinical data from patients across the U.S., China and Australia to date. To further advance DB-1303, we formed a global strategic partnership with BioNTech in 2023 to accelerate its development and maximize its global value.

Highlights of DB-1303 include:

- *Most clinically advanced HER2 ADC globally for EC patients across HER2-expression levels*. EC is known to be one of the most common gynecological malignancies globally, with approximately 400,000 new cases reported worldwide in 2023, according to Frost & Sullivan. Approved first- and second-line standard-of-care treatments for EC, including chemotherapy and targeted therapies, have shown limited efficacy in advanced or metastatic EC patients, highlighting an unmet medical need.

  We aim to improve treatment for EC patients across HER2-expression levels. DB-1303 is differentiated by observed anti-tumor activity across both HER2-low (IHC 1+ and IHC 2+) and HER2+ EC patients, which potentially expands its suitability to over 70% of the EC patient population. Notably, DB-1303 demonstrated an overall objective response rate ("**ORR**") of 58.8% and disease control rate ("**DCR**") of 94.1% in heavily pre-treated HER2-expressing EC patients (IHC 1/2/3+ or ISH-positive), including those with prior immunotherapy or anti-HER2 antibody treatments, in its phase 1/2a trial, preliminary data of which were published at the 2023 European Society of Gynaecological Oncology Congress ("**ESGO**"). We and BioNTech have completed patient enrollment for DB-1303's potential registrational cohort in HER2-expressing advanced/recurrent EC patients and plan to commence a confirmatory phase 3 trial in this patient population in 2025.

- *Potential treatment for chemo-naïve HR+/HER2-low BC patients*. BC is known to be the second largest cancer type in the world by incidence, according to Frost & Sullivan, with approximately 2.4 million new cases reported in 2023 of which HR+/HER2-low patients accounted for approximately 50%. According to Frost & Sullivan, the only HER2 ADC approved for HER2-low BC to date is currently indicated for patients who have received a prior chemotherapy in the metastatic setting or developed disease recurrence during or within six months of completing adjuvant chemotherapy. We are advancing, in collaboration with BioNTech, a phase 3 global registrational trial for DB-1303 in chemo-naïve HR+/HER2-low metastatic BC patients with first patient dosed in January 2024.

- *Phase 3 topoisomerase-based ADC for HER2+ BC in China*. About 15-30% of BC patients are HER2+, with a significant patient population of approximately 92.7 thousand in China in 2023, according to Frost & Sullivan. Despite the potential of topoisomerase-based ADCs to offer significantly improved progression-free survival and overall survival compared to existing treatments, there is only one topoisomerase-based HER2 ADC approved in China to date. We plan to complete our phase 3 registrational trial in China in 2026 for DB-1303 versus T-DM1 (trastuzumab emtansine) in patients with HER2+ unresectable and/or metastatic BC previously treated with trastuzumab and taxane and file biologics license application ("**BLA**") with the NMPA by the end of 2025.

- *Promising efficacy and manageable safety data in phase 1/2a global trial*. DB-1303 demonstrated encouraging efficacy results in its phase 1/2a global trial, based on preliminary data as of January 13, 2023 published at the 2023 American Society of Clinical Oncology Annual Meeting ("**ASCO**"). The uORR and DCR across all dose levels was 44.2% and 88.5%, respectively, in patients with HER2-expressing solid tumors with a median of seven previous lines of treatment, including prior HER2 ADC regimens, as of January 13, 2023. In addition, preliminary antitumor activity has also been observed in other tumor types, including OC, CRC and esophageal cancer, signifying DB-1303's potential for indication expansion. DB-1303 was well-tolerated with no dose-limiting toxicity ("**DLT**") observed in all six dose levels (ranging from 2.2 mg/kg to 10 mg/kg) during dose escalation and no treatment-emergent adverse event ("**TEAEs**") associated with death in phase 1/2a global trial as of January 13, 2023.

DB-1311/BNT324, a B7-H3 ADC candidate with global market potential, our Core Product

DB-1311 is a clinically advanced B7-H3 ADC candidate under global development. B7-H3 is a prominent member of the B7 family that plays a critical role in promoting tumor progression and metastasis. DB-1311 is designed to harness the potential of B7-H3 as a therapeutic target, leveraging its widespread overexpression in a broad range of tumor types, including SCLC, NSCLC, CRPC, ESCC and HNSCC. Notably, DB-1311 demonstrates strong selectivity by targeting a specific isoform predominantly found on B7-H3-overexpressing tumor cells, which, combined with its potent payload, stable linker-payload and Fc-silenced mAb, potentially translates into a favorable safety profile and a wide therapeutic window.

In collaboration with BioNTech, we are actively pursuing a comprehensive clinical development plan to unlock the full potential of DB-1311, both as monotherapy and in combination with immunotherapy. DB-1311 has shown encouraging antitumor activity and a manageable safety profile in its ongoing phase 1/2a trial, including in patients with advanced SCLC, CRPC and multiple other solid tumors. Besides SCLC and CRPC, we are also investigating DB-1311's treatment potential in HNSCC, HCC, CC, and melanoma. In 2024, the FDA granted DB-1311 Fast Track Designation for the treatment of patients with advanced/unresectable, or metastatic CRPC and Orphan Drug Designations for the treatment of ESCC and SCLC.

Highlights of DB-1311 include:

- *Key player in the global B7-H3 ADC landscape*. Despite the current absence of approved B7-H3-targeted therapies, B7-H3 ADCs have demonstrated encouraging clinical efficacy, notably in SCLC patients, sparking substantial interest and high-profile licensing deals in the field, according to Frost & Sullivan. DB-1311 is currently one of the top three B7-H3 ADCs undergoing global MRCTs in terms of clinical development progress for advanced SCLC, according to Frost & Sullivan. SCLC is an aggressive form of lung cancer characterized by rapid growth and high rates of recurrence. We are also investigating DB-1311's potential in treating CRPC patients, another cancer population that is highly underserved. To date, there are no B7-H3 ADC candidates indicated for CRPC that have entered into phase 3 registrational trial worldwide, according to Frost & Sullivan.

- *Novel design with the potential to enable tumor killing and wide therapeutic window*. DB-1311 is designed to deliver potent tumor killing while reducing off-target toxicities. Conjugated at a higher drug-to-antibody ratio ("**DAR**") value of 6, DB-1311 showed more potent antitumor activity compared to DS-7300 *in vitro* and *in vivo* in both high and medium B7-H3 expression models, based on preclinical results published at the 2023 American Association for Cancer Research ("**AACR**") Annual Meeting. DB-1311 demonstrated high selectivity by targeting the 4IgB7-H3 isoform, which is predominantly found on B7-H3-overexpressing tumor cells, with over 1,000-fold greater affinity compared to the 2IgB7-H3 isoform commonly expressed on normal cells. This high selectivity differentiates DB-1311 and aims to

enable the delivery of DB-1311's payload directly into tumor cells. Meanwhile, DB-1311's Fc-silenced mAb is designed to reduce unwanted immune responses. In preclinical studies, DB-1311 has shown a significantly highest non-severely toxic dose ("**HNSTD**") and better binding to B7-H3-expressing lung cancer cells compared to DS-7300.

- *Promising clinical efficacy and manageable safety profile observed in phase 1/2a trial*. DB-1311 showed encouraging antitumor activity in its phase 1/2a global trial in advanced solid tumors. Preliminary data from this trial were presented in an oral session at 2024 ESMO Asia. As of September 27, 2024, the data cut-off date for 2024 ESMO Asia, among all evaluable patients with at least one post-baseline tumor assessment (n=238), the overall uORR was 32.4%, and the DCR was 82.4%. As of the same date, among patients with SCLC (n=73), the uORR was 56.2%, and the DCR was 89.0%. Among patients with CRPC (n=32), DB-1311 demonstrated early antitumor activity with a uORR of 28.0% and a DCR of 92.0%; rPFS data were not yet mature, with a median rPFS of 7.2 months and a 6-month rPFS rate of 94.7%.

  We are also investigating DB-1311's treatment potential in several prevalent cancer types under-explored by other clinical-stage B7-H3 ADCs. Preliminary data from DB-1311's phase 1/2a global trial also showed an acceptable and manageable safety profile, with low rates of treatment-related adverse events ("**TRAEs**") associated with drug discontinuation, dose reduction, drug interruption or death.

- *Combination potential as frontline treatment for prevalent cancers*. We believe the combination of DB-1311 with immunotherapy holds therapeutic promise, as the direct cytotoxic effects of this B7-H3 ADC synergize with the immune-activating properties of immunotherapies, potentially leading to a more powerful anti-tumor response and improved patient outcomes. We are actively exploring DB-1311's combination potential to expand into earlier treatment lines in various solid tumors, such as CRPC, SCLC and NSCLC.

- *Opt-in rights to co-develop and co-commercialize in the U.S.* Under our collaboration agreement with BioNTech, we have retained an option to co-develop and co-commercialize DB-1311 in the U.S. If we elect to exercise this option, we will become eligible to share the profits/losses and costs from DB-1311's development and commercialization in this major market. This strategic partnership not only demonstrates our confidence in and commitment to DB-1311's global development, but also allows us to leverage BioNTech's complementary strengths and resources while capturing the asset's significant economic interest and upside potential overseas. As such, we are well-positioned to efficiently navigate the complex global market landscape and accelerate DB-1311's entry into both domestic and international markets.

DB-1310, a HER3 ADC candidate in phase 1/2a trial, our key product

DB-1310 is one of the world's most clinically advanced HER3 ADC candidates, according to Frost & Sullivan, for which we hold global rights. HER3, along with EGFR and HER2, are growth factor receptors in the HER family that play crucial roles in tumor survival and growth. Despite the growing research and clinical interest in HER3, it remains under-explored and has faced two decades of drug development challenges due to the complexity in achieving signaling inhibition and the potential for escape pathway activation. Guided by our team of leading experts in HER3 research, we have built a deep knowledge base in HER3 biology, including its dimerization patterns and intricate interactions with EGFR and HER2, and its involvement in resistance mechanisms. These insights have informed DB-1310's innovative design and equipped it with a high internalization capability to deliver payloads directly into HER3-expressing cancer cells, which leads to targeted tumor killing and improved therapeutic outcomes.

We believe HER3 ADCs present opportunities to cover a broad patient population with limited reliance on biomarker-based patient selection and overcome resistance to standard of care. We have developed a rational and differentiated clinical development strategy focused on carefully selected indications that maximize its commercial potential. For EGFRm NSCLC, while our peers explore HER3 ADCs as a second-line or later monotherapy, we have taken a differentiated strategy to investigate DB-1310's combination potential with osimertinib in EGFRm NSCLC patients resistant to osimertinib or other third-generation TKI therapy, with opportunity as first-line treatment to cover a broader patient population. DB-1310 is also one of the few global clinical-stage HER3 ADCs being investigated as a potential treatment for KRASm NSCLC. We are also exploring the efficacy signals of DB-1310 in various other solid tumors, including BC, CRPC, HNSCC, ESCC and BTC.

Highlights of DB-1310 include:

- *Differentiated EGFRm NSCLC combination strategy*. DB-1310 is a global clinical-stage HER3 ADC candidate being developed for EGFRm NSCLC patients resistant to osimertinib or other third-generation TKI treatments, according to Frost & Sullivan. We are developing DB-1310 in combination with osimertinib based on our translational medicine research that EGFR inhibition synergistically promotes HER3 ADC internalization and efficacy. We are enrolling patients in our phase 1 global dose escalation study for this combination therapy in China and the U.S.

- *Unique coverage of KRASm NSCLC*. KRAS mutations are estimated to occur in approximately 30% of NSCLC cases. There are currently no global registrational trials for HER3 ADC candidates specifically targeting KRASm NSCLC, highlighting the potential of DB-1310 in this underserved area. Patients with KRASm NSCLC typically experience rapid disease progression after KRAS TKI

treatments, and those who develop drug resistance face severely limited subsequent treatment options. We have observed preliminary efficacy in KRASm NSCLC patients, including partial response in dose expansion, in DB-1310's phase 1/2a global trial.

- *Encouraging efficacy in multiple BC subtypes*. DB-1310 has demonstrated efficacy signals across multiple BC subtypes, including in TNBC patients with prior Trodelvy® treatment. DB-1310 has significant potential to treat HER2+ BC patients, including those with prior Enhertu® treatment, given HER3's critical role in drug resistance and pathway synergies with HER2.

- *Treatment potential for CRPC*. HER3 protein is frequently overexpressed in prostate cancer, correlating with faster progression to castration resistance and reduced overall survival. In preclinical studies, DB-1310 has demonstrated significant antitumor activity against prostate cancer, indicating its potential as a promising treatment for this cancer type. We are currently recruiting patients with CRPC in DB-1310's phase 1/2a trial.

- *Promising preliminary data from phase 1/2a trial*. DB-1310 demonstrated tumor reduction in patients with advanced or metastatic EGFRm NSCLC who failed previous standard therapies in the dose escalation cohort of its phase 1/2a clinical trial. In EGFRm NSCLC patients, as of May 17, 2024, uORR and DCR reached 39% and 94.4%, respectively, across dose levels from 1.5 to 5.5 mg/kg. The uORR and DCR was 50% and 100% at 4.5 mg/kg, respectively, and 100% and 100% at 5.5 mg/kg, respectively. DB-1310 also demonstrated an acceptable and manageable safety profile in its phase 1/2a global trial. As of May 17, 2024, the incidence of grade 3 or above TRAEs was 19.3%.

DB-1305/BNT325, a TROP2 ADC candidate with potential as a frontline backbone therapy, our key product

DB-1305 is a TROP2 ADC candidate with a global development strategy. TROP2, a validated and highly expressed ADC target across a wide spectrum of cancers, plays a pivotal role in tumor progression. To date, there is only one TROP2 ADC approved globally, indicated for advanced TNBC, UC and HR+/HER2- BC, according to Frost & Sullivan. The global TROP2 ADC market is expected to increase from US$1.1 billion in 2023 to US$7.7 billion by 2028, representing a CAGR of 48.8%.

DB-1305 targets indications currently under-explored by other TROP2 ADC candidates, such as OC. DB-1305 also has combination potential as a backbone therapy in earlier lines of treatment, starting from NSCLC, OC, CC and TNBC. We believe this well-rounded strategy may position DB-1305 as a potential backbone therapy in the TROP2 ADC landscape. In collaboration with BioNTech, we are advancing DB-1305's global clinical development, including an ongoing phase 1/2a global trial in patients with advanced solid tumors, where encouraging preliminary efficacy signals in NSCLC and multiple other solid tumors have been observed.

Highlights of DB-1305 include:

- *Well-positioned to address underserved needs in OC treatment*. Despite the encouraging therapeutic benefits shown by TROP2 ADCs, the global clinical development of TROP2 ADCs is currently heavily focused on TNBC, HR+/HER2- BC, UC and NSCLC. Because TROP2 is a significant prognostic biomarker and therapeutic target across other prevalent or hard-to-treat cancers, this leaves unmet needs among patients. OC, for example, is one of the leading causes of cancer death in women globally with over 300,000 diagnosed each year.

  Traditionally, ADC development has focused on FRα-positive OC patients, who constitute a limited subset of the OC population. Compared to FRα-directed ADCs, DB-1305 demonstrates broader treatment potential among a wide range of OC patients, due to TROP2's high overexpression rate (~83%) in this cancer type. In January 2024, DB-1305 was granted Fast Track Designation by the FDA for patients with platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, acknowledging its potential to address unmet medical needs.

- *Combination potential as backbone therapy in multiple solid tumors*. We and BioNTech are actively exploring DB-1305's combination potential as a backbone therapy in early lines of treatment, starting from NSCLC, OC, cervical cancer ("**CC**") and TNBC. In June 2024, the first patient was dosed in a combination cohort of DB-1305's ongoing phase 1/2a global trial to evaluate the combination of DB-1305 and BNT327, a bsAb targeting PD-L1 and VEGF, aiming to harness the potent anti-tumor activity of ADCs along with the sustained benefit of immunomodulators. In October 2024, we received IND approval from the NMPA to initiate a phase 1/2a trial for DB-1305 in combination with BNT327 in patients with late-stage/metastatic solid tumors.

- *Encouraging efficacy and manageable safety profile from phase 1/2a trial*. Based on preliminary data from DB-1305's ongoing phase 1/2a global trial, which were published at the 2023 European Society for Medical Oncology Congress ("**ESMO**"), DB-1305's uORR was 30.4% and unconfirmed DCR was 87.0% among heavily pretreated patients with advanced solid tumors as of April 7, 2023. Among the 23 patients with post-baseline tumor scans, encouraging preliminary efficacy signals were observed in NSCLC patients: uORR was 46.2% and unconfirmed DCR was 92.3%. Encouraging preliminary efficacy signals of DB-1305 have also been observed in multiple other solid tumors. Based on preliminary data from its phase 1/2a global trial, DB-1305 was well-tolerated and all TEAEs were generally manageable at lower dose levels, with grade 3 or above TRAEs reported at 34.1% (15/44) in all patients and low incidences of blood-related TRAEs.

Innovator in ADC development powered by versatile platforms to target underserved therapeutic areas

We push the boundaries of ADC innovation through continued development and iteration of three cutting-edge technology platforms, DIBAC, DIMAC and DUPAC. Based on the successful development of our DITAC platform, we have built each of DIBAC, DIMAC and DUPAC upon our accumulated antibody engineering, linker chemistry and toxin technologies and know-how, as well as our deep disease biology and target insights. These platforms are tailored to explore next generation ADC formats, mechanism of action, and diseases within and beyond the realm of cancer.

Our technology platforms serve as the foundation for continuous and sustained innovation and value creation by empowering our cutting-edge R&D and strategic collaborations with global partners. In addition to our clinical-stage assets, we are advancing multiple preclinical programs, including five expected to initiate clinical trials by the end of 2026.

DIBAC — Next-generation BsADC platform

BsADCs are next-generation therapeutics that combine the targeting precision of bsAbs with the potent cytotoxicity of ADCs. By incorporating two distinct binding moieties in a single therapeutic entity, BsADCs can potentially offer meaningful advantages over traditional monospecific ADCs and their combination therapies.

While promising, the complexity of BsADCs introduces new challenges in antibody engineering, stability and manufacturing. Our innovative DIBAC platform features our understanding of disease and target biology, rich experience in bispecific antibody engineering, and artificial intelligence-empowered target selection and antibody design.

Our DIBAC platform features proprietary design strategies under two approaches:

- *Synergistic tumor-associated antigen ("**TAA**") + IO approach.* We have designed BsADCs with dual function antibodies that enhance anti-tumor effect by simultaneously targeting (i) TAA on tumor cells to induce tumor cell death, and (ii) IO antigen to harness the immune system for more potent and lasting anti-tumor activity. We believe this presents a novel and promising approach to cancer treatment.

  DB-1419, a potential first-in-class B7-H3xPD-L1 BsADC candidate, being the only B7-H3xPD-L1 BsADC currently under clinical development globally, according to Frost & Sullivan, is a representative TAA+IO asset. We believe B7-H3's pan-cancer expression coupled with PD-L1's immune-modulating function may offer enhanced anti-tumor effects across broad indications. Preclinical studies showed that DB-1419 exhibits both direct cancer cell killing and immune-modulation, with more potent tumor growth inhibition activity than the monospecific B7-H3 ADC and the monospecific B7-H3 ADC in combination with a PD-L1 mAb in immune

reconstitute models. Moreover, it was well tolerated with repeat dose administration up to 120 mg/kg in monkeys. We have obtained IND approval from the FDA for DB-1419 and we initiated DB-1419's phase 1/2a global trial in September 2024.

- *Dual-TAA approach.* Due to tumor heterogeneity, monospecific antigen targeting often has suboptimal therapeutic outcomes. Under this approach, we design BsADCs that target two distinct and optimally selected TAAs co-expressed on the same cancer cells to improve binding specificity toward cancer cells and reduce off-tumor toxicity.

  DB-1418, a EGFRxHER3 BsADC, is a representative asset of this approach. Due to target synergies, EGFRxHER3 BsADCs have demonstrated enhanced efficacy and ability to overcome resistance to EGFR-directed treatments in clinical studies. Our DB-1418 is differentiated by a "1+1" format molecule design (two binding sites, one for each target) that translates to higher binding capacity to tumor cells as opposed to healthy cells. DB-1418 has also shown better efficacy in EGFR-resistant or EGFR-low models compared to BsADCs with a "2+2" design, potentially covering a broad patient population currently under-served. We are conducting IND-enabling studies for DB-1418 and expect to advance this molecule into clinical stage in the first half of 2025.

DIMAC — Next-generation Immune-modulating ADC platform

We believe immune-modulating ADCs hold the potential to open the ADC modality to a significant white-space market in autoimmune and other therapeutic areas. Many patients with chronic autoimmune diseases, such as SLE and CLE, are currently treated with therapies that often lead to severe side effects. Long term use of glucocorticoids, for example, are commonly associated with increased risks of bone fractures, weight gain, diabetes, immune system suppression, and other chronic conditions. We believe ADCs can reshape the treatment paradigm of autoimmune diseases by offering a targeted treatment with low systemic exposure, enhanced efficacy and reduced side effects. Immune-modulating ADCs have been validated by preliminary clinical data from peers, showing better safety and efficacy profiles compared to the antibody alone.

We are a global pioneer in this space with the ability to mobilize our accumulated technology in oncology into innovation of autoimmune ADCs, according to Frost & Sullivan. Leveraging our technology accumulation in target and payload selection and ADC design, our DIMAC platform has demonstrated broad anti-inflammatory activity, long duration of action, sustained stability, and low systemic exposure in preclinical studies. We have developed a deep technological moat for DIMAC with patent protection extending beyond 2040.

DB-2304, the representative asset for our DIMAC platform, is a potential global first-in-class BDCA2 ADC candidate for SLE and CLE. SLE and CLE are autoimmune diseases that together affect over eight million patients globally, being one of the most advanced BDCA2 ADCs in terms of development progress. A major shortcoming of mainstay treatments, such as glucocorticoids and immunosuppressants, is their inability to address the high heterogeneity of pathogenesis in these complex diseases, which often result in limited efficacy and serious side effects, especially when used long term for chronic disease management.

We designed DB-2304 with a novel BDCA2 mAb conjugated with a proprietary glucocorticoid receptor ("**GR**") agonist as a payload. BDCA2 is a validated target that is specifically expressed on plasmacytoid dendritic cells ("**pDCs**"), whose over-production of type I interferon ("**IFN-I**") is crucial in SLE and CLE pathogenesis. Although BDCA2-targeted mAbs have demonstrated reduced disease activity in SLE patients, their clinical efficacy is generally limited. By selectively targeting BDCA2, DB-2304 can deliver the immune-modulating payload directly to pDCs, which has demonstrated greater potency with synergistic effects in suppressing production of IFN-I as well as other pro-inflammatory cytokines in preclinical studies. Moreover, by delivering the GR agonist in a site-specific manner, DB-2304 showed good drug stability and serum stability, as well as a promising safety profile with a no observed adverse effect level ("**NOAEL**") of 85 mg/kg in monkeys.

DUPAC — Unique Novel MOA payload ADC platform

We are looking ahead to the next innovation to disrupt the ADC landscape. We anticipate a growing need for ADC payloads with a novel mechanism of action as more patients develop resistance to existing ADCs. Moreover, we believe ADCs with new mechanism of action are the future direction in combating hard-to-treat tumors out of the reach of existing ADCs.

We are building DUPAC to develop linker-payload complexes with novel mechanisms of action ("**MOA**") beyond traditional cytotoxic agents to combat growing drug resistance and hard-to-treat tumors. We have made promising progress in a number of unique payload mechanisms and have obtained prototypes with broad-spectrum anti-tumor activity across multiple solid tumors, and potent direct and bystander killing effects in preclinical studies. In particular, our in-house discovered lead prototype has a unique MOA that demonstrates broad-spectrum anti-tumor activity across multiple solid tumors and remains potent in tumors resistant to deruxtecan. ADCs designed with our lead prototype have also shown potent direct and bystander killing effects and induce strong immunogenic cell death.

Strategic and value-enhancing partnerships to sustain long-term global development

We have set our sights on being a global ADC powerhouse from day one. In line with our global strategy, we have established an array of strategic partnerships to accelerate the development of our pipeline across key global markets, expand our global clinical development capabilities, and fuel our future innovation and long-term growth. In our short operating history, we have entered into several out-licensing and collaboration deals with leading industry players worldwide to date, including BioNTech, BeiGene, Adcendo, GSK, and Avenzo, with over US$6.0 billion in total deal value (of which approximately US$400 million had been received as of the Latest Practicable Date). We believe our proven partnership model has the following advantages:

- ***Validation of industry-leading innovation***. Our high-profile partnerships served as industry validation of our platform technologies and pipeline assets. Since deal signing, through the consistent and timely achievement of R&D and clinical milestones, we have solidified and deepened our collaboration with our partners. We believe our partnerships have elevated our strengths, especially in executing global trials and managing multicenter studies, hence expanding our cross-border clinical development capabilities. Our partnerships have also enabled our exploration into new R&D programs. With our established reputation, we strive to become a partner-of-choice for global biopharmaceutical companies seeking innovative ADC programs.

- ***Strong commercial upside***. We had received approximately US$400 million in upfront and milestone payments from collaboration partners as of the Latest Practicable Date, providing significant capital support for our R&D and operations. In addition, we have structured our partnerships favorably to provide strong commercial upside and visibility. For example, we have preserved the opportunity to capture the commercial upside of DB-1311 by retaining the opt-in rights to co-develop and co-commercialize this asset with BioNTech in the U.S. As part of our partnership with Adcendo, we also have an exclusive option to license the Greater China rights for the development and commercialization of Adcendo's novel ADC candidates arising from this collaboration, after such assets have completed proof-of-concept trials.

- ***Fueling future innovation***. The replicability of our partnership model delineates a sustainable path for future innovation. Cash flows generated from our partnerships contribute to our agile pipeline development strategy, sustaining our R&D engine to deliver more cutting-edge technologies and assets. Through external collaboration, we create flexible deal structures to allow our partners and us to leverage each other's strengths to accelerate the development of drug candidates that are valued by patients and the biopharmaceutical industry. We believe our partnership model creates a virtuous business cycle that will drive our long-term value creation and generate future partnership opportunities.

World-class management team of ADC experts and seasoned entrepreneurs with a proven track record

We are a dynamic and driven ADC company that values quality, efficiency and speed. Within just four years since our inception, seven of our ADC candidates have advanced from program initiation to IND approval. In addition, we have seven ongoing global MRCTs, including two registrational trials (one global trial and one in China) and one potential global registrational study.

We owe these successes to our leadership team, who guides our strategic direction. We believe their complementary expertise across R&D, clinical execution and entrepreneurship have been the pillars of our success:

- ***Dr. ZHU Zhongyuan***, MBA, Ph.D., our founder, chairman of the Board and chief executive officer, is a key figure in the biotech landscape with a unique background in both the scientific and business facets of the industry. Dr. Zhu brings strong business acumen, industry insights, and over 20 years of experience in pharmaceutical entrepreneurship and investment as a former partner at leading venture capital firms such as 6 Dimensions Capital and Wuxi Healthcare Ventures. Dr. Zhu has consistently demonstrated his ability to navigate market dynamics and make investment decisions that drive innovation and value creation, playing a significant role in the incubation and growth of several notable biotechnology companies, including CStone Pharmaceuticals (HKEX: 2616), RemeGen Co., Ltd. (HKEX: 9995), Gan & Lee Pharmaceuticals (SHA: 603087), and BGI Genomics Co., Ltd. (SHE: 300676). With a Ph.D. from the University of Massachusetts at Worcester in biomedical science and an MBA from the University of California at Berkeley, Dr. Zhu combines his scientific background with entrepreneurial judgment and foresight, guiding our Company to capitalize on opportunities, forge strategic partnerships worldwide, and remain at the forefront of ADC development.

- ***Dr. QIU Yang***, Ph.D., our chief scientific officer, drives the scientific direction of our pipeline programs, with over two decades of experience in drug discovery and translational medicine at MNCs. Prior to joining us, Dr. Qiu served as co-chair of the cross-functional ADC forum and senior director of translational medicine at Daiichi Sankyo, where she was a leading contributor to the development of innovative ADC therapy, most notably HER3-DXd (U3-1402, patritumab deruxtecan), which received FDA Breakthrough Therapy Designation in 2021. Before Daiichi Sankyo, Dr. Qiu held key positions as director and head of biomarker research at Janssen China Discovery Center and director leading the progress of early drug discovery at GSK R&D China. Throughout her distinguished career, Dr. Qiu has demonstrated success in leading drug discovery, translational medicine, and early clinical development programs, contributing to the discovery and advancement of over 15 drug candidates into clinical trials and the approval of multiple innovative drugs. Dr. Qiu's understanding of the ADC landscape and track record are foundational to our continued success as we develop cutting-edge ADC technologies that transform patient care.

- ***Ms. GU Wei***, M.D., our chief medical officer, brings over ten years of expertise in clinical development across the globe, highlighted by her extensive experience leading numerous clinical studies. Ms. Gu has built a successful track record for clinical development at renowned MNCs, including Boehringer Ingelheim, AstraZeneca, and Bristol Myers Squibb, and her strategic oversight plays a key role in our efficient trial execution and alignment with regulatory standards. Earlier in her career, Ms. Gu had six years of physician experience at a top-grade hospital in China.

- ***Mr. WANG Xin***, CFA, is our senior vice president of strategy and business development. Mr. Wang is a seasoned executive with nearly 20 years' industry experience. Before joining us, he was responsible for research on the global healthcare sector and advising corporate clients on business strategy and development at Mizuho Bank in New York. Before that, Mr. Wang was a member of the top-ranked pharmaceutical research teams at UBS. Earlier in his career, Mr. Wang worked at the pharmaceutical R&D team at Schering-Plough Research Institute (now Merck).

- ***Dr. HUA Haiqing***, Ph.D., our senior vice president and head of drug discovery, leads our strategies for novel drug discovery and CMC development. Over the past 15 years, Dr. Hua has established a strong track record of leading the discovery of innovative drugs and advancing them into the clinic. Prior to joining us, Dr. Hua held senior positions at Hansoh Pharma and as a principal scientist at Lilly China R&D Center. Dr. Hua's extensive experience and leadership in drug discovery and CMC development contribute to the seamless integration of cutting-edge science with robust manufacturing processes, facilitating the efficient translation of our ADC research into transformative therapies.

Our core leadership team has assembled a highly experienced senior management team, each with over 15 years of experience in key functions of our business, including drug discovery, translational medicine, clinical development, chemistry, manufacturing and controls ("**CMC**"), business development, finance, and human resources, to lead our operations. By bringing together experts in all facets of ADC drug development, we aim to push boundaries and deliver innovative medicine to patients in need.

We are supported by a scientific advisory board of world-renowned ADC experts to guide our R&D activities and provide invaluable strategic advice. Key members of our scientific advisory board include Dr. Antoine Yver and Dr. Pasi Jänne, two leading minds in ADC drug development in the world. We have had the privilege of working with both Dr. Yver and Dr. Jänne since our inception. With the deep relationships we have built, Dr. Yver, Dr. Jänne and other members of our scientific advisory board have shared years of knowledge and insights that have been instrumental in our pipeline R&D, clinical development and global collaboration.

- ***Dr. Antoine Yver***, M.D., M.S., is the chairman of our scientific board. Dr. Yver is a world-leading scientist in ADC research and development with over 34 years of pharmaceutical experience. Dr. Yver formerly served as the executive vice president, global head of oncology R&D and chair of the cancer enterprise at Daiichi Sankyo from 2016 to 2021, where his strategic leadership transformed Daiichi Sankyo from a small molecule drug company to a world-class oncology company. Dr. Yver was the vision leader for Daiichi Sankyo's ADC pipeline and led the successful accelerated and practice-changing development of Enhertu® (trastuzumab deruxtecan). He previously had been a senior vice president and head of oncology global medicines development at AstraZeneca, where he led equally successful development and approvals of TAGRISSO® and LYNPARZA®. In addition, he held various clinical development roles at Johnson & Johnson, Schering-Plough, Aventis Group and Rhone Poulenc Rorer. Dr. Yver is currently an independent director at Sanofi, a member of the scientific committee of Institut Gustave Roussy at Paris, France, as well as board member or special advisor to various companies.

- ***Dr. Pasi A. Jänne***, M.D., Ph.D., is a world-renowned medical oncologist and translational scientist. Dr. Jänne is currently a professor of medicine at Harvard Medical School, the senior vice president for translational medicine and a director of the Belfer Center for Applied Cancer Science, and an active thoracic medical oncologist within the Lowe Center for Thoracic Oncology, at the Dana-Farber Cancer Institute. As a leading PI of early clinical development, he has 25 years of experience in early clinical development and translational research for oncology drugs, with a particular focus on lung cancer. He has made seminal therapeutic discoveries, including as one of the inventors of patents on EGFR mutations. Dr. Jänne has also contributed instrumentally to the development of several innovative drugs, including HER3-DXd of Daiichi Sankyo, TAK-788 of Takeda Pharmaceutical, osimertinib of AstraZeneca, crizotinib of Pfizer, trastuzumab deruxtecan of Daiichi Sankyo and Astra Zeneca and adagrasib of Mirati Therapeutics and Bristol Myers Squibb.

Our shareholder base consists of leading healthcare investors, including Lilly Asia Ventures, King Star Med, AZ-CICC, Yinglian Investment, Golden Sword, and 6 Dimensions Capital.

OUR BUSINESS STRATEGIES

Our mission is to become a global powerhouse in the discovery, development, and commercialization of innovative ADC therapies. We adhere to a "CP^2" strategy, our formula centered around Clinical development, Platforms and Pipeline and are expanding its adoption for the global market. Led by our founder and chief executive officer Dr. ZHU Zhongyuan and an experienced scientific team, we have established a dedicated global ADC development engine. Within just four years since our inception, we have built four proprietary technology platforms and a differentiated and tiered in-house pipeline of innovative ADCs assets.

Building upon these efforts, we will accelerate the global development and commercialization of our clinical-stage programs to unlock their commercial value. We will also continue to enhance our global research, clinical development and regulatory expertise to drive future waves of ADC innovation. By harnessing our innovation capabilities and value-accretive partnerships, we aim to unlock the full potential of ADCs to transform the treatment paradigm for oncology, autoimmune diseases and beyond.

Accelerating global development and commercialization of clinical-stage assets

For our first wave of clinical-stage ADC assets, we will continue to drive their global development and accelerate market entry by leveraging our clinical execution speed and efficiency and deep regulatory expertise. We have designed bespoke clinical strategies for each asset for market entrance, broaden coverage to large patient populations and potentially become the new standard of care.

- ***First-to-market approach***. To maximize the global competitiveness of our pipeline, we will select and address initial target indications that are commercially attractive and often underserved, which enable us to demonstrate key asset differentiation, and rapidly enter and establish a strong presence in the global market. For example, DB-1303 is the most clinically advanced HER2 ADC candidate globally that targets EC across HER2-expression levels, according to Frost & Sullivan. We and BioNTech have completed patient enrollment for DB-1303's potential registrational cohort in HER2-expressing advanced/recurrent EC patients and plan to commence a confirmatory phase 3 trial in this patient population in 2025.

- ***Fast-to-commercial approach***. Complementing our first-to-market strategy, we utilize a fast-to-commercial approach to accelerate access to our differentiated assets for a wider addressable population of patients in need. For instance, DB-1303 is a leading candidate for HER2 low-expressing BC, according to Frost & Sullivan, with potential for extension to other underserved cancer indications. DB-1303 is undergoing a phase 3 global registrational trial in chemo-naïve HR+/HER2-low metastatic BC patients with first patient dosed in January 2024. Furthermore, DB-1311 is currently one of the top three B7-H3 ADCs undergoing global MRCTs in terms of clinical development progress for advanced SCLC, according to Frost & Sullivan.

- ***Combination and indication expansion strategy***. We adopt combination therapy strategies to unlock the frontline and backbone potential for our assets and offer improved clinical benefits to patients. For instance, DB-1310 is a global clinical-stage HER3 ADC candidate being developed for EGFRm NSCLC patients resistant to osimertinib or other third-generation TKI treatments through combination with osimertinib. Together with BioNTech, we are actively exploring DB-1305's combination potential as a backbone therapy in early lines of treatment, starting from NSCLC, OC, CC and TNBC. In June 2024, the first patient was dosed in a combination cohort of DB-1305's ongoing phase 1/2a global trial to

evaluate the combination of DB-1305 and BNT327, a bsAb targeting PD-L1 and VEGF, aiming to harness the potent anti-tumor activity of ADCs along with the sustained benefit of immunomodulators. In October 2024, we received IND approval from the NMPA to initiate a phase 1/2a trial for DB-1305 in combination with BNT327 in patients with late-stage/metastatic solid tumors.

Based on DB-1303's anticipated market launch timeline in China, we have formulated a cross-functional commercialization plan. Key initiatives include establishing manufacturing and supply chain management systems, final marketing approval application, as well as trademark registration and packaging design. We have also begun building our core commercialization teams, with strategic planning, supply chain management, and partnership management positions already filled. In January 2025, we entered into a collaboration agreement with 3SBio Inc. (HKEX: 1530, "**3SBio**") through its subsidiaries, pursuant to which we have appointed 3SBio as our strategic partner in Mainland China, Hong Kong, and Macau (the "**Territory**") to promote DB-1303 for various indications. 3SBio will also provide related commercialization services to support DB-1303's market access, medical affairs, channel management and other commercial activities in the Territory. As the Marketing Authorization Holder, we will continue to be responsible for advancing the clinical development and registration of DB-1303 in the Territory before and after commercial launch. Together with 3SBio, we are formulating a comprehensive marketing and promotional plan for DB-1303 in the Territory. We intend to implement competitive pricing and market access strategies, including participating in NRDL negotiations, volume-based procurement programs, and leveraging other opportunities to maximize DB-1303's market potential and accessibility. See "— Commercialization — Partnership with 3SBio to Commercialize DB-1303 in the China Market" for details.

We believe that the market entry of our clinical-stage assets over the next few years will propel us into a new phase as a biopharmaceutical company, expanding beyond R&D to commercialize drugs and maximize their value. In anticipation of this next phase, we will actively assess potential collaborations and partnerships that could help us establish and grow our global presence, while building up our in-house capabilities — which span market access, channel management, medical affairs, and sales and marketing — to drive our overall commercial strategy, including post-launch clinical development, pricing, healthcare insurance negotiations, and distribution. We aim to maintain flexibility in our commercialization approach and adapt to the unique needs of different regions.

Through our first wave of assets, we showcase the strength and versatility of our technology platform and our translational medicine capabilities, as well as accumulate global clinical execution and regulatory expertise. As we bring our innovative therapies to patients in need, we solidify our position as a leader in the industry, poised for sustained growth and success.

Rapidly advance next wave of ADC assets by leveraging accumulated global R&D and regulatory expertise

With our first wave of assets approaching commercialization, we are actively developing next-generation ADCs that address limitations of existing therapeutics and further improve the anti-tumor activity and toxicity profiles of earlier generations of ADCs. In line with our overarching goal to optimize ADCs to treat challenging diseases with improved clinical outcomes, we are exploring new antibody, payload and linker formats, such as BsADCs and immune-modulating ADCs. We believe these novel ADC formats can potentially treat patients that are unresponsive or develop resistance, and expand the therapeutic coverage of ADCs to new tumor types and disease areas.

We aim to bring multiple bispecific and immune-modulating ADCs into the clinic in the next few years, with at least one or two INDs obtained each year. We initiated a phase 1/2a global trial for DB-1419 (B7-H3xPD-L1 BsADC) in 2024. We initiated a phase 1 study in healthy adults for DB-2304 in Australia in October 2024. We have submitted IND applications to both the FDA and NMPA for DB-2304 and, subject to regulatory approval, expect to complete DB-2304's phase 1 global trial in 2026. We are conducting IND-enabling studies for DB-1418 (EGFRxHER3 BsADC) and expect to advance this molecule into clinical stage in the first half of 2025.

We are devising global clinical development plans and regulatory approval strategies to rapidly advance our second wave of assets into the clinic. In doing so, we will leverage our accumulated know-how and insights in translational medicine across the world to optimize drug candidates and clinical trial design for the target indications. Moreover, we will harness our experience in regulatory affairs to navigate and develop global regulatory strategies and engage with key regulatory authorities across the U.S., China, the EU and worldwide. Our global clinical strategy ensures diverse demographic representation, hence enabling wider market access across various ethnicities and genetic variations. This approach also facilitates a coordinated and potentially streamlined approval process by adhering to regulatory standards across jurisdictions. Leveraging our regulatory expertise accumulated over the years, we aim to continuously advance global drug development with enhanced in-house control and execution speed.

Continue technology innovation to unlock the full potential of ADCs and disrupt treatment landscape

We believe disruptive ADC technology innovation will redefine the treatment landscape for many therapeutic areas. We will continue to invest extensively in innovation, with a focus on the following directions:

- ***Novel payload and linker technology***. With our understanding of limitations of traditional ADCs, such as inadequate efficacy and acquired drug resistance to existing therapy, our research in the next few years will focus on novel payloads and linkers to broaden the therapeutic index of our ADCs. We are actively exploring new

mechanism of action and formats to achieve new heights in terms of safety, potency and activity, and have a number of prototypes under development with promising broad-spectrum anti-tumor activity and potent bystander killing effects. We believe these innovations will redefine ADC functionality and chart the course for a new revolution of the ADC modality.

- ***AI-driven drug discovery and development***. We plan to leverage the power of AI to accelerate our drug discovery and development efforts, and to remain competitive in ADC innovation. We have built an AI team to support our R&D efforts with a large language model-based, machine learning approach. We will continue to invest into our dedicated computational infrastructure with integrated AI capabilities, based upon iterative learning through both our "Duality Target Engine," that comprises comprehensive omics computational analysis and automatic literature review, and "Duality Knowledge Base and Retrieval-Augmented Generation Chatbot," that centralize internal data and knowledge repositories to further improve efficiency and accuracy of R&D. By utilizing AI-driven tools and data-based support, we aim to systematically optimize every stage of our R&D, from target identification, ADC design and engineering to biomarker discovery, enabling us to finetune our engineering of next generation ADC candidates to prioritize high-potential targets and indications.

- ***Expansion to autoimmune, metabolic and cardiovascular diseases***. We believe the ADC modality represents a more targeted, enhanced and better tolerated approach for many diseases and conditions beyond oncology. We have designed our technology platforms with a plug-and-play architecture, which enables us to engineer different ADCs to unlock the significant potential in multiple non-oncology therapeutic areas, including autoimmune, metabolic and cardiovascular diseases.

Maximize clinical and commercial potential of our assets through value accretive partnerships

Our proven track record of successful global R&D partnerships underscores the effectiveness of our approach to maximizing value through strategic collaborations. Building on this foundation, we will continue to actively seek and evaluate different modes of external partnerships to accelerate the delivery of our innovative therapies to patients across various markets worldwide. By leveraging the strengths and expertise of our partners, we aim to expand and deepen our global reach, optimize resource allocation, and ultimately, determine the right development strategy for the asset program towards approval and commercialization.

- To accelerate global clinical development and maximize commercial value of our drugs, we will primarily focus on partnerships with leading global biopharmaceutical companies that will bring synergies to our pipeline and operations, and innovative global biotech companies with a proven record of successful drug development. We will maintain flexibility in the form of collaboration to fully capitalize the value of our assets. In particular, we may seek to structure the partnerships to retain significant economic interest and upside

potential, and optimize the joint development and control of our clinical and preclinical programs. Moreover, we will maintain our agile pipeline development, which leverage our partnerships to provide funding for our in-house assets development. To date, we have been actively assessing opportunities extended by various MNCs on our technology platforms and preclinical stage assets.

- In addition to partnerships on an asset level, we will also actively evaluate collaborative R&D opportunities to enhance and supplement our in-house drug discovery and research efforts. We will focus on identifying and engaging with partners who possess complementary expertise and technologies that can synergize with our own capabilities. These collaborations may span various aspects of ADC design, such as antibody engineering, novel linker technologies and cutting-edge payload development. By strategically combining our strengths with those of our partners, we aim to accelerate future waves of ADC innovation.

Continue to build our global presence and teams across drug research, clinical development, regulatory affairs and commercialization

In line with our global vision, continued global development of our drug assets and building robust teams across critical functions will be paramount to our success. We will continue to conduct global MRCTs with increased in-house control and oversight. This approach will allow us to ensure consistent quality, maintain regulatory compliance, and gather diverse patient data to support our global registration strategies.

In parallel, we will focus on attracting, developing, and retaining top-tier talent across key areas of drug research and development, including discovery, translational medicine, clinical operations, regulatory affairs, and commercialization. As we strengthen our global talent pool, we will be well-positioned to continue to develop innovative assets with global clinical development strategies executed with speed and efficiency. Ultimately, these efforts will propel us forward in our journey to become a truly globalized biopharmaceutical company, recognized for our scientific expertise, operational excellence, and unwavering commitment to improving patient lives on a global scale.

OUR BUSINESS MODEL

Since our inception, we have focused primarily on the independent discovery and development of ADC assets. We have assembled a highly experienced team of experts in all facets of ADC drug development. Their accumulated experience and expertise have driven our technology platform and pipeline development, executed with quality and operational efficiency. With our commitment to organic in-house R&D, we have developed four cutting-edge technology platforms and a pipeline of 12 internally discovered ADC candidates covering a diverse range of indications, which reflects our understanding of disease biology and unique insights into target selection.

In the rapidly iterating and highly competitive ADC market, we understand that development speed is as crucial as asset quality in determining the ultimate success of an ADC drug. As a biotech company founded in 2019, we have strategically focused our core competencies on our technology platforms and the critical initial phases of drug development, from drug discovery to proof-of-concept clinical trials. For late-stage clinical development (such as global MRCTs) across multiple drug assets, we have taken a strategic and flexible approach to drug development, leveraging both our internal resources and external partnerships to rapidly bring our drugs to market. This efficient model allows us to maintain our agility and innovation as a young biotech company while tapping into the scale and experience necessary for successful late-stage global development.

Our successful in-house R&D has drawn the attention of global biopharmaceutical companies, and we have entered into collaborations to accelerate the global expansion of our drug programs and maximize their impact on patients worldwide. These collaborations are win-win for us and our partners. We have retained development and commercialization rights to these assets in certain territories, and have continued to play a core role in the overall development strategy and direction of these assets on a global level. The partnerships enable us to maximize the clinical value of our in-house discovered assets and provide financial resources to further invest in our pipeline development. Moreover, these collaborations provide our partners with high-quality clinical-stage ADC assets to complement their drug portfolios and support their long-term strategies.

Going forward, we expect to continue to implement this business model. We will continue to lead the development activities of our clinical-stage assets in the regions where we retain rights, and expect to have multiple assets entering the clinic in the next few years and more in preclinical studies. We will also continue to optimize our ADC platforms to support further innovation and remain open to value-accretive R&D partnerships that support our growth. Anticipating commercialization of our late-stage ADCs, we are proactively developing a tailored commercial strategy for each asset, harnessing both our in-house capabilities and external collaboration.

OUR PIPELINE

Overview

As of the Latest Practicable Date, our pipeline comprised 12 in-house discovered ADC candidates, which we have rapidly established in our short operating history leveraging our four cutting-edge ADC technology platforms, execution capabilities and experienced R&D team. Our technology platforms, namely DITAC, DIBAC, DIMAC and DUPAC, serve as the foundation of our drug discovery and development efforts.

We take a tiered strategy in ADC development, leading the waves of technology iteration that place us at the forefront of ADC innovation:

- ***First wave of assets***, empowered by DITAC and serving as proof of concept of our leading ADC technology, our proprietary topoisomerase-based ADC platform, includes (i) ADC candidates with clinically validated targets strategically developed for differentiated indications, represented by our Core Product DB-1303, a HER2 ADC, and our key product DB-1305, a TROP2 ADC; and (ii) ADC candidates under global development for high-potential targets and under-explored indications, represented by our Core Product DB-1311, a B7-H3 ADC, and our key product DB-1310, a HER3 ADC;

- ***Second wave of assets***, leveraging DIBAC and DIMAC, our bispecific and immune-modulating ADC platforms, is represented by next-generation ADCs with novel formats and components that open ADCs to front-line or difficult-to-treat settings and new therapeutic areas, such as BsADCs, including DB-1419 (B7-H3xPD-L1 BsADC), DB-1418 (EGFRxHER3 BsADC) and DB-1421, and immune-modulating ADCs for autoimmune diseases, including DB-2304 (BDCA2 ADC), and others; and

- ***Third wave of assets***, enabled by DUPAC, our novel MOA payload ADC platform, is the driving force behind our novel ADC payload and linker technologies that potentially disrupt the ADC modality, opening the possibility to reach hard-to-treat tumors and staying ahead of the growing need to overcome acquired resistance to existing ADCs.

The pipeline chart below summarizes the development status of our clinical-stage drug candidates and selected preclinical assets, all of which are in-house discovered.

	Program	Target	Indications (lines of treatment)	Mono/Combo	Preclinical/ IND-Enabling	Phase 1	Phase 2a/ Phase 2	Phase 3	Key Regulatory Authorities	Trial Location	NCT Number	Upcoming Milestone	Commercial Rights	Partners
Oncology	**DITAC – Leading TOP1i ADC Platform**													
	★ **DB-1303 /BNT323**	HER2	HER2-expressing EC (2L+)	Mono		Single-arm, Potential Registrational Study			FDA, NMPA	Global	NCT05150691	Trial completion: 2027	**Mainland China, Hong Kong, Macau**	BIONTECH
				Mono			Planned Phase 3 Confirmatory Trial	*	FDA, NMPA	Global	NCT06340568	Trial completion: 2029		
			HR+/HER2- low BC (chemo naïve)	Mono					FDA, NMPA	Global	NCT06018337	Trial completion: 2028		
			HER2+ BC (2L+)	Mono					NMPA	China	NCT06265428	Trial completion: 2026		
			HER2+ BC (1L)	+ Pertuzumab					FDA, NMPA	Global	NCT05150691	Trial completion: 2027		
			Solid Tumors (OC, CRC, esophageal cancer, etc.)	Mono					FDA, NMPA	Global				
	★ **DB-1311 /BNT324**	B7-H3	SCLC (2L+)	Mono					FDA, NMPA	Global	NCT05914116	Trial completion: 2026	**Mainland China, Hong Kong, Macau** (U.S.: Option to Co-develop and Co-commercialize)	BIONTECH
			CRPC (late line)	Mono					FDA, NMPA	Global				
			ESCC (2L+)	Mono					FDA, NMPA	Global				
			NSCLC (2L+)	Mono					FDA, NMPA	Global				
			Solid Tumors (HNSCC, HCC, CC, melanoma, etc)	Mono					FDA, NMPA	Global				
	☆ **DB-1310**	HER3	EGFRm NSCLC (TKI-resistant)	+ Osimertinib					FDA, NMPA	Global	NCT05785741	Trial completion: 2026	**Global**	
			KRASm NSCLC (2L+)	Mono					FDA, NMPA	Global				
			HER2+ BC (Post-Enhertu)	+ Trastuzumab					FDA, NMPA	Global				
			Solid Tumors	Mono					FDA, NMPA	Global				
	☆ **DB-1305 /BNT325**	TROP2	OC (2L+)	Mono					FDA, NMPA	Global	NCT05438329	Trial completion: 2025	**Mainland China, Hong Kong, Macau**	BIONTECH
			NSCLC (2L+)	Mono					FDA, NMPA	Global				
			NSCLC, OC, CC, TNBC (multiple lines)	+PD-L1xVEGF bsAb					FDA, NMPA	Global				
			Solid Tumors (CC, TNBC, etc.)	Mono					FDA, NMPA	Global				
	DB-1312 /BG-C9074	B7-H4	Solid Tumors	Mono/ + Tislelizumab		**			FDA, NMPA	Global	NCT06233942	Trial completion: 2027	/	BeiGene
	DB-1314	Undisclosed	Solid Tumors	Mono					N.A.	/	/	IND submission: 2026	**Global**	
	DB-1317	Undisclosed	Solid Tumors	Mono					N.A.	/	/	IND submission: 2025	**Global**	
	DB-1324	Undisclosed	Solid Tumors	Mono					N.A.	/	/		**Mainland China, Hong Kong, Macau**	GSK
	DIBAC – Leading Bispecific ADC Platform													
	☆ **DB-1419**	B7-H3 x PD-L1	Solid Tumors	Mono					FDA, NMPA	Global	NCT06554795	Trial completion: 2027	**Global**	
	DB-1418 /AVZO-1418	EGFR x HER3	Solid Tumors	Mono					N.A.	/	/	IND submission: 2025	**Greater China**	AVENZO THERAPEUTICS
	DB-1421	Undisclosed	Solid Tumors	Mono					N.A.	/	/	IND submission: 2026	**Global**	
	DUPAC – Unique Novel MOA Payload ADC Platform													
	DB-1316	Undisclosed	Solid Tumors	Mono					N.A.	/	/	IND submission: 2026	**Global**	
Autoimmune	**DIMAC – Leading Immune-modulating ADC Platform**													
	☆ **DB-2304**	BDCA2	SLE, CLE	Mono					FDA, NMPA	Global	NCT06625671	Trial completion: 2026	**Global**	

★ Core Products ☆ Key Products — FDA Breakthrough Therapy Designation — NMPA Breakthrough Therapy Designation — FDA Fast Track Designation — FDA Orphan Drug Designation

Notes: (1) Abbreviations: Mono = Monotherapy, Combo = Combination Therapy, IND = Investigational New Drug, NCT = National Clinical Trial, ADC = Antibody-drug Conjugate, HER2 = Human Epidermal Growth Factor Receptor 2, HER2-expressing = HER2 Status of Tumor Cells Identified with a Test Score of IHC 1+ or Above, EC = Endometrial Cancer, HR+ = Hormone Receptor Positive, HER2-low=HER2 Status of Tumor Cells Identified with a Test Score of IHC 1+ or IHC 2+/ISH-, BC = Breast Cancer, Chemo = Chemotherapy, HER2+ = HER2 Status of Tumor Cells Identified with a Test Score of Either IHC 3+ or IHC 2+/ISH+, OC = Ovarian Cancer, CRC = Colorectal Cancer, SCLC = Small Cell Lung Cancer, CRPC = Castration-resistant Prostate Cancer, ESCC= Esophageal Squamous Cell Carcinoma, NSCLC = Non-small Cell Lung Cancer, HNSCC = Head and Neck Squamous Cell Carcinoma, HCC= Hepatocellular Carcinoma, CC = Cervical Cancer, HER3 = Human Epidermal Growth Factor Receptor 3, EGFRm = EGFR Mutant, TKI = Tyrosine Kinase Inhibitor, KRASm = Kirsten Rat Sarcoma Virus Mutant, BTC = Biliary Tract Cancer, TROP2 = Human Trophoblast Cell-surface Antigen 2, TNBC = Triple-negative Breast Cancer, PD-L1 = PD-1 Ligand 1, VEGF = Vascular Endothelial Growth Factor, bsAb = Bispecific Antibody, EGFR = Epidermal Growth Factor Receptor, BDCA2 = Blood Dendritic Cell Antigen 2, MOA = Mechanism of Action, SLE = Systemic Lupus Erythematosus, CLE = Cutaneous Lupus Erythematosus, FDA = U.S. Food and Drug Administration, NMPA = National Medical Products Administration of the PRC, 1L: first-line treatment, 2L+: second-line or later treatment

(2) For each drug candidate, our clinical development typically begins with a combined phase 1/2a trial, where multiple patient groups across different tumor types or indications are enrolled to assess both safety and efficacy of the drug candidate. Based on the results from these phase 1/2 trials, we determine which indications to prioritize for advancement into later-stage clinical development. All ongoing clinical trials are subject to regulatory oversight by both the FDA and NMPA, except for DB-1303's phase 3 trial in HER2+ BC patients, which is conducted solely in China and regulated by the NMPA.

* BioNTech was the sponsor of this global trial as of the Latest Practicable Date.

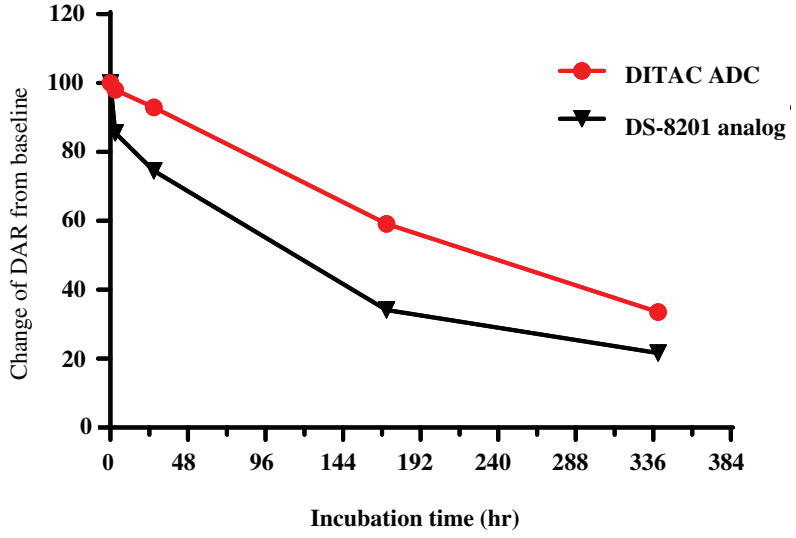
** BeiGene was serving as the sponsor of this trial as of the Latest Practicable Date.

ADC Assets Developed from DITAC Technology Platform

DITAC — A Globally Leading TOP1i ADC Platform

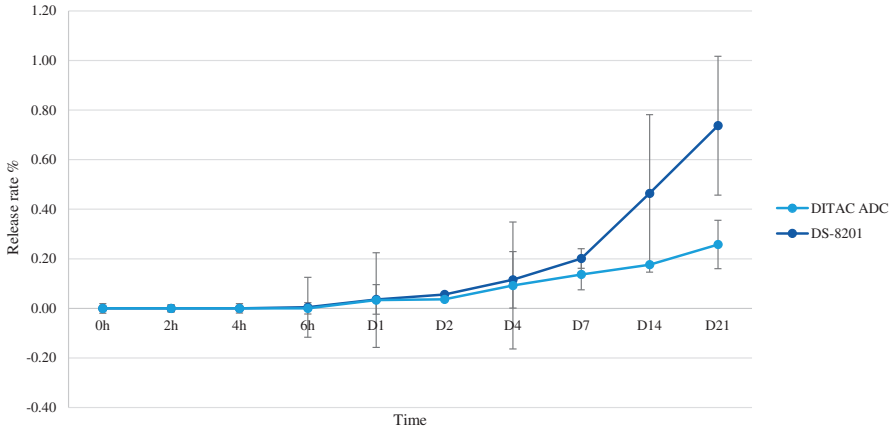
Our clinical-stage assets have shared roots in DITAC, our topoisomerase-based ADC platform. DITAC is validated by the global clinical data from over 2,000 patients (more than 50% located in the U.S., EU and Australia) across the U.S., China, Europe, Australia and other major markets. Compared to ADCs with earlier-generation payloads such as MMAE, topoisomerase-based ADCs are distinguished for their ability to target a broader range of tumors. Notably, the bystander effect of topoisomerase-based ADCs enhances efficacy by allowing the cytotoxic payload to affect neighboring tumor cells that may not express the target antigen.

DITAC takes a holistic approach to ADC design based on our innovative research in disease pathology and biological targets. We have developed a library of proprietary linkers and payloads with meaningful technological improvements, giving us critical optionality in optimizing each ADC component for the target indication. In various clinical and preclinical studies, DITAC-based ADCs have demonstrated improved systemic stability, tumor-specific payload release, bystander-killing effects, and rapid payload clearance, which potentially translates to a significantly improved therapeutic window. For example, one of our DITAC ADCs showed superior *in vitro* plasma stability in human plasma than an in-house produced DS-8201 analog, as illustrated below.



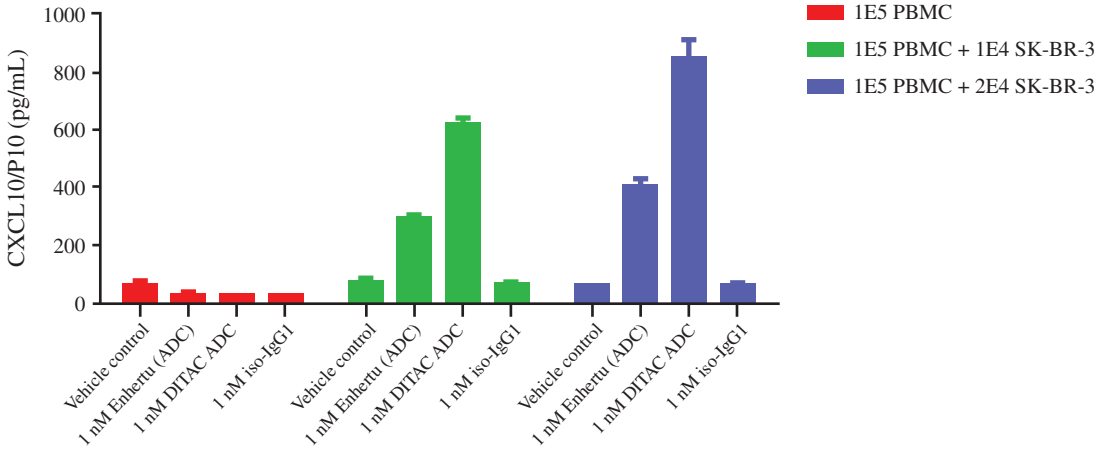
Our DITAC ADCs also exhibit sustained, tumor-selective payload release in tumor-bearing mice and, as illustrated in a preclinical study below, significantly lower free payload level in circulation.

Free payload release rate



Furthermore, ADCs derived from our DITAC platform have demonstrated promising immune-modulating properties, showing a strong potential to overcome drug resistance and improve treatment outcome for cancer patients, especially in combination with immunotherapy. Notably, DITAC ADCs can robustly induce immunogenic cell death ("**ICD**") of tumor cells, a clinically validated therapeutic approach where anti-tumor treatments stimulate an immune response to antigens released by dying cancer cells, followed by dendritic cell activation and T-cell recruitment. Cytotoxic compounds, such as ADC payloads, vary in their ability to induce ICD. In a preclinical investigation, our DITAC ADC showed a superior immunologic effect in a head-to-head comparison with Enhertu®, evidenced by higher levels of CXCL10/IP-10, a reported marker of ICD, in peripheral blood mononuclear cells and breast cancer cells co-culture, as illustrated below.

Innate cytokine CXCL10/IP-10



DB-1303/BNT323, a late clinical-stage HER2 ADC candidate, our Core Product

Overview

Our Core Product DB-1303 is a in-house discovered, late clinical-stage HER2 ADC candidate with two ongoing registrational trials (one global trial and one in China) and one potential global registrational study, with the first indication (HER2-expressing EC) projected to file for accelerated approval with the FDA as early as 2025. DB-1303 is designed with a stable, cleavable linker and proprietary topoisomerase-based payload that aim to lower off-target toxicity and enhance anti-tumor activity, including bystander killing effects. These features may enable DB-1303 to potentially serve as a new therapeutic option for patients with HER2-expressing advanced solid tumors, including both patients with high and low expression levels of HER2. The global HER2 ADC market is expected to increase from US$4.8 billion in 2023 to US$18.5 billion by 2028, representing a CAGR of 30.8%, according to Frost & Sullivan.

DB-1303 is the most clinically advanced HER2 ADC candidate globally that targets EC across HER2-expression levels and a candidate in advanced clinical development for HER2 low-expressing BC, according to Frost & Sullivan, with potential for extension to other underserved cancer indications. DB-1303 has obtained Fast Track and Breakthrough Therapy Designations from the FDA and Breakthrough Therapy Designation from the NMPA for the treatment of advanced EC in patients who progressed on or after treatment with immune checkpoint inhibitors, demonstrating DB-1303's potential to treat advanced EC patients who currently have low survival rates and a strong medical need for new and more effective treatments. Moreover, DB-1303's antitumor activity has been observed in a range of tumors, including BC, EC, OC, CRC and esophageal cancer, supported by global clinical data from patients across the U.S., China and Australia to date.

To further advance DB-1303, we formed a global strategic partnership with BioNTech in 2023 to accelerate its development and maximize its global value. We have granted to BioNTech an exclusive, royalty-bearing and sublicensable license under certain patents and know-how owned or otherwise controlled by us to develop, manufacture, commercialize or otherwise exploit DB-1303 and pharmaceutical products comprising DB-1303 (together "**DB-1303 Products**") for all uses worldwide except Mainland China, Hong Kong and Macau. We retain the full rights to develop, manufacture, commercialize and otherwise exploit DB-1303 and DB-1303 Products in Mainland China, Hong Kong and Macau. See "— Our Collaboration and Licensing Arrangements — License and Collaboration Agreement with BioNTech for DB-1303/BNT323" for details.

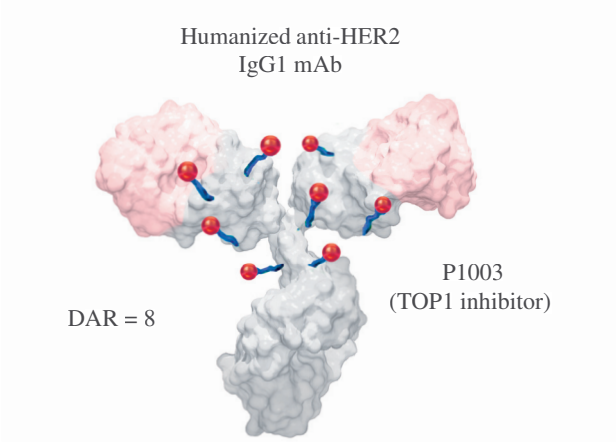
Drug Design and Mechanism of Action

HER2 is a cell surface receptor protein within the HER family that plays a key role in regulating cellular growth, division and survival. Upon activation by ligand binding or overexpression, HER2 dimerizes with other HER family members, leading to the activation of downstream signaling cascades such as the PI3K/AKT and MAPK/ERK pathways. These pathways promote cell proliferation, inhibit apoptosis, and enhance cell migration and invasion.

The HER2 gene has been shown to be overexpressed in various human cancers, including cancers of the breast, gastric, colon, salivary gland, bladder and uterine serous carcinoma. HER2 overexpression results in tumor cell proliferation, apoptosis inhibition, and enhanced cell migration and invasion, ultimately contributing to the development and progression of HER2-expressing tumors. Moreover, HER2 overexpression have been associated with increased tumor aggressiveness, metastatic potential, and resistance to certain chemotherapeutic agents.

DB-1303 is a HER2-targeted ADC designed with a humanized anti-HER2 immunoglobulin G1 ("**IgG1**") mAb, covalently linked to a proprietary topoisomerase I inhibitor payload (P1003) via a maleimide tetrapeptide-based cleavable linker, with a DAR of 8. The core components of DB-1303 are illustrated below.

DB-1303



DB-1303's anti-HER2 IgG1 mAb has the same amino acid sequence as Herceptin (trastuzumab), a clinically proven HER2 mAb. Designed with a cleavable linker that is stable in plasma, DB-1303 travels through the bloodstream upon IV administration with low free payload in the system, translating to a potentially favorable safety profile. Upon selectively binding to HER2 on the surface of tumor cells, DB-1303 is endocytosed into the tumor cell, where the tetrapeptide-based linker is cleaved by lysosomal enzymes preferentially expressed in tumor cells, releasing the highly potent P1003 payload. P1003, a derivative of exatecan,

leads to apoptosis of the target tumor cells via the inhibition of topoisomerase I. DB-1303 is also expected to exhibit HER2-specific antitumor activity through antibody-dependent cellular cytotoxicity ("**ADCC**") activity and bystander killing effect.

Market Opportunity and Competition

As of the Latest Practicable Date, Kadcyla®, Aidixi® and Enhertu® were the only three HER2 ADCs approved globally or in China, with Enhertu® being the only topoisomerase-based ADC, and there were three HER2 ADCs in phase 3 clinical development or beyond under global MRCTs. The global HER2 ADC market was US$4.8 billion in 2023 and is projected to increase to US$18.5 billion in 2028, representing a CAGR of 30.8%. In China, the HER2 ADC market was US$0.3 billion in 2023 and is projected to increase to US$1.7 billion in 2028, representing a CAGR of 46.0%. For more details on the addressable market and competitive landscape of HER2 ADCs, see "Industry Overview — Global HER2 ADC Market — Market Opportunities of HER2 ADCs."

We face fierce competition in the HER2 ADC market from existing and future ADCs directed against the same molecular targets and indicated for the same indications. Such competition may become more intense by future collaborations, mergers and acquisitions in the biopharmaceutical industry. For details of the key features of DB-1303 in comparison with other HER2 ADCs, see also "Industry Overview — Global HER2 ADC Market — Competitive Landscape."

To compete effectively in the HER2 ADC markets, we are driving the clinical development of DB-1303 with a differentiated strategy focused on under-served indications, such as HER2-expressing EC and HER2 low-expressing BC, where existing treatments fail to offer satisfactory clinical benefits to patients. DB-1303 is designed with a stable, cleavable linker and proprietary topoisomerase-based payload that aim to lower off-target toxicity and enhance anti-tumor activity, including bystander killing effects. These features may enable DB-1303 to potentially serve as a new therapeutic option for patients with HER2-expressing advanced solid tumors, including both patients with high and low expression levels of HER2.

HER2-expressing EC. EC is one of the most common gynecological cancers in the world. As one of the fastest growing cancers in terms of incidence, new cases of EC increased from 343.9 thousand in 2018 to 401.7 thousand in 2023 and are projected to reach 494.1 thousand in 2032. While EC has traditionally been more prevalent in post-menopausal women, there is a growing incidence in younger women, indicating increasing medical needs. HER2 overexpression is reported in 17-30% of total EC cases and HER2 low-expression is reported in 47-53% of total EC cases.

In China and the U.S., primary treatment options for HER2-expressing EC include taxane-based chemotherapy, HER2 mAbs, and immunotherapies such as PD-(L)1 inhibitors. For details of the treatment paradigm of EC in China and the U.S., see "Industry Overview — Global HER2 ADC Market — Market Opportunities of HER2 ADCs — Endometrial Cancer." The current treatment paradigm for EC has significant limitations. For patients not suitable for total hysterectomy, traditional drug treatments have substantial side effects. In addition, a significant percentage of patients develop advanced and recurrent disease after first-line treatment, and have limited response to second- or third-line treatment.

As of the Latest Practicable Date, no HER2 ADC had been approved for EC across HER2-expressing level globally. As of the same date, there were five HER2 ADCs targeting EC across HER2-expressing level in phase 2 clinical development or beyond globally. For details, see "Industry Overview — Global HER2 ADC Market — Competitive Landscape."

HR+/HER2-low BC. HER2-low BC is the most prevalent subtype of BC, accounting for approximately 50% of total BC cases. Global incidence of HER2-low BC increased from 1,044.4 thousand cases in 2018 to 1,204.0 thousand cases in 2023, and is projected to reach 1,597.9 thousand cases by 2032. Traditionally, HER2 ADCs were designed to target and were believed to be effective only against HER2+ BC. However, recent advancements in ADC design, including the development of topoisomerase-based payloads, have resulted in successful applications of HER2 ADCs for HER2-low BC patients.

Endocrine therapies ("**ET**"), such as aromatase inhibitors and a selective estrogen receptor degrader, represent the cornerstone of standard first-line and second-line treatment options for advanced HER2-low BC in China and the U.S. However, the recurrence rate after using ET is approximately 40-50%. Limited effective treatment options are available for recurrent patients, leaving a need for effective non-endocrine therapy-based treatment. Trastuzumab deruxtecan (Enhertu®, HER2 ADC) is recommended as second-line or later treatment for HER2-low BC patients in China and the U.S. For details of the treatment paradigm of HR+/HER2-low BC in the U.S and in China, see "Industry Overview — Global HER2 ADC Market — Market Opportunities of HER2 ADCs — Breast Cancer — HER2-low BC."

As of the Latest Practicable Date, only one HER2 ADC, Enhertu®, was approved for HR+/HER2-low BC and only for patients who have received a prior chemotherapy in the metastatic setting or developed disease recurrence during or within six months of completing adjuvant chemotherapy. As of the same date, there were nine HER2 ADCs targeting HR+/HER2-low BC in phase 2 clinical development or beyond globally. For details, see "Industry Overview — Global HER2 ADC Market — Competitive Landscape."

HER2+ BC. HER2+ BC is an aggressive type of BC, representing approximately 15-30% of total BC cases. About 20-25% of HER2+ BC patients present with advanced disease at the time of diagnosis, and 20% of early-stage patients eventually develop advanced disease. The global incidence of HER2+ BC increased from 470.0 thousand cases in 2018 to 541.8 thousand cases in 2023 and is expected to reach 719.0 thousand cases in 2032.

The treatment paradigm for HER2+ BC in China and the U.S. primarily comprises combination therapy of taxane-based chemotherapy plus HER2 mAbs such as pertuzumab and trastuzumab, HER2 ADCs and other targeted therapy options. For details of the treatment paradigm of HER2+ BC in China and the U.S., see "Industry Overview — Global HER2 ADC Market — Market Opportunities of HER2 ADCs — Breast Cancer — HER2+ BC." With the approval of effective treatments such as HER2 ADCs in recent years, HER2+ BC patients have experienced increased progression free survival ("**PFS**") and overall survival ("**OS**"). However, there is still a risk of acquired resistance and need for safer treatments for long-term use. Kadcyla®, for example, carry a black box warning issued by the FDA for hepatic, cardiac and embryo-fetal toxicities. These limitations highlight a need for safer treatments that can prolong the survival for relapsed or refractory patients.

As of the Latest Practicable Date, Kadcyla® and Enhertu® were the only two HER2 ADCs indicated for HER2+ BC approved both in the U.S and in China. As of the same date, there were 15 HER2 ADCs targeting HER2+ BC in phase 2 clinical development or beyond globally. For details, see "Industry Overview — Global HER2 ADC Market — Competitive Landscape."

In addition to the indications described above, DB-1303's antitumor activity has been observed in a range of tumors, including OC, CRC and esophageal cancer, signifying its potential for indication expansion.

Key Advantages

- Most clinically advanced HER2 ADC globally for EC patients across HER2-expression levels. EC is known to be one of the most common gynecological malignancies globally. Both the reported incidence and mortality of EC have increased in the last decade, especially in younger women, with approximately 400,000 new cases reported worldwide in 2023, according to Frost & Sullivan. Approved first- and second-line standard-of-care treatments for EC, including chemotherapy and targeted therapies, have shown limited efficacy in advanced or metastatic EC patients, highlighting an unmet medical need. The five-year survival rate for EC patients with advanced, metastatic or recurrent disease is estimated at only 18%. The global EC drug market is expected to increase from US$5.3 billion in 2023 to US$9.0 billion by 2028, representing a CAGR of 11.2%, according to Frost & Sullivan.

We aim to improve treatment for EC patients across HER2-expression levels. To date, the only approved HER2 ADC available for EC patients globally is indicated for pan-HER2+ solid tumors and hence covers only HER2+ (IHC 3+) EC, which is estimated to account for around 17-30% of the EC patient population. Beyond this small subset of patients, approximately 47-53% of EC patients are HER2 low-expressing with very limited treatment options, according to Frost & Sullivan. DB-1303 is differentiated by observed anti-tumor activity across both HER2-low (IHC 1+ and IHC 2+) and HER2+ EC patients, which potentially expands its suitability to over 70% of the EC patient population. Notably, DB-1303 demonstrated an ORR of 58.8% and DCR of 94.1% in heavily pre-treated HER2-expressing EC patients (IHC 1/2/3+ or ISH-positive), including those with prior immunotherapy or anti-HER2 antibody treatments, in its phase 1/2a trial, preliminary data of which were published at the 2023 ESGO.

DB-1303 has obtained Fast Track and Breakthrough Therapy Designations from the FDA and Breakthrough Therapy Designation from the NMPA for the treatment of advanced EC in patients who progressed on or after treatment with immune checkpoint inhibitors. We and BioNTech have completed patient enrollment for DB-1303's potential registrational cohort in HER2-expressing advanced/recurrent EC patients and plan to commence a confirmatory phase 3 trial in this patient population in 2025.

- Potential treatment for chemo-naïve HR+/HER2-low BC patients. BC is known to be the second largest cancer type in the world by incidence, according to Frost & Sullivan, with approximately 2.4 million new cases reported in 2023 of which HER2-low patients accounted for approximately 50%. The global HER2-low BC drug market is expected to increase from US$17.2 billion in 2023 to US$25.9 billion by 2028, representing a CAGR of 8.5%, according to Frost & Sullivan. Response to first-line therapies, including ET in combination with CDK4/6 inhibitors or chemotherapy, is limited and patients face even fewer available treatment options and poor prognosis after disease progression. According to Frost & Sullivan, the only HER2 ADC approved for HER2-low BC to date is currently indicated for patients who have received a prior chemotherapy in the metastatic setting or developed disease recurrence during or within six months of completing adjuvant chemotherapy. We are advancing, in collaboration with BioNTech, a phase 3 global registrational trial for DB-1303 in chemo-naïve HR+/HER2-low metastatic BC patients with first patient dosed in January 2024.

- Phase 3 topoisomerase-based ADC for HER2+ BC in China. About 15-30% of BC patients are HER2+, with a significant patient population of approximately 92.7 thousand in China in 2023, according to Frost & Sullivan. Despite the potential of topoisomerase-based ADCs to offer significantly improved progression-free survival and overall survival compared to existing treatments, there is only one topoisomerase-based HER2 ADC approved in China to date. We plan to complete

our phase 3 registrational trial in China in 2026 for DB-1303 versus T-DM1 (trastuzumab emtansine) in patients with HER2+ unresectable and/or metastatic BC previously treated with trastuzumab and taxane and file BLA with the NMPA by the end of 2025.

- Promising efficacy data in phase 1/2a global trial. DB-1303 demonstrated encouraging efficacy results in its phase 1/2a global trial, based on preliminary data as of January 13, 2023 published at the 2023 ASCO. The uORR and DCR across all dose levels was 44.2% and 88.5%, respectively, in patients with HER2 expressing solid tumors with a median of seven previous lines of treatment, including prior HER2 ADC regimens, as of January 13, 2023. ORR and DCR were 38.5% and 84.6% in heavily pre-treated HER2-low BC patients, respectively, and 50% and 96.2% in heavily pre-treated HER2+ BC patients, respectively, supporting the initiation of later-stage trials. In addition, preliminary antitumor activity has also been observed in other tumor types, including OC, CRC and esophageal cancer, signifying DB-1303's potential for indication expansion.

- Manageable safety profile. DB-1303 was well-tolerated with no DLT observed in all six dose levels (ranging from 2.2 mg/kg to 10 mg/kg) during dose escalation and no TEAEs associated with death in phase 1/2a global trial as of January 13, 2023, with grade 3 or above TRAEs reported in 12.9% (11/85) of patients. Few patients experienced neutropenia (11.8%) and alopecia (3.5%). Based on preclinical data published at the 2022 AACR Annual Meeting, the HNSTD of DB-1303 is 80 mg/kg in cynomolgus monkeys while the reported HNSTD of DS-8201 was 30 mg/kg. In the same study, DB-1303 also exhibited superior stability and systemic clearance of payload compared to DB-8201a, which potentially contributes to a better safety profile resulting from maintenance of efficacy and reduction of systemic toxicity risk from free payload.

Clinical Development Plan

Based on the IND approvals from the FDA and NMPA, we initiated a phase 1/2a global trial for DB-1303 in advanced or metastatic solid tumors in January 2022. As the first-in-human study for DB-1303, this phase 1/2a clinical trial provides foundational data that informs our regulatory discussions with the competent authorities and shapes our late-stage clinical development strategy. We completed the phase 1 dose escalation study of the phase 1/2a global trial in January 2023, and initiated the phase 2a dose expansion study of this trial in the same month. DB-1303 is being investigated in multiple cohorts for various solid tumors in an ongoing phase 2a dose expansion study and has advanced into two registrational trials (one global trial and one in China) and one potential global registrational study. In general, if approved, DB-1303 with different indications would be regulated as the same product by each competent authority.

In collaboration with BioNTech, we are advancing DB-1303 towards the market with the first indication projected to file for accelerated approval with the FDA as early as 2025:

- First-to-market approach. We strategically adopt a first-to-market approach for DB-1303 as a potential treatment for EC across all HER2-expression levels (IHC3+, 2+, 1+ or ISH-positive) to rapidly establish a presence in the global market. As of the Latest Practicable Date, patient enrollment had been completed for DB-1303's registrational cohort in HER2-expressing patients with advanced/recurrent EC, with a confirmatory phase 3 trial planned to commence in 2025. DB-1303 has obtained Fast Track and Breakthrough Therapy Designations by the FDA and Breakthrough Therapy Designation by the NMPA for the treatment of advanced EC in patients who progressed on or after treatment with immune checkpoint inhibitors. Subject to the results of this potential registrational study, we and BioNTech plan to file for accelerated approval with the FDA as early as 2025.

- Fast-to-market approach. We are advancing, in collaboration with BioNTech, a phase 3 global registrational trial for DB-1303 in chemo-naïve HR+/HER2-low metastatic BC patients, with the first patient dosed in January 2024. We plan to develop DB-1303 for other prevalent tumor types, including HER2+ BC. We are conducting a phase 3 registrational trial in China for unresectable and/or metastatic BC patients previously treated with trastuzumab and taxanes and plan to file BLA with the NMPA for this indication by the end of 2025. Building on DB-1303's clinical data from its ongoing trials, we plan to further explore its combination potential as an early line treatment, including for HER2-low BC.

The table below sets forth details of DB-1303's clinical development plan:

	Indication (lines of treatment)	Mono/ Combo-therapy	Trial phase	Region	Trial status	(Planned) Trial start date	(Planned) Trial completion date
1.	Advanced or metastatic solid tumors*	Mono/ Combo[(1)]	Phase 1/2a	Global	Phase 1: completed Phase 2a: ongoing	January 2022	(2027)
2.	HER2-expressing EC (2L+)*	Mono	Potential registrational study[(2)]	Global	Ongoing	September 2023	(2025)
3.	HR+/HER2-low BC (chemo naïve) *DYNASTY-Breast02**	Mono	Phase 3 registrational trial	Global	Ongoing	January 2024	(2028)
4.	HER2+ BC (2L+) *DYNASTY-Breast01**	Mono	Phase 3 registrational trial	China	Ongoing	January 2024[(3)]	(2026)
5.	HER2-expressing EC (2L+)**	Mono	Planned phase 3 confirmatory trial[(2)]	Global	Planned	(2025)	(2029)

Notes:

* We were the sponsor of this study as of the Latest Practicable Date.

** BioNTech was the sponsor of this study as of the Latest Practicable Date and the holder of IND approval from the FDA.

(1) As part of this trial, DB-1303 is being investigated as a potential first-line treatment for HER2+ BC in combination with pertuzumab.

(2) Based on communications with the FDA and NMPA in September 2023 and April 2024, respectively, we and BioNTech are (i) conducting a potential registrational study of DB-1303 in HER2-expressing EC patients (which is a single arm study converted from DB-1303's phase 2a dose expansion cohort for the same indication), results from which will be used to support the application for accelerated approval (in the U.S.) and conditional approval (in China) for this indication; and (ii) planning a phase 3 confirmatory trial for DB-1303 in HER2-expressing EC patients, as required for full marketing approval post-accelerated/conditional approval. For more details on the regulatory pathways of accelerated approval (U.S.) and conditional approval (China), see "Regulatory Overview — PRC Regulation — Regulations on Pharmaceutical Product — Accelerated Approval for Clinical Trial and Registration" and "Regulatory Overview — Overview of Laws and Regulations in the United States — Laws and Regulations in Relation to New Drug — Expedited Development and Review Programs."

(3) We conducted preliminary trial preparations, such as trial site selection and CRO engagement, in parallel with our IND application to the NMPA for this phase 3 registrational trial, which was approved in April 2024.

The table below sets forth the drug development timeline for DB-1303.

Milestone/Stage	Timeline
Preclinical development	September 2020 to December 2021
IND approval from FDA	December 2021
IND approval from NMPA	April 2022
Phase 1/2a clinical trial in advanced or metastatic solid tumors	Start date: U.S.: January 2022 China: June 2022 Completion date: Phase 1: January 2023 Phase 2a: 2027 (planned)
License and collaboration agreement with BioNTech	March 2023
Potential registrational study in HER2-expressing EC	September 2023-ongoing
Phase 3 registrational trial in HR+/HER2-low BC (*DYNASTY-Breast02*)	January 2024-ongoing
Phase 3 registrational trial in HER2+ BC (*DYNASTY-Breast01*)	January 2024-ongoing

Milestone/Stage	Timeline
Commence confirmatory phase 3 trial in HER2-expressing EC patients	2025 (planned)
Filing for accelerated approval with the FDA for HER2-expressing EC	2025 (planned)
Filing for BLA with the NMPA for HER2+ BC	2025 H2 (planned)
Data readout from phase 3 registrational trial in HER2+ BC in China	2026 H1 (planned)

Summary of Clinical Trial Data

DYNASTY-Breast02, a Phase 3 Global Clinical Trial for HR+/HER2-low BC *(NCT06018337)*

This is a phase 3, randomized, multicenter, open-label study of DB-1303 vs investigator's choice chemotherapy in HR+/HER2-low metastatic BC subjects whose disease has progressed on at least two lines of prior ET or within six months of first line ET + CDK4/6 inhibitor in the metastatic setting.

Trial Design. Approximately 532 subjects with HER2 low-expression (IHC 2+/ISH- and IHC 1+) will be randomized 1:1 across approximately 230 centers globally to receive either DB-1303, at a dosage of 8 mg/kg Q3W, or investigator's choice single agent chemotherapy (capecitabine, paclitaxel or nab-paclitaxel) until Response Evaluation Criteria in Solid Tumors ("**RECIST**") v1.1 defined disease progression, unless there is unacceptable toxicity, withdrawal of consent, or another criterion for discontinuation is met.

Trial Objectives. The primary purpose of the study is to determine the efficacy and safety of DB-1303 compared with investigator's choice single agent chemotherapy in chemotherapy-naïve patients with HR+/HER2-low metastatic BC that have progressed on hormone therapy. The study's primary endpoint is PFS by Blinded Independent Central Review ("**BICR**") according to RECIST v1.1 in the HR+/HER2-low population. Secondary endpoints include OS, ORR, PFS by investigator assessment, duration of response ("**DOR**"), safety parameters including TEAEs and serious adverse events ("**SAEs**") per National Cancer Institute Common Terminology Criteria for Adverse Events v5.0, and quality of life of patients evaluated using the European Organization for Research and Treatment of Cancer ("**EORTC**") Quality of Life Questionnaire, among other outcome measures.

Trial Progress. This trial was initiated in January 2024 and is currently ongoing.

DYNASTY-Breast01, a Phase 3 Clinical Trial for HER2+ BC in China *(NCT06265428)*

This is a phase 3, multicenter, open-label, randomized controlled study evaluating DB-1303 versus T-DM1 (trastuzumab emtansine) in patients with HER2+ unresectable and/or metastatic BC previously treated with trastuzumab and taxane.

Trial Design. Approximately 224 patients with unresectable or metastatic HER2+ BC will be randomized 1:1 to receive DB-1303, at a dosage of 8 mg/kg Q3W, or T-DM1, at a dosage of 3.6 mg/kg Q3W, respectively, until RECIST v1.1 defined disease progression, unless there is unacceptable toxicity, withdrawal of consent, or another criterion for discontinuation is met.

Trial Objectives. The primary purpose of the study is to compare the PFS benefit of DB-1303 with T-DM1 in patients with HER2+ unresectable/metastatic BC previously treated with trastuzumab and paclitaxel. The study's primary endpoint is PFS by BICR according to RECIST v1.1.

Trial Progress. This trial was initiated in January 2024 and is currently ongoing.

Potential Registrational Study for HER2 Expressing EC *(NCT05150691)*

This is a potential registrational study conducted as part of DB-1303's phase 1/2a global trial in advanced/metastatic solid tumors. This study is a multicenter, open-label, non-randomized study to assess DB-1303 for use as a potential treatment for patients with advanced EC who have progressed on or after standard systemic treatment.

Based on communications with the FDA and NMPA in September 2023 and April 2024, respectively, results from this potential registrational study will be used to support the application for accelerated approval (in the U.S.) and conditional approval (in China) for HER2-expressing EC. A phase 3 confirmatory trial for DB-1303 in HER2-expressing EC patients is required for full marketing approval post-accelerated/ conditional approval. For more details on the regulatory pathways of accelerated approval (U.S.) and conditional approval (China), see "Regulatory Overview — PRC Regulation — Regulations on Pharmaceutical Product — Accelerated Approval for Clinical Trial and Registration" and "Regulatory Overview — Overview of Laws and Regulations in the United States — Laws and Regulations in Relation to New Drug — Expedited Development and Review Programs."

Study Design. Patients with advanced/unresectable, recurrent, or metastatic HER2-expressing (IHC 1/2/3+ or ISH+) EC have been enrolled and are treated with DB-1303, including subjects with or without prior immune checkpoint inhibitor ("**ICI**") treatments.

Study Objectives. The primary objectives of the study are to asses the safety and tolerability of DB-1303 and evaluate the efficacy of DB-1303 among HER2 expressing EC patients. The study's primary endpoints include SAEs, TEAEs and ORR assessed by independent review committees ("**IRC**") in all HER2-expressing (confirmed by central laboratory) subjects.

Study Progress. This study is currently ongoing. We published the preliminary data from DB-1303's dose escalation and expansion studies in patients with HER2-expressing advanced/metastatic EC at the 2023 ESGO.

As of May 8, 2023, the data cut-off date for the 2023 ESGO, 32 patients with EC received 7 or 8 mg/kg doses of DB-1303. The median treatment duration was 2.6 (range, 0.7-10.4) months with 29 patients (90.6%) remaining on treatment. Median number of prior regimens for metastatic disease was 2 (range, 1-10). Nineteen patients (59.4%) had prior immunotherapy therapy.

Efficacy Data. DB-1303 demonstrated promising antitumor activity with high disease control in patients with advanced/metastatic EC, including serous and carcinosarcomas. As of May 8, 2023, 17 patients were evaluable for response. Ten patients (58.8%) had objective partial tumor response per RECIST v1.1. The ORRs for patients at 7 and 8 mg/kg dose were 50.0% (2/4) and 61.5% (8/13), respectively. The overall DCR was 94.1%. The table below sets forth a summary of the efficacy data as of May 8, 2023.

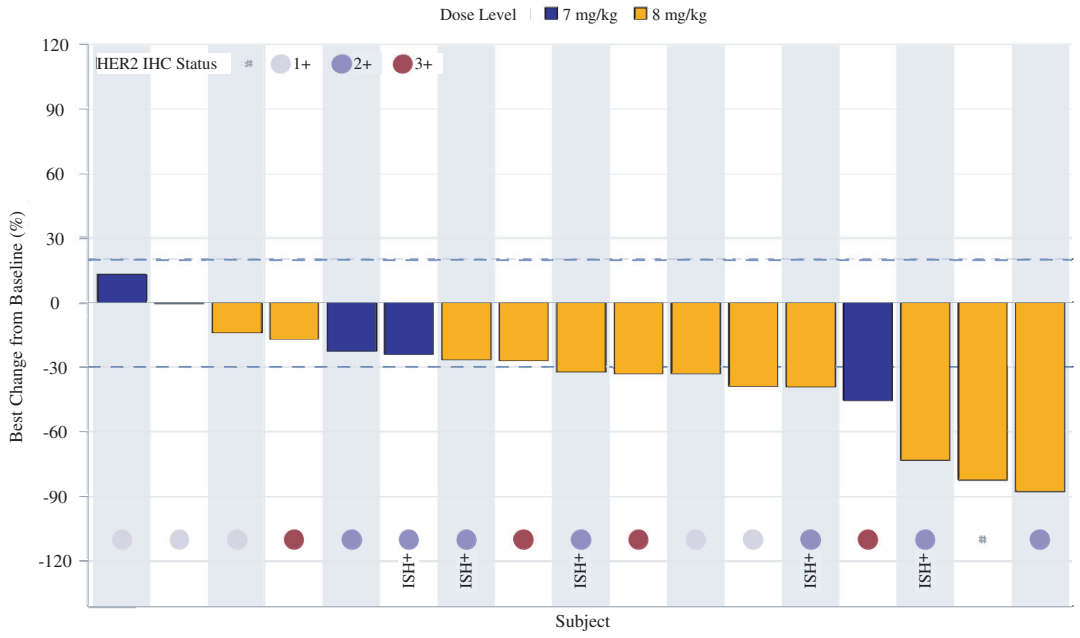
	Dose Escalation		Dose Expansion		
Response[1]	**7 mg/kg (n=4)[2]**	**8 mg/kg (n=4)[2]**	**8 mg/kg (n=9)[2]**	**Pooled 8 mg/kg (n=13)**	**Total (n=17)[2]**
Best Overall Response, n (%)					
PR	2 (50.0)	4 (100)	4 (44.4)	8 (61.5)	10 (58.8)
SD	2 (50.0)	0	4 (44.4)	4 (30.8)	6 (35.3)
PD	0	0	1 (11.1)	1 (7.7)	1 (5.9)
Unconfirmed ORR, n (%)	2 (50.0)	4 (100)	4 (44.4)	8 (61.5)	10 (58.8)
Confirmed ORR, n (%)	1 (25.0)	3 (75.0)	0	3 (23.1)	4 (23.5)
Pending Confirmation ORR, n (%)	1 (25.0)	1 (25.0)	4 (44.4)	5 (38.5)	6 (35.3)[3]
Unconfirmed ORR By Histology, n/N (%)					
Serous Carcinoma	1/1 (100)	4/4 (100)	2/3 (66.7)	6/7 (85.7)	7/8 (87.5)
Adenocarcinoma	1/2 (50.0)	–[4]	0/1	0/1	1/3 (33.3)
Carcinosarcoma	–[4]	–[4]	1/2 (50.0)	1/2 (50.0)	1/2 (50.0)
Mixed Adenocarcinoma	–[4]	–[4]	1/2 (50.0)	1/2 (50.0)	1/2 (50.0)
Unconfirmed DCR, n (%)	4 (100)	4 (100)	8 (88.9)	12 (92.3)	16 (94.1)

Notes:

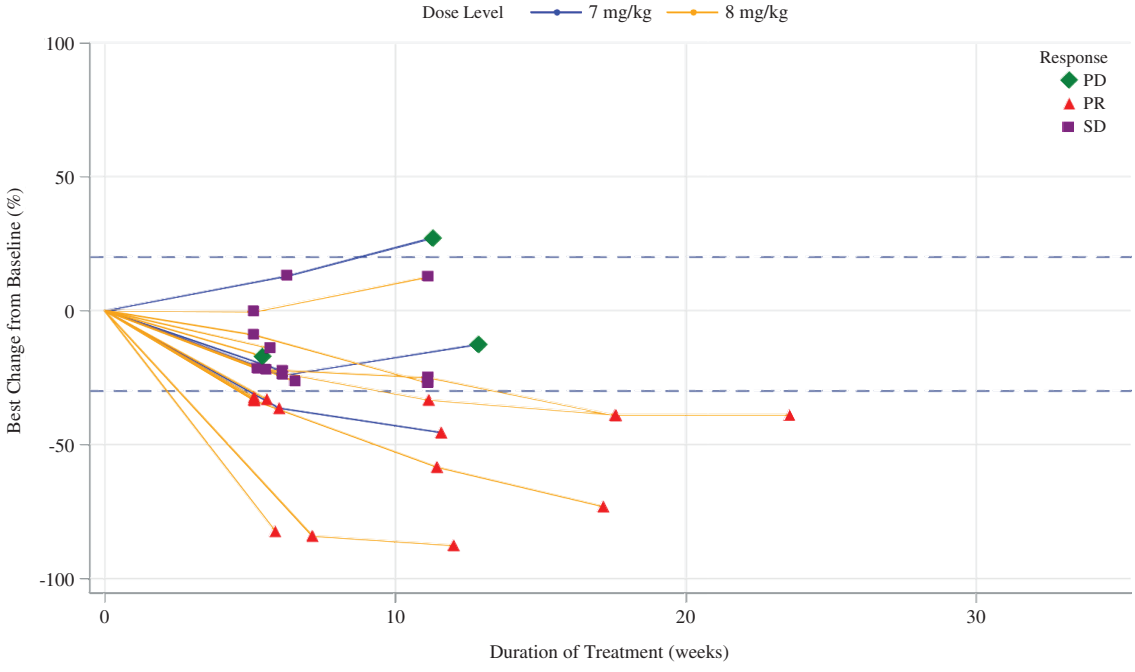
1. By investigator
2. Response evaluable participants, which includes participants with 1 post-baseline overall response
3. As of the Latest Practicable Date, all six PRs had been confirmed
4. No efficacy evaluable participants

Nearly all participants with post-baseline scans had a reduction in target lesions. The waterfall plot below shows the best percentage change from baseline of target lesions in all patients with post-baseline scans.

Best Tumor Response for EC PTs with Post-baseline Scans



The spider plot below sets forth the target lesion tumor response over time in all patients with post-baseline scans.



Safety Data. DB-1303 showed a manageable safety profile. As of May 8, 2023, no TEAEs leading to death or dose discontinuation occurred. No adverse event of special interest ("**AESI**") occurred, and no DLT was observed in dose escalation. The following table sets forth a summary of the safety data as of May 8, 2023.

	Dose Escalation		Dose Expansion		
Events, n (%)	**7 mg/kg (n=4)[2]**	**8 mg/kg (n=4)[2]**	**8 mg/kg (n=9)[2]**	**Pooled 8 mg/kg (n=13)**	**Total (n=17)[2]**
TEAEs	4 (100)	4 (100)	22 (91.7)	26 (92.9)	30 (93.8)
Study treatment related	4 (100)	4 (100)	18 (75.0)	22 (78.6)	26 (81.2)
Grade ≥ 3 TEAEs	2 (50.0)	1 (25.0)	7 (29.2)	8 (28.6)	10 (31.2)
Study treatment related	1 (25.0)	0	4 (16.7)	4 (14.3)	5 (15.6)
Serious TEAEs	1 (25.0)	0	3 (12.5)	3 (10.7)	4 (12.5)
TEAEs associated with dose reduction	0	0	1 (4.2)	1 (3.6)	1 (3.1)
Study treatment related	0	0	1 (4.2)	1 (3.6)	1 (3.1)
TEAEs associated with dose interruption	0	0	3 (12.5)	3 (10.7)	3 (9.4)
Study treatment related	0	0	2 (8.3)	2 (7.1)	2 (6.2)
TEAEs associated with dose discontinuation	0	0	0	0	0

Notes:

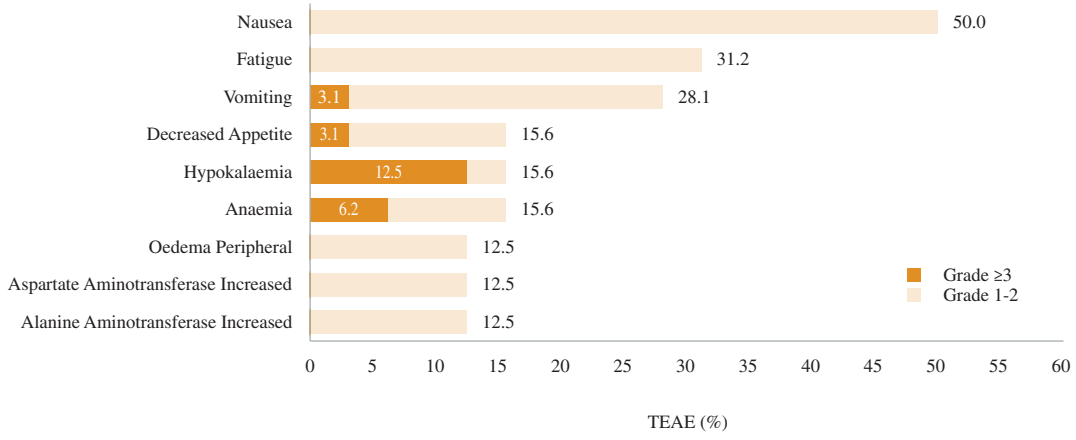
AESI = Adverse event of special interest; DLT = Dose-limiting toxicity; ILD = Interstitial lung disease; LVEF = Left ventricular ejection fraction; TEAE = Treatment emergent adverse event

1. TEAEs was defined as AEs with a start or worsening data on or after the start of study treatment

2. AESIs include LVEF decrease (grade ≥ 3), ILD/pneumonitis, and IRRs (grade ≥ 3)

3. DLT was defined as any TEAE not attributable to disease or any disease-related process that occurs during the DLT evaluation period (days 1-21 in cycle 1)

The most frequent TEAEs of any grade were nausea (16 grade 1-2; 0 ≥ grade 3), fatigue (10 grade 1-2; 0 ≥ grade 3) and vomiting (8 grade 1-2; 1 ≥ grade 3). The chart below sets forth the TEAEs occurring in ≥10% of the participants. No interstitial lung disease occurred.



Phase 1/2a Global Clinical Trial for Advanced/Metastatic Solid Tumors *(NCT05150691)*

This is a phase 1/2a, multicenter, open-label, first-in-human study to assess the safety, tolerability, pharmacokinetics, and preliminary antitumor activity of DB-1303 in patients with advanced/metastatic solid tumors.

Trial Design. This study enrolls patients with HER2 (high or low)-expressing solid tumors to receive DB-1303 as a monotherapy. This trial consists of two parts: phase 1 dose escalation study and phase 2a dose expansion study. The dose escalation study adopts an accelerated titration at first dose level (2.2 mg/kg) followed with a classic "3+3" dose escalation design (4.4, 6.0, 7.0, 8.0, 10.0 and 12.0 mg/kg) given intravenous Q3W to identify the maximum tolerated dose ("**MTD**") and RP2D. In the dose expansion study, patients are assigned to different cohorts to receive DB-1303 at the MTD/RP2D to confirm the safety, tolerability and explore efficacy in selected malignant solid tumors.

Trial Objectives. The primary objective of the phase 1 dose escalation study is to evaluate the safety and tolerability and determine the MTD/RP2D. The primary endpoints of the phase 1 study are safety and tolerability measured by DLT, SAEs, TEAEs, MTD and RP2D, among others. Secondary endpoints include efficacy (measured by ORR, DoR, DCR, TTR, PFS, OS per RECIST v1.1), PK, and immunogenicity.

The primary objective of the phase 2a dose expansion study is to assess safety, tolerability and efficacy of DB-1303 at the MTD/RP2D. The primary endpoints of the phase 2a study include SAEs, TEAEs and ORR, among others. Secondary endpoints include efficacy (measured by percentage change in target lesions, DoR, DCR, TTR and time on therapy per RECIST v1.1), PK, and immunogenicity.

Trial Progress. The phase 1 dose escalation study was initiated in January 2022 and completed in January 2023, with all primary endpoints met and RP2D determined at 8 mg/kg. The phase 2a dose expansion study was initiated in January 2023 and is currently ongoing. The preliminary results from the phase 1 dose escalation study were published at the 2023 ASCO Annual Meeting. As of January 13, 2023, the data cut-off date for the 2023 ASCO, 85 patients had received DB-1303 at six dose levels (2.2, 4.4, 6.0, 7.0, 8.0, and 10.0 mg/kg). As of the same date, the median duration of treatment was 63.0 (range, 21-211) days and 68 pts (80.0%) remained on treatment.

These patients were heavily pretreated and had received a median of seven (range, 1-27) prior lines of therapy, including 28 patients (32.9%) who had received prior anti-HER2 ADC therapy. The table below sets forth the baseline and characteristics of the 85 patients.

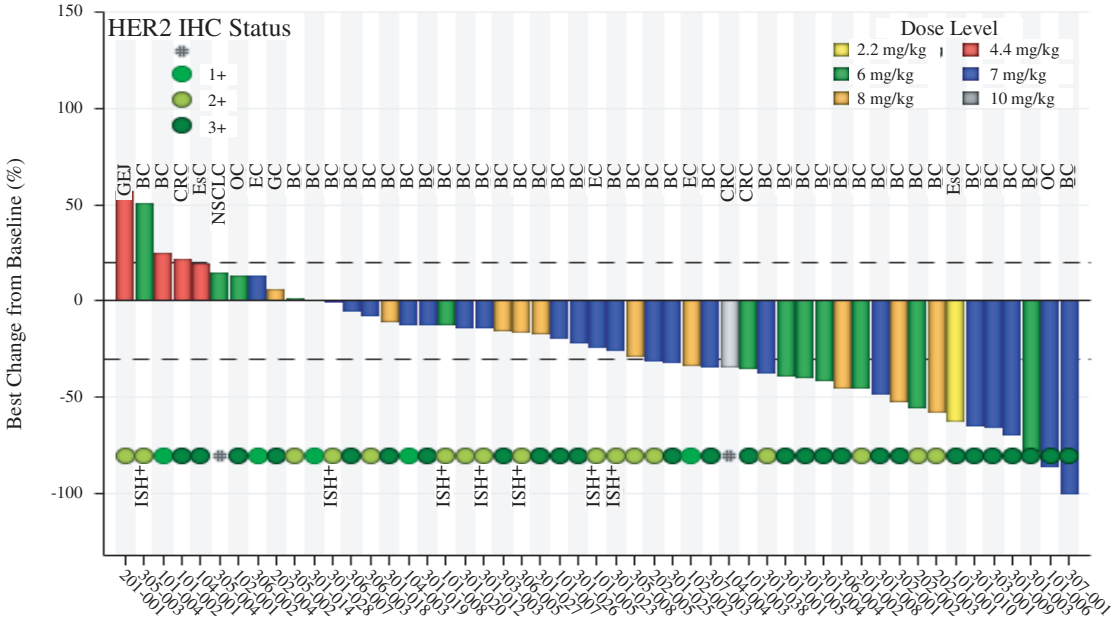
	Total (n=85)
Age, median (range)	52.0 (30.0-79.0)
Female, n (%)	78 (91.8%)
Region, n (%)	
US/AUS	30 (35.3%)
CHN	55 (64.7%)
ECOG PS, n (%)	
0	22 (25.9%)
1	63 (74.1%)
Number of Prior Systematic Regimens in the Metastatic Disease, median (range)	7.0 (1-27)
Cancer Type, n (%)	
HER2 Positive Breast Cancer	42 (49.4%)
HER2 Low Breast Cancer	21 (24.7%)
Endometrial Carcinoma	6 (7.1%)
Colorectal Cancer	3 (3.5%)
Ovarian Cancer	3 (3.5%)
Esophageal Cancer	2 (2.4%)
Gastric Cancer	1 (1.2%)
Gastroesophageal Junction Adenocarcinoma	1 (1.2%)
Non-small Cell Lung Cancer	1 (1.2%)
Vaginal Cancer	1 (1.2%)
Site of Metastasis, n (%)	
Lungs	43 (50.6%)
Liver	34 (40.0%)
Brain	18 (21.2%)
HER2 IHC Results, n (%)	
1+	8 (9.4%)
2+	29 (34.1%)
ISH Positive	10 (11.8%)
ISH Negative or NE	18 (21.2%)
3+	40 (47.1%)
Prior Anti-HER2 ADC Therapy, n (%)	28 (32.9%)
Prior Anti-HER2 Antibody Therapy, n (%)	47 (55.3%)
Prior Anti-HER2 TKI Therapy, n (%)	35 (41.2%)
SOD in Target Lesion, median (n, range)	55.0 (81,10.5-206.0)

Efficacy Data. As of January 13, 2023, a total of 52 patients had undergone at least one post-baseline tumor scan. Overall, promising antitumor activity was observed in heavily pretreated patients with HER2-expressing solid tumors with an uORR of 44.2% (23/52) and DCR of 88.5% (46/52), as shown in the table below. Encouraging anti-tumor activity of DB-1303 was observed in advanced BC patients, including 26 with HER2+ BC and 13 with HER2-low BC. Antitumor activity of DB-1303 was also observed in non-BC tumor types, including CRC, EC, OC and esophageal cancer.

	ORR,%	DCR,%
All patients (n=52)	44.2 (23/52)	88.5 (46/52)
HER2+ BC (n=26)	50 (13/26)	96.2 (25/26)
HER2+ BC with brain metastases (n=9)	55.6 (5/9)	100 (9/9)
HER2 low BC (n=13)	38.5 (5/13)	84.6 (11/13)

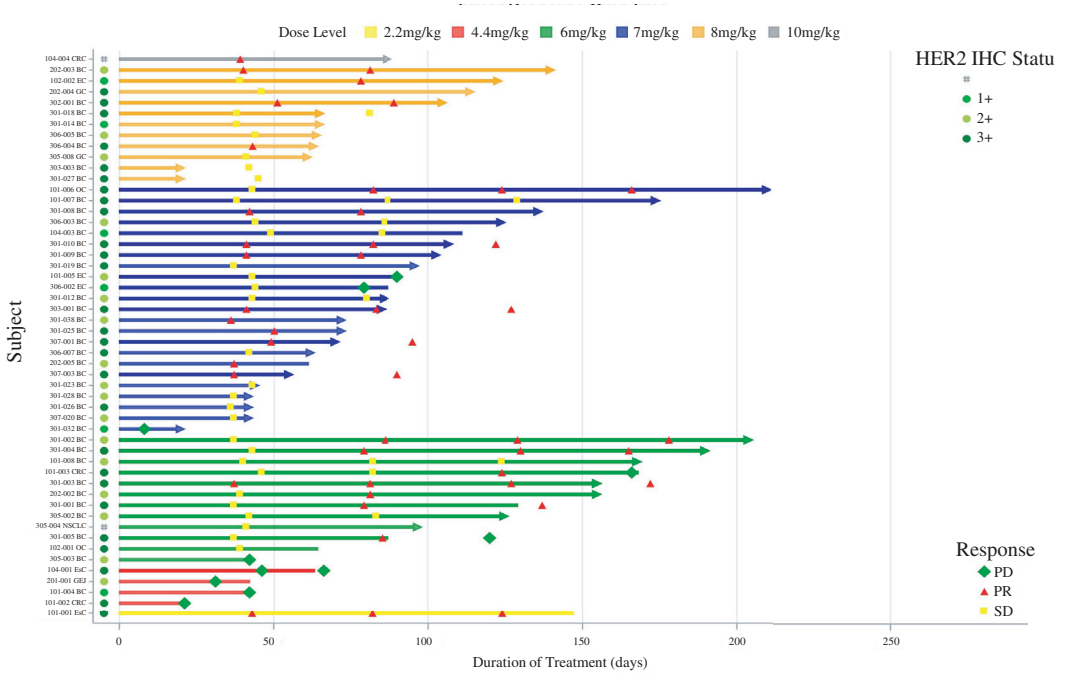
The waterfall plot below sets forth the best tumor response for all patients with post-baseline scans as of January 13, 2023.

Best Tumor Response by Subject ID



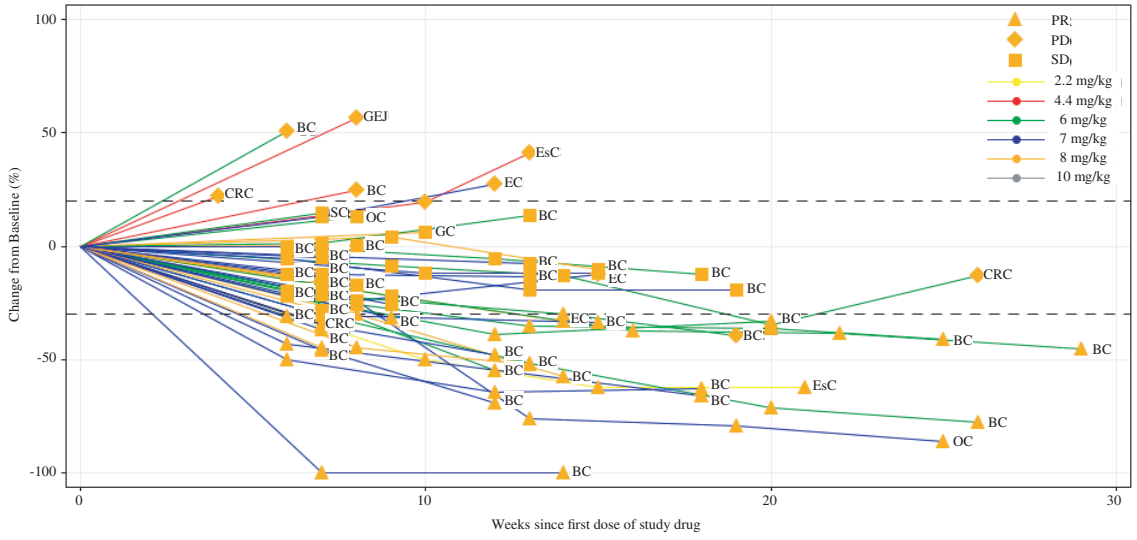
The swimmer plot shows the tumor responses over time in all patients with post-baseline scans.

Tumor Response Over Time



The spider plot below sets forth the response with changes of tumor size in all patients with post-baseline scans.

Tumor Response Over Change of Target Lesion



Safety Data. DB-1303 was well tolerated and all AEs were manageable. As of January 13, 2023, no DLT was observed in all six dose levels during dose escalation and no TEAEs associated with death occurred. TRAEs primarily included nausea, vomiting, platelet count decreased, anemia, aspartate aminotransferase increased, decreased appetite, fatigue and alanine aminotransferase increased, with grade 3 or above TRAEs reported in 12.9% (11/85) of patients. Interstitial lung disease occurred in two patients (2.4%, both were grade 1). Few patients experienced neutropenia (11.8% (10/85); grade 3 or above in 1.2% (1/85)) and alopecia (3.5% (3/85), all were grade 1). The median duration of treatment was 63.0 (range, 21-211) days, and the median duration of follow-up was 77.0 (range, 7-350) days. The following table sets forth a summary of the safety data as of January 13, 2023.

	2.2 mg/kg (n=1)	4.4 mg/kg (n=5)	6.0 mg/kg (n=15)	7.0 mg/kg (n=29)	8.0 mg/kg (n=32)	10.0 mg/kg (n=3)	Total (n=85)
Any TEAEs	1 (100.0%)	5 (100.0%)	14 (93.3%)	26 (89.7%)	26 (81.2%)	2 (66.7%)	74 (87.1%)
Associated with:							
Treatment withdrawal	0	0	0	1 (3.4%)	0	0	1 (1.2%)
Treatment dose reduction	0	0	0	2 (6.9%)	1 (3.1%)	0	3 (3.5%)
Treatment dose interruption	0	0	4 (26.7%)	8 (27.6%)	5 (15.6%)	0	17 (20.0%)
Grade ≥3	0	3 (60.0%)	3 (20.0%)	9 (31.0%)	2 (6.2%)	1 (33.3%)	18 (21.2%)
Serious AEs	0	3 (60.0%)	4 (26.7%)	4 (13.8%)	2 (6.2%)	0	13 (15.3%)
Treatment-related TEAEs	1 (100.0%)	3 (60.0%)	12 (80.0%)	26 (89.7%)	25 (78.1)	2 (66.7%)	69 (81.2%)
Grade ≥3	0	1 (20.0%)	2 (13.3%)	6 (20.7%)	1 (3.1%)	1 (33.3%)	11 (12.9%)
Serious AEs	0	0	2 (13.3)%	0	0	0	2 (2.4%)

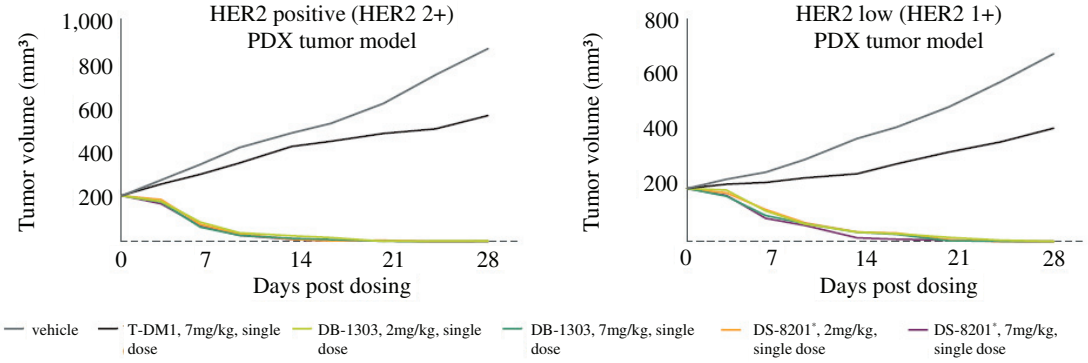
The table below sets forth a summary of AEs occurring in ≥20% of the patients and AESI.

	TEAEs		TRAEs		AESI	
	All grade	**Grade ≥3**	**All grade**	**Grade ≥3**	**All grade**	**Grade ≥3**
Nausea	44 (51.8%)	3 (3.5%)	42 (49.4%)	2 (2.4%)	–	–
Vomiting	37 (43.5%)	1 (1.2%)	32 (37.6%)	0	–	–
Platelet count decreased	30 (35.3%)	3 (3.5%)	30 (35.3%)	3 (3.5%)	–	–
Anemia	25 (29.4%)	5 (5.9%)	23 (27.1%)	5 (5.9%)	–	–
Aspartate aminotransferase increased	22 (25.9%)	0	21 (24.7%)	0	–	–
Decreased appetite	22 (25.9%)	0	21 (24.7%)	0	–	–
Fatigue	18 (21.2%)	1 (1.2%)	15 (17.6%)	0	–	–
Alanine aminotransferase increased	17 (20.0%)	0	17 (20.0%)	0	–	–
Ejection fraction decreased	–	–	–	–	3 (3.5%)	0
Infusion related reaction	–	–	–	–	2 (2.4%)	0
Interstitial lung disease	–	–	–	–	2 (2.4%)	0
Electrocardiogram QT prolonged	–	–	–	–	1 (1.2%)	0

Selected Preclinical Data

In preclinical studies in cynomolgus monkeys, DB-1303 showed reduced toxicity compared to the published profile of DS-8201, enabling rapid systemic payload clearance in monkeys. Highest non-severely toxic dose was 80mg/kg, potentially translating to a large safety margin.

DB-1303 also induced dose-dependent tumor growth inhibition and tumor regression, demonstrating potent anti-tumor effect in both HER2+ and HER2 low tumor models with a wide therapeutic window.



* An in-house produced analog of DS-8201.

Material Communications with Competent Authorities

We received IND approval from the FDA in December 2021 and from the NMPA in April 2022, respectively, to investigate DB-1303 for advanced/metastatic solid tumors, pursuant to which we initiated DB-1303's phase 1/2a global clinical trial. Our phase 1/2a comprised two standalone studies, namely, the phase 1 dose escalation study and the phase 2a dose expansion study. The primary endpoints of the phase 1 dose escalation study were safety and tolerability, including MTD/RP2D, whereas the primary endpoints of the phase 2a study were ORR and safety endpoints. We completed the phase 1 dose escalation study of the phase 1/2a clinical trial in January 2023, with all primary endpoints of this study reached, and initiated the phase 2a dose expansion study in the same month. For details, see "— Our Pipeline — ADC Assets Developed from DITAC Technology Platform — DB-1303/BNT323, a late clinical-stage HER2 ADC candidate, our Core Product — Summary of Clinical Trial Data."

Taking into account the industry practice as advised by Frost & Sullivan, the phase 1 dose escalation study constituted a completed clinical trial with its main purpose aligning with the overall purpose of a conventional phase 1 trial, which is typically to assess safety and determine the dosage for phase 2 trial. Therefore, the completion of the phase 1 dose escalation study is equivalent to the completion of a conventional phase 1 trial.

The INDs we obtained from the FDA and NMPA covered both the phase 1 dose escalation study and the phase 2a dose expansion study. As advised by our PRC Legal Advisor, we are not required to obtain additional approval or confirmation from the NMPA for commencing phase 2a study of the phase 1/2a trial in China. Since initiating the phase 2a dose expansion study, we have not received any material objection from the FDA or NMPA on the commencement or progress of this study. Under the clinical trial design submitted to and reviewed by the regulatory authorities for IND approval, our phase 2a study comprised of multiple cohorts exploring the efficacy of DB-1303 in different cancer indications. Under Measures for the Administration of Drug Registration (《藥品註冊管理辦法》) in China and our IND from the NMPA, we are required to consult the CDE before commencing pivotal or registrational studies, which we had duly fulfilled before initiating DB-1303's phase 3 registrational trials for HR+/HER2- low BC and HER2+BC in China.

Since 2023, we have had several rounds of communications with the FDA and NMPA, including EOP2 meetings for certain indications to seek feedback on the proposed clinical development plans. For clarity, the initiation of DB-1303's phase 3 registrational trial or confirmatory trial is not contingent upon the completion of its ongoing phase 2a dose expansion study. We are authorized to proceed with such phase 3 trials upon securing the requisite regulatory confirmation, such as IND approvals (which we have obtained from the NMPA for initiating DB-1303's phase 3 registrational trials in HR+/HER2-low BC and HER2+BC patients), or positive feedback at EOP2 meetings (which we have received from the NMPA for DB-1303's potential registrational study in HER2-expressing EC patients and planned confirmatory trial in China). Specifically:

- For EC, an EOP2 meeting was held with the FDA in September 2023, where the FDA (i) agreed to the conversion of DB-1303's phase 2a dose expansion cohort in HER2-expressing EC patients into a single arm study to support the filing of an accelerated approval, and (ii) provided comments on the design of the planned confirmatory trial for this indication, which will be used to support DB-1303's full marketing approval in the U.S.

  EOP2 meetings with the NMPA were also held in April 2024 for the same indication, where the NMPA agreed that, in parallel to DB-1303's clinical progress overseas, (i) we should continue to advance DB-1303's potential registrational study in HER2-expressing EC patients in China, results from which may be used to support our application for conditional approval in China for this indication, and (ii) a phase 3 confirmatory trial for the same indication will be required for DB-1303's full marketing approval post-conditional approval in China.

  Unlike regular registrational trials conducted before marketing approval, confirmatory trials are designed to verify a drug's clinical benefits after it has previously received accelerated or conditional approval and is already available to patients. In the United States, China and many other jurisdictions, this accelerated/conditional approval pathway allows promising therapies to reach patients sooner, while still requiring robust evidence of long-term clinical benefit

through post-market studies before final marketing approvals are granted. For more details on the regulatory pathways of accelerated approval (U.S.) and conditional approval (China), see "Regulatory Overview — PRC Regulation — Regulations on Pharmaceutical Product — Accelerated Approval for Clinical Trial and Registration" and "Regulatory Overview — Overview of Laws and Regulations in the United States — Laws and Regulations in Relation to New Drug — Expedited Development and Review Programs."

- For HR+/HER2-low BC, an EOP2 meeting with the FDA in September 2023 to seek feedback on our planned phase 3 global registrational trial, and communicated with the NMPA in November 2023 regarding the same matter. Based on communications with the FDA in this meeting, DB-1303's phase 3 registrational trial for HR+/HER2-low BC was initiated in the United States. We received the NMPA's IND approval in March 2024 to commence DB-1303's phase 3 registrational trial for HR+/HER2-low BC in China.

- For HER2+ BC, we received the NMPA's IND approval to conduct a phase 3 registrational trial in China and initiated this trial in 2024.

We did not receive any major concerns or objections from the abovementioned regulatory authorities with respect to the clinical development plans for DB-1303. We and BioNTech will continue to maintain close communications with competent authorities at key milestones of DB-1303's clinical development.

The following table sets forth a summary of material communications with regulatory authorities regarding DB-1303.

Milestone/Stage	Timeline
Submission of IND application (phase 1/2a clinical trial) to the FDA	November 2021
IND approval (phase 1/2a clinical trial) from the FDA[(1)]	December 2021
Submission of IND application (phase 1/2a clinical trial) to the NMPA	January 2022
IND approval (phase 1/2a clinical trial) from the NMPA[(1)]	April 2022
Completion of the phase 1 study and initiation of phase 2a study of phase 1/2a trial in advanced or metastatic solid tumors	January 2023
Fast Track Designation from the FDA for the treatment of advanced EC	January 2023

Milestone/Stage	Timeline
EOP2 meeting with the FDA regarding EC indication to discuss the conversion of DB-1303's phase 2a dose expansion cohort in EC patients into a single arm study to support the filing of an accelerated approval, and seek comments on the design of confirmatory study	September 2023
EOP2 meeting with the FDA regarding HR+/HER2-low BC indication to seek feedback on our planned phase 3 global registrational trial	September 2023
IND approval (HR+/HER2-low BC phase 3 global registrational trial) from the FDA	September 2023
EOP2 meeting with the NMPA regarding HR+/HER2-low BC indication to seek feedback on our planned phase 3 global registrational trial	November 2023
Breakthrough Therapy Designation from the FDA for the treatment of advanced EC	December 2023
Breakthrough Therapy Designation by the NMPA for the treatment of advanced EC	March 2024
IND approval (HR+/HER2-low BC phase 3 global registrational trial) from the NMPA	March 2024
IND approval (HER2+ BC phase 3 China registrational trial) from the NMPA	April 2024
EOP2 meeting with the NMPA regarding the progress of DB-1303's potential registrational study in HER2-expressing EC patients, the anticipated filing for conditional approval, and planned confirmatory trial	April 2024

Note:

(1) In connection with the IND application, we submitted the trial protocol of DB-1303's phase 1/2a clinical trial, which set forth a detailed description of the study, including its purpose, the primary and secondary objectives, patient selection criteria, and trial design, among other information. The FDA and NMPA granted IND approval after reviewing the trial protocol we submitted and other information pertaining to DB-1303's development plan.

DB-1303/BNT323 MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED.

DB-1311/BNT324, a B7-H3 ADC candidate with global market potential, our Core Product

Overview

DB-1311 is an in-house discovered, clinically advanced B7-H3 ADC candidate under global development. B7-H3 is a prominent member of the B7 family that plays a critical role in promoting tumor progression and metastasis. DB-1311 is designed to harness the potential of B7-H3 as a therapeutic target, leveraging its widespread overexpression in a broad range of

tumor types, including SCLC, NSCLC, CRPC, ESCC and HNSCC. Notably, DB-1311 demonstrates strong selectivity by targeting a specific isoform predominantly found on B7-H3-overexpressing tumor cells, which, combined with its potent payload, stable linker-payload and Fc-silenced mAb, potentially translates into a favorable safety profile and a wide therapeutic window.

In collaboration with BioNTech, we are actively pursuing a comprehensive clinical development plan to unlock the full potential of DB-1311, both as monotherapy and in combination with immunotherapy. DB-1311 has shown preliminary efficacy signals and a manageable safety profile in its ongoing phase 1/2a trial, including in patients with advanced SCLC, CRPC and multiple other solid tumors. Preliminary data from this trial were presented in an oral session at 2024 ESMO Asia. As of September 27, 2024, the data cut-off date for 2024 ESMO Asia, among all evaluable patients with at least one post-baseline tumor assessment (n=238), the overall uORR was 32.4%, and the DCR was 82.4%. As of the same date, among patients with SCLC (n=73), the uORR was 56.2%, and the DCR was 89.0%. Among patients with CRPC (n=32), DB-1311 demonstrated early antitumor activity with a uORR of 28.0% and a DCR of 92.0%; rPFS data were not yet mature, with a median rPFS of 7.2 months and a 6-month rPFS rate of 94.7%. Besides SCLC and CRPC, we are also investigating DB-1311's treatment potential in HNSCC, HCC, CC, and melanoma. In 2024, the FDA granted DB-1311 Fast Track Designation for the treatment of patients with advanced/unresectable, or metastatic CRPC and Orphan Drug Designations for the treatment of ESCC and SCLC.

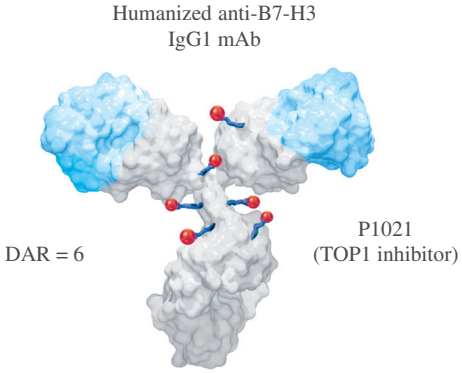
We entered into a license and collaboration agreement with BioNTech for DB-1311 in March 2023, where we granted to BioNTech an exclusive, royalty-bearing and sublicensable license under certain patents and know-how owned or otherwise controlled by us to develop, manufacture, commercialize or otherwise exploit DB-1311 and pharmaceutical products comprising DB-1311 (together "**DB-1311 Products**") for all uses worldwide except Mainland China, Hong Kong and Macau. We retain the full rights to develop, manufacture, commercialize and otherwise exploit DB-1311 and DB-1311 Products in Mainland China, Hong Kong and Macau. See "— Our Collaboration and Licensing Arrangements — License and Collaboration Agreement with BioNTech for DB-1311/BNT324" for details.

Drug Design and Mechanism of Action

B7-H3, also known as CD276, is a type I transmembrane protein belonging to the B7 family. Its overexpression has been observed in many solid tumors including lung, prostate, esophageal, endometrial, and breast cancers, with limited expression in healthy tissues. The high B7-H3 expression is also linked to disease progression and/or poor prognosis in many cancer types. Due to its frequent expression in multiple tumors with high internalization capability, B7-H3 has emerged as a promising target for ADC development. Several ADC candidates are currently being studied in clinical trials and have showed manageable safety profile and encouraging clinical efficacy in patients with various solid tumors.

DB-1311 is designed with three key components: a Fc-silenced, humanized anti-B7-H3 IgG1 mAb, a cleavable linker, and a proprietary DNA topoisomerase I inhibitor (P1021). The core components of DB-1311 are illustrated below.

DB-1311



DB-1311 is designed to deliver potent tumor killing while reducing off-target toxicities. Conjugated at a higher DAR value of 6, DB-1311 showed more potent antitumor activity compared to DS-7300 *in vitro* and *in vivo* in both high and medium B7-H3 expression models, based on preclinical results published at the 2023 AACR Annual Meeting. DB-1311 demonstrated high selectivity by targeting the 4IgB7-H3 isoform, which is predominantly found on B7-H3-overexpressing tumor cells, with over 1,000-fold greater affinity compared to the 2IgB7-H3 isoform commonly expressed on normal cells. This high selectivity differentiates DB-1311 and aims to enable the delivery of DB-1311's payload directly into tumor cells. Meanwhile, DB-1311's Fc-silenced mAb is designed to reduce unwanted immune responses. In preclinical studies, DB-1311 has shown a significantly higher HNSTD and better binding to B7-H3-expressing lung cancer cells compared to DS-7300.

Market Opportunity and Competition

As of the Latest Practicable Date, there were no approved B7-H3-targeted therapies, including ADCs, globally or in China, and there were six B7-H3 ADCs under global MRCTs. For more details on the competitive landscape of B7-H3 ADCs, see "Industry Overview — Global B7-H3 ADC Market — Market Opportunities of B7-H3 ADCs." For details of the key features of DB-1311 in comparison with other B7-H3 ADCs, see also "Industry Overview — Global B7-H3 ADC Market — Competitive Landscape."

To compete effectively in the B7-H3 ADC markets, we are actively pursuing a comprehensive clinical development plan to unlock the full potential of DB-1311, with a strategic focus on SCLC and CRPC. DB-1311 is also designed to deliver potent tumor killing while reducing off-target toxicities, which differentiates DB-1311 with its competitors in the B7-H3 ADC markets.

SCLC. Lung cancer is the most common cancer and the leading cause of cancer death worldwide. SCLC represents 10-15% of all lung cancer cases globally. The global incidence of SCLC increased from 332.9 thousand cases in 2018 to 382.8 thousand cases in 2023, and is projected to reach 484.1 thousand cases by 2032. In China, incidence of SCLC increased from 142.7 thousand cases in 2018 to 163.5 thousand cases in 2023, and is projected to reach 202.1 thousand cases by 2032. As a highly aggressive cancer, the average five-year survival rate for SCLC patients in extensive stage is less than 5%.

Chemotherapy is still the mainstay for SCLC treatment. However, SCLC patients often develop resistance to chemotherapy and the disease often relapses within one year. Relapsed SCLC patients often have worse prognosis, with limited treatment options available. While immunotherapies such as PD-(L)1 inhibitors are recommended in frontline settings for extensive stage SCLC patients, there remains a unmet need for new and more effective treatments for SCLC patients. For details of the treatment paradigm of SCLC in China and the U.S., see "Industry Overview — Global B7-H3 ADC Market — Market Opportunities of B7-H3 ADCs — Small-cell Lung Cancer."

As of the Latest Practicable Date, no B7-H3 targeted therapies, including ADCs, had been approved for SCLC globally. As of the same date, there were nine B7-H3 ADCs targeting SCLC under clinical development globally. For details, see "Industry Overview — Global B7-H3 ADC Markets — Competitive Landscape."

CRPC. CRPC is a severe form of prostate cancer that exhibits resistance to treatments aiming to reduce testosterone levels. Among the subtypes of CRPC, mCRPC is particularly advanced and challenging. The global incidence of mCRPC increased from 176.4 thousand cases in 2018 to 203.9 thousand cases in 2023, and is projected to reach 244.8 thousand cases by 2032. The incidence of mCRPC in China increased from 42.8 thousand cases in 2018 to 50.5 thousand cases in 2023, and is projected to reach 72.2 thousand cases by 2032.

The current treatment paradigm for CRPC remains limited in its ability to provide durable and effective long-term control. Drug resistance remains a critical challenge in the treatment of mCRPC. While androgen deprivation therapy ("**ADT**") like enzalutamide and abiraterone provide initial benefits, most patients eventually develop resistance, leading to disease progression, underscoring the potential of innovative targeted therapy to address this unmet need. For details of the treatment paradigm of CRPC in China and the U.S., see "Industry Overview — Global B7-H3 ADC Market — Market Opportunities of B7-H3 ADCs — Castration-resistant Prostate Cancer."

As of the Latest Practicable Date, no B7-H3 targeted therapies, including ADCs, had been approved for CRPC globally. As of the same date, there were six B7-H3 ADCs targeting CRPC under clinical development globally. For details, see "Industry Overview — Global B7-H3 ADC Markets — Competitive Landscape."

We and BioNTech are also actively exploring DB-1311's therapeutic potential across several prevalent cancer types under-explored by other clinical-stage B7-H3 ADCs. On July 16 and August 26, 2024, DB-1311 was granted Orphan Drug Designations by the FDA as a treatment for ESCC and SCLC, respectively.

Key Advantages

- Key player in the global B7-H3 ADC landscape. Despite the current absence of approved B7-H3-targeted therapies, B7-H3 ADCs have demonstrated encouraging clinical efficacy, notably in SCLC patients, sparking substantial interest and high-profile licensing deals in the field, according to Frost & Sullivan. These developments underscore the potential of B7-H3 ADCs to improve cancer patient outcomes.

  DB-1311 is currently one of the top three B7-H3 ADCs undergoing global MRCTs in terms of clinical development progress for advanced SCLC, according to Frost & Sullivan. SCLC is an aggressive form of lung cancer characterized by rapid growth and high rates of recurrence with a five-year survival rate of less than 7%, compared to 28% for NSCLC. However, available treatments for SCLC remain limited, primarily to chemotherapy and PD-L1 inhibitors, with few targeted therapies approved globally for this indication to date. The global SCLC drug market is expected to increase from US$4.1 billion in 2023 to US$7.6 billion by 2028, representing a CAGR of 13.0%, according to Frost & Sullivan.

  We are also investigating DB-1311's potential in treating CRPC patients, another cancer population that is highly underserved. To date, there are no B7-H3 ADC candidates indicated for CRPC that have entered into phase 3 registrational trial worldwide, according to Frost & Sullivan. In June 2024, DB-1311 was granted Fast Track Designation by the FDA for the treatment of patients with advanced/unresectable, or metastatic CRPC who have progressed on or after standard systemic regimens, in recognition of DB-1311's potential for the treatment of this challenging tumor type. While patients with metastatic prostate cancer initially respond to hormone therapy, most patients progress after 18-24 months and develop mCRPC, leading to a poor prognosis. The global CRPC drug market is expected to increase from US$3.9 billion in 2023 to US$6.5 billion by 2028, representing a CAGR of 10.9%, according to Frost & Sullivan.

- Novel design with the potential to enable tumor killing and wide therapeutic window. DB-1311 is designed to deliver potent tumor killing while reducing off-target toxicities. Conjugated at a higher DAR value of 6, DB-1311 showed more potent antitumor activity compared to DS-7300 *in vitro* and *in vivo* in both high and medium B7-H3 expression models, based on preclinical results published at the 2023 AACR Annual Meeting. DB-1311 demonstrated high selectivity by targeting the 4IgB7-H3 isoform, which is predominantly found on B7-H3-overexpressing tumor cells, with over 1,000-fold greater affinity compared to the 2IgB7-H3 isoform commonly expressed on normal cells. This high selectivity differentiates DB-1311

and aims to enable the delivery of DB-1311's payload directly into tumor cells. Meanwhile, DB-1311's Fc-silenced mAb is designed to reduce unwanted immune responses. In preclinical studies, DB-1311 has shown a significantly higher HNSTD and better binding to B7-H3-expressing lung cancer cells compared to DS-7300.

- Promising clinical efficacy and manageable safety profile observed in phase 1/2a trial. DB-1311 showed encouraging antitumor activity in its phase 1/2a global trial in advanced solid tumors. Preliminary data from this trial were presented in an oral session at 2024 ESMO Asia. As of September 27, 2024, the data cut-off date for 2024 ESMO Asia, among all evaluable patients with at least one post-baseline tumor assessment (n=238), the overall uORR was 32.4%, and the DCR was 82.4%. As of the same date, among patients with SCLC (n=73), the uORR was 56.2%, and the DCR was 89.0%. Among patients with CRPC (n=32), DB-1311 demonstrated early antitumor activity with a uORR of 28.0% and a DCR of 92.0%; rPFS data were not yet mature, with a median rPFS of 7.2 months and a 6-month rPFS rate of 94.7%.

  We are also investigating DB-1311's treatment potential in several prevalent cancer types under-explored by other clinical-stage B7-H3 ADCs. Preliminary data from DB-1311's phase 1/2a global trial also showed an acceptable and manageable safety profile, with low rates of TRAEs associated with drug discontinuation, dose reduction, drug interruption or death.

- Combination potential as frontline treatment for prevalent cancers. We believe the combination of DB-1311 with immunotherapy holds therapeutic promise, as the direct cytotoxic effects of this B7-H3 ADC synergize with the immune-activating properties of immunotherapies, potentially leading to a more powerful anti-tumor response and improved patient outcomes. We are actively exploring DB-1311's combination potential to expand into earlier treatment lines in various solid tumors, such as CRPC, SCLC and NSCLC.

- Opt-in rights to co-develop and co-commercialize in the U.S. Under our collaboration agreement with BioNTech, we have retained an option to co-develop and co-commercialize DB-1311 in the U.S. If we elect to exercise this option, we will become eligible to share the profits/losses and costs from DB-1311's development and commercialization in this major market. This strategic partnership not only demonstrates our confidence in and commitment to DB-1311's global development, but also allows us to leverage BioNTech's complementary strengths and resources while capturing the asset's significant economic interest and upside potential overseas. As such, we are well-positioned to efficiently navigate the complex global market landscape and accelerate DB-1311's entry into both domestic and international markets.

Clinical Development Plan

Based on IND approvals from the FDA and the NMPA, we initiated a phase 1/2a global trial for DB-1311 for patients with advanced/metastatic solid tumors in September 2023 and were the sponsor of this trial as of the Latest Practicable Date. As the first-in-human study for DB-1311, this phase 1/2a clinical trial provides foundational data that informs our regulatory discussions with the competent authorities and shapes our late-stage clinical development strategy. We completed the phase 1 study of this phase 1/2a trial in March 2024.

We are focused on DB-1311's strategic positioning as one of the top three B7-H3 ADCs undergoing global MRCTs in terms of clinical development progress for advanced SCLC, according to Frost & Sullivan. Leveraging DB-1311's Fast Track Designation from the FDA, we are also actively exploring DB-1311's potential in CRPC. We and BioNTech will continue to advance the phase 2a dose expansion study of DB-1311's phase 1/2a trial in cancer types under-explored by other clinical-stage B7-H3 ADC candidates. In general, if approved, DB-1311 with different indications would be regulated as the same product by each competent authority.

The table below sets forth the drug development timeline for DB-1311.

Milestone/Stage	Timeline
Preclinical development	May 2021 to May 2023
License and collaboration agreement with BioNTech	March 2023
IND approval from FDA	May 2023
IND approval from NMPA	August 2023
Phase 1/2a clinical trial in advanced or metastatic solid tumors	Start date: September 2023 Completion date: Phase 1: March 2024 Phase 2a: 2026 (planned)
Data readout from phase 1/2a trial and oral presentation at ESMO Asia	December 2024

Summary of Clinical Trial Data

Phase 1/2a Clinical Trial in Patients with Advanced/Metastatic Solid Tumors (*NCT05914116*)

This is a phase 1/2a, multicenter, open label, first in human study to assess the safety, tolerability, pharmacokinetics, and preliminary antitumor activity of DB-1311 in patients with advanced/metastatic solid tumors who progressed on previous standard therapies or for whom no standard therapy is available.

Trial Design. This trial consists of two parts: phase 1 dose escalation study and phase 2a dose expansion study. Phase 1 adopts an accelerated titration at first dose level (3 mg/kg) followed with classic "3+3" design (6, 9, 12 and 15 mg/kg) given intravenous Q3W to identify the MTD and/or RP2D. Phase 2a is a dose expansion phase to confirm the safety, tolerability and explore efficacy in selected malignant solid tumors treated with DB-1311 as monotherapy.

Trial Objectives. The primary objective of the phase 1 dose escalation study is to evaluate safety and tolerability and determine the MTD/RP2D. The primary endpoints of the phase 1 study are safety and tolerability measured by DLTs, SAEs, TEAEs, MTD and/or RP2D. Secondary endpoints include efficacy (measured by ORR, DoR, DCR, TTR, PFS, OS), PK, and immunogenicity.

The primary objective of the phase 2a dose expansion study is to assess safety and tolerability of DB-1311 at the MTD/RP2D and evaluate the efficacy of DB-1311 at the MTD/RP2D. The primary endpoints of the phase 2a study are SAEs, TEAEs and ORR as determined by investigator. Secondary endpoints include efficacy (measured by DoR , DCR, TTR, PFS, OS, among others), PK, and immunogenicity.

Trial Progress. The phase 1 dose escalation study was initiated in September 2023 completed in March 2024, with all primary endpoints met. Phase 2a dose expansion study is currently ongoing. Preliminary data from this trial were presented in an oral session at 2024 ESMO Asia.

As of September 27, 2024, the data cut-off date for 2024 ESMO Asia, there were 277 evaluated patients across various solid tumor types including SCLC, NSCLC, CRPC, and squamous cell carcinoma of the head and neck ("SCCHN"). About 75% of participants had an Eastern Cooperative Oncology Group ("ECOG") performance status of 1, and approximately 61% had undergone two or more lines of therapy.

Efficacy Data. DB-1311 shows encouraging antitumor activity across heavily pre-treated patients with locally advanced or metastatic solid tumors. As of September 27, 2024, among all evaluable patients with at least one post-baseline tumor assessment (n=238), the overall uORR was 32.4% and the DCR was 82.4%.

Among patients with SCLC (n=73), the uORR was 56.2%, and the DCR was 89.0%. The majority of patients with SCLC received 6 mg/kg and 9 mg/kg of DB-1311, with no significant difference in uORR between the two dose groups (54.5% and 58.8%, respectively).

Most patients with NSCLC had non-squamous histology (n=41), exhibiting a uORR of 22.0%, while patients with squamous NSCLC (n=25) had a uORR of 16.0%.

Among patients with CRPC (n=32), DB-1311 demonstrated early antitumor activity with a uORR of 28.0% and a DCR of 92.0%. rPFS data were not yet mature, with a median rPFS of 7.2 months and a 6-month rPFS rate of 94.7%.

In other tumor types, including CC (n=4), HCC (n=12), HNSCC (n=3), and melanoma (n=11), DB-1311 also exhibited antitumor activity with uORRs of 75.0%, 25.0%, 100.0%, and 36.4%, respectively.

Safety Data. DB-1311 showed a manageable safety profile across all evaluated patients and tumor types (n=277) as of September 27, 2024. The most common TRAEs reported included nausea, neutrophil count decreased, anemia, white blood cell count decreased, decreased appetite, and platelet count decreased.

Material Communications with Competent Authorities

We received IND approval from the FDA and the NMPA in May 2023 and August 2023, respectively, to investigate DB-1311 for advanced/metastatic solid tumors, pursuant to which we initiated DB-1311's phase 1/2a global clinical trial in advanced/metastatic solid tumors. Our phase 1/2a comprised two standalone studies, namely, the phase 1 dose escalation study and the phase 2a dose expansion study. The primary endpoints of the phase 1 dose escalation study were safety and tolerability, including MTD/RP2D, whereas the primary endpoints of the phase 2a study were ORR and safety endpoints. We completed the phase 1 dose escalation study of the phase 1/2a clinical trial in March 2024, with all primary endpoints of this study reached. For details, see "— Our Pipeline — ADC Assets Developed from DITAC Technology Platform — DB-1311/BNT324, a B7-H3 ADC candidate with global market potential, our Core Product — Summary of Clinical Trial Data."

Taking into account the industry practice as advised by Frost & Sullivan, the phase 1 dose escalation study constituted a completed clinical trial with its main purpose aligning with the overall purpose of a conventional phase 1 trial, which is typically to assess safety and determine the dosage for phase 2 trial. Therefore, the completion of the phase 1 dose escalation study is equivalent to the completion of a conventional phase 1 trial.

As advised by our PRC Legal Advisor, we are not required to obtain additional approval or confirmation from the NMPA for commencing phase 2a study of the phase 1/2a trial in China. This is because we have obtained an IND approval to conduct DB-1311's phase 1/2a trial in its entirety, which covers both the phase 1 dose escalation study and the phase 2a dose expansion study. Furthermore, the FDA explicitly stated in its IND approval that we may proceed with our clinical investigation based on the clinical protocol for the entire phase 1/2a trial.

We did not receive any major concerns or objections from the abovementioned regulatory authorities to the clinical development plans for DB-1311. We and BioNTech plan to maintain close communications with the competent authorities at key milestones of DB-1311's clinical development, including before initiating any phase 3 registrational studies and combination trials.

The following table sets forth a summary of material communications with regulatory authorities regarding DB-1311.

Milestone/Stage	Timeline
Submission of IND application (phase 1/2a clinical trial) to the FDA[(1)]	April 2023
Submission of IND application (phase 1/2a clinical trial) to the NMPA[(1)]	June 2023
IND approval (phase 1/2a clinical trial) from the FDA	May 2023
IND approval (phase 1/2a clinical trial) from the NMPA	August 2023
Fast Track Designation from the FDA for the treatment of advanced CRPC	June 2024
Orphan Drug Designation from the FDA for the treatment of ESCC	July 2024
Orphan Drug Designation from the FDA for the treatment of SCLC	August 2024

Note:

(1) In connection with the IND application, we submitted the trial protocol of DB-1311's phase 1/2a clinical trial, which set forth a detailed description of the study, including its purpose, the primary and secondary objectives, patient selection criteria, and trial design, among other information. The FDA and NMPA granted IND approval after reviewing the trial protocol we submitted and other information pertaining to DB-1311's development plan.

DB-1311/BNT324 MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED.

DB-1310, a HER3 ADC candidate in phase 1/2a trial, our key product

Overview

DB-1310 is our self-discovered HER3 ADC and one of the world's most clinically advanced HER3 ADC candidates, according to Frost & Sullivan, for which we hold global rights. HER3, along with EGFR and HER2, are growth factor receptors in the HER family that play crucial roles in tumor survival and growth. Despite the growing research and clinical interest in HER3, it remains under-explored and has faced two decades of drug development challenges due to the complexity in achieving signaling inhibition and the potential for escape pathway activation. Guided by our team of leading experts in HER3 research, we have built a deep knowledge base in HER3 biology, including its dimerization patterns and intricate interactions with EGFR and HER2, and its involvement in resistance mechanisms. These insights have informed DB-1310's innovative design and equipped it with a high internalization capability to deliver payloads directly into HER3-expressing cancer cells, which leads to targeted tumor killing and improved therapeutic outcomes.

We believe HER3 ADCs present opportunities to cover a broad patient population with limited reliance on biomarker-based patient selection and overcome resistance to standard of care. We have developed a rational and differentiated clinical development strategy focused on carefully selected indications that maximize its commercial potential. For EGFRm NSCLC, while our peers explore HER3 ADCs as a second-line or later monotherapy, we have taken a differentiated strategy to investigate DB-1310's combination potential with osimertinib in EGFRm NSCLC patients resistant to osimertinib or other third-generation TKI therapy, with opportunity as first-line treatment to cover a broader patient population. DB-1310 is also one of the few global clinical-stage HER3 ADCs being investigated as a potential treatment for KRASm NSCLC. We are also exploring the efficacy signals of DB-1310 in various other solid tumors, including BC, CRPC, HNSCC, ESCC and BTC.

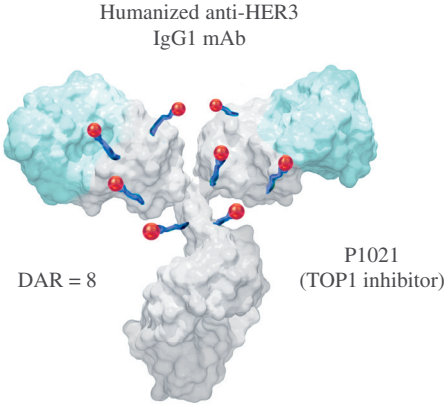
Drug Design and Mechanism of Action

HER3 is a member of the HER family that plays a crucial role in the development and progression of various types of cancer. In contrast to EGFR and HER2, HER3 is the only family member of the HER family that lacks an active kinase domain, which makes it an obligate binding partner with other receptors for its oncogenic role. Despite lacking intrinsic tyrosine kinase activity, HER3 is activated by dimerization with another receptor, with EGFR and HER2 being its preferred dimerization partners. Moreover, ubiquitous HER3 expression is detected in various solid tumors, including breast, lung, colorectal, prostate, and head and neck cancers. High HER3 expression is also associated with a more aggressive disease, increased metastatic potential, and poorer clinical outcomes for patients.

Activation of HER3 through dimerization promotes pro-survival and pro-proliferative signaling pathways, making it an attractive therapeutic target in oncology. HER3 expression also acts as a bypass mechanism for various targeted therapies.

DB-1310 is a HER3-targeted ADC designed with a highly potent topoisomerase I inhibitor payload P1021, a cleavable linker containing tetrapeptide and a novel humanized anti-HER3 IgG1 monoclonal antibody. The core components of DB-1310 are illustrated below.

DB-1310



DB-1310's antibody is designed to bind to a novel epitope on the domain I of HER3. Upon binding and internalization into the target tumor cell, the ADC is cleaved by lysosomal enzymes, releasing the P1021 payload in the cytoplasm. The P1021 payload prevents re-ligation of the DNA strand by binding to topoisomerase I-DNA complex, and causes double-strand DNA breakage and cancer cell death. DB-1310 is designed with a DAR of 8, enabling a high concentration of the cytotoxic agent to be delivered to the tumor cell. In preclinical studies, DB-1310's mAb demonstrated higher affinity for HER3 compared to patritumab (the antibody used in U3-1402) and was more effectively internalized.

Market Opportunity and Competition

As of the Latest Practicable Date, there were no approved HER3-directed therapies, including ADCs, globally or in China, and there were four HER3 ADC candidates under global MRCTs. For more details on the competitive landscape of HER3 ADCs, see "Industry Overview — Global HER3 ADC Market — Market Opportunities of HER3 ADCs." For details of the key features of DB-1310 in comparison with other HER3 ADCs, see also "Industry Overview — Global HER3 ADC Market — Competitive Landscape."

To compete effectively in the HER3 ADC markets, we have built a deep knowledge base in HER3 biology, including its dimerization patterns and intricate signaling crosstalk with EGFR and HER2, and its involvement in resistance mechanisms. These insights have informed DB-1310's innovative design and equipped it with a high internalization capability to deliver payloads directly into HER3-expressing cancer cells, which leads to targeted tumor killing and improved therapeutic outcomes. We are currently developing DB-1310 for multiple subtypes of NSCLC and BC and may further expand to other solid tumors such as CRPC.

NSCLC. NSCLC is the most common subtype of lung cancer and represents approximately 85% of all lung cancer cases globally. Global incidence of NSCLC cases increased from 1,886.3 thousand cases in 2018 to 2,169.4 thousand cases in 2023 and is projected to reach 2,614.2 thousand cases by 2030. In China, NSCLC incidence increased from 808.7 thousand cases in 2018 to 926.6 thousand cases in 2023, and is projected to reach 1,100.0 thousand cases by 2030.

EGFRm NSCLC is a prevalent subtype of NSCLC with approximately 700 thousand new cases each year globally. EGFR mutations are particularly prevalent in the Asian population, accounting for over 50% of all NSCLC cases in this demographic group.

In China and the U.S., the first-line treatment for EGFRm NSCLC patients include TKIs, such as afatinib, erlotinib, dacomitinib, gefitinib and osimertinib. However, most of these patients eventually acquire resistance with median relapse occurring approximately 9-14 months after treatment with TKIs. For patients who have failed TKIs, effective treatment options are limited, which primarily include platinum-based doublet chemotherapy with or without bevacizumab (VEGF mAb), single-agent chemotherapy, or PD-(L)1 inhibitors. For

details of the treatment paradigm of EGFRm NSCLC in China and the U.S., see "Industry Overview — Global HER3 ADC Market — Market Opportunities of HER3 ADCs — Non-small Cell Lung Cancer — EGFR-mutant NSCLC."

HER3 has become a validated target for EGFRm NSCLC, supported by promising efficacy data shown in pivotal trials. EGFR and HER3 can together form heterodimeric complexes, leading to the activation of downstream signaling pathways. HER3 is also shown to be an escape mechanism involved in resistance to EGFR TKI therapies.

BC. The global incidence of BC increased from 2,088.8 thousand cases in 2018 to 2,408.0 thousand in 2023, and is projected to reach 3,195.7 thousand cases by 2032. HER3-overexpression is reported in 18-43% of BC patients.

While HER2 is a well-established target for BC treatments, approximately 15-40% of all BC cases are HER2 null, which show limited response to current HER2-targeted therapies. In addition, HER2-expressing BC commonly exhibit co-expression and activation of HER3. Inhibition of HER2 can lead to a compensatory upregulation or activation of HER3, which can limit the efficacy of HER2-targeted therapies, including HER2 ADCs such as Enhertu®. This feedback loop between the two receptors highlights the importance of developing HER3-targeted therapies to overcome potential resistance to HER2-targeted therapies. For details of the treatment paradigm of BC in China and the U.S., see "Industry Overview — Global HER3 ADC Market — Market Opportunities of HER3 ADCs — Breast Cancer."

Key Advantages

- Differentiated EGFRm NSCLC combination strategy. DB-1310 is a global clinical-stage HER3 ADC candidate being developed for EGFRm NSCLC patients resistant to osimertinib or other third-generation TKI treatments, according to Frost & Sullivan. We are developing DB-1310 in combination with osimertinib based on our translational medicine research that EGFR inhibition synergistically promotes HER3 ADC internalization and efficacy. Preclinical studies demonstrate more potent anti-tumor activity from DB-1310 and osimertinib combination therapy than either DB-1310 or osimertinib as monotherapy. We are enrolling patients in our phase 1 global dose escalation study for this combination therapy in China and the U.S.

- Unique coverage of KRASm NSCLC. KRAS mutations are estimated to occur in approximately 30% of NSCLC cases. There are currently no global registrational trials for HER3 ADC candidates specifically targeting KRASm NSCLC, highlighting the potential of DB-1310 in this underserved area. Patients with KRASm NSCLC typically experience rapid disease progression after KRAS TKI treatments, and those who develop drug resistance face severely limited subsequent treatment options. We have observed preliminary efficacy in KRASm NSCLC patients, including partial response in dose expansion, in DB-1310's phase 1/2a global trial.

- Encouraging efficacy in multiple BC subtypes. DB-1310 has demonstrated efficacy signals across multiple BC subtypes, including in TNBC patients with prior Trodelvy® treatment. DB-1310 has significant potential to treat HER2+ BC patients, including those with prior Enhertu® treatment, given HER3's critical role in drug resistance and pathway synergies with HER2.

- Treatment potential for CRPC. HER3 protein is frequently overexpressed in prostate cancer, correlating with faster progression to castration resistance and reduced overall survival. In preclinical studies, DB-1310 has demonstrated significant antitumor activity against prostate cancer, indicating its potential as a promising treatment for this cancer type. We are currently recruiting patients with CRPC in DB-1310's phase 1/2a trial.

- Promising preliminary data from phase 1/2a trial. DB-1310 demonstrated tumor reduction in patients with advanced or metastatic EGFRm NSCLC who failed previous standard therapies in the dose escalation cohort of its phase 1/2a clinical trial. In EGFRm NSCLC patients, as of May 17, 2024, uORR and DCR reached 39% and 94.4%, respectively, across dose levels from 1.5 to 5.5 mg/kg. The uORR and DCR was 50% and 100% at 4.5 mg/kg, respectively, and 100% and 100% at 5.5 mg/kg, respectively. DB-1310 also demonstrated an acceptable and manageable safety profile in its phase 1/2a global trial. As of May 17, 2024, the incidence of grade 3 or above TRAEs was 19.3%.

Summary of Clinical Trial Data

We received IND approvals from the FDA and NMPA in March 2023 and May 2023, respectively, and commenced DB-1310's first-in-human global MRCT phase 1/2a clinical trial for advanced/metastatic solid tumors. Set forth below is a summary of the key information on DB-1310's ongoing clinical trial.

Phase 1/2a Clinical Trial in Patients with Advanced/Metastatic Solid Tumors *(NCT05785741)*

This is a phase 1/2a, multicenter, open-label, non-randomized first-in-human study to assess the safety, tolerability, pharmacokinetics, and preliminary antitumor activity of DB-1310 in patients with advanced/metastatic solid tumors who failed previous standard therapies or no standard therapy is available, regardless of HER3 expression.

Trial Design. This trial consists of two parts: a phase 1 dose escalation study and phase 2a dose expansion study. The phase 1 study has three arms: (i) DB-1310 monotherapy (solid tumors), using a classic "3+3" design with six dose levels, (ii) DB-1310 combo-therapy A (HER2+ BC), combining DB-1310 with trastuzumab, and (iii) DB-1310 combo-therapy B (NSCLC with EGFR Ex19del or L858R mutation), combining DB-1310 with osimertinib. Each arm of the phase 1 study adopts a "3+3" dose escalation design to identify: the MTD and/or

RP2D of DB-1310 as monotherapy, the recommended combination dose A ("**RCD_A**") of DB-1310 in combination with trastuzumab and the recommended combination dose B ("**RCD_B**") of DB-1310 in combination with osimertinib.

Phase 2a study expands into multiple cohorts of advanced/metastatic solid tumors, each exploring specific subtypes and/or combinations, to further assess the efficacy and safety of DB-1310.

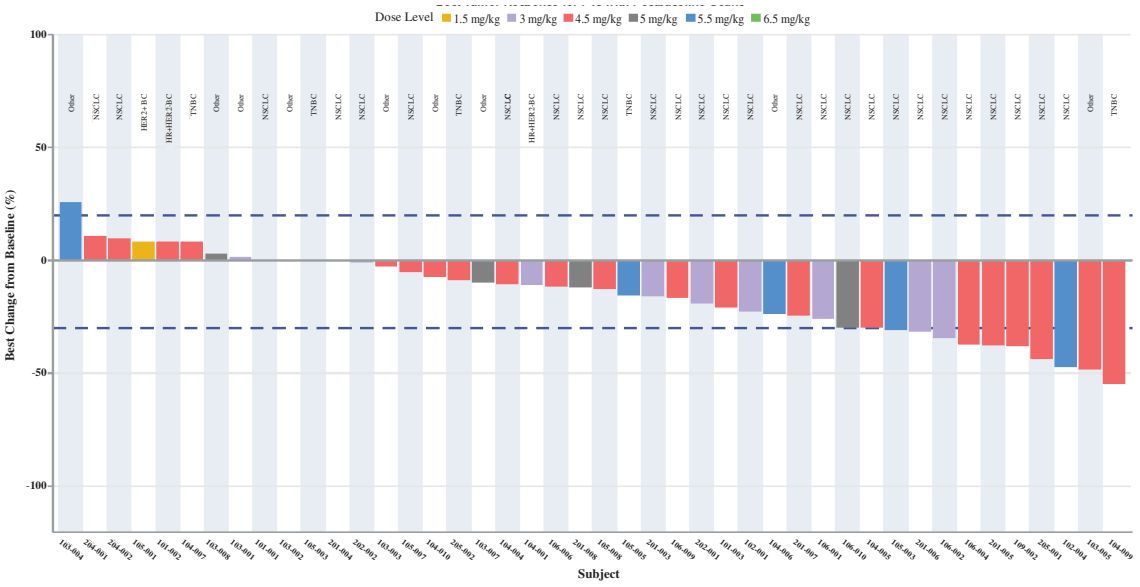
Trial Objectives. The primary objective of the phase 1 dose escalation study is to assess safety and tolerability of DB-1310 as monotherapy or in combination with trastuzumab or in combination with osimertinib, and to determine the MTD/RP2D of DB-1310 as monotherapy or the RCD_A of DB-1310 in combination with trastuzumab or the RCD_B of DB-1310 in combination with osimertinib. The primary endpoints of the phase 1 study are safety and tolerability measured by DLTs, SAEs, TEAEs, MTD and/or RP2D, among others. Secondary endpoints include efficacy (measured by ORR, DoR, DCR, TTR, PFS, OS per RECIST v1.1), PK, and immunogenicity.

The primary objective of the phase 2a dose expansion study is to assess the safety and tolerability of DB-1310 as monotherapy or in combination with trastuzumab or in combination with osimertinib in targeted subject populations, and to assess the effectiveness of DB-1310 as monotherapy or in combination with trastuzumab or in combination with osimertinib by assessment of ORR by investigator. The primary endpoints of the phase 2a study are SAEs, TEAEs and ORR. Secondary endpoints include efficacy (measured by DoR, DCR, TTR, PFS or rPFS, OS, PSA50 response rate, PSA-PFS for mCRPC per RECIST v1.1), PK, and immunogenicity.

Trial Progress. The phase 1 dose escalation study was initiated in April 2023 and is currently ongoing. As of May 17, 2024, the data cut-off date of the preliminary phase 1 results, 57 subjects from the DB-1310 monotherapy arm received at least one dose of DB-1310.

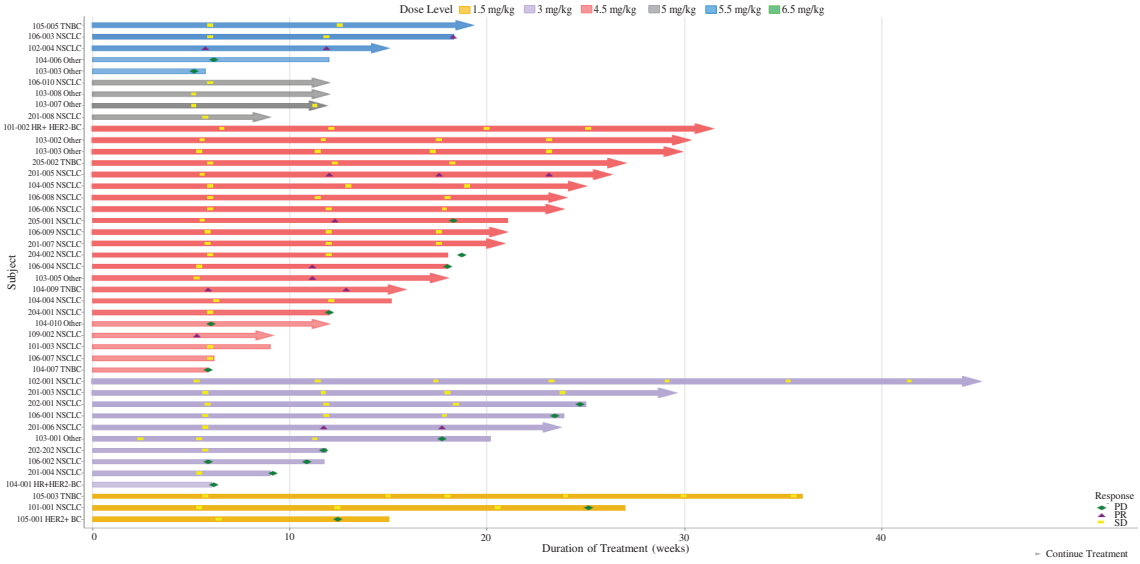
Efficacy Data. As of May 17, 2024, of the 18 efficacy-evaluable EGFRm NSCLC patients, DB-1310 achieved a uORR of 39% (7/18) and DCR of 94.4% (17/18) across all dose levels from 1.5 to 5.5 mg/kg. The chart below sets forth the best tumor response for all patients across various tumor types.

Best Tumor Response for Patients with Post-baseline Scans

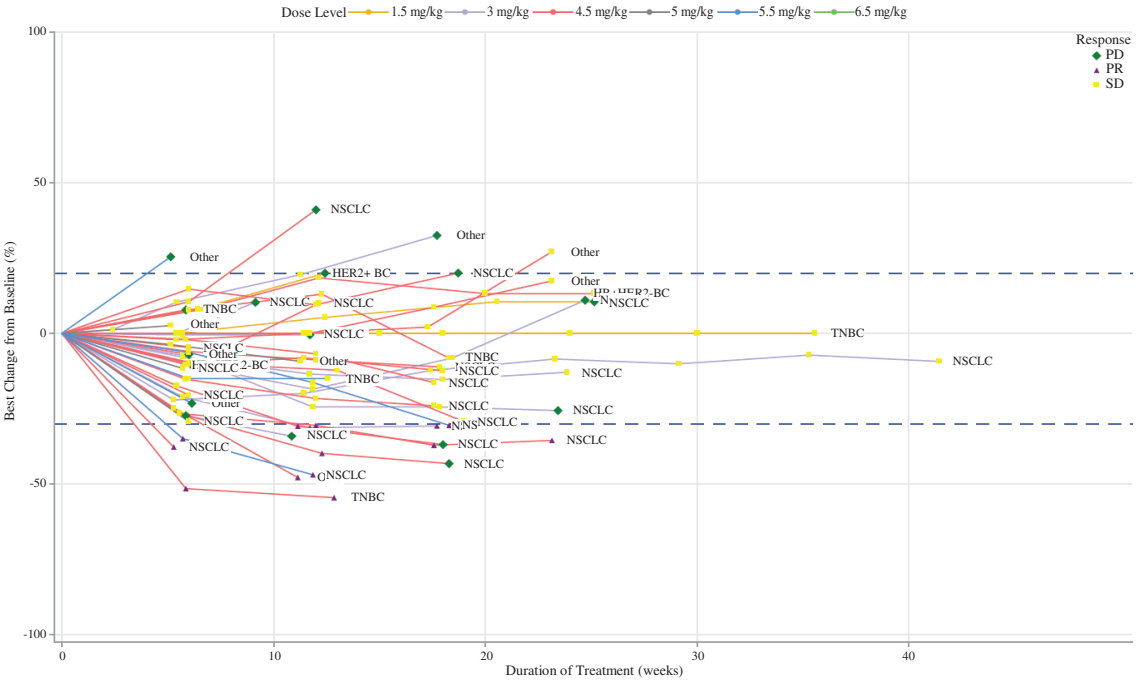


Tumor shrinkage with durable response was observed in various tumor types. The two charts below set forth the tumor response over time for patients with post-baseline scans and target lesion tumor response over time for patients with post-baseline scans as of May 17, 2024.

Tumor Response Over Time for Patients with Post-baseline Scans

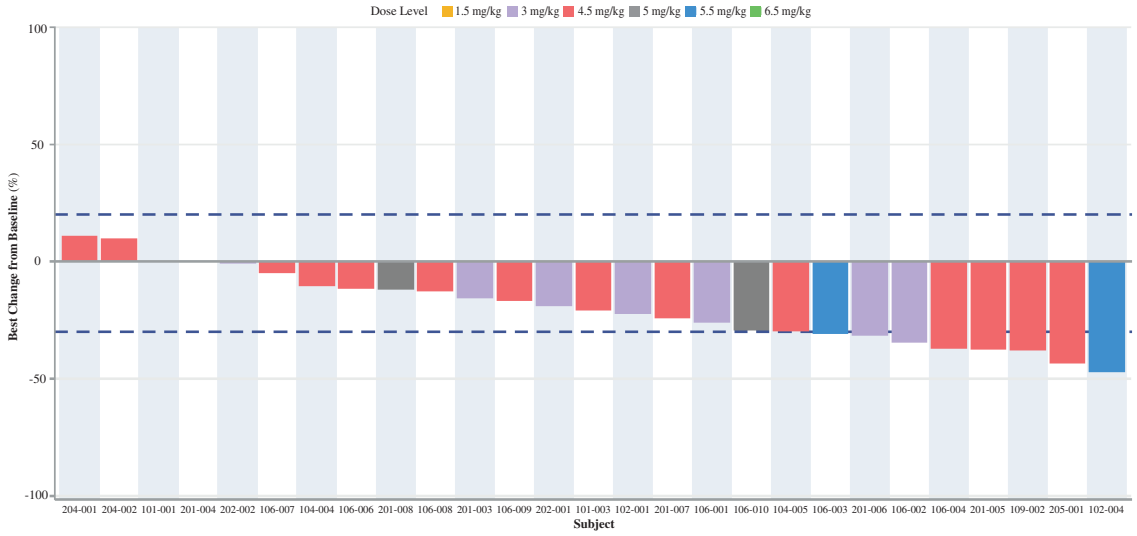


Target Lesion Tumor Response Over Time for Patients with Post-baseline Scans



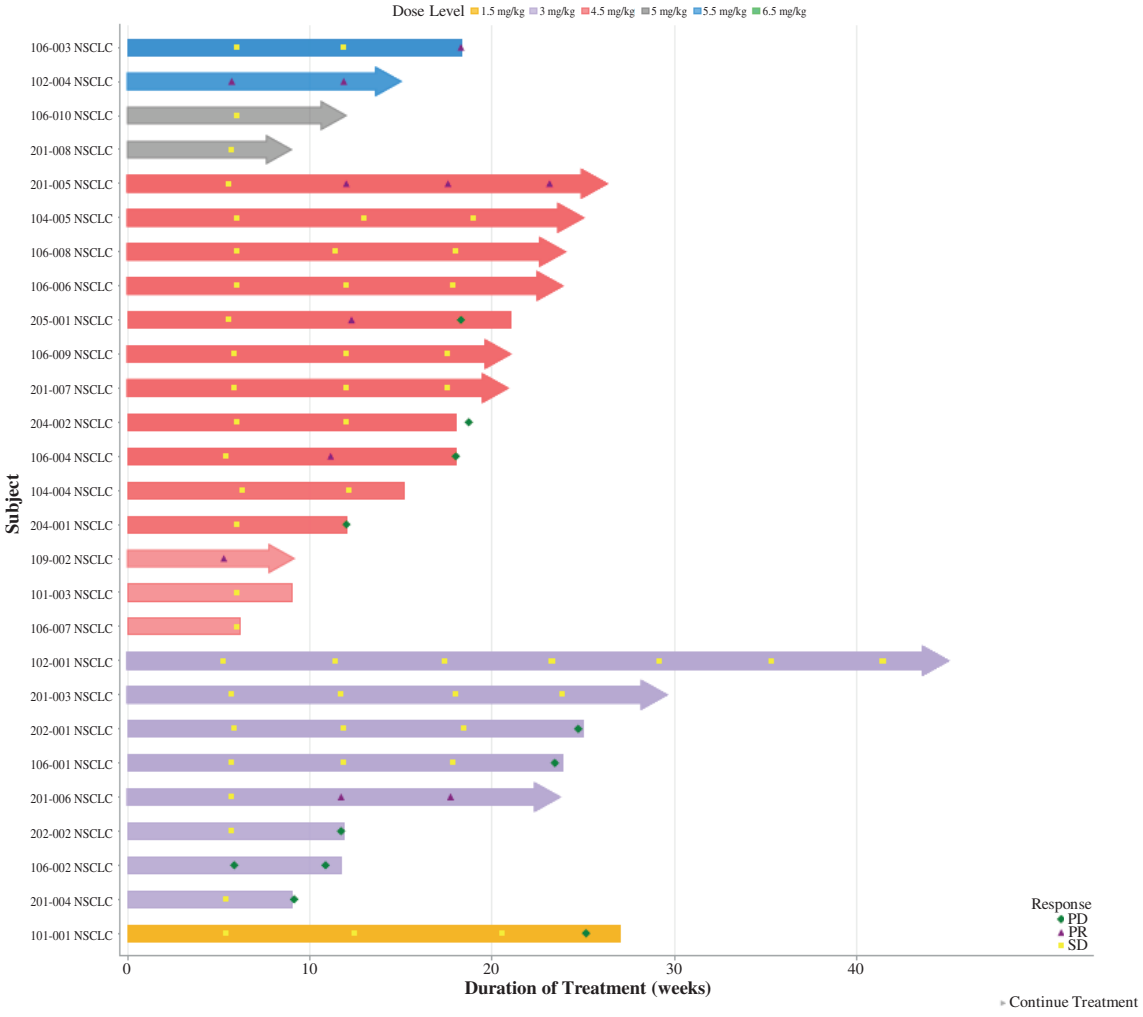
In particular, preliminary efficacy was observed among the patients with NSCLC, with tumor target lesion shrinkage observed in most patients. The chart below sets forth best tumor response for NSCLC patients as of May 17, 2024.

Best Tumor Response for NSCLC Patients with Post-baseline Scans

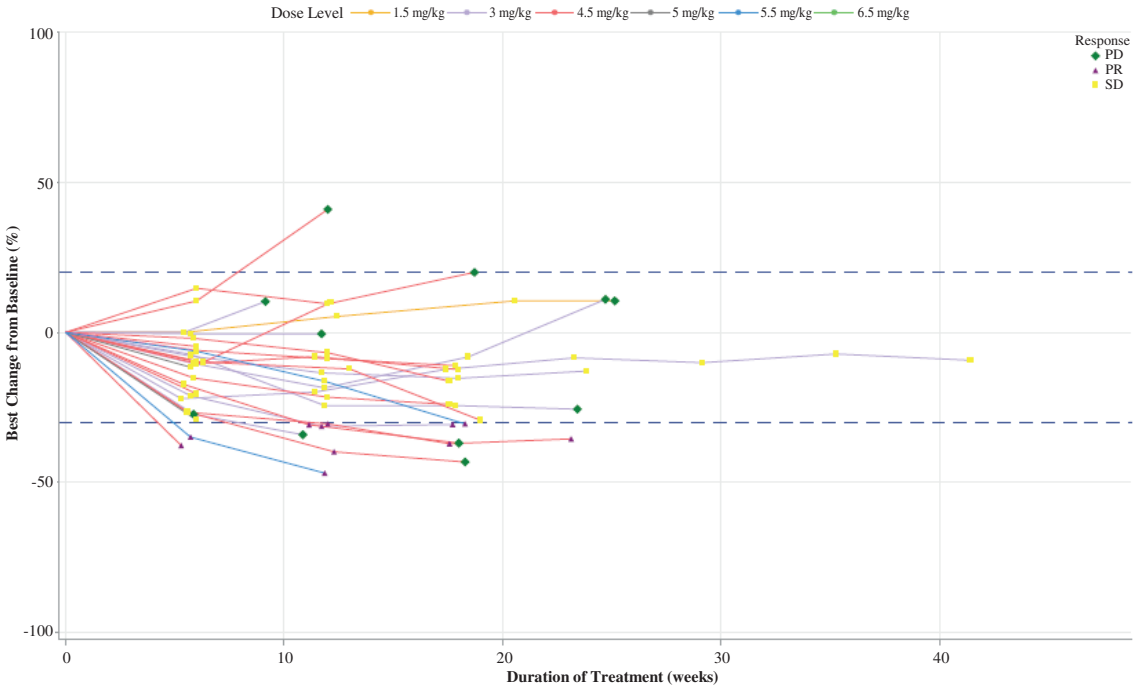


Tumor shrinkage was also durable in NSCLC patients. The two charts below set forth the tumor response over time for NSCLC patients with post-baseline scans and target lesion tumor response over time for NSCLC patients with post-baseline scans.

Tumor Response Over Time for NSCLC Patients with Post-baseline Scans



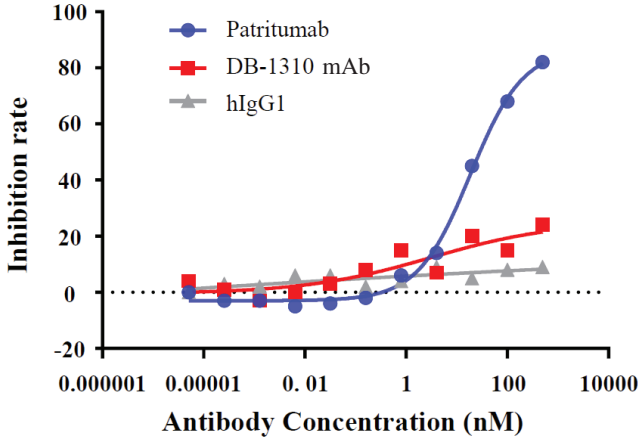
Target Lesion Tumor Response Over Time for NSCLC Patients with Post-baseline Scans



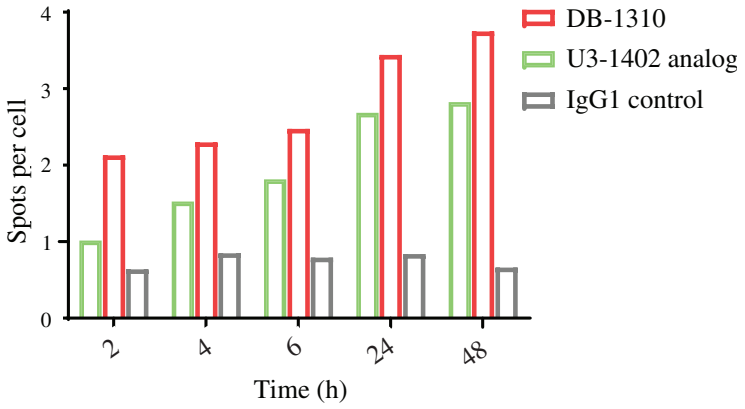
Safety Data. As of May 17, 2024, DB-1310 had an acceptable and manageable safety profile. The incidence of TEAEs was 91.2% and incidence of grade 3 or above TEAEs was 29.8%. The incidence of TRAEs was 80.7% and incidence of grade 3 or above TRAEs was 19.3%. The most common TRAEs observed were neutrophil count decreased (29.8%), nausea (28.1%), anemia (26.3%), platelet count decreased (24.6%), and white blood cell count decreased (21.1%).

Selected Preclinical Data

In preclinical studies, DB-1310's mAb binds to HER3 with a novel epitope different from patritumab (the antibody used in U3-1402).

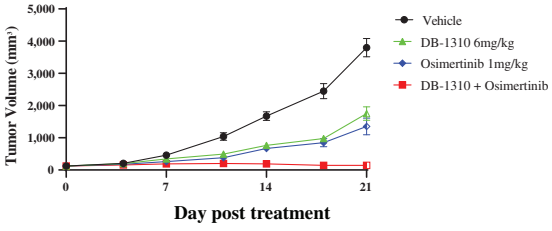


The internalization of DB-1310 and an in-house produced U3-1402 analog was measured on cancer cells expressing HER3. The results showed that DB-1310 is more effectively internalized by HER3-expressing cancer cells than the reference ADC.

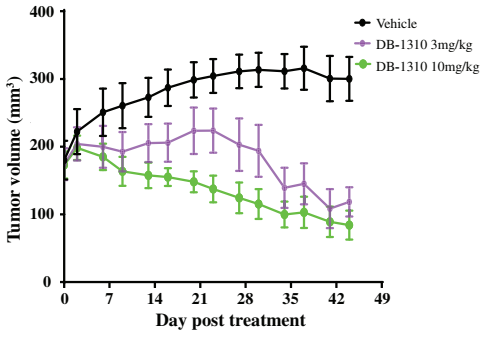


DB-1310 also displayed robust anti-tumor activity in multiple tumor models, including for PC, NSCLC and BC, and superior results compared to an in-house produced U3-1402 analog in various models. In addition, DB-1310 in combination with EGFR TKI osimertinib showed greater anti-tumor effects in an NSCLC preclinical model, as illustrated below.

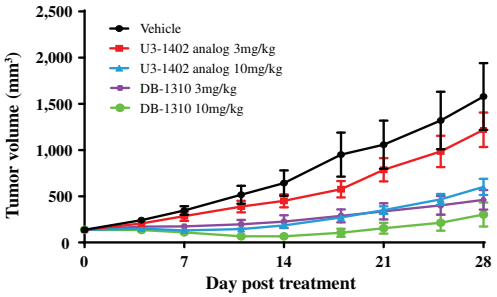
NCI-H1975 NSCLC CDX Model



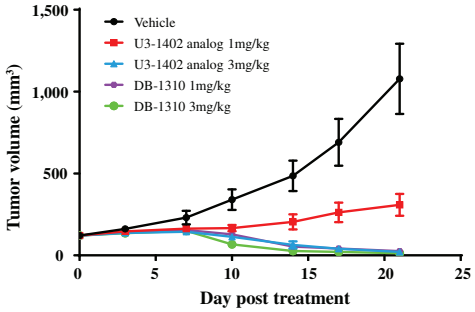
PR9587 Prostate Cancer PDX Model



LU1542 NSCLC PDX Model



H CC1569 HER3 High BC CDX Model



Next Steps

We are rapidly advancing the phase 1/2a clinical trial for DB-1310 for patients with advanced or metastatic solid tumors. As the first-in-human study for DB-1310, this phase 1/2a clinical trial provides foundational data that informs our regulatory discussions with the competent authorities and shapes our late-stage clinical development strategy. We plan to announce interim data from DB-1310's phase 2a expansion cohorts in the second half of 2025.

DB-1310 MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED.

DB-1305/BNT325, a TROP2 ADC candidate with potential as a frontline backbone therapy, our key product

Overview

DB-1305 is an in-house discovered TROP2 ADC candidate with a global development strategy. TROP2, a validated and highly expressed ADC target across a wide spectrum of cancers, plays a pivotal role in tumor progression. To date, there is only one TROP2 ADC approved globally, indicated for advanced TNBC, UC and HR+/HER2- BC, according to Frost & Sullivan. The global TROP2 ADC market is expected to increase from US$1.1 billion in 2023 to US$7.7 billion by 2028, representing a CAGR of 48.8%.

DB-1305 targets indications currently under-explored by other TROP2 ADC candidates, such as OC. DB-1305 also has combination potential as a backbone therapy in earlier lines of treatment, starting from NSCLC, OC, CC and TNBC. We believe this well-rounded strategy may position DB-1305 as a potential backbone therapy in the TROP2 ADC landscape. In collaboration with BioNTech, we are advancing DB-1305's global clinical development, including an ongoing phase 1/2a global trial in patients with advanced solid tumors, where encouraging preliminary efficacy signals in NSCLC and multiple other solid tumors have been observed.

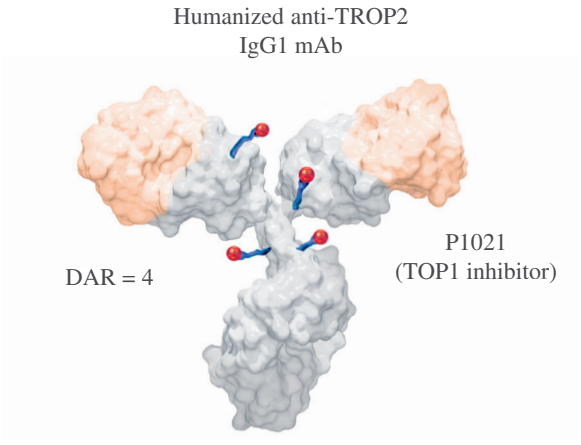
We entered into a license and collaboration agreement with BioNTech in August 2023, where we granted to BioNTech an exclusive, royalty-bearing and sublicensable license under certain patents and know-how owned or otherwise controlled by us to develop, manufacture, commercialize or otherwise exploit DB-1305 and pharmaceutical products comprising DB-1305 (together "**DB-1305 Products**") for all uses worldwide except Mainland China, Hong Kong and Macau. We retain the full rights to develop, manufacture, commercialize and otherwise exploit DB-1305 and DB-1305 Products in Mainland China, Hong Kong and Macau. See "— Our Collaboration and Licensing Arrangements — License and Collaboration Agreement with BioNTech for DB-1305/BNT325" for details.

Drug Design and Mechanism of Action

TROP2 is a transmembrane glycoprotein encoded by the Tacstd2 gene. It is an intracellular calcium signal transducer that is differentially expressed in many cancers. It signals cells for self-renewal, proliferation, invasion, and survival. It has stem cell-like qualities. TROP2 overexpression has been reported in many epithelial cancers, particularly in prevalent or hard-to-treat cancers including BC, NSCLC, GC and OC, and is associated with tumor aggressiveness, progression, and metastasis. Importantly, TROP2 overexpression in tumor cells relative to normal tissue has been well documented, making it a promising cancer drug target.

DB-1305 is a TROP2-targeted ADC designed with a humanized anti-TROP2 IgG1 mAb, a cleavable linker, and a proprietary DNA topoisomerase I inhibitor (P1021) conjugated at a DAR value of 4. The core components of DB-1305 are illustrated below.

DB-1305



After administration, DB-1305's anti-TROP2 IgG1 mAb directs the ADC selectively to TROP2-expressing tumor cells. Upon binding and internalization, P1021 is released, and inhibits DNA topoisomerase-1 activity, thereby suppressing the proliferation of TROP2-expressing tumor cells. DB-1305's optimized drug-to-antibody ratio of ~4 helps strike a

balance between potency and tolerability. The linker used is highly stable in circulation. The payload itself is highly potent but has a short systemic half-life. Additionally, DB-1305 demonstrates a bystander antitumor effect.

Market Opportunity and Competition

As of the Latest Practicable date, Trodelvy®, SKB264 (brand name: 佳泰莱®) and Datroway® were the only three TROP2 ADCs approved globally or in China. As of the same date, there were eight TROP2 ADCs indicated for OC under clinical development globally and eight TROP2 ADCs in combination with immunotherapies in phase 1/2 clinical development or beyond globally. The global TROP2 ADC market reached US$1.1 billion in 2023. Driven by TROP2 ADCs' proven success in indication expansion and the continued exploration of new clinical applications, the global TROP2 ADC market is expected to further increase to US$7.7 billion in 2028, with a CAGR of 48.8% from 2023. In China, the market size for TROP2 ADCs is projected to reach US$3.4 billion in 2032, representing a CAGR of 63.8% from 2028. For more details on the addressable market and competitive landscape of TROP2 ADCs, see "Industry Overview — Global TROP2 ADC Market — Market Opportunities of TROP2 ADCs."

We face fierce competition in the TROP2 ADC market from existing and future ADCs directed against the same molecular targets and indicated for the same indications. Such competition may become more intense by future collaborations, mergers and acquisitions in the biopharmaceutical industry. For details of the key features of DB-1305 in comparison with other TROP2 ADCs, see also "Industry Overview — Global TROP2 ADC Market — Competitive Landscape."

To compete effectively in the TROP2 ADC markets, we are developing DB-1305 by strategically targeting indications previously under-explored by other TROP2 ADC candidates, such as OC. We are also exploring the combination potential as backbone therapy in multiple solid tumors, aiming to harness the potent anti-tumor activity of ADCs along with the sustained benefit of immunomodulators. We and BioNTech are actively exploring DB-1305's combination potential as a backbone therapy in early lines of treatment, starting from NSCLC, OC, CC and TNBC.

OC. OC is the third most common cancer of the female reproductive system worldwide. High expression of TROP2 is reported in about 83% of OC patients. The global incidence of OC increased from 295.4 thousand cases in 2018 to 333.9 thousand cases in 2023, and is projected to further increase to 396.8 thousand cases by 2032. In China, incidence of OC increased from 57.8 thousand cases in 2018 to 61.6 thousand cases in 2023, and is projected to increase to 66.6 thousand cases by 2032.

Chemotherapy represents the mainstay of standard treatments for advanced OC in China and the U.S., which involves platinum-based and taxane-based chemotherapy with or without antiangiogenic mAb bevacizumab. However, the disease often recurs in a more resistant form even after initial successful treatment with surgery and chemotherapy. Patients with persistent

disease or progression during first-line treatment are treated with second-line approaches, primarily consisting of bevacizumab and PARP inhibitors, such as olaparib and niraparib, and platinum-based or non-platinum-based chemotherapy, depending on whether they are platinum-sensitive or platinum-resistant. Immunotherapy, such as programmed cell death protein 1 ("**PD-1**") inhibitors may be considered for patients with certain immunotherapy biomarkers who have no satisfactory alternative treatment options. However, immunotherapies, while promising, has shown limited effectiveness in OC when used as a monotherapy. This limited efficacy and high recurrence rate underscores the need for more effective and durable treatment options that can improve long-term survival outcomes for patients. For details of the treatment paradigm of OC in China and the U.S., see "Industry Overview — Global TROP2 ADC Market — Market Opportunities of TROP2 ADCs — Ovarian Cancer."

Traditionally, ADC development has focused on FRα-positive OC patients, who constitute a limited subset of the OC population. Given that TROP2 is overexpressed in the majority of OC patients and the under-exploration of OC as an indication for other TROP2 ADC candidates, TROP2 ADCs targeting OC patients represent a promising therapeutic strategy with vast potential. In addition, TROP2 ADCs can potentially bypass platinum resistance, providing a novel therapeutic option when standard platinum-based chemotherapy is no longer effective. They can also be used in combination with or as a complement to standard platinum-based chemotherapy, potentially enhancing treatment efficacy.

As of the Latest Practicable Date, no TROP2-targeted drugs, including ADCs, had been approved for OC globally. As of the same date, there were eight TROP2 ADCs targeting OC under clinical development globally. For details, see "Industry Overview — Global TROP2 ADC Markets — Competitive Landscape."

NSCLC. TROP2 is broadly overexpressed in NSCLC, making TROP2 ADCs a promising modality for treating advanced NSCLC regardless of driver mutation status.

The treatment paradigm of advanced NSCLC in China and the U.S. can be broadly classified based on the presence or absence of driver mutations. For driver mutation-positive advanced NSCLC, the first-line treatment options include TKIs directed against specific actionable driver mutations. However, most of these patients eventually acquire resistance to this treatment. For patients who have failed TKIs, platinum-based doublet chemotherapy with or without bevacizumab, single-agent chemotherapy, or PD-(L)1 inhibitor is usually considered. In China and the U.S., for driver mutation-negative advanced NSCLC, the first-line or later treatment options include chemoimmunotherapy with or without anti-angiogenic mAb bevacizumab, immunotherapies such as PD-1 and CTLA-4 inhibitors with or without chemotherapy. For details of the treatment paradigm of NSCLC in China and the U.S., see "Industry Overview — Global TROP2 ADC Market — Market Opportunities of TROP2 ADCs — Non-small Cell Lung Cancer."

As of the Latest Practicable Date, no TROP2-targeted drugs, including ADCs, had been approved for NSCLC globally. As of the same date, there were 12 TROP2 ADCs targeting NSCLC under clinical development globally.

Key Advantages

Highlights of DB-1305 include:

- Well-positioned to address underserved needs in OC treatment. We are actively investigating DB-1305 for the treatment of advanced OC. Despite the encouraging therapeutic benefits shown by TROP2 ADCs, the global clinical development of TROP2 ADCs is currently heavily focused on TNBC, HR+/HER2- BC, UC and NSCLC. Because TROP2 is a significant prognostic biomarker and therapeutic target across other prevalent or hard-to-treat cancers, this leaves unmet needs among patients. OC, for example, is one of the leading causes of cancer death in women globally with over 300,000 diagnosed each year. Frequently diagnosed at an advanced stage, OC is associated with a higher mortality rate and poor prognosis, and many OC patients develop resistance to platinum-based chemotherapies and other standard treatments. The global OC drug market is expected to increase from US$4.8 billion in 2023 to US$8.1 billion by 2028, representing a CAGR of 11.1%.

  Traditionally, ADC development has focused on FRα-positive OC patients, who constitute a limited subset of the OC population. Compared to FRα-directed ADCs, DB-1305 demonstrates broader treatment potential among a wide range of OC patients, due to TROP2's high overexpression rate (~83%) in this cancer type. In its ongoing phase 1/2a global trial, DB-1305 has shown preliminary efficacy in an all-comer cohort of advanced PROC patients. In January 2024, DB-1305 was granted Fast Track Designation by the FDA for patients with platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, acknowledging its potential to address unmet medical needs.

- Combination potential as backbone therapy in multiple solid tumors. We and BioNTech are actively exploring DB-1305's combination potential as a backbone therapy in earlier lines of treatment, starting from NSCLC, OC, CC and TNBC. In June 2024, the first patient was dosed in a combination cohort of DB-1305's ongoing phase 1/2a global trial to evaluate the combination of DB-1305 and BNT327, a bsAb targeting PD-L1 and VEGF, aiming to harness the potent anti-tumor activity of ADCs along with the sustained benefit of immunomodulators. In October 2024, we received IND approval from the NMPA to initiate a phase 1/2a trial for DB-1305 in combination with BNT327 in patients with late-stage/metastatic solid tumors.

- Encouraging efficacy and manageable safety profile from phase 1/2a trial. Based on preliminary data from DB-1305's ongoing phase 1/2a global trial, which were published at the 2023 ESMO, DB-1305's uORR was 30.4% and unconfirmed DCR was 87.0% among heavily pre-treated patients with advanced solid tumors as of April 7, 2023. Among the 23 patients with post-baseline tumor scans, encouraging preliminary efficacy signals were observed in NSCLC patients: uORR was 46.2% and unconfirmed DCR was 92.3%. Encouraging preliminary efficacy signals of DB-1305 have also been observed in multiple other solid tumors. Based on preliminary data from its phase 1/2a global trial, DB-1305 was well-tolerated and all TEAEs were generally manageable at lower dose levels, with grade 3 or above TRAEs reported at 34.1% (15/44) in all patients and low incidences of blood-related TRAEs.

Summary of Clinical Trial Data

We received IND approvals from the FDA and NMPA in May 2022 and August 2022, respectively, and commenced DB-1305's first-in-human global MRCT phase 1/2a clinical trial for advanced/metastatic solid tumors. We were the sponsor of this trial as of the Latest Practicable Date. Set forth below is a summary of the key information on DB-1305's ongoing clinical trial.

Phase 1/2a Clinical Trial for Advanced/Metastatic Solid Tumors (*NCT05438329*)

This is an open-label, multicenter, multiple-dose, phase 1/2a study, including phase 1 dose escalation and phase 2a dose expansion for DB-1305 in patients with advanced solid tumors.

Trial Design. This study consists of two parts, phase 1 dose escalation study and phase 2a dose expansion study. Phase 1 adopts an accelerated titration at first dose (2 mg/kg) followed by the classic "3+3" design (4, 6, 8 and 10 mg/kg) to identify MTD and RP2D of DB-1305. Phase 2a is a dose expansion phase to confirm the safety, tolerability and explore efficacy in selected malignant solid tumors treated with DB-1305 as monotherapy or combination therapy. Phase 2a dose expansion study has 17 expansion cohorts. Subjects with solid tumors will be enrolled to treat with DB-1305 in monotherapy (cohorts 1-11) or in combination with pembrolizumab (cohort 12) or in combination with BNT327 (cohorts 13-17) at the RP2D to assess the preliminary anti-tumor activity, safety, tolerability, PK and other endpoints of DB-1305 when dosed alone, in combination with pembrolizumab and in combination with BNT327.

Trial Objectives. The primary objective of the phase 1 dose escalation study is to evaluate safety and tolerability and determine the MTD/RP2D. The primary endpoints of the phase 1 study are safety and tolerability measured by TEAEs, SAEs, laboratory abnormalities reported up through the safety follow-up period, and AEs meeting DLT criteria, and to determine the MTD and/or the RP2D of DB-1305 monotherapy. Secondary endpoints include efficacy (measured by ORR, DoR, DCR, TTR, PFS, OS per RECIST v1.1), PK, and immunogenicity.

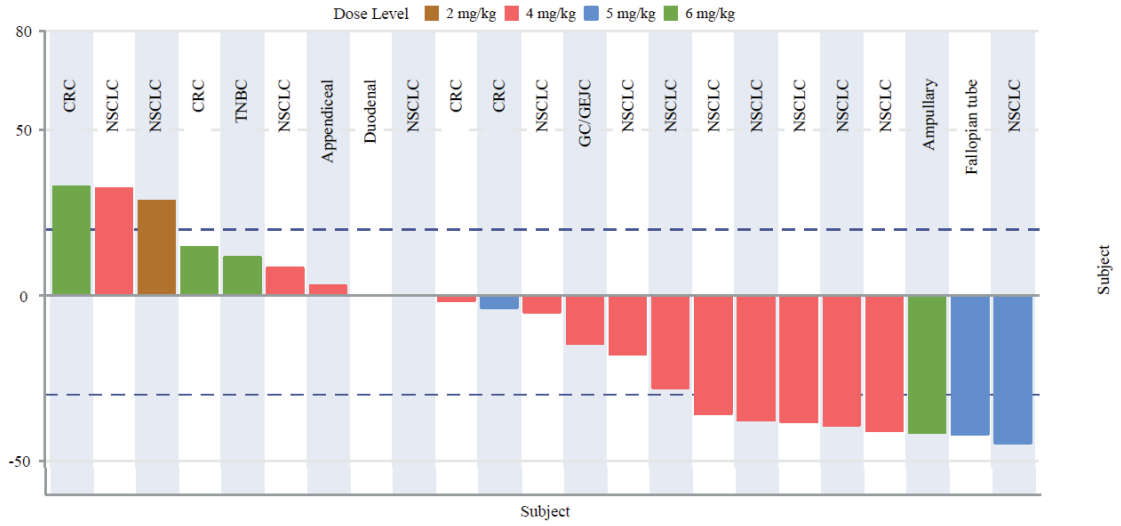
The primary objective of the phase 2a dose expansion study is to assess safety and tolerability of DB-1305 at the MTD/RP2D and evaluate the efficacy of DB-1305 at the MTD/RP2D. The primary endpoints of the phase 2a study include SAEs, TEAEs and ORR. Secondary endpoints include efficacy (measured by DoR, DCR, TTR, PFS, OS per RECIST v1.1), PK, and immunogenicity.

Trial Progress. This trial was initiated in July 2022 and is currently ongoing. We published the preliminary clinical data at the 2023 ESMO. As of April 7, 2023, the data cutoff date for 2023 ESMO, 44 patients received DB-1305 at four dose levels (2 mg/kg, n=1; 4 mg/kg, n=20; 5 mg/kg, n=17; 6 mg/kg, n=6; all were enrolled in the phase 1) and received a median of 3 (range, 1-6) prior lines of therapy. The median treatment duration was 1.5 (range, 0.7-6.1) months, and a total of 25 patients (56.8%) remained on treatment. The table below sets forth details of the baseline and characteristics.

	Total (n=44)
Age, Median (range)	59.0 (40.0-78.0)
Female, n (%)	26 (59.1)
Region, n (%)	
United States	21 (47.7)
China	23 (52.3)
ECOG Performance Status, n (%)	
0	7 (15.9)
1	37 (84.1)
Median Prior Lines of Therapy, Median (range)	3.0 (1-6)
Cancer Types, n (%)	
Non-small Cell Lung Cancer	30 (68.2)
Colorectal Cancer	4 (9.1)
HR+HER2-breast cancer	2 (4.5)
Ovarian Cancer	2 (4.5)
Ampullary Carcinoma	1 (2.3)
Appendiceal Cancer	1 (2.3)
Duodenal Cancer	1 (2.3)
Gastric or Gastroesophageal Junction Adenocarcinoma	1 (2.3)
Primary Malignant Neoplasm of Fallopian Tube	1 (2.3)
Triple-negative Breast Cancer	1 (2.3)
Prior Anticancer Systematic Therapy, n (%)	
With Prior Immunotherapy Therapy	20 (45.5)
With Prior Platinum Therapy	39 (88.6)

Efficacy Data. As of April 7, 2023, a total of 23 patients had undergone at least one post-baseline tumor scan. The overall uORR was 30.4% (7/23) and unconfirmed DCR was 87.0% (20/23) in patients with TROP2-expressing advanced solid tumors (n = 23) who had received a median of 3 prior lines of therapy (range, 1-6). In the NSCLC cohort, the uORR was 46.2% (6/13) and the unconfirmed DCR was 92.3% (12/13). Antitumor activity was also

observed in a patient with fallopian tube cancer, with one unconfirmed PR at the 5 mg/kg dose level, resulting in an ORR of 1/1 in that patient. The table below sets forth details of the best tumor response for all patients with post-baseline scans.



Safety Data. As of April 7, 2023, DLT occurred in three patients who received the 6 mg/kg dose. As such, 5 mg/kg was established as the MTD. No TEAE led to death. TRAEs primarily included stomatitis, nausea, infusion-related reaction, decreased appetite, mucosal inflammation and interstitial lung disease. Grade 3 or above TRAEs were reported in 34.1% (15/44) of patients, with the most common being stomatitis (22.7%), nausea (2.3%), and mucosal inflammation (2.3%). DB-1305 was tolerable and all TEAEs were generally manageable at lower dose levels (i.e., 2 and 4 mg/kg). The table below sets forth details of the safety data as of April 7, 2023.

	2 mg/kg (n=1) n (%)	4 mg/kg (n=20) n (%)	5 mg/kg (n=17) n (%)	6 mg/kg (n=6) n (%)	Total (n=44) n (%)
Any TEAEs	1 (100.0)	19 (95.0)	15 (88.2)	6 (100.0)	41 (93.2)
Grade ≥3	1 (100.0)	13 (65.0)	6 (35.3)	5 (83.3)	25 (56.8)
Serious TEAEs	0	6 (30.0)	5 (29.4)	4 (66.7)	15 (34.1)
Led to does reduction	0	1 (5.0)	2 (11.8)	3 (50.0)	6 (13.6)
Led to does interruption	0	9 (45.0)	6 (35.3)	4 (66.7)	19 (43.2)
Led to dose discontinuation	0	2 (10.0)*	0	0	2 (4.5)
Any TRAEs	0	19 (95.0)	15 (88.2)	6 (100)	40 (90.9)
Grade ≥3	0	7 (35.0)	5 (29.4)	3 (50.0)	15 (34.1)
Serious TRAEs	0	3 (15.0)	4 (23.5)	3 (50.0)	10 (22.7)
Led to dose reduction	0	1 (5.0)	2 (11.8)	3 (50.0)	6 (13.6)
Led to dose interruption	0	6 (30.0)	5 (29.4)	4 (66.7)	15 (34.1)
Led to dose discontinuation	0	1 (5.0)	0	0	1 (2.3)
Dose-limiting toxicities	0	0	0	3 (50.0)	3 (6.8)

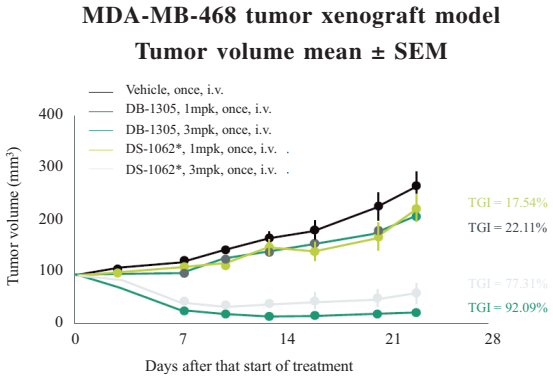
* One patient died by suicide on day 18 after first dose and one patient experienced double pneumonia on day 49.

PK Data. Exposure parameters (maximum plasma concentration ("**C_{max}**") and area under the curve ("**AUC**")) of DB-1305 ADC increased with dose in the dose range of 2 to 6 mg/kg. The half-life of DB-1305 ADC is approximately 3.0-4.5 days for a dose range of 4 to 6 mg/kg. The exposure of release payload was magnitudes lower than that of DB-1305 ADC, with ADC/payload molar ratio of approximately 80, demonstrating stability of the ADC in systemic circulation.

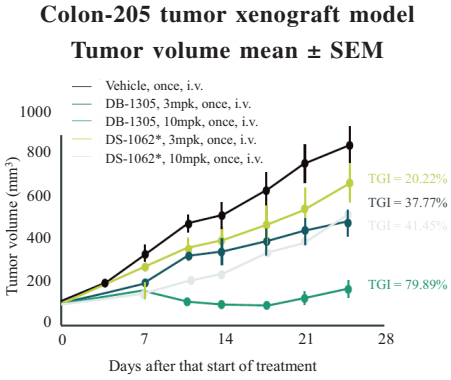
Selected Preclinical Data

In preclinical studies, DB-1305 induced dose-dependent tumor growth inhibition and tumor regression. Potent anti-tumor effect was observed in TROP2 high and low tumor models with a wide therapeutic window.

TROP2-high CDX MDA-MB-468 (breast cancer)



TROP2-low CDX Colon-205 (colon cancer)



* *An in-house produced analog of DS-1062.*

Next Steps

We are rapidly advancing the phase 1/2a clinical trial for DB-1305 for patients with advanced or metastatic solid tumors. As the first-in-human study for DB-1305, this Phase 1/2a clinical trial provides foundational data that informs our regulatory discussions with the competent authorities and shapes our late-stage clinical development strategy. Subject to clinical progress and communications with the competent authorities, we and BioNTech plan to initiate a global potential registrational study for DB-1305 in 2025.

DB-1305/BNT325 MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED.

Other ADC assets derived from our DITAC platform include (i) DB-1312, a novel B7H4 ADC we out-licensed to BeiGene in 2023 in a transaction exceeding US$1.3 billion in deal value. DB-1312 is currently at clinical stage. See also "— Our Collaboration and Licensing Arrangements — Out-license and Collaboration Agreement with BeiGene on DB-1312"; and (ii) DB-1314 and DB-1317, two preclinical ADC candidates. Going forward, we will continue to leverage our DITAC platform to optimize the design and engineering of ADC drugs for cancer treatment.

ADC Assets Developed from DIMAC Technology Platform

DIMAC — Next-generation Immune-modulating ADC Platform

We believe immune-modulating ADCs holds the potential to open the ADC modality to a significant white-space market in autoimmune and other therapeutic areas. Many patients with chronic autoimmune diseases, such as SLE and CLE, are currently treated with therapies that often lead to severe side effects. Long term use of glucocorticoids, for example, are commonly associated with increased risks of bone fractures, weight gain, diabetes, immune system suppression, and other chronic conditions. We believe ADCs can reshape the treatment paradigm of autoimmune diseases by offering a targeted treatment with low systemic exposure, enhanced efficacy and reduced side effects. Immune-modulating ADCs have been validated by preliminary clinical data from peers, showing better safety and efficacy profiles compared to the antibody alone.

We are a global pioneer in this space with the ability to mobilize our accumulated technology in oncology into innovation of autoimmune ADCs, according to Frost & Sullivan. Leveraging our technology accumulation in target and payload selection and ADC design, our DIMAC platform has demonstrated broad anti-inflammatory activity, long duration of action, sustained stability, and low systemic exposure in preclinical studies. We have developed a deep technological moat for DIMAC with patent protection extending beyond 2040.

DB-2304, Potential First-in-class Autoimmune ADC for SLE/CLE, our Key Product

Overview

DB-2304 is an in-house discovered, potential first-in-class BDCA2 ADC candidate for SLE and CLE, being one of the most advanced BDCA2 ADCs in terms of development progress, according to Frost & Sullivan. DB-2304 offers a selective therapeutic approach specifically targeting the upstream signaling pathways of SLE/CLE pathogenesis, differentiating it from existing lupus treatments that often have broader effects on the immune system. We believe DB-2304 holds promise to substantially improve upon the standard of care for SLE and CLE, such as glucocorticoids and immunosuppressants, and represents a major

step in the innovation of autoimmune ADCs. We initiated a phase 1 study in healthy adults for DB-2304 in Australia in October 2024. We have submitted IND applications to both the FDA and NMPA for DB-2304 and, subject to regulatory approval, expect to complete DB-2304's phase 1 global trial in 2026.

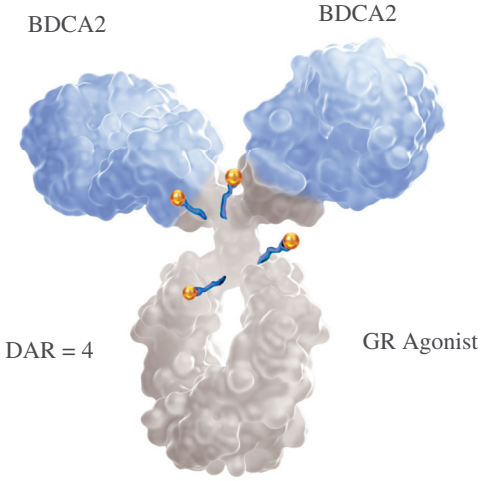
Drug Design and Mechanism of Action

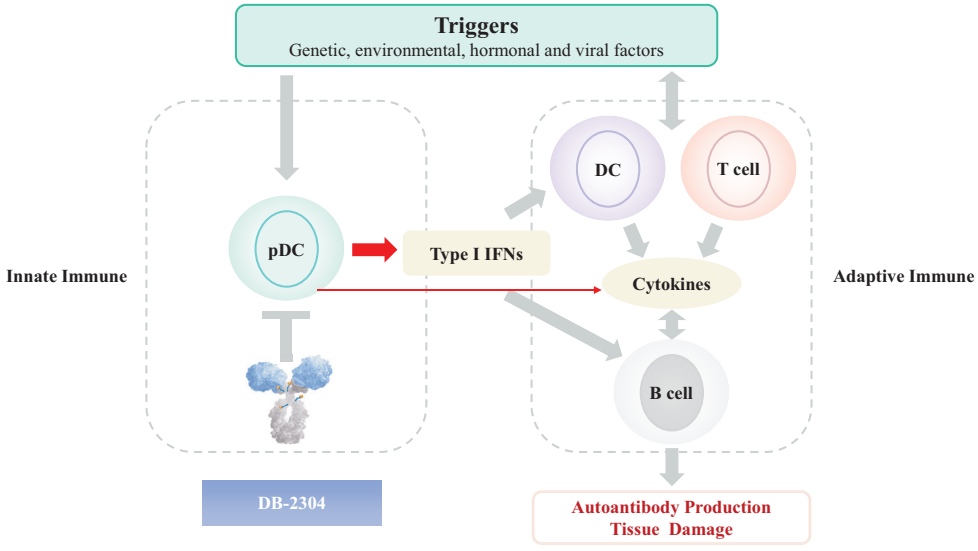
SLE is a complex autoimmune disorder characterized by the dysregulation of the immune system, leading to widespread inflammation and tissue damage. A key pathogenic feature of SLE is the abnormal production of IFN-I, which are signaling molecules that play a central role in driving autoimmune response, including the maturation and differentiation of autoreactive B cells, promotion of antibody production, and enhancement of adaptive immune response generation. The excessive and sustained production of IFN-I is primarily driven by the over-activation of pDCs.

BDCA2 is a unique and clinically validated receptor expressed on pDCs, according to Frost & Sullivan. When BDCA2 is engaged by mAb, it triggers an inhibitory signaling cascade that suppresses activation of pDCs and reduces IFN-I production. This negative feedback mechanism helps to control pDC activation and prevent excessive IFN-I production.

DB-2304 is a BDCA2-directed ADC designed with a novel BDCA2-targeting antibody conjugated to a proprietary GR agonist payload at a DAR of 4. DB-2304's core components and mechanism of action are illustrated below.

DB-2304





The engagement of BDCA2 by the antibody contributes to the suppression of pDC activation and IFN-I production. Upon binding to BDCA2, DB-2304 is internalized into the pDCs, where its novel GR agonist payload is released. The GR agonist acts to drive the transcription of glucocorticoid response genes suppressing pro-inflammatory cytokine secretion. These two mechanisms combined result in synergistic modulation of a broad spectrum of anti-inflammatory responses, beyond IFN regulation in pDCs.

By eliminating the primary source of interferon overproduction, DB-2304 aims to interrupt the self-perpetuating cycle of immune dysregulation and inflammation that is central to the pathogenesis of SLE. Reducing the abnormal levels of type I interferons could have multiple beneficial effects, including inhibiting the activation of antigen presentation, limiting the differentiation of autoantibody-producing plasma cells, and dampening the overall autoimmune response.

Market Opportunity and Competition

SLE. SLE is an autoimmune disease characterized by the production of autoantibodies that target the body's own tissues and cells. It is the most common type of lupus, causing widespread inflammation and tissue damage in the affected organs. The global prevalence of SLE grew from 7,632.8 thousand cases in 2018 to 8,048.8 thousand cases in 2023. It is projected to increase to 8,800.3 thousand cases by 2032. In China, the prevalence of SLE grew from 1,015.6 thousand cases in 2018 to 1,048.3 thousand cases in 2023. It is projected to increase to 1,078.3 thousand cases by 2032.

With advancements in diagnostic tools and treatment options, the prognosis for individuals with SLE has improved significantly over the past few decades. However, SLE remains a chronic and potentially life-threatening condition, and calls for innovative treatment options with improved efficacy. A major shortcoming of mainstay treatments for SLE, such as glucocorticoids and immunosuppressants, is their inability to address the high heterogeneity of pathogenesis in these complex diseases, which often result in limited efficacy and serious side effects, especially when used long term for chronic disease management. For details of the treatment paradigm of SLE in China and the U.S., see "Industry Overview — Global BDCA2 ADC Market — Market Opportunities of BDCA2 ADCs — Systemic Lupus Erythematosus."

Given the complex and heterogeneous nature of SLE, an ideal treatment modality for SLE should be able to achieve optimal disease control and minimize long-term side effects, calling for the development of targeted therapies such as ADCs. As a validated target that is specifically expressed on pDCs, BDCA2's over-production of IFN-I is crucial in SLE pathogenesis, making BDCA2-targeted ADCs promising for the treatment of SLE.

CLE. CLE is an autoimmune disorder that primarily affects the skin. CLE is characterized by a range of inflammatory skin lesions and rashes that can appear on various parts of the body, including the face, scalp, arms, and trunk. The global annual incidence of CLE remained relatively stable at approximately 330 thousand cases from 2018 to 2023, and is projected to reach 363.4 thousand cases in 2032. In China, the incidence of CLE grew from 55.8 thousand cases in 2018 to 57.2 thousand cases in 2023, and is projected to remain at an annual incidence of approximately 58 thousand cases from 2023 to 2032.

In China, first-line systematic therapy for CLE patients is hydroxychloroquine. Glucocorticoids, thalidomide, retinoids and amidostine are used as second-line treatments. Third-line treatments include methotrexate, mycophenolate mofetil. In the U.S., first-line systemic therapy for CLE patients is the use of an oral antimalarial medication. In second-line settings, oral retinoids such as acitretin and isotretinoin, immunosuppressants such as methotrexate are recommended. For details of the treatment paradigm of CLE in China and the U.S., see "Industry Overview — Global BDCA2 ADC Market — Market Opportunities of BDCA2 ADCs — Cutaneous Lupus Erythematosus."

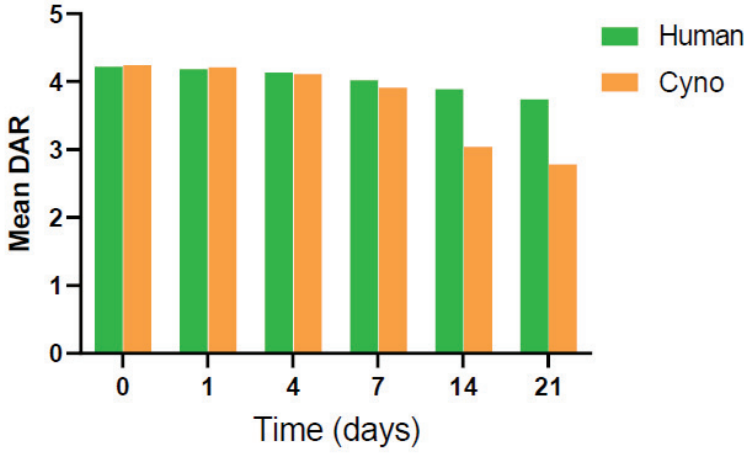
Despite the available treatment options, many patients continue to experience suboptimal disease control, highlighting the need for more effective and targeted therapies such as ADCs to improve outcomes for individuals living with this debilitating autoimmune skin condition.

As of the Latest Practicable Date, there were no approved BDCA2 ADCs and no BDCA2 ADCs indicated for SLE or CLE under clinical development globally or in China.

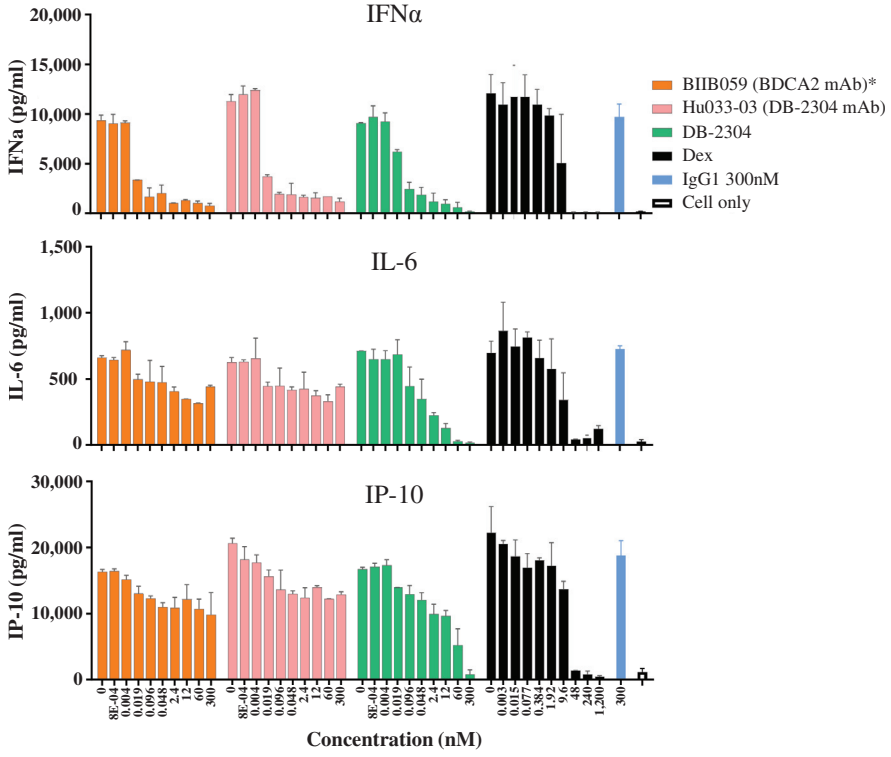
Key Advantages

- Novel targeted treatment to address unmet needs for SLE and CLE. SLE and CLE are autoimmune diseases that together affect over eight million patients globally, according to Frost & Sullivan. A major shortcoming of mainstay treatments, such as glucocorticoids and immunosuppressants, is their inability to address the high heterogeneity of pathogenesis in these complex diseases, which often result in limited efficacy and serious side effects, especially when used long term for chronic disease management. DB-2304 offers a selective therapeutic approach specifically targeting the upstream signaling pathways of SLE/CLE pathogenesis, differentiating it from existing lupus treatments that often have broader effects on the immune system.

- Good stability and safety profile. In preclinical studies, DB-2304 showed strong stability in plasma with little change in concentration or DAR value up to 21 days. Good stability and low level of systemic exposure of free payload indicates a good safety profile, as illustrated below. DB-2304 also showed promising safety profile with a NOAEL of 85 mg/kg.



- Strong efficacy with synergistic functions. Preclinical studies also show that DB-2304 demonstrates greater potency with synergistic effects in suppressing production of both IFN-I and pro-inflammatory cytokines. DB-2304 is designed to combine the efficacy of mechanisms mediated by BDCA2-targeting mAb (demonstrated by INFα suppression) and the GR agonist payload (demonstrated by IL-6 and IP-10 suppression), as illustrated below.



* Litifilimab (known as BIIB059), a BDCA-targeting mAb developed by Biogen

Summary of Clinical Trial Data

We submitted clinical trial notification to the Therapeutic Goods Administration ("**TGA**") of Australia in September 2024 to conduct DB-2304's phase 1 clinical trial in healthy subjects in Australia, and received the TGA's acknowledgment in the same month. Set forth below is a summary of the key information on DB-2304's ongoing clinical trial.

Phase 1 Clinical Trial in Healthy Adults in Australia *(NCT06625671)*

This is a randomized, double-blind, placebo- and positive-controlled, single ascending dose phase 1 study to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of DB-2304 injection in healthy adult participants.

Trial Design. Participants will be enrolled in five cohorts and randomized to receive escalating doses of DB-2304 or placebo. This trial will be performed in a single ascending dose design. The decision to escalate to subsequent dose levels will be made based on the review of all available safety information and PK/PD data in each cohort.

Trial Objectives. The primary objective is to evaluate the safety and tolerability of single ascending dose of DB-2304 in healthy adult participants. The primary endpoints are safety parameters such as TEAE and SAE.

Trial Progress. This trial was initiated in October 2024 and is currently ongoing.

Next Steps

We initiated a phase 1 study in healthy adults for DB-2304 in Australia in October 2024. We have submitted IND applications to both the FDA and NMPA for DB-2304 and, subject to regulatory approval, expect to complete DB-2304's phase 1 global trial in 2026 through separate protocols assessing single ascending doses in healthy volunteers and multiple ascending doses in SLE/CLE patients. Subject to clinical progress and communications with the competent authorities, we plan to achieve proof-of-concept in SLE patients in 2025 and enroll the first patient in DB-2304's phase 2 clinical trial in 2026.

DB-2304 MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED.

ADC Assets Developed from DIBAC Technology Platform

DIBAC — Next-generation BsADC Platform

BsADCs are next-generation ADCs with an innovative targeting backbone, according to Frost & Sullivan. By incorporating two distinct binding moieties in a single therapeutic entity, BsADCs can potentially offer meaningful advantages over traditional monospecific ADCs and combination therapies.

While promising, the complexity of BsADCs introduces new challenges in antibody engineering, stability and manufacturing. Our innovative DIBAC platform features our understanding of disease and target biology, rich experience in bispecific antibody engineering, and artificial intelligence-empowered target selection and antibody design. For details on the differentiating features of our DIBAC platform, see "— Our Competitive Strengths — Innovator in ADC development powered by versatile platforms to target underserved therapeutic areas."

DB-1419, Potential Global First-in-class B7-H3xPD-L1 BsADC Candidate

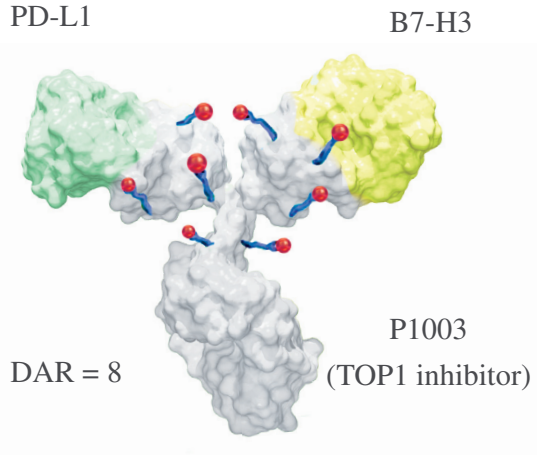
Overview

DB-1419 is an in-house discovered, potential first-in-class B7-H3xPD-L1 BsADC candidate with a DNA topoisomerase I inhibitor, being the only B7-H3xPD-L1 BsADC currently under clinical development globally, according to Frost & Sullivan. The simultaneous action of delivering the toxin to tumor cell and modulate T cell activation provides potential synergistic anti-tumor effect. Combining payload mediated cytotoxicity with antibody mediated immunotherapy activity, DB-1419 provides an innovative approach for cancer treatment. We have obtained IND approval from the FDA for DB-1419 and we initiated DB-1419's phase 1/2a global trial in September 2024.

Drug Design and Mechanism of Action

DB-1419 is a B7-H3/PD-L1-directed ADC composed of a humanized B7-H3/PD-L1 bispecific antibody, covalently linked to a topoisomerase inhibitor (P1003) via a cleavable linker, with a DAR value of 8. DB-1419's core components are illustrated below.

DB-1419



DB-1419 selectively binds to human B7-H3 and PD-L1 with no cross reactivity to other B7 family proteins. DB-1419 can selectively bind to and be endocytosed into the lysosome of B7-H3-positive cells. DB-1419 induces B7-H3-dependent cytotoxicity, causes G2/M cell cycle arrest, induces DNA damage, and inhibits cell proliferation in a concentration-dependent manner towards B7-H3-expressing cells. Simultaneously, by binding to PD-L1, DB-1419 blocks the interaction between PD-L1 and PD-1 receptors, reversing PD-L1-mediated immune suppression and enhancing T cell activation. This dual mechanism results in effective direct cytotoxicity against tumor cells and robust immune modulation, significantly inhibiting tumor growth and demonstrating improved therapeutic outcomes in preclinical models.

Key Advantages

- First-mover advantage. DB-1419 is a potential first-in-class B7-H3xPD-L1 BsADC candidate, being the only B7-H3xPD-L1 BsADC currently under clinical development globally, according to Frost & Sullivan. As of the Latest Practicable Date, there were no approved drugs targeting both B7-H3 and PD-L1 globally and no B7-H3xPD-L1 BsADC candidates under clinical development worldwide. We believe B7-H3's pan-cancer expression coupled with PD-L1's immune-modulating function may offer enhanced anti-tumor effects across broad indications.

- Synergistic immune modulation. By targeting PD-L1, DB-1419 blocks the interaction between PD-L1 and PD-1. This blockade reverses PD-L1-mediated immune suppression, enhancing T cell activation and promoting a robust anti-tumor immune response. The dual action of direct cytotoxicity and immune modulation can potentially improve overall therapeutic efficacy.

- Better efficacy than monospecific B7-H3 ADC. DB-1419 demonstrated superior efficacy over a monospecific B7-H3 ADC in syngeneic model and immune reconstitute model in preclinical studies. The results indicated that DB-1419 exhibit tumor growth inhibition effect through the simultaneous action of immune check point inhibitor activity and payload toxicity activity.

Summary of Clinical Trial Data

We obtained IND approval from the FDA for DB-1419 in September 2024 and initiated DB-1419's phase 1/2a trial. Set forth below is a summary of the key information on DB-1419's ongoing clinical trial.

Phase 1/2a Clinical Trial in Patients with Advanced/Metastatic Solid Tumors *(NCT06554795)*

This is a phase 1/2a, multicenter, open-label, first in human study to assess the safety, tolerability, pharmacokinetics, and preliminary antitumor activity of DB-1419 in patients with advanced/metastatic solid tumors.

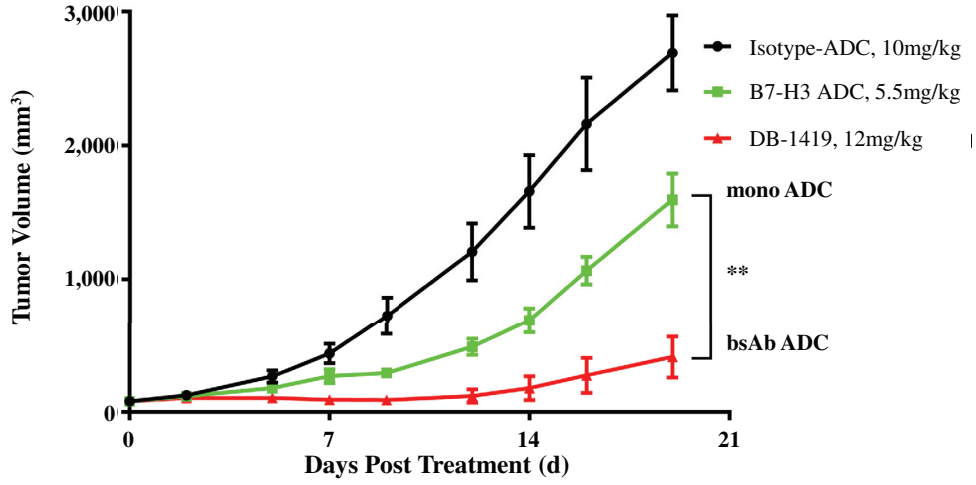
Trial Design. Participants will be enrolled in six cohorts to receive six dose levels of DB-1419. In addition to these initial dosing groups, this trial also includes eight dose expansion phases.

Trial Objectives. The primary objective is to evaluate the safety and tolerability of DB-1419 and determine the MTD/RP2D. The primary endpoints are safety parameters such as TEAE and SAE.

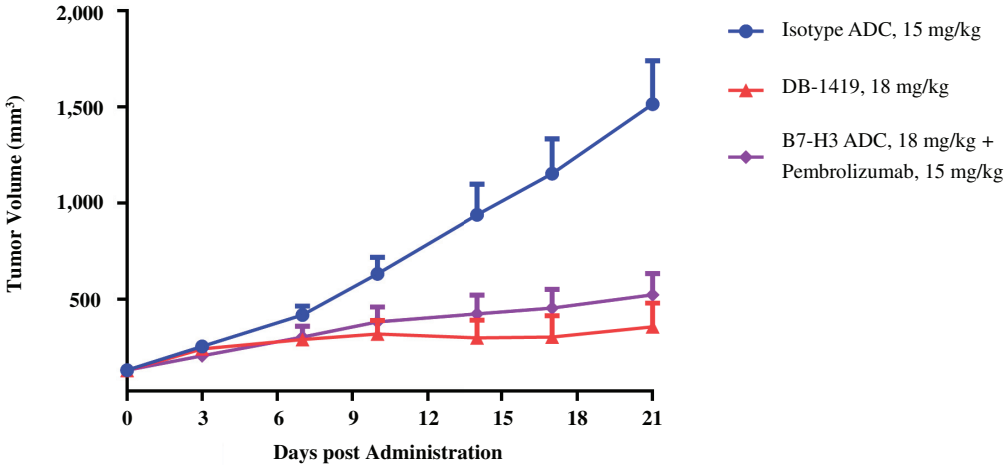
Trial Progress. This trial was initiated in September 2024 and is currently ongoing.

Selected Preclinical Data

DB-1419 showed a more pronounced and sustained tumor volume reduction effect than a monospecific B7-H3 ADC during the study period, as illustrated below, in a syngeneic mouse tumor model.



In an efficacy comparison study, DB-1419 demonstrated comparable tumor reduction effect compared to a B7-H3 ADC and PD-1 mAb combination therapy (monospecific B7-H3 ADC + pembrolizumab) during the study period.



Next Steps

We have obtained IND approval from the FDA for DB-1419 and we initiated DB-1419's phase 1/2a global trial in September 2024. We submitted IND application to the NMPA in December 2024 to initiate DB-1419's phase 1/2a trial in China. We plan to explore the potential of DB-1419 across various solid tumors, including SCLC, HCC, NSCLC, melanoma, ESCC, and TNBC. We plan to publish the study design for DB-1419's phase 1/2a global trial at the 2025 AACR Annual Meeting, with data readout anticipated in 2026, and to complete this

trial by 2027. As the first-in-human study for DB-1419, this phase 1/2a clinical trial provides foundational data that informs our regulatory discussions with the competent authorities and shapes our late-stage clinical development strategy.

DB-1419 MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED.

DB-1418/AVZO-1418, Differentiated EGFRxHER3 BsADC

Overview

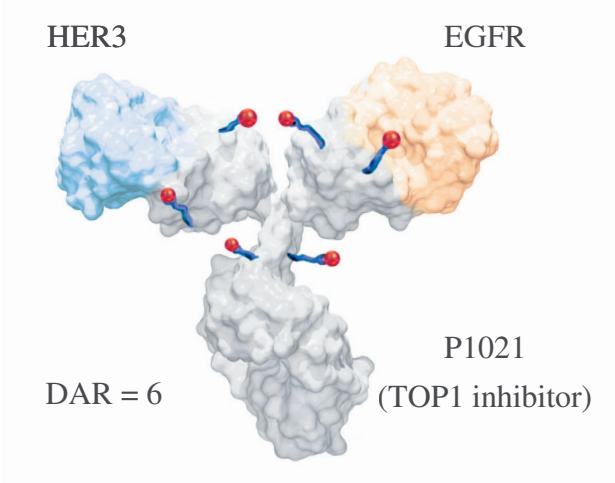
DB-1418 is an in-house discovered EGFRxHER3 BsADC. Due to target synergies, EGFRxHER3 BsADCs have demonstrated enhanced efficacy and ability to overcome resistance to EGFR- or HER3-directed treatments in clinical studies. Our DB-1418 is differentiated by a "1+1" format molecule design (two binding sites, one for each target) that translates to higher binding affinity to tumor cells as opposed to healthy cells. DB-1418 has also shown better efficacy in EGFR-resistant, EGFR-low or HER3-resistant models, potentially offering broader patient coverage. We are conducting IND-enabling studies for DB-1418 and expect to advance this molecule into clinical stage in the first half of 2025.

We entered into a collaboration and license agreement with Avenzo in December 2024, pursuant to which we granted Avenzo an exclusive license to develop, manufacture and commercialize DB-1418 globally excluding Greater China. We have also granted to Avenzo a non-exclusive license to develop and manufacture DB-1418 in Greater China solely for the development of DB-1418, for purposes of obtaining regulatory approval of DB-1418 and for the other exploitation of DB-1418 outside Greater China. We retain all other rights to develop, manufacture, commercialize and otherwise exploit DB-1418 in Greater China.

Drug Design and Mechanism of Action

DB-1418 is EGFR and HER3 dual targeting ADC comprised of a fully human EGFRxHER3 bispecific antibody conjugated to a topoisomerase I inhibitor payload P1021 via a cleavable linker. DB-1418's core components are illustrated below.

DB-1418

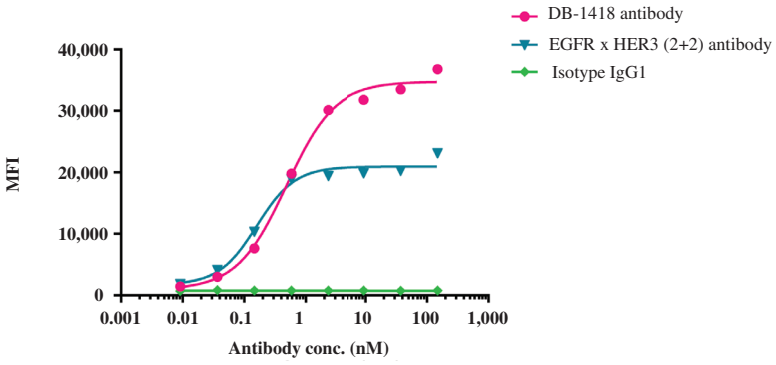


DB-1418 is designed with a unique "1+1" format molecule design, in contrast to the "2+2" format (four binding sites, two for each target) used in other BsADCs. Compared to BsADCs with a "2+2" format, DB-1418's "1+1" format has the potential to bring more payloads to tumor in addition to enhanced selectivity between tumor versus normal tissues.

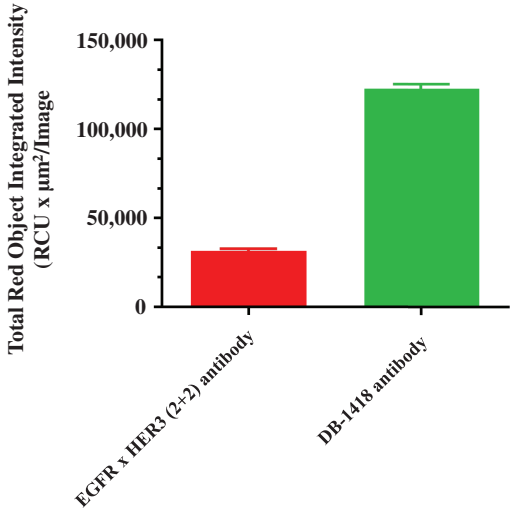
Key Advantages

- Differentiated "1+1" format molecule design. Leveraging the "1+1" format molecule design, DB-1418 exhibited higher binding affinity to tumor cells (which express both EGFR and HER3) compared to other BsADCs with a "2+2" design. Due to the "1+1" design, DB-1418 also demonstrates better internalization than other "2+2" format EGFRxHER3 BsADCs, as illustrated below.

NCI-H1975 (L858R/T790M)
EGFR ++, HER3 +

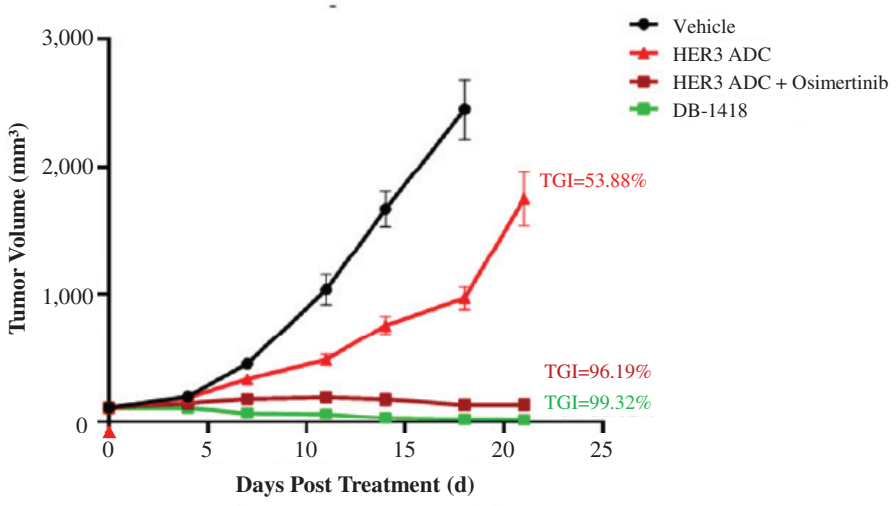


Internalization Assay on NCI-H1975 – 48 h
(Sample: 1 nM)



- Synergistic efficacy. Simultaneously binding to EGFR and HER3 by DB-1418 potentially translates to synergistic anti-tumor effects, significantly enhancing its therapeutic impact compared to traditional monospecific ADCs. In preclinical studies, DB-1418 achieved tumor growth inhibition ("**TGI**") of 99.32% in the NCI-H1975 model (EGFR++, HER3+) at 6mg/kg, significantly higher than the TGI of 53.88% for a HER3-targeting ADC.

NCI-H1975 (EGFR++, HER3+) model



- Overcoming resistance. A major advantage of DB-1418 is its ability to overcome resistance to conventional EGFR-targeted therapies. EGFR can bind to multiple ligands and, once internalized, the ligand-receptor complex can be recycled to cell surface. The recycling of ADCs may lead to inefficient payload processing in lysosome and potentially contribute to resistance mechanism of anti-EGFR monospecific ADCs. BsADCs like DB-1418 can better modulate intracellular trafficking by targeting two receptors and hence enhance intracellular release of payload.

Next Steps

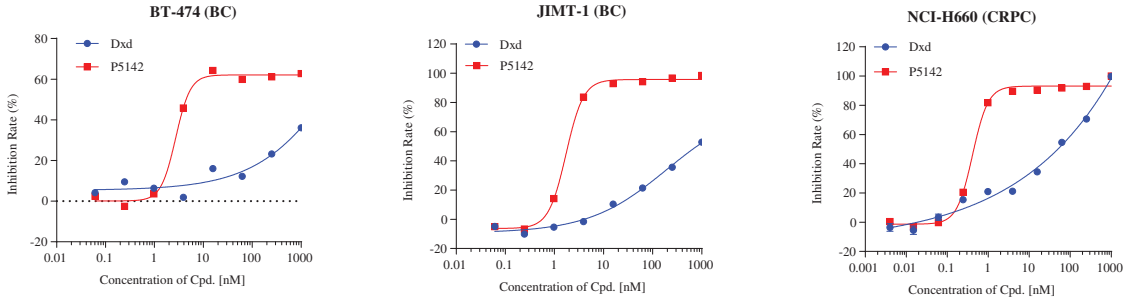
We are conducting IND-enabling studies for DB-1418 and expect to advance this molecule into clinical stage in the first half of 2025. We plan to explore the potential of DB-1418 across various solid tumors, including ESCC, HNSCC, CRC, non-melanoma skin cancer, NSCLC, GC, pancreatic adenocarcinoma, nasopharyngeal cancer, bladder cancer, and BC.

DB-1418/AVZO-1418 MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED.

ADC Assets Developed from Novel MOA Payload Technology Platform

DUPAC — Unique Novel MOA payload ADC platform

We are building DUPAC to develop linker-payload complexes with novel mechanisms of action beyond traditional cytotoxic agents to combat growing drug resistance and hard-to-treat tumors. Notably, the anti-proliferation activity of our unique payload, P5142, was examined on various cancer type cells and compared with Dxd, a DNA topoisomerase I inhibitor. Cell viability was evaluated after five days' treatment using the CellTiter-Glo® Luminescent Cell Viability kit. Significantly superior potency of P5142 was observed in Dxd-insensitive (low-response) cancer cells BT-474, JIMT-1 and NCI-H660. Overall, the different susceptibility of cells to Dxd and P5142 is due to the distinct mechanism of action of these two payloads.



We have made promising progress in a number of unique payload mechanisms and have obtained prototypes with broad-spectrum anti-tumor activity across multiple solid tumors, and potent direct and bystander killing effects in preclinical studies. In particular, our in-house discovered lead prototype has a unique mechanism of action with demonstrated broad-spectrum anti-tumor activity across multiple solid tumors and remains potent in tumors resistant to deruxtecan. ADCs designed with our lead prototype have also shown potent direct and bystander killing effects and induce strong immunogenic cell death. DB-1316, for example, is a novel ADC asset derived from the DUPAC platform currently in preclinical stage positioned to target deruxtecan-resistant solid tumors. We aim to receive the first IND approval for an ADC candidate derived from our DUPAC platform as early as 2026.

OUR COLLABORATION AND LICENSING ARRANGEMENTS

We have entered into several out-licensing and collaboration deals with leading industry players worldwide to date, including BioNTech, BeiGene, Adcendo, GSK, and Avenzo, with over US$6.0 billion in total deal value (of which approximately US$400 million had been received as of the Latest Practicable Date). Each of BioNTech, BeiGene, Adcendo, GSK, and Avenzo is an Independent Third Party. Additionally, we have strategically in-licensed advanced antibody technologies to enhance our drug development efficiency, while complementing our in-house capabilities in antibody research and drug discovery.

We believe our collaboration strategy promotes the growth of a strong, interconnected ecosystem that benefits both ourselves and our upstream and downstream partners. Through collaboration with diverse stakeholders across the industry chain, we create synergies that not only drive innovation but also broaden market opportunities for all participants, laying a foundation for our long-term, sustainable growth.

License and Collaboration Agreement with BioNTech for DB-1303/BNT323

On March 16, 2023, we entered into a license and collaboration agreement with BioNTech SE (Nasdaq: BNTX, "**BioNTech**") (as may be amended from time to time, the "**DB-1303 License and Collaboration Agreement**"), where we granted to BioNTech an exclusive, royalty-bearing and sublicensable license under certain patents and know-how owned or otherwise controlled by us to develop, manufacture, commercialize or otherwise exploit DB-1303 and pharmaceutical products comprising DB-1303 (together "**DB-1303 Products**") for all uses worldwide except Mainland China, Hong Kong and Macau (the "**Territory**"). We retain the full rights to develop, manufacture, commercialize and otherwise exploit DB-1303 and DB-1303 Products in Mainland China, Hong Kong and Macau (collectively, the "**Retained Territory**").

We and BioNTech have established a joint steering committee ("**JSC**") comprised of an equal number of representatives from each party to oversee the development of DB-1303 Products in the Territory and facilitate information exchange under this agreement. As of the Latest Practicable Date, the JSC comprised six members, equally represented by three members each from our Company and BioNTech. The JSC will endeavor to make decisions by consensus, with the representatives of each party having, collectively, one vote. If the representatives on the JSC cannot reach an agreement, such disagreement shall be referred to the chief executive officers of both parties for resolution. If the chief executive officers cannot resolve such matter, we shall generally have the final decision-making authority with respect to the development of DB-1303 and DB-1303 Products in the Retained Territory, while BioNTech shall generally have the final decision-making authority with respect to the development of DB-1303 Products in the Territory. Furthermore, BioNTech shall be entitled to make final decisions with respect to global trials in which patients in both the Territory and the Retained Territory are enrolled (with our prior written consent for enrollment in the Retained Territory) and are solely sponsored by BioNTech, provided that if such decision would increase our financial or operational obligations in a manner not contemplated under the Development

Plan (as defined below) or development budget, our prior written consent shall be required. In respect of global trials in which patients in the Retained Territory are enrolled (with our prior written consent), we are entitled to make final decisions in the Retained Territory, provided that BioNTech's prior written consent shall be required. For clarity, BioNTech shall not conduct any global trial in the Retained Territory without obtaining our prior written consent, and we have the right, in our sole discretion, to decide whether to participate in any additional global clinical trials in relation to DB-1303 Products where we contribute patients from the Retained Territory.

In the event a deadlock occurs with respect to the decision-making process of the JSC, such deadlock shall be subject to binding determination by an expert panel in Hong Kong. The expert panel shall consist of three members, one of which is appointed by each party and the third member shall be selected by the other two members (collectively, the "**Experts**"). Each Expert shall be a person having experience in the area of expertise in the business of pharmaceuticals and having no conflict of interest with either BioNTech or us. The decision of the Experts shall be final and binding on the applicable parties involved in such dispute and deadlock resolution procedure.

Pursuant to the DB-1303 License and Collaboration Agreement, we and BioNTech agreed to have a development plan ("**Development Plan**") which sets forth the scope, timeline and responsibilities of each party for DB-1303 and the DB-1303 Products in the Territory, which may be amended upon the approval of JSC. BioNTech shall be responsible, at its own expense, for the development of DB-1303 Products in the Territory under the oversight of JSC. To ensure that DB-1303's ongoing phase 1/2a global clinical trial (NCT05150691) ("**DB-1303 Ongoing Clinical Trial,**" including (i) a phase 1 clinical study, which had since been completed, and (ii) phase 2a dose expansion study) can be conducted without interruption, the parties have agreed that we will continue to be the sponsor of the DB-1303 Ongoing Clinical Trial in both the Territory and the Retained Territory. Except for the DB-1303 Ongoing Clinical Trial and other additional clinical trials for which BioNTech may designate us to be the sponsor, BioNTech shall be the sponsor and holder of all regulatory approvals for the DB-1303 Products in the Territory, and shall lead and control the preparation and submission of all regulatory filings related to DB-1303 and DB-1303 Products in the Territory at its sole cost and expense. Following the completion of the DB-1303 Ongoing Clinical Trial, we shall transfer and assign to BioNTech our right, title and interest in all regulatory approvals in the Territory with respect to DB-1303 and DB-1303 Products. For clarity, we shall be the sponsor of any clinical trial for DB-1303 Products conducted solely in the Retained Territory (unless otherwise agreed), and are responsible for the preparation and submission of any regulatory filings in the Retained Territory at our sole cost and expense. With respect to regulatory filings for the DB-1303 Ongoing Clinical Trial that are prepared by us, we shall submit all such regulatory filings to the JSC for its review and approval.

Each party grants to the other party a right of reference to regulatory filings related to DB-1303 and DB-1303 Products, for use in regulatory filings related to the DB-1303 and DB-1303 Products. The parties have agreed under the DB-1303 License and Collaboration Agreement and a separate data agreement for providing reasonably sufficient access to data relating to the DB-1303 and DB-1303 Products generated pursuant to activities conducted under the DB-1303 License and Collaboration Agreement, for regulatory approvals for DB-1303 and DB-1303 Products.

In partial consideration of our granting of the licenses and rights to BioNTech under the DB-1303 License and Collaboration Agreement, BioNTech has made a non-refundable upfront payment to us. In addition, BioNTech agreed to provide funding to and reimburse us for the reasonable costs and expenses incurred in the Territory in relation to us conducting the DB-1303 Ongoing Clinical Trial on behalf of BioNTech, subject to the applicable cap set out in the agreement. After the end of each calendar quarter, we shall submit to BioNTech an invoice setting forth the amount of actual costs incurred during such quarter by or on behalf of us performing development activities agreed under the DB-1303 License and Collaboration Agreement in the Territory, along with supporting documentation itemizing the breakdown of the costs and expenses that were incurred and are reimbursable hereunder. Upon BioNTech's request for us to conduct additional clinical studies of any DB-1303 Product, the parties shall, through the JSC, discuss BioNTech's funding and reimbursement of our costs and expenses incurred in connection with such studies in the Territory and, subject to mutual agreement, reflect these arrangements in the Development Plan. To date, we have received US$110.8 million in reimbursement from BioNTech. We are also eligible to receive payments upon the achievement of specified development, regulatory and commercial milestones, potentially up to an aggregate of US$857.5 million. Such milestones include: completion of the first phase II and phase III clinical trials in the Territory for each of the initial indications, securing marketing authorizations or approvals for a DB-1303 Product in the U.S. or other specified jurisdictions, first achievement of certain annual net sales thresholds of DB-1303 Products in the Territory, among other events. To date, milestone payments of US$21.0 million have been paid under this agreement. BioNTech further agreed to pay tiered royalties between high-single-digit to low-double-digit percentage on the annual net sales of all DB-1303 Products in the Territory (subject to certain royalty reduction adjustments) upon commercialization. Such royalties shall be payable, on a country-by-country and product-by-product basis, during the period beginning on the date of the first commercial sale of such DB-1303 Product in such country and continuing until the end of the royalty term of such DB-1303 Product in such country of sale.

Under the DB-1303 License and Collaboration Agreement, intellectual property generated, developed, conceived solely by one of the parties or jointly by us and BioNTech during the performance of this agreement shall be solely owned by one of the parties or jointly and equally owned by both parties depending on inventorship, subject matter and/or by which party it was funded. For the purpose of allocating IP ownership, inventorship shall be determined in accordance with patent law of the United States, irrespective of where such conception, discovery, development, or making occurs.

The DB-1303 License and Collaboration Agreement will continue, on a country-by-country and product-by-product basis, until the expiration of the respective royalty term for such DB-1303 Product in such country. Upon expiration (but not early termination) of the royalty term for a given DB-1303 Product in a given country, the license granted to BioNTech with respect to such product in such country will automatically convert into a fully paid up, royalty-free, perpetual, and irrevocable license (i.e., allowing permanent use of the license granted without further payments or risk of revocation). In general, either party may terminate this agreement in the event of the other party's uncured material breach or insolvency. BioNTech may also terminate the agreement without cause, in whole or in part, by giving us prior written notice.

In general, neither expiration nor any termination of the DB-1303 License and Collaboration Agreement shall relieve either party of any obligation or liability (including any payment obligations) accruing prior to such expiration or termination. If the DB-1303 License and Collaboration Agreement is terminated by BioNTech without cause, in whole or in part, the respective license granted by us will automatically terminate. If BioNTech is confirmed to be in uncured or non-curable material breach of the DB-1303 License and Collaboration Agreement, we may, in our sole discretion, (i) elect to continue the DB-1303 License and Collaboration Agreement, in which case the remaining development milestone payments by BioNTech under the DB-1303 License and Collaboration Agreement shall automatically increase by a certain percentage, or (ii) elect to terminate the DB-1303 License and Collaboration Agreement, in which case the respective license granted by us will automatically terminate. If we are confirmed to be in uncured or non-curable material breach of the DB-1303 License and Collaboration Agreement, BioNTech may (i) elect to continue the DB-1303 License and Collaboration Agreement, in which case the remaining payments by BioNTech under the DB-1303 License and Collaboration Agreement would be reduced by a certain percentage, or (ii) elect to terminate the DB-1303 License and Collaboration Agreement.

License and Collaboration Agreement with BioNTech for DB-1311/BNT324

On March 31, 2023, we entered into a license and collaboration agreement with BioNTech (as may be amended from time to time, the "**DB-1311 License and Collaboration Agreement**"), where we granted to BioNTech an exclusive, royalty-bearing and sublicensable license under certain patents and know-how owned or otherwise controlled by us to develop, manufacture, commercialize or otherwise exploit DB-1311 and pharmaceutical products comprising DB-1311 (together "**DB-1311 Products**") for all uses worldwide except Mainland China, Hong Kong and Macau (the "**Territory**"). We retain the full rights to develop, manufacture, commercialize and otherwise exploit DB-1311 and DB-1311 Products in Mainland China, Hong Kong and Macau (collectively, the "**Retained Territory**"). Under the same agreement, we also granted to BioNTech an exclusive, royalty-bearing and sublicensable license to exploit certain patents and know-how controlled by us for the development, manufacture and commercialization of non-ADC modalities containing the antibody sequences in DB-1311 in the Territory, which we in-licensed from WuXi Biologics Ireland Limited ("**WuXi Biologics**") pursuant to a license agreement we entered into with WuXi Biologics to use its B7H3 antibody for the development of DB-1311 and potentially other B7H3-directed drugs.

We and BioNTech have established a joint steering committee ("**JSC**") comprised of an equal number of representatives from each party to oversee the development, manufacture and regulatory activities of DB-1311 Products in the Territory and, if and after we exercise the DB-1311 Cost & Profit/Loss Sharing Option (as described below), the U.S. commercialization of DB-1311 Products, and to facilitate information exchange under this agreement. As of the Latest Practicable Date, the JSC comprised six members, equally represented by three members each from our Company and BioNTech. The JSC will endeavor to make decisions by consensus, with the representatives of each party having, collectively, one vote. If the representatives on the JSC cannot reach an agreement, such disagreement shall be referred to the chief executive officers of both parties for resolution. If the chief executive officers cannot resolve such matter, we shall generally have the final decision-making authority with respect to the development of DB-1311 and DB-1311 Products in the Retained Territory, while BioNTech shall generally have the final decision-making authority with respect to the development of DB-1311 Products in the Territory (including global trials where patients in both the Territory and the Retained Territory are enrolled (with our prior written consent for enrollment in the Retained Territory)).

In the event a deadlock occurs with respect to the decision-making process of the JSC, such deadlock shall be subject to binding determination by an expert panel in Hong Kong. The expert panel shall consist of three members, one of which is appointed by each party and the third member shall be selected by the other two members (collectively, the "**Experts**"). Each Expert shall be a person having experience in the area of expertise in the business of pharmaceuticals and having no conflict of interest with either BioNTech or us. The decision of the Experts shall be final and binding on the applicable parties involved in such dispute and deadlock resolution procedure.

Pursuant to the DB-1311 License and Collaboration Agreement, we and BioNTech agreed to have a development plan which sets forth the scope, timeline and responsibilities of each party for DB-1311 and the DB-1311 Products in the Territory, which may be amended upon the approval of JSC. BioNTech shall be responsible, at its own expense, for the development of DB-1311 Products in the Territory under the oversight of JSC. The parties have agreed that we will conduct all clinical trials for DB-1311, including those in the Territory, until the completion of the phase II study (being the phase 2a dose expansion study) of DB-1311's ongoing phase 1/2a trial (NCT05914116) (together, the "**DB-1311 Planned Trials**"), *provided* that if we conduct the DB-1311 Planned Trials in accordance with the DB-1311 License and Collaboration Agreement and the development plan, BioNTech shall reimburse us for the development costs of the DB-1311 Products in the Territory in accordance with the terms of the agreement. Except for the DB-1311 Planned Trials and other additional clinical trials for which BioNTech may designate us to be the sponsor, BioNTech shall be the sponsor and holder of all regulatory approvals for the DB-1311 Products in the Territory, and shall lead and control the preparation and submission of all regulatory filings related to DB-1311 and DB-1311 Products in the Territory at its sole cost and expense. Following the completion of a DB-1311 Planned Trial, we shall transfer and assign to BioNTech our right, title and interest in all regulatory approvals in the Territory with respect to DB-1311 and DB-1311 Products. For clarity, we shall be the sponsor of any clinical trial for DB-1311 Products conducted solely in

the Retained Territory (unless otherwise agreed), and are responsible for the preparation and submission of any regulatory filings in the Retained Territory at our sole cost and expense. With respect to regulatory filings for the DB-1311 Planned Trials that are prepared by us, we shall submit all such regulatory filings to the JSC for its review and approval.

Each party grants to the other party a right of reference to regulatory filings related to DB-1311 and DB-1311 Products, for use in regulatory filings related to the DB-1311 and DB-1311 Products. The parties have agreed under the DB-1311 License and Collaboration Agreement and a separate data agreement for providing reasonably sufficient access to data relating to the DB-1311 and DB-1311 Products generated pursuant to activities conducted under the DB-1311 License and Collaboration Agreement, for regulatory approvals for DB-1311 and DB-1311 Products.

Under the DB-1311 License and Collaboration Agreement, BioNTech has also granted us an exclusive option to share the development and commercialization costs and profits and losses from the exploitation of the first DB-1311 Product in the United States (the "**DB-1311 Cost & Profit/Loss Sharing Option**"), in accordance with the terms set out in the agreement. We are entitled to exercise this option at any time during a specified period following the completion of the first phase II clinical trial of the first DB-1311 Product (signified by the JSC's agreement to proceed into a phase III clinical trial). If we elect to exercise the DB-1311 Cost & Profit/Loss Sharing Option, we and BioNTech shall promptly engage in good faith negotiations and enter into a separate cost & profit/loss sharing agreement. As of the Latest Practicable Date, we had not exercised the DB-1311 Cost & Profit/Loss Sharing Option and retained the right to do so in the future.

BioNTech has paid us a non-refundable upfront payment and agreed to reimburse us for the reasonable costs and expenses incurred in the Territory in relation to us conducting the DB-1311 Planned Trials, to the extent they are explicitly set out in the development budget or approved in advance by the JSC. After the end of each calendar quarter, we shall submit to BioNTech an invoice setting forth the amount of actual costs incurred during such quarter by or on behalf of us performing development activities agreed under the DB-1311 License and Collaboration Agreement in the Territory, along with supporting documentation itemizing the breakdown of the costs and expenses that were incurred and are reimbursable hereunder. Upon BioNTech's request for us to conduct additional clinical studies of any DB-1311 Product, the parties shall, through the JSC, discuss BioNTech's funding and reimbursement of our costs and expenses incurred in connection with such studies in the Territory and, subject to mutual agreement, reflect these arrangements in the development plan. To date, we have received US$33.6 million in reimbursement from BioNTech. We are also eligible to receive payments upon the achievement of specified development, regulatory and commercial milestones, potentially up to an aggregate of US$901.0 million, subject to adjustments in the event the DB-1311 Cost & Profit/Loss Sharing Option is exercised. Such milestones include: dosing of patients in the first phase I and phase II clinical trials in the Territory for each of the initial indications, securing marketing authorizations or approvals for a DB-1311 Product in the U.S. or other specified jurisdictions, first achievement of certain annual net sales thresholds of DB-1311 Products in the Territory, among other events. To date, milestone payments of

US$24.0 million have been paid under this agreement. BioNTech further agreed to pay tiered royalties between high-single-digit to low-double-digit percentage on the annual net sales of all DB-1311 Products in the Territory (subject to certain royalty reduction adjustments and adjustments in the event the DB-1311 Cost & Profit/Loss Sharing Option is exercised). Such royalties shall be payable, on a country-by-country and product-by-product basis, during the period beginning on the date of the first commercial sale of such DB-1311 Product in such country and continuing until the end of the royalty term of such DB-1311 Product in such country of sale.

Under the DB-1311 License and Collaboration Agreement, intellectual property generated, developed, conceived solely by one of the parties or jointly by us and BioNTech during the performance of this agreement shall be solely owned by one of the parties or jointly and equally owned by both parties depending on inventorship, subject matter and/or by which party it was funded. For the purpose of allocating IP ownership, inventorship shall be determined in accordance with patent law of the United States, irrespective of where such conception, discovery, development, or making occurs.

The DB-1311 License and Collaboration Agreement will continue, on a country-by-country and product-by-product basis, until the expiration of the respective royalty term for such DB-1311 Product in such country. Upon expiration (but not early termination) of the royalty term for a given DB-1311 Product in a given country, the license granted to BioNTech with respect to such product in such country will automatically convert into a fully paid up, royalty-free, perpetual, and irrevocable license (i.e., allowing permanent use of the license granted without further payments or risk of revocation). In general, either party may terminate this agreement in the event of the other party's uncured material breach or insolvency. BioNTech may also terminate the agreement without cause, in whole or in part, by giving us prior written notice.

In general, neither expiration nor any termination of the DB-1311 License and Collaboration Agreement shall relieve either party of any obligation or liability (including any payment obligations) accruing prior to such expiration or termination. If the DB-1311 License and Collaboration Agreement is terminated by BioNTech without cause, in whole or in part, the respective license granted by us will automatically terminate. If BioNTech is confirmed to be in uncured or non-curable material breach of the DB-1311 License and Collaboration Agreement, we may, in our sole discretion, (i) elect to continue the DB-1311 License and Collaboration Agreement, in which case the remaining development milestone payments by BioNTech under the DB-1311 License and Collaboration Agreement shall automatically increase by a certain percentage, or (ii) elect to terminate the DB-1311 License and Collaboration Agreement, in which case the respective license granted by us will automatically terminate. If we are confirmed to be in uncured or non-curable material breach of the DB-1311 License and Collaboration Agreement, BioNTech may (i) elect to continue the DB-1311 License and Collaboration Agreement, in which case the remaining payments by BioNTech under the DB-1311 License and Collaboration Agreement would be reduced by a certain percentage, or (ii) elect to terminate the DB-1311 License and Collaboration Agreement.

License and Collaboration Agreement with BioNTech for DB-1305/BNT325

On August 4, 2023, we entered into a license and collaboration agreement with BioNTech (as may be amended from time to time, the "**DB-1305 License and Collaboration Agreement**"), where we granted to BioNTech an exclusive, royalty-bearing and sublicensable license under certain patents and know-how owned or otherwise controlled by us to develop, manufacture, commercialize or otherwise exploit DB-1305 and pharmaceutical products comprising DB-1305 (together "**DB-1305 Products**") for all uses worldwide except Mainland China, Hong Kong and Macau (the "**Territory**"). We retain the full rights to develop, manufacture, commercialize and otherwise exploit DB-1305 and DB-1305 Products in Mainland China, Hong Kong and Macau (collectively, the "**Retained Territory**").

We and BioNTech have established a joint steering committee ("**JSC**") comprised of an equal number of representatives from each party to oversee the development, manufacture and regulatory activities of DB-1305 Products in the Territory and facilitate information exchange under this agreement. As of the Latest Practicable Date, the JSC comprised six members, equally represented by three members each from our Company and BioNTech. The JSC will endeavor to make decisions by consensus, with the representatives of each party having, collectively, one vote. If the representatives on the JSC cannot reach an agreement, such disagreement shall be referred to the chief executive officers of both parties for resolution. If the chief executive officers cannot resolve such matter, we shall generally have the final decision-making authority with respect to the development of DB-1305 and DB-1305 Products in the Retained Territory, while BioNTech shall generally have the final decision-making authority with respect to the development of DB-1305 Products in the Territory (including global trials where patients in both the Territory and the Retained Territory are enrolled (with our prior written consent for enrollment in the Retained Territory)).

In the event a deadlock occurs with respect to the decision-making process of the JSC, such deadlock shall be subject to binding determination by an expert panel in Hong Kong. The expert panel shall consist of three members, one of which is appointed by each party and the third member shall be selected by the other two members (collectively, the "**Experts**"). Each Expert shall be a person having experience in the area of expertise in the business of pharmaceuticals and having no conflict of interest with either BioNTech or us. The decision of the Experts shall be final and binding on the applicable parties involved in such dispute and deadlock resolution procedure.

Pursuant to the DB-1305 License and Collaboration Agreement, we and BioNTech agreed to have a development plan which sets forth the scope, timeline and responsibilities of each party for DB-1305 and the DB-1305 Products in the Territory, which may be amended upon the approval of JSC. BioNTech shall be responsible, at its own expense, for the development of DB-1305 Products in the Territory under the oversight of JSC. The parties have agreed that we will conduct all clinical trials for DB-1305, including those in the Territory, until the completion of the phase II study (being the phase 2a dose expansion study) of DB-1305's ongoing phase 1/2a clinical trial (NCT05438329) (together, the "**DB-1305 Planned Trials**"), *provided* that if we conduct the DB-1305 Planned Trials in accordance with the DB-1305

License and Collaboration Agreement and the development plan, BioNTech shall reimburse us for the development costs of the DB-1305 Products in the Territory in accordance with the terms of the agreement. Except for the DB-1305 Planned Trials and other additional clinical trials for which BioNTech may designate us to be the sponsor, BioNTech shall be the sponsor and holder of all regulatory approvals for the DB-1305 Products in the Territory, and shall lead and control the preparation and submission of all regulatory filings related to DB-1305 and DB-1305 Products in the Territory at its sole cost and expense. Following the completion of a DB-1305 Planned Trial, we shall transfer and assign to BioNTech our right, title and interest in all regulatory approvals in the Territory with respect to DB-1305 and DB-1305 Products. For clarity, we shall be the sponsor of any clinical trial for DB-1305 Products conducted solely in the Retained Territory (unless otherwise agreed), and are responsible for the preparation and submission of any regulatory filings in the Retained Territory at our sole cost and expense. With respect to regulatory filings for the DB-1305 Planned Trials that are prepared by us, we shall submit all such regulatory filings to the JSC for its review and approval.

Each party grants to the other party a right of reference to regulatory filings related to DB-1305 and DB-1305 Products, for use in regulatory filings related to the DB-1305 and DB-1305 Products. The parties have agreed under the DB-1305 License and Collaboration Agreement and a separate data agreement for providing reasonably sufficient access to data relating to the DB-1305 and DB-1305 Products generated pursuant to activities conducted under the DB-1305 License and Collaboration Agreement, for regulatory approvals for DB-1305 and DB-1305 Products.

In partial consideration of our granting of the licenses and rights to BioNTech under the DB-1305 License and Collaboration Agreement, BioNTech has made a non-refundable upfront payment to us. In addition, BioNTech agreed to reimburse us for the reasonable costs and expenses incurred in the Territory in relation to us conducting the DB-1305 Planned Trials, to the extent they are explicitly set out in the development budget or approved in advance by the JSC. After the end of each calendar quarter, we shall submit to BioNTech an invoice setting forth the amount of actual costs incurred during such quarter by or on behalf of us performing development activities agreed under the DB-1305 License and Collaboration Agreement in the Territory, along with supporting documentation itemizing the breakdown of the costs and expenses that were incurred and are reimbursable hereunder. Upon BioNTech's request for us to conduct additional clinical studies of any DB-1305 Product, the parties shall, through the JSC, discuss BioNTech's funding and reimbursement of our costs and expenses incurred in connection with such studies in the Territory and, subject to mutual agreement, reflect these arrangements in the development plan. To date, we have received US$29.0 million in reimbursement from BioNTech. We are also eligible to receive payments upon the achievement of specified development, regulatory and commercial milestones, potentially up to an aggregate of US$826.0 million. Such milestones include: completion of the first phase II and registrational clinical trials in the Territory for each of the initial indications, securing marketing authorizations or approvals for a DB-1305 Product in the U.S. or other specified jurisdictions, first achievement of certain annual net sales thresholds of DB-1305 Products in the Territory, among other events. To date, no milestone payments have become due under this agreement. BioNTech further agreed to pay tiered royalties between high-single-digit to

low-double-digit percentage on the annual net sales of all DB-1305 Products in the Territory (subject to certain royalty reduction adjustments). Such royalties shall be payable, on a country-by-country and product-by-product basis, during the period beginning on the date of the first commercial sale of such DB-1305 Product in such country and continuing until the end of the royalty term of such DB-1305 Product in such country of sale.

Under the DB-1305 License and Collaboration Agreement, intellectual property generated, developed, conceived solely by one of the parties or jointly by us and BioNTech during the performance of this agreement shall be solely owned by one of the parties or jointly and equally owned by both parties depending on inventorship, subject matter and/or by which party it was funded. For the purpose of allocating IP ownership, inventorship shall be determined in accordance with patent law of the United States, irrespective of where such conception, discovery, development, or making occurs.

The DB-1305 License and Collaboration Agreement will continue, on a country-by-country and product-by-product basis, until the expiration of the respective royalty term for such DB-1305 Product in such country. Upon expiration (but not early termination) of the royalty term for a given DB-1305 Product in a given country, the license granted to BioNTech with respect to such product in such country will automatically convert into a fully paid up, royalty-free, perpetual, and irrevocable license (i.e., allowing permanent use of the license granted without further payments or risk of revocation). In general, either party may terminate this agreement in the event of the other party's uncured material breach or insolvency. BioNTech may also terminate the agreement without cause, in whole or in part, by giving us prior written notice.

In general, neither expiration nor any termination of the DB-1305 License and Collaboration Agreement shall relieve either party of any obligation or liability (including any payment obligations) accruing prior to such expiration or termination. If the DB-1305 License and Collaboration Agreement is terminated by BioNTech without cause, in whole or in part, the respective license granted by us will automatically terminate. If BioNTech is confirmed to be in uncured or non-curable material breach of the DB-1305 License and Collaboration Agreement, we may, in our sole discretion, (i) elect to continue the DB-1305 License and Collaboration Agreement, in which case the remaining development milestone payments by BioNTech under the DB-1305 License and Collaboration Agreement shall automatically increase by a certain percentage, or (ii) elect to terminate the DB-1305 License and Collaboration Agreement, in which case the respective license granted by us will automatically terminate. If we are confirmed to be in uncured or non-curable material breach of the DB-1305 License and Collaboration Agreement, BioNTech may (i) elect to continue the DB-1305 License and Collaboration Agreement, in which case the remaining payments by BioNTech under the DB-1305 License and Collaboration Agreement would be reduced by a certain percentage, or (ii) elect to terminate the DB-1305 License and Collaboration Agreement.

Out-license and Collaboration Agreement with BeiGene on DB-1312

On July 9, 2023, we entered into an exclusive option, license and collaboration agreement with BeiGene, Ltd. ("**BeiGene**") (HKEX: 6160) (the "**BeiGene Agreement**"), pursuant to which we granted to BeiGene an exclusive option to obtain a license for the development, manufacturing, commercialization and exploitation of DB-1312, our B7-H4-targeted ADC and all modifications, derivatives, mutations, and variants thereof that is a monospecific ADC against B7-H4 controlled by us (the "**DB-1312 Compound**"), or any biological or pharmaceutical product incorporating the DB-1312 Compound (the "**DB-1312 Product**"), for all uses in humans worldwide.

On February 18, 2024 (the "**BeiGene Option Exercise Date**"), BeiGene exercised this exclusive option, pursuant to which we granted to BeiGene (i) an exclusive, non-transferable, royalty-bearing license, with the right to grant sublicenses, of certain know-how and patent rights controlled by us (the "**DB-1312 Licensed IP**"), excluding patent rights specifically related to DB-1312's linker-payload, and (ii) a non-exclusive, non-transferable, royalty-bearing license, with the right to grant sublicenses, of patent rights specifically related to DB-1312's linker-payload (together, the "**BeiGene License**"), to develop, manufacture, commercialize and otherwise exploit any DB-1312 Compound or DB-1312 Product for all uses in humans worldwide.

Pursuant to the BeiGene Agreement, following the BeiGene Option Exercise Date, BeiGene shall be responsible, at its own costs and expenses, for all development activities with respect to the DB-1312 Compounds and DB-1312 Products as permitted under the BeiGene License. BeiGene shall be responsible, at its sole cost and expense, for the conduct of all regulatory activities with respect to the DB-1312 Compound(s) and any DB-1312 Products for all uses in humans worldwide.

We and BeiGene have established a Joint Steering Committee ("**BeiGene JSC**") to discuss the overall coordination and oversight of the activities under the BeiGene Agreement. As of the Latest Practicable Date, the JSC comprised eight members, equally represented by four members each from our Company and BeiGene. The BeiGene JSC will endeavor to make decisions by consensus, with each of BeiGene and us having one vote. If the BeiGene JSC cannot reach consensus, such matter shall be referred to the chief executive officer of both parties (or executive officers designated by the chief executive officers) for resolution. If the executive officers of each party are unable to resolve a matter referred to them in the event that the BeiGene JSC fails to reach a consensus, BeiGene shall generally have the final decision-making authority with respect to all exploitation activities related to the DB-1312 Products, subject to certain limitations.

In partial consideration of the BeiGene License, we have received an upfront payment of US$15.0 million from BeiGene and one-time payment of US$25.0 million after it exercised the option. We are eligible to receive payments totaling up to US$1,287.0 million upon the achievement of certain development, regulatory and commercialization milestones set forth for the applicable DB-1312 Product. Such milestones include: dosing of patients in the first phase

1, phase 2 and registrational trials for each of the initial indications, submission of BLA and receipt of BLA approvals for the first DB-1312 Product in the U.S., China and other specified jurisdictions for each of the initial indications, first achievement of certain annual net sales thresholds of the first DB-1312 Product worldwide, among other events. To date, milestone payments of US$5.0 million have been paid under this agreement. Upon commercialization, we are also eligible for tiered royalties of high-single-digit to low-double-digit percentage on the annual net sales of each DB-1312 Product, subject to certain adjustments. BeiGene's obligation to make royalty payments for each DB-1312 Product in each country shall commence on the date of first commercial sale of such DB-1312 Product in such country and continue until the end of the royalty term of such DB-1312 Product in such country. As we in-licensed DB-1312's B7-H4 antibody pursuant to an agreement we entered into with Harbour BioMed Suzhou Co., Ltd. (和鉑醫藥(蘇州)有限公司) (currently known as Nona Biosciences (Suzhou) Co., Ltd. (諾納生物(蘇州)有限公司)) ("**Harbour BioMed**") on January 18, 2022 (as amended on October 31, 2023, the "**Harbour BioMed Agreement**"), BeiGene acknowledges and agrees that the BeiGene License is subject to the terms and conditions of the Harbour BioMed Agreement.

BeiGene shall solely own all inventions conceived or first reduced to practice solely by or on behalf of BeiGene and we shall solely own all inventions conceived or first reduced to practice solely by or on behalf of us. Inventions conceived or first reduced to practice jointly by or on behalf of BeiGene and us shall be jointly owned, with each party having the right to freely practice and license any such jointly owned inventions without accounting to the other.

The BeiGene Agreement will remain in effect a country-by-country and product-by-product basis, until the expiration of the royalty term applicable to such DB-1312 Product in such country. BeiGene may terminate the BeiGene Agreement at any time in its entirety or on a product-by-product, country-by-country basis by providing prior written notice to us. We may terminate the BeiGene Agreement if BeiGene or its affiliates or sublicensees challenge the validity of the patent rights under the DB-1312 Licensed IP by providing prior written notice to BeiGene. In addition, either party may terminate the BeiGene Agreement if (i) the other party is in material breach and fails to remedy such breach, or (ii) the other party files for bankruptcy, faces an unresolved involuntary insolvency petition, or assigns most of its assets to creditors.

If the BeiGene Agreement is terminated, all rights and licenses granted by us to BeiGene pursuant to this agreement, including the BeiGene License and all other rights granted by us to BeiGene under the DB-1312 Licensed IP shall terminate. If BeiGene has the right to terminate this agreement due to our uncured material breach then, at BeiGene's option, it may elect (i) not to terminate this agreement, provided that our rights to receive and BeiGene's obligations to make royalty payments pursuant may be offset by the damages determined by arbitration, or (ii) to terminate this agreement.

Out-license and Collaboration Agreement with Adcendo on ADC Assets Utilizing Our Proprietary Payload-linkers

On December 23, 2022, we entered into an exclusive license agreement with Adcendo ApS, a Denmark-based biotech company focused on the development of breakthrough ADCs for the treatment of underserved cancers ("**Adcendo**") (as amended, the "**Adcendo Agreement**"), pursuant to which we granted to Adcendo an irrevocable (subject to the termination provisions therein), exclusive, royalty-bearing and sublicensable license under certain of our technologies, including payload-linkers derived from our proprietary DITAC platform, to develop, manufacture and commercialize Adcendo's uPARAP-ADC product (the "**Adcendo ADC Product**") worldwide.

Under the Adcendo Agreement, we shall have an exclusive option, by giving notice to Adcendo at any time during a three-month period following (i) the completion of a phase 2 clinical trial, or (ii) the completion of a phase 1 clinical trial demonstrating the proof-of-concept of the Adcendo ADC Product and the practical potential of such Adcendo ADC Product in late-stage clinical trials, to negotiate to acquire (i) an exclusive license from Adcendo to develop and commercialize the Adcendo ADC Product in Greater China and (ii) a non-exclusive license from Adcendo to manufacture the Adcendo ADC Product in Greater China ("**Adcendo Granted License**"). As consideration for Adcendo Granted License, if we decide to exercise this option, we agree to pay Adcendo an upfront payment and a milestone payment upon our receipt of the first regulatory approval from the NMPA for an Adcendo ADC Product in Greater China.

We and Adcendo have established a Joint Steering Committee ("**Adcendo JSC**") to discuss and oversee the activities under this agreement. The Adcendo JSC is composed of an equal number of representatives from Adcendo and us. The Adcendo JSC will use good faith efforts to promptly resolve any such matter for which it has authority. If consensus cannot be reached, such matter may be referred for resolution to the parties' chief executive officers. If the chief executive officers are unable to reach an agreement, Adcendo shall have the final decision-making authority provided that it has considered our position in good faith, and such decision-making authority shall not be used in such a manner that would be reasonably expected to materially increase the costs incurred by us, require us to violate any applicable law, or is reasonably likely to give rise to a safety concern with respect to such Adcendo ADC Product.

Subject to the terms of the Adcendo Agreement, Adcendo shall be responsible for developing and commercializing the Adcendo ADC Product at its own cost and expense. Adcendo shall be responsible for all regulatory activities and interaction with regulatory authorities for the Adcendo ADC Product and will notify us of any decision by any regulatory authorities. Adcendo will use commercially reasonable efforts to commercialize the Adcendo ADC Product in major markets, at its sole cost and expense, unless otherwise agreed between the parties. Upon written notice to us, Adcendo may change the antibody used in its Adcendo ADC Product, subject to certain conditions set out in the agreement.

In partial consideration of the Adcendo Agreement, we have received non-refundable upfront payments. In addition, we are entitled to milestone payments up to an aggregate of US$414.25 million upon the achievement of specified clinical, regulatory and sales milestone events of the Adcendo ADC Product. Such milestones include: initiation of certain clinical trials, IND clearance and regulatory approval in specified jurisdictions, and achievement of certain annual net sales thresholds, among other events. To date, milestone payment of US$3.3 million in total has been made under this agreement. Furthermore, Adcendo agrees to pay us tiered royalties of low-single-digit percentage on the annual net sales of the Adcendo ADC Product, subject to certain adjustments. Such royalties will be payable on a product-by-product and country-by-country basis until the end of the royalty term of such Adcendo ADC Product in such region.

Under the Adcendo Agreement, each party shall solely own all inventions made solely by its personnel. We and Adcendo shall jointly own all inventions made jointly by personnel of both parties, provided that, subject to the rights and licenses granted under and the restrictions set forth in the Adcendo Agreement, each party may practice and exploit any such jointly owned invention without the consent of the other party. Inventorship shall generally be determined in accordance with the rules of inventorship under U.S. patent law or other applicable law.

The Adcendo Agreement will remain in effect on a product-by-product and region-by-region basis until the expiration of the royalty term applicable to such Adcendo ADC Product and such region, unless terminated earlier in accordance with its terms. Adcendo has the right to terminate the Adcendo Agreement without cause upon prior written notice to us. In general, either party may terminate the agreement upon (i) the other party's uncured material breach of the agreement, or (ii) the other party's bankruptcy, insolvency or similar arrangements. Upon termination of the Adcendo Agreement, Adcendo shall remain liable to us for all its duties and obligations accrued prior to the termination, including all payments accrued for the achievement of any development milestone event or sales milestone event.

We have continued to broaden and expand our collaboration with Adcendo. On November 4, 2024, Adcendo entered into a new license agreement with us to develop ADC products directed to an additional target using our proprietary DITAC platform, with terms similar to the existing Adcendo Agreement.

Agreement with WuXi Biologics to In-license B7-H3 MAb

On May 26, 2022, we entered into a license agreement with WuXi Biologics Ireland Limited ("**WuXi Biologics**"), a limited company incorporated in Ireland and an indirect wholly owned subsidiary of WuXi Biologics (Cayman) Inc. (HKEX: 2269), which was amended, restated and superseded by a license agreement dated March 31, 2023 between the same parties (the "**WuXi Biologics Agreement**"). Pursuant to the WuXi Biologics Agreement, we obtained an exclusive (even as to WuXi Biologics and its affiliates), irrevocable (subject to the termination provisions therein), non-transferable, royalty-bearing and sublicensable license from Wuxi Biologics to research, develop, use, manufacture, commercialize or otherwise

exploit products ("**B7-H3 ADC Products**") that contain a B7-H3-targeted antibody validly covered by WuXi Biologics' certain patent rights ("**B7-H3 Antibody**") for all uses worldwide, including to generate ADCs ("**ADC Field**") and other biologics modalities (together, the "**WuXi Biologics License**"). As of the Latest Practicable Date, DB-1311, one of our Core Products and a B7-H3-targeted ADC, was the only B7-H3 ADC Product under the WuXi Biologics Agreement.

Under the WuXi Biologics Agreement, we shall have the sole authority to determine all regulatory plans and strategies for the B7-H3 Antibody and any B7-H3 ADC Product worldwide. We will also be responsible as the registered holder for preparing, seeking, filing, submitting and maintaining all regulatory approvals for the B7-H3 ADC Products worldwide at our own expense and shall have the sole responsibility for communicating with the regulatory authorities regarding any such regulatory approval relating to the B7-H3 ADC Products. For clarity, as the holder of all regulatory approvals for the B7-H3 ADC Products worldwide, we have the rights and authority to determine the commercialization strategy of such B7-H3 ADC Products, including DB-1311, subject to the license we have granted to BioNTech under the DB-1311 License and Collaboration Agreement, as defined and described under "— Our Collaboration and Licensing Arrangements — License and Collaboration Agreement with BioNTech for DB-1311/BNT324."

In partial consideration of the WuXi Biologics License, we have paid WuXi Biologics an upfront payment. WuXi Biologics also received a one-time payment of US$12.0 million as a sublicensing fee after we entered into the DB-1311 License and Collaboration Agreement. WuXi Biologics is eligible to potentially receive milestone payments totaling up to US$56.75 million for the use of B7-H3 Antibody in the ADC Field, and up to US$39.725 million for its use in each modality in other fields, if applicable. To date, we have paid a total of US$4.75 million in milestone payments, all of which were related to the development of DB-1311. Upon commercialization, WuXi Biologics is eligible to receive royalties at a low-single-digit percentage on the annual net sales of each B7-H3 ADC Product in the ADC Field and other fields on a product-by-product and region-by-region basis, subject to certain adjustments. The royalties shall be payable for a period from the first commercial sale of such B7-H3 ADC Product in such region until the later of (i) the last to expire of the valid claims in the licensed patent rights that cover the manufacture or commercialization of such B7-H3 ADC Product in such region, (ii) the period of regulatory exclusivity for such B7-H3 ADC Product in such region, and (iii) ten years commencing upon the first commercial sale of such B7-H3 ADC Product in such region.

Unless otherwise agreed between the parties, inventorship of all inventions made under the WuXi Biologics Agreement shall be determined in accordance with U.S. patent laws or other applicable laws. We will be the sole and exclusive owner of the intellectual rights of or claiming a B7-H3 ADC Product, any improvement to such B7-H3 ADC Product, and any intellectual property generated, developed, conceived or reduced to practice (constructively or actually) in connection with the performance under this agreement by or on behalf of us or our Affiliate, whether alone or jointly with WuXi Biologics or its affiliates ("**B7-H3 Product IP**"), unless otherwise agreed between the parties. We shall have the sole right to file patent

applications that claim a B7-H3 ADC Product or B7-H3 Product IP, and the sole right to control the preparation, filing, prosecution, maintenance and defense of such patents worldwide. Wuxi Biologics and its affiliates will remain the sole and exclusive owner of the intellectual property rights licensed to us.

The WuXi Biologics Agreement will remain in effect until the expiration of the royalty term on a product-by-product and region-by-region basis. Upon expiration of this agreement, we shall retain the WuXi Biologics License granted to us, and such license will convert into, non-exclusive, irrevocable, perpetual, fully-paid-up WuXi Biologics License. Before the expiration of the royalty term, the WuXi Biologics Agreement may generally be terminated if (i) either party reasonably believes the other party is in material breach and fails to remedy such breach, or (ii) either party enters into liquidation, dissolution, bankruptcy, or similar insolvency proceedings. WuXi Biologics shall have the right to terminate this agreement upon prior written notice to us, if we indirectly or directly initiate or assist a challenge to the any of the patents licensed to us. We may terminate this agreement upon prior written notice to WuXi Biologics, on a region-by-region and product-by-product basis, (i) if WuXi Biologics grants the licenses to any third party in violation of the WuXi Biologics Agreement, (ii) if a regulatory authority in a region has ordered us to stop all development, manufacturing or commercialization of a B7-H3 ADC Product in such region, or (iii) if in our reasonable opinion there is a safety, patient tolerability or efficacy concern, or the profile or the commercial viability of B7-H3 ADC Product does not justify continued development, manufacturing or commercialization by us.

Agreement with Harbour BioMed to In-license B7-H4 mAb

On January 18, 2022, we entered into a license agreement with Harbour BioMed Suzhou Co., Ltd. (和鉑醫藥(蘇州)有限公司) (currently known as Nona Biosciences (Suzhou) Co., Ltd. (諾納生物(蘇州)有限公司)) ("**Harbour BioMed**"), a company established in the PRC and an indirect wholly owned subsidiary of HBM Holdings Limited (HKEX: 2142) (as amended on October 31, 2023, the "**Harbour BioMed Agreement**"). Pursuant to the Harbour BioMed Agreement, we obtained an exclusive (even as to Harbour BioMed), royalty-bearing and sublicensable license from Harbour BioMed to use an H2L2 antibody developed by Harbour BioMed that targets B7-H4 ("**B7-H4 Antibody**") to research, develop, manufacture and commercialize any ADCs containing such B7-H4 Antibody ("**B7-H4 ADC Products**") worldwide (together, the "**Harbour BioMed License**"). As of the Latest Practicable Date, DB-1312, a B7-H4-targeted ADC we out-licensed to BeiGene in 2023, was the only B7-H4 ADC Product under the Harbour BioMed Agreement. See also "— Our Collaboration and Licensing Arrangements — Out-license and Collaboration Agreement with BeiGene on DB-1312/BNT323."

In partial consideration of the Harbour BioMed License, we have paid Harbour BioMed an upfront payment of US$2.0 million. Harbour BioMed also shared a single-digit percentage of the upfront payment we received pursuant to the BeiGene Collaboration Agreement (as defined above) for DB-1312. Harbour BioMed is eligible to potentially receive milestone payments totaling up to US$214.7 million for the development and commercialization of each

B7-H4 ADC Product. To date, we have paid a total of US$2.3 million for the milestones achieved by the development of DB-1312. Furthermore, Harbour BioMed is eligible to receive royalties at a low- to mid-single-digit percentage on the annual net sales of the B7-H4 ADC Products. The royalties shall be payable on a region-by-region basis from the first commercial sale of such B7-H4 ADC Product in such region until the later of (i) the last to expire of the valid patent claims under the licensed intellectual property covering the B7-H4 ADC Product in such region, (ii) the expiration of market exclusivity for the B7-H4 ADC Product in such region, and (iii) 15 years commencing upon the first commercial sale of the B7-H4 ADC Product in such region ("**Harbour BioMed Royalty Term**").

We shall be the sole owner of the intellectual rights generated in the process of our development, manufacturing and commercialization of B7-H4 ADC Product, including any of our improvements to the B7-H4 Antibody for the purpose of developing the B7-H4 ADC Product.

The Harbour BioMed Agreement will remain in effect until the expiration of the license term or completion of performance of both parties. Before the expiration of the term, the B7-H4 Agreement may generally be terminated if (i) mutually agreed by both parties, (ii) either party is in material breach of the Harbour BioMed Agreement and fails to remedy such breach, (iii) either party enters into liquidation, dissolution, bankruptcy, or similar insolvency proceedings, or (iv) we decide to terminate the development of the B7-H4 ADC Product upon written notice to the Harbour BioMed.

Agreement with Beijing Sinotau to In-license HER3 Antibodies

On November 29, 2021, we entered into a technology licensing and collaboration agreement with Beijing Sinotau International Pharmaceutical Technology Co., Ltd. (北京先通國際醫藥科技股份有限公司) ("**Beijing Sinotau**") to in-license certain patents and know-how owned or controlled by Beijing Sinotau relating to its in-house developed HER3 mAb ("**HER3 MAb Licensed IP**") (as further amended on March 18, 2024, the "**Sinotau Mab Agreement**"). On March 18, 2024, we entered into another technology licensing and collaboration agreement with Beijing Sinotau to in-license certain patents and know-how owned or controlled by Beijing Sinotau relating to its in-house developed HER3 bispecific and multi-specific antibodies (together with the HER3 MAb Licensed IP, the "**HER3 Antibody Licensed IP**") (the "**Sinotau BsAb and MsAb Agreement**" and, together with the Sinotau Mab Agreement, the "**Sinotau Agreements**").

Pursuant to the Sinotau Agreements, we obtained an exclusive (even as to Beijing Sinotau), royalty-bearing, irrevocable and sublicensable license from Beijing Sinotau to use the HER3 Antibody Licensed IP to develop, manufacture, commercialize and otherwise exploit ADC compounds (the "**HER3 ADC Compounds**") and pharmaceutical products containing any HER3 ADC Compound in any form, formulation or dosage form (the "**HER3 ADC Products**" which, for clarity, comprise HER3-monospecific, bispecific and multi-specific ADC

products) globally in all uses (the "**Sinotau Licenses**"). As of the Latest Practicable Date, DB-1310, our HER3 ADC, and DB-1418, our EGFRxHER3 bispecific ADC, were the only two HER3 ADC Products under the Sinotau Agreements.

We shall bear all development and commercialization-related expenses for the HER3 ADC Products and are responsible for the preparation and submission of the requisite regulatory filings, to the extent such activities are within the scope of the Sinotau Licenses. Beijing Sinotau shall use commercially reasonable efforts to provide necessary assistance in the process. We and Beijing Sinotau have established a Joint Steering Committee ("**Sinotau JSC**"), composed of three representatives from each of Sinotau and us, to discuss the overall coordination and oversight of the activities under the Sinotau Agreements. The Sinotau JSC will endeavor to make decisions by consensus. If consensus is not reached by the Sinotau JSC, senior executives from both parties shall engage in consultation and decision-making. If consensus still cannot be reached through good-faith negotiation, we shall have the final decision-making authority with respect to the R&D, clinical studies, manufacturing, and commercialization of HER3 ADC Compounds and HER3 ADC Products developed under the Sinotau licenses. Both parties have the right to be informed of the final decisions regarding any disagreements.

Pursuant to the Sinotau Mab Agreement, we have made an upfront payment of US$1.25 million, and are required to pay, for each HER3 ADC Product developed under this agreement, (i) up to US$9.0 million upon the achievement of specified development and regulatory milestones, and (ii) up to US$110.5 million upon the achievement of sales-based milestones. Pursuant to the Sinotau BsAb and MsAb Agreement, we have made an upfront payment of US$1.0 million. Beijing Sinotau may receive from us, for each HER3 ADC Product developed under this agreement, (i) up to US$5.86 million upon the achievement of specified development and regulatory milestones, and (ii) up to US$71.83 million upon the achievement of sales-based milestones. To date, we have paid a total of US$0.5 million for the milestones achieved by the development of DB-1310.

Upon commercialization, Beijing Sinotau is eligible to receive royalties at a percentage not exceeding 1% on the annual net sales of each HER3 ADC Product on a region-by-region basis. The royalties shall be payable for a period from the first commercial sale of HER3 ADC Product in such region until the later of (i) ten years commencing upon the first commercial sale of such HER3 ADC Product in such region, and (ii) the loss of valid patent protection of the HER3 Antibody Licensed IP covering the HER3 ADC Compound or HER3 ADC Product in such region.

We shall be the sole owner of all intellectual property rights independently developed by us in relation to (i) the HER3 ADC Compounds and HER3 ADC Products, and (ii) our ADC technology platforms, including our improvements performed within the scope of the Sinotau Licenses to the HER3 ADC Compounds, HER3 ADC Products, and the HER3 antibodies licensed to us. Beijing Sinotau retains ownership of the intellectual property rights independently developed by it outside the scope of the Sinotau Licenses in relation to the HER3 antibodies out-licensed to us, including improvements performed to such HER3

antibodies and the relevant products. Any improvements jointly made by us and Beijing Sinotau in relation to the HER3 ADC Compounds, HER3 ADC Products, and the HER3 antibodies licensed to us will be jointly owned by the parties.

The Sinotau Agreements will remain in effect until terminated in accordance therewith. Either of the Sinotau Agreements may generally be terminated earlier: (i) by mutual consent, (ii) if Beijing Sinotau is in material breach of such Sinotau Agreement and fails to remedy such breach, in which case we are entitled to either terminate such Sinotau Agreement or elect to retain the Sinotau Licenses by continuing to perform our contractual obligations, (iii) if we are in material breach of the Sinotau Agreements and fail to remedy such breach, in which case Beijing Sinotau shall have the right to terminate the Sinotau Agreements or convert the exclusive license to a non-exclusive license, (iv) if either party enters into liquidation, dissolution, bankruptcy, winding-up or similar insolvency proceedings, or (v) if we are in material default of our payment obligations.

Agreement with Dartsbio Pharmaceutical to In-license B7-H3xPD-L1 BsAb

On October 9, 2022, we entered into a technology licensing and collaboration agreement with Dartsbio Pharmaceutical (Guangdong) Co., Ltd. (達石藥業(廣東)有限公司) and its affiliates (collectively, "**Dartsbio Pharmaceutical**") to in-license certain patents and know-how owned by Dartsbio Pharmaceutical relating to certain of its in-house developed B7-H3xPD-L1 bsAbs ("**Dartsbio Licensed IP**") (as further amended on May 15, 2023, the "**Dartsbio Agreement**").

Pursuant to the Dartsbio Agreement, we obtained an exclusive (even as to Dartsbio Pharmaceutical), royalty-bearing, irrevocable, sub-licensable and transferable license to use the Dartsbio Licensed IP and certain of Dartsbio's B7-H3xPD-L1 bsAbs (the "**B7-H3xPD-L1 Licensed BsAbs**," including, where applicable, the amino acid sequence, cell lines and other related materials related to such bsAbs) to develop, manufacture and commercialize, using our ADC technology platform, ADC products (including any derivatives or improvements thereof, the "**B7-H3xPD-L1 ADC Products**") worldwide (the "**Dartsbio License**"). As of the Latest Practicable Date, DB-1419, our B7-H3xPD-L1 bispecific ADC, was the only B7-H3xPD-L1 ADC Products under the Dartsbio Agreement.

We shall bear all development and commercialization-related expenses for the B7-H3xPD-L1 ADC Products and are responsible for the preparation and submission of the requisite regulatory filings, to the extent such activities are within the scope of the Dartsbio License, unless otherwise agreed between the parties. Dartsbio Pharmaceutical shall use commercially reasonable efforts to provide necessary assistance in the process. We and Dartsbio Pharmaceutical have established a Joint Steering Committee ("**Dartsbio JSC**"), composed of three representatives from each of Dartsbio and us, to discuss the overall coordination and oversight of the activities under the Dartsbio Agreement. The Dartsbio JSC will endeavor to make decisions by consensus. If consensus is not reached by the Dartsbio JSC, senior executives from both parties shall engage in consultation and decision-making. If the senior executives are unable to reach a consensus, we shall have the final decision-making

authority on matters within the scope of the Dartsbio License. For matters outside the scope of the Dartsbio License or where Dartsbio Pharmaceutical retains rights that do not affect our rights and interests under the Dartsbio Agreement, Dartsbio Pharmaceutical shall have the final decision-making authority. Both parties have the right to be informed of the final decisions regarding any disagreements.

Pursuant to the Dartsbio Agreement, we have made an upfront payment of US$0.5 million and are required to pay technology transfer milestone payments of up to an aggregate of RMB9.0 million contingent on the progress of such transfer. Dartsbio Pharmaceutical may receive from us, for each B7-H3xPD-L1 ADC Product, (i) up to US$20.5 million upon the achievement of specified development and regulatory milestones, and (ii) up to US$15.0 million upon the achievement of sales-based milestones. To date, we have paid a total of US$1.0 million in milestone payments, all of which were related to the development of DB-1419. Upon commercialization, Dartsbio Pharmaceutical is eligible to receive tiered royalties at a percentage not exceeding 2% on the annual net sales of each B7-H3xPD-L1 ADC Product on a product-by-product and region-by-region basis. The royalties shall be payable for a period from the first commercial sale of such B7-H3xPD-L1 ADC Product in such region until the earliest of (i) the expiration of valid claims which may arise from the infringement due to the importation, manufacture, use, sale, or offer for sale of the B7-H3xPD-L1 Licensed BsAb in such region; (ii) the expiration of regulatory exclusivity for the B7-H3xPD-L1 Licensed BsAb in such region; or (iii) ten years following such first commercial sale of the B7-H3xPD-L1 ADC Product in such region.

We shall be the sole owner of all intellectual property rights generated in development, manufacture or commercialization of the B7-H3xPD-L1 ADC Products by us, including any improvements performed within the scope of the Dartsbio License to the B7-H3xPD-L1 Licensed BsAbs. Dartsbio Pharmaceutical retains ownership of the intellectual property rights independently developed by it in relation to the B7-H3xPD-L1 Licensed BsAbs. Dartsbio Pharmaceutical will also own improvements performed outside the scope of the Dartsbio License to the B7-H3xPD-L1 Licensed BsAbs and Dartsbio Licensed IP.

The Dartsbio License will remain in effect until the expiration of the license term, unless the Dartsbio Agreement is terminated earlier. The Dartsbio Agreement may generally be terminated: (i) by mutual consent, (ii) if either party is in material breach of the Dartsbio Agreement and fails to remedy such breach, (iii) if either party enters into liquidation, dissolution, bankruptcy, winding-up or similar insolvency proceedings, or (iv) if we are in material default of our payment obligations.

RESEARCH AND DEVELOPMENT

We conduct R&D activities primarily through our in-house R&D team. We also engage contract research organizations ("**CROs**") from time to time to support our preclinical research and clinical trials. In addition, we have established an array of strategic partnerships to accelerate the development of our pipeline across key global markets, expand our global clinical development capabilities, and fuel our future innovation and long-term growth. See "— Our Collaboration and Licensing Arrangements" for details.

In 2022, 2023 and for the nine months ended September 30, 2024, our costs and expenses in relation to R&D activities, which represented our cost of revenue and research and development expenses, were RMB339.9 million, RMB986.7 million and RMB1,404.4 million, respectively. In particular, costs and expenses in relation to R&D activities incurred for our Core Products were RMB137.0 million, RMB635.3 million and RMB878.9 million during the same periods, respectively, accounting for 40.3%, 64.4% and 62.6% of our total costs and expenses in relation to R&D activities for the corresponding periods. In 2022, 2023 and for the nine months ended September 30, 2024, our research and development expenses accounted for 91.4%, 89.9% and 82.6% of our total operating expenses (which equals the sum of research and development expenses and administrative expenses), respectively.

In-house R&D Team

As of September 30, 2024, our in-house R&D team consisted of 119 members across PRC and the U.S., over 80% of whom held a doctoral or master's degree, mainly in medical science, biology, pharmacology, and chemistry and other related fields. The average industry experience of our R&D team is over 12 years. We place a strong emphasis on academic qualifications, industry experience, and complementary expertise when building our R&D team, which has allowed us to assemble strong talent that can effectively leverage their accumulated expertise across all aspects of drug R&D.

Notably, our R&D leadership have extensive prior experience in ADC research and a demonstrated track record contributing to the advancement of this innovative drug modality. Our in-house R&D team is led by Dr. QIU Yang, our chief scientific officer, Ms. GU Wei, our chief medical officer, and Dr. HUA Haiqing, our senior vice president and head of drug discovery:

- Dr. QIU Yang drives the scientific direction of our pipeline programs, with over two decades of experience in drug discovery and translational medicine at MNCs. Prior to joining us, Dr. Qiu served as co-chair of the cross-functional ADC forum and senior director of translational medicine at Daiichi Sankyo, where she was a leading contributor to the development of innovative ADC therapy, most notably HER3-DXd (U3-1402, patritumab deruxtecan), which received FDA Breakthrough Therapy Designation in 2021. Before Daiichi Sankyo, Dr. Qiu held key positions as director and head of biomarker research at Janssen China Discovery Center and director leading the progress of early drug discovery at GSK R&D China. Throughout her

distinguished career, Dr. Qiu has demonstrated success in leading drug discovery, translational medicine, and early clinical development programs, contributing to the discovery and advancement of over 15 drug candidates into clinical trials and the approval of multiple innovative drugs. Dr. Qiu's understanding of the ADC landscape and track record are foundational to our continued success as we develop cutting-edge ADC technologies that transform patient care.

- Ms. GU Wei brings over ten years of expertise in clinical development across the globe, highlighted by her extensive experience leading numerous clinical studies. Ms. Gu has built a successful track record for clinical development at renowned MNCs, including Boehringer Ingelheim, AstraZeneca, and Bristol Myers Squibb, and her strategic oversight plays a key role in our efficient trial execution and alignment with regulatory standards. Earlier in her career, Ms. Gu had six years of physician experience at a top-grade hospital in China.

- Dr. HUA Haiqing leads our strategies for novel drug discovery and CMC development. Over the past 15 years, Dr. Hua has established a strong track record of leading the discovery of innovative drugs and advancing them into the clinic. Prior to joining us, Dr. Hua held senior positions at Hansoh Pharma and as a principal scientist at Lilly China R&D Center. Dr. Hua's extensive experience and leadership in drug discovery and CMC development contribute to the seamless integration of cutting-edge science with robust manufacturing processes, facilitating the efficient translation of our ADC research into transformative therapies.

Our in-house R&D team consists of several key functionalities, including drug research and clinical development. The following table sets forth the composition of our R&D team as of September 30, 2024:

R&D Centers	Number	% of total
Drug research	49	41.2%
China	44	37.0%
U.S.	5	4.2%
Clinical development	70	58.8%
China	58	48.7%
U.S.	12	10.1%
Total	**119**	**100.0%**

During the Track Record Period and up to the Latest Practicable Date, substantially all key R&D personnel involved in the research and development of our Core Products, DB-1303 and DB-1311, remained employed by us.

Industry-leading Scientific Advisory Board

We have built strong relationships with renowned industry experts. Regularly, we engage our scientific advisory board of distinguished scientists to advise on our research strategy and clinical development plan. Our scientific advisory board is led by Dr. Antoine Yver and Dr. Pasi A. Jänne, two leading minds in ADC drug development in the world:

- ***Dr. Antoine Yver*** is the chairman of our scientific board. Dr. Yver is a world-leading scientist in ADC research and development with over 34 years of pharmaceutical experience. Dr. Yver formerly served as the executive vice president, global head of oncology R&D and chair of the cancer enterprise at Daiichi Sankyo from 2016 to 2021, where his strategic leadership transformed Daiichi Sankyo from a small molecule drug company to a world-class oncology company. Dr. Yver was the vision leader for Daiichi Sankyo's ADC pipeline and led the successful accelerated and practice-changing development of Enhertu® (trastuzumab deruxtecan). He previously had been a senior vice president and head of oncology global medicines development at AstraZeneca, where he led equally successful development and approvals of TAGRISSO® and LYNPARZA®. In addition, he held various clinical development roles at Johnson & Johnson, Schering-Plough, Aventis Group and Rhone Poulenc Rorer. Dr. Yver is currently an independent director at Sanofi, a member of the scientific committee of Institut Gustave Roussy at Paris, France, as well as board member or special advisor to various companies.

- ***Dr. Pasi A. Jänne*** is a world-renowned medical oncologist and translational scientist. Dr. Jänne is currently a professor of medicine at Harvard Medical School, the senior vice president for translational medicine and a director of the Belfer Center for Applied Cancer Science, and an active thoracic medical oncologist within the Lowe Center for Thoracic Oncology, at the Dana-Farber Cancer Institute. As a leading PI of early clinical development, he has 25 years of experience in early clinical development and translational research for oncology drugs, with a particular focus on lung cancer. He has made seminal therapeutic discoveries, including as one of the inventors of patents on EGFR mutations. Dr. Jänne has also contributed instrumentally to the development of several innovative drugs, including HER3-DXd of Daiichi Sankyo, TAK-788 of Takeda Pharmaceutical, osimertinib of AstraZeneca, crizotinib of Pfizer, trastuzumab deruxtecan of Daiichi Sankyo and AstraZeneca and adagrasib of Mirati Therapeutics and Bristol Myers Squibb.

With the deep relationships we have built, Dr. Yver, Dr. Jänne and other members of our scientific advisory board have shared years of knowledge and insights that have been instrumental in our pipeline R&D, clinical development and global collaboration.

R&D Process

We have formulated a comprehensive in-house R&D system, which sets forth procedures governing key aspects of the drug development process. Key steps of the R&D process for our ADC candidates are set forth below.

- ***Target identification/validation and drug discovery.*** Before initiating an ADC candidate R&D project, we leveraged insights from our seasoned scientists to identify targets with high potential. For each identified target, we will conduct a comprehensive analysis to assess market size, patentability, competitive landscape, and potential risks, ensuring strategic alignment and high success potential. Our rigorous target validation includes assessment of scientific rationale, risk and safety considerations, commercial viability, and future clinical and regulatory plans.

  After target identification and validation, we will conduct a comprehensive drug discovery process including antibody discovery, ADC engineering, as well as evaluation of systemic stability, tumor-specific payload release, direct and bystander-killing effects, *in vivo* efficacy and safety.

- ***Preclinical research and translational medicine.*** During the preclinical stage, we assess PK, toxicity, pharmacology, and safety through *in vitro* and animal studies, making informed decisions about advancing candidates and setting key development milestones. Our translational medicine team bridges the gap between preclinical research and clinical application. Their interdisciplinary research encompasses a wide range of studies from drug metabolism and pharmacokinetics ("**DMPK**"), toxicology and biomarker development, to quantitative and clinical pharmacology. Our translational medicine team plays a key role in improving the success rates, time-efficiency and cost-effectiveness of our clinical trials.

  In addition, we have built an AI team to support our R&D efforts with a large language model-based, machine learning approach. We will continue to invest into our dedicated computational infrastructure with integrated AI capabilities, based upon iterative learning through both our "Duality Target Engine," that comprises comprehensive omics computational analysis and automatic literature review, and "Duality Knowledge Base and Retrieval-Augmented Generation Chatbot," that centralize internal data and knowledge repositories to further improve efficiency and accuracy of R&D. By utilizing powerful AI-driven tools and data-based support, we aim to systematically optimize every stage of our R&D, from target identification, ADC design and engineering to biomarker discovery, enabling us to finetune our engineering of next generation ADC candidates to prioritize high-potential targets and indications.

- ***Clinical development.*** During clinical trials, we maintain close communication with trial sites and principal investigators to ensure adherence to study protocols and good clinical practice ("**GCP**") guidelines. We select reputable principal investigators, clinical trial institutions and hospitals based on their quality, resources, expertise, and patient availability. Additionally, our regulatory affairs team oversees the registration strategy and submission processes required by regulatory authorities, maintaining continuous dialogue with regulatory authorities. We also maintain close communication with these authorities, including the NMPA and the FDA, so as to closely follow the regulatory requirements for IND and NDA/BLA approvals.

- ***CMC and quality management.*** We have implemented comprehensive CMC testing protocols to ensure consistent quality across our ADC batches. These measures include monitoring the number of payloads attached to each antibody, checking the purity and stability of the payload, analyzing the antibody structure, and conducting various tests to verify the final product's physical appearance, chemical properties, and biological effectiveness under different storage conditions. See also "— Social, Health, Work Safety and Environmental Matters — Manufacturing and Quality Management."

Collaboration with CROs

In addition to our in-house R&D activities, we also collaborate with reputable CROs to manage, conduct, and support our preclinical research and clinical trials. The services they provide under our oversight include site management, patient recruitment, and pharmacovigilance for our clinical trials, as well as preclinical and clinical laboratory testing and other specialized tasks aligned with our needs. During the Track Record Period, we collaborated with over 200 CROs.

When selecting CRO partners, we consider a range of factors such as their professional qualifications, relevant research experience, service quality and efficiency, industry reputation, and pricing competitiveness. Depending on the specific services required, we enter into project-based service agreements with our CROs that outline the detailed scope of work, sample size, procedures, deliverables, timelines, and payment terms. Many CROs we collaborate with are among the leading and well-recognized players in the industry.

We maintain close supervision of our CRO partners to ensure their performance fully complies with our protocols and all applicable regulations. We hold regular meetings with CROs to keep track of project progress and execution details and conduct periodic audits on them. This rigorous oversight helps protect the integrity and authenticity of the data generated from our trials and studies.

We currently expect to continue in the engagement of our key existing CROs and do not expect delays from them within or outside China. To the best knowledge of our Directors, except for WuXi Biologics (Cayman) Inc., our CROs are independent of the Company. Wuxi Venture, a wholly-owned subsidiary of WuXi Biologics (Cayman) Inc. is one of our Shareholders. For details, see "History and Corporate Structure — Pre-[**REDACTED**] Investments — Information regarding the Pre-[**REDACTED**] Investors."

Key terms of our agreements that we typically enter into with our CROs are set forth below.

- ***Services.*** The CRO provides us with ancillary services in the course of our preclinical studies and clinical trials, such as implementing animal studies, providing clinical support, record keeping and report preparation.

- ***Term.*** The CRO is required to perform its services within the prescribed time limit set out in each work order, usually on a project basis.

- ***Payments.*** We are required to make payments to the CROs in accordance with a payment schedule agreed by the parties.

- ***Intellectual property rights.*** We generally own the intellectual property rights arising from the projects conducted by the CROs within the stipulated work scope.

R&D Facilities

Our R&D activities were primarily conducted in China and the U.S.. Our Suzhou facility serves as the core of our R&D activities, housing our key technology platforms and well-equipped research laboratory to support our drug discovery, preclinical, and clinical needs. In addition to this central R&D hub, we also conduct R&D activities across Shanghai, Beijing, and the U.S. The collective efforts across our multi-regional research infrastructure and operations are instrumental to the rapid, smooth and efficient execution of our drug development plans in China and globally.

MANUFACTURING

To date, our manufacturing activities are conducted through contract development and manufacturing organizations ("**CDMOs**") to support our drug development process. We currently outsource our manufacturing activities to industry recognized CDMOs in China. We intend to continue this practice in the near term and at the initial stage of commercialization, as we believe it is cost-effective and efficient to engage CDMOs for manufacturing activities and enables us to focus on, and allocate our resources to, the discovery and clinical development of our ADC candidates. We plan to continue to work together with our industry-leading CDMO partners to optimize our manufacturing process, technologies, and know-how to enhance product quality, improve cost efficiency, and shorten the time from bench to bedside. We have maintained a relationship with the majority of our six existing CDMOs for over three years.

When selecting CDMOs we take into account a number of factors, including manufacturing capacity, qualifications, geographic, track record, adherence to applicable regulations and standards, as well as compatibility with our R&D priorities. We conduct quality assurance audit programs to ensure monitor and evaluate the services of our CDMOs.

We enter into long-term master service agreements with our CDMO partners. We then place specific orders as our R&D activities progress. Key terms of our agreements that we typically enter into with our CDMOs are set forth below.

- **Services.** The CDMOs provide us with manufacturing services according to the types of deliverables, location, unit price, volume and requested delivery date specified by us.

- **Quality control and inspections.** We are entitled to conduct on-site audits and regular inspections to ensure compliance of our CDMOs with the relevant current good manufacturing practice ("**cGMP**") and regulatory requirements.

- **Payments.** We are required to make payments to the CDMOs in accordance with the payments schedule set forth in the agreement, which is typically linked to the stages of the manufacturing process and the deliverables we receive.

- **Intellectual property rights.** We own all intellectual property rights relating to our products arising from the outsourced manufacturing processes.

- **Remedies for non-conforming products.** Remedies for non-conforming products. We are entitled to remedies for products that fail to conform to our specifications. The CDMOs are required to replace the non-conforming products and compensate us for any direct losses due to the delay.

For risks relating to our relationship with CDMOs, see "Risk Factors — Risks Relating to Dependence on Third Parties — We may rely on third parties to manufacture our drug products for clinical development and commercial sales and to provide a stable and adequate supply of quality materials and products for our drug development and commercialization needs. Our business could be harmed if these third parties suffer substantial disruption to supply chain and production facilities, encounter problems in manufacturing or fail to deliver sufficient quantities of product or at acceptable quality or price levels" for details.

QUALITY MANAGEMENT

We maintain a comprehensive quality management system which is developed and continuously refined to meet the stringent regulations and guidelines in China, the U.S., and Europe. We closely monitor the evolving cGxP standards and regulatory changes in these key markets, updating our internal procedures accordingly. Our quality management procedures span all key stages of the ADC development process.

We carry out our R&D activities in compliance with detailed quality control and quality assurance procedures to comply with relevant regulatory requirements and our internal standards. We maintain documentation of our R&D activities to ensure proper records are maintained for regulatory submissions and audits. For the manufacturing process, we conduct rigorous qualification and selection of raw material suppliers and ensure raw materials are tested and verified before entering the manufacturing process. We regularly audit and inspect CDMOs to verify that their processes align with our quality requirements and regulatory standards. Furthermore, we provide trainings for our quality and research and development teams to keep them updated on the latest quality standards and regulatory requirements.

COMMERCIALIZATION

As of the Latest Practicable Date, we had not obtained marketing approval for any drug candidates, nor had we generated any revenue from product sales. Anticipating commercialization of our late-stage ADCs in the next few years, we plan to maximize the value of our drug candidates by selecting the optimal commercial model, including building our in-house commercialization capabilities, and/or collaboration with third parties such as distributors, CSOs, and licensing partners.

DB-1303, one of our Core Products, is projected to file for accelerated approval with the FDA as early as 2025 as a treatment for HER2-expressing EC. DB-1303 is the most clinically advanced HER2 ADC candidate globally that targets EC across HER2-expression levels, according to Frost & Sullivan, with potential for extension to other underserved cancer indications. We are also developing DB-1311, our other Core Product, which is currently one of the top three B7-H3 ADCs undergoing global MRCTs in terms of clinical development progress for advanced SCLC, according to Frost & Sullivan.

Partnership with 3SBio to Commercialize DB-1303 in the China Market

On January 10, 2025, we entered into a collaboration agreement with 3SBio Inc. (HKEX: 1530, "**3SBio**") through its subsidiaries (the "**3SBio Collaboration Agreement**"), pursuant to which we have appointed 3SBio as our strategic partner in Mainland China, Hong Kong, and Macau (the "**Territory**") to promote DB-1303 for certain indications. Such promotion generally encompasses activities directed at healthcare professionals and other promotional and sales channels for DB-1303 (which, for the avoidance of doubt, does not include the actual sales of drug products). 3SBio will also provide related commercialization services to support DB-1303's market access, medical affairs, channel management and other commercial activities in the Territory.

We retain all rights related to DB-1303 not expressly granted to 3SBio, including the exclusive rights to (i) conduct R&D, regulatory (including as Marketing Authorization Holder), and manufacturing activities for DB-1303 in the Territory, and promote DB-1303 outside the Territory; (ii) maintain responsibility for DB-1303's sales and distribution activities, except where 3SBio is authorized to provide assistance for channel management, distributor

recommendations, and other limited functions as specified in the 3SBio Collaboration Agreement; and (iii) perform safety monitoring and pharmacovigilance, provided that 3SBio's ability to carry out its responsibilities with respect to pharmacovigilance is not impeded.

We and 3SBio have established a joint steering committee ("**JSC**") comprised of three representatives from each party to oversee the strategic direction of DB-1303's commercialization activities and monitor the performance of the 3SBio Collaboration Agreement. JSC decisions shall generally require unanimous approval of both parties, with representatives from each party having one collective vote. If the JSC is unable to reach consensus, the matter will be escalated to both parties' chief executive officers or their authorized representatives for resolution. If an agreement still cannot be reached, we shall have final decision-making authority on: (i) DB-1303's branding strategies, as well as patient assistance and service programs, (ii) reviewing and approving 3SBio's proposed commercial channel strategies and its recommended distributors, and overall channel management within the Territory, (iii) initial product pricing, (iv) post-launch multi-center investigator-initiated clinical trials and real-world studies, (v) reviewing and approving promotional materials submitted by 3SBio, and (vi) all matters that fall within the authority of the Marketing Authorization Holder under the applicable laws and regulations.

3SBio agrees to use commercially reasonable efforts to promote DB-1303 and carry out its obligations under the 3SBio Collaboration Agreement, including: (i) developing detailed promotional plans for JSC approval, and executing JSC-approved promotional plans; (ii) consulting with us on channel management principles and processes, and recommending distributors for product channel management; (iii) implementing market access strategies and initiatives approved by the JSC or jointly developed by the parties (including participation in NRDL negotiations and volume-based procurement programs); (iv) jointly developing reasonable pricing strategies and annual sales targets through the JSC; and (v) providing support in pharmacovigilance and adverse event reporting.

In partial consideration of the 3SBio Collaboration Agreement, 3SBio has paid us a non-refundable upfront payment of US$25 million. We agree to pay 3SBio a service fee calculated as a tiered percentage of DB-1303's net sales in the Territory in exchange for the promotion and commercialization services they provide, subject to performance-based adjustments determined through a comprehensive KPI assessment framework evaluating, among other defined metrics, sales target achievement, hospital coverage expansion, and resource deployment. We are eligible to receive payments from 3SBio upon the achievement of specified development and regulatory milestones, potentially up to an aggregate of US$42.0 million, as well as potential sales-based milestone payments.

We have granted 3SBio the rights to use our designated trademarks and intellectual property rights related to DB-1303 within the Territory for the sole purpose of facilitating its performance of the 3SBio Collaboration Agreement, and such rights shall be non-transferable and non-sublicensable. Any intellectual property arising from the performance of the 3SBio

Collaboration Agreement by the parties that relates to DB-1303 shall be solely owned by us, regardless of how such intellectual property is conceived and developed, whether individually or jointly by either or both parties.

The initial term of the 3SBio Collaboration Agreement shall be 15 years, commencing from the date we deliver the first commercial batch of DB-1303 following its first marketing approval (including conditional approval) in Mainland China. The initial term may be extended for additional five-year period(s) upon mutual agreement. The 3SBio Collaboration Agreement may be terminated with immediate effect by mutual agreement. Additionally, either party may terminate the agreement upon the other party's uncured material breach or insolvency, or if the parties cannot reach a resolution upon a force majeure event, among other circumstances specified in the 3SBio Collaboration Agreement.

BUSINESS DEVELOPMENT

We have a dedicated business development team led by Mr. WANG Xin, our Head of Strategy and Business Development, who has over 20 years of expertise in healthcare research and cross-border corporate advisory roles. In our short operating history, we have entered into several out-licensing and collaboration deals with leading industry players worldwide to date, including BioNTech, BeiGene, Adcendo, GSK, and Avenzo, with over US$6.0 billion in total deal value (of which approximately US$400 million had been received as of the Latest Practicable Date). Additionally, we have strategically in-licensed advanced antibody technologies to enhance our drug development efficiency, while complementing our in-house capabilities in antibody research and drug discovery. While using in-licensed antibody components, we retain independence over the development of our novel ADC assets. Our in-licensing agreements are carefully structured to ensure we maintain ownership and control over our ADC assets and the intellectual property generated during drug development, including the ability to out-license the full drug candidate. For further details, see "— Our Collaboration and Licensing Arrangements."

We will continue to implement our hybrid model of external collaboration and internal development to maximize the clinical and commercial value of our programs. For details, see "— Our Business Strategies — Maximize clinical and commercial potential of our assets through value accretive partnerships."

INTELLECTUAL PROPERTY

We are committed to the development and protection of our intellectual properties. Our future success depends significantly on our ability to obtain and maintain robust patent coverage, as well as other forms of intellectual property and proprietary protections, for the key technologies, inventions, and know-how fundamental to our ADC pipeline and technology platforms. Equally important is our capacity to defend and enforce these patents, preserve the confidentiality of our trade secrets, and ensure our freedom to operate without infringing upon, misappropriating, or otherwise violating the valid and enforceable intellectual property rights held by third parties.

We have a global portfolio of patents to protect our drug candidates and technologies. As of the Latest Practicable Date, we owned (i) three issued patents in China, (ii) six issued patents in the U.S., (iii) two issued patents in other jurisdictions, and (iv) 158 patent applications, including 37 in China, eight in the U.S., 19 under the Patent Cooperation Treaty ("**PCT**"), ten in Europe, and 84 in other jurisdictions.

As of the Latest Practicable Date, with respect to our two Core Products, DB-1303 and DB-1311, we owned three issued patents in China and six issued patents in the U.S., one issued patent in other jurisdiction, and also had 38 patent applications (30 of which are owned by us and eight of which are in-licensed from our collaboration partners), including three in China, one in the U.S., two pending PCT patent applications, and 32 in other jurisdictions. These patents and patent applications owned or in-licensed by us cover material aspects of our Core Products.

The following table summarizes the details of the material granted patents and patent applications in connection with our Core Products and our technology platforms. For more details, please see "Appendix IV — Statutory and General Information — B. Further Information about Our Business — 2. Intellectual Property Rights — (ii) Patents."

Related product	Patent/patent application[1]	Category	Patent/patent application number	Jurisdiction	Patent holder/ applicant	Application date	Date of grant	Expiration date[2]
DB-1303	Anti-tumor Compound and Preparation Method and Application Thereof (一種抗腫瘤化合物及其製備方法和應用)	Invention patent	CN115925796B	PRC	Duality Suzhou	Sept. 29, 2021	May 31, 2024	Sept. 28, 2041
DB-1303	Anti-tumor Compound and Preparation Method and Use Thereof	Invention patent	US11685742B2	U.S.	Duality Suzhou	Sept. 29, 2021	Jun. 27, 2023	Sept. 28, 2041
DB-1311	Anti-tumor Compound and Preparation Method and Use Thereof	Invention patent	US11607459B1	U.S.	Duality Suzhou	Sept. 29, 2021	Mar. 21, 2023	Sept. 28, 2041
DB-1311	Anti-B7H3 Antibody-Drug Conjugates and Uses Thereof (抗B7H3抗體-藥物偶聯物及其用途)[3]	Invention patent	PCT/CN2023/098596	PCT	Duality Suzhou	Jun. 6, 2023	N/A	N/A
DITAC and DIBAC	Antitumor Compound, and Preparation Method Therefor and Use Thereof (一種抗腫瘤化合物及其製備方法和應用)[4]	Invention patent	PCT/CN2021/121721	PCT	Duality Suzhou	Sept. 29, 2021	N/A	N/A
DIMAC	Steroid Compound and Conjugate Thereof (一種甾體化合物及其綴合物)[5]	Invention patent	PCT/CN2022/114855	PCT	Duality Suzhou	Aug. 25, 2022	N/A	N/A

Notes:

(1) Each of these patents/patent applications protects, among others, the structures of the whole ADC molecules. Additionally, most of these patents/patent applications also protect the payload component of the relevant ADC candidates, preventing competitors from commercializing ADCs using payloads that are identical to or within the scope of the protected payloads. This comprehensive, multi-layered approach enhances the exclusivity and competitive positioning of our ADC portfolio.

(2) Patent expiration date does not include any applicable patent term extensions.

(3) PCT patent application which has the opportunity to enter national phases within specified deadline.

(4) PCT patent application which has entered national phases in various jurisdictions.

(5) We are applying for patent in relation to our DUPAC platform.

We conduct our business under the brand name of "Duality (映恩)." As of the Latest Practicable Date, we had (i) 41 registered trademarks in China, (ii) 20 trademark applications in China, and (iii) five trademark applications in other jurisdictions. We are also the registered owner of one domain name.

We have entered into license and collaboration arrangements with our business partners, through which we may grant access to our own intellectual property or gain access to the intellectual property of others. See "— Our Collaboration and Licensing Arrangements."

We have engaged IP counsel to oversee comprehensive planning and development of our intellectual property portfolio, with the objective of mitigating IP-related risks. Furthermore, our employment contracts contain specific intellectual property provisions prohibiting employees from infringing third-party intellectual property rights, including those of their former employers.

During the Track Record Period and up to the Latest Practicable Date, neither our Company nor, to the best knowledge of our Directors, our R&D personnel had been involved in any proceedings in respect of any claims of infringement of any intellectual property rights which may have a material adverse effect on our business, financial condition and results of operations. See also "Risk Factors — Risks Relating to Intellectual Property Rights — We may from time to time be involved in legal proceedings and disputes to protect or enforce our intellectual property rights, or defend against infringement and other claims alleged by third parties, which could be expensive, time consuming and unsuccessful."

In June 2024, we engaged JunHe LLP to conduct certain freedom-to-operate searches and analyses ("**FTO Analysis**") in China and the U.S. in relation to our Core Products, namely DB-1303 and DB-1311. Our Directors confirm that no substantial risk of infringement had been identified from the FTO Analysis in relation to the constructs, amino acid sequences, chemical structures or indications currently under development of our Core Products.

SUPPLIERS AND PROCUREMENT

During the Track Record Period, our major suppliers primarily included (i) CROs and CDMOs, (ii) licensing partners, and (iii) equipment and device suppliers and renovation/construction service providers for our R&D facilities and offices. We have maintained stable business relationships with our major suppliers. During the Track Record Period, we did not experience any material disputes with our suppliers, difficulties in the procurement of raw materials or services, disruptions to our operations due to a shortage of or delay in supply of raw materials or services, or significant fluctuations in raw material and/or service prices.

For the years ended December 31, 2022 and 2023 and the nine months ended September 30, 2024, our purchases from our five largest suppliers in each year/period in aggregate accounted for 51.5%, 42.0% and 62.0% of our total purchases for the respective year/period, respectively. Our purchases from our largest supplier in each year/period accounted for 18.8%, 12.5% and 20.8% of our total purchases for the respective year/period, respectively. The following table summarizes information about our five largest suppliers and our purchases from them during each year/period of the Track Record Period.

Ranking	Supplier	Background	Purchase amount	% of total purchase	Credit Term	Commencement of business relationships
			RMB'000	%		
	For the nine months ended September 30, 2024					
1	Supplier A	A leading China-based CRO with global presence and a listed company on the Stock Exchange	253,306	20.8	10 or 30 days	2021
2	Supplier B	A leading China-based CRO with global presence and a listed company on the Stock Exchange	240,877	19.7	60 days	2021
3	Supplier C	A leading U.S.-based CRO with global presence and a listed company on the New York Stock Exchange	96,514	7.9	45 days	2023
4	Supplier D	A leading China-based CRO with global presence	89,988	7.4	21 or 60 days	2020
5	Supplier E	A leading U.S.-based CRO with global presence	75,070	6.2	30 days	2022
Total			**755,755**	**62.0**		

Ranking	Supplier	Background	Purchase amount	% of total purchase	Credit Term	Commencement of business relationships
			RMB'000	*%*		
	For the year ended December 31, 2023					
1	Supplier A	A leading China-based CRO with global presence and a listed company on the Stock Exchange	139,499	12.5	10 or 30 days	2021
2	Supplier B	A leading China-based CRO with global presence and a listed company on the Stock Exchange	129,463	11.6	60 days	2021
3	Supplier F	A leading China-based CRO with global presence and a listed company on the Shanghai Stock Exchange	74,798	6.7	30 days	2020
4	Supplier C	A leading U.S.-based CRO with global presence and a listed company on the New York Stock Exchange	71,685	6.4	45 days	2023
5	Supplier D	A prominent China-based CRO with global presence	53,643	4.8	21 or 60 days	2020
Total			**469,088**	**42.0**		

Ranking	Supplier	Background	Purchase amount	% of total purchase	Credit Term	Commencement of business relationships
			RMB'000	*%*		
	For the year ended December 31, 2022					
1	Supplier A	A leading China-based CRO with global presence and a listed company on the Stock Exchange	72,141	18.8	10 or 30 days	2021
2	Supplier G	A leading China-based CRO with global presence and a listed company on the Stock Exchange	63,434	16.5	30 days	2020
3	Supplier B	A leading China-based CRO with global presence and a listed company on the Stock Exchange	22,786	5.9	60 days	2021
4	Supplier F	A leading China-based CRO with global presence and a listed company on the Shanghai Stock Exchange	21,691	5.6	30 days	2020
5	Supplier H	A prominent China-based CRO with global presence	18,186	4.7	14 days	2021
Total			**198,238**	**51.5**		

To monitor the quality of supplies, we implement a standardized operating system, setting out the procedures and guidelines for quality control inspection. This includes rigorous supplier qualification and selection based on stringent quality standards, detailed material specifications, and standards that outline required characteristics.

To the best knowledge of our Directors, none of our Directors, their respective associates or any of our Shareholders holding more than 5% of our issued share capital immediately following the completion of the [**REDACTED**] had an interest in any of our five largest suppliers during the Track Record Period.

CUSTOMERS

During the Track Record Period, our revenue was primarily derived from our license and collaboration agreements with our business partners. For further details, please refer to "Financial Information — Description of Certain Consolidated Statements of Comprehensive Loss Items — Revenue." For the years ended December 31, 2022 and 2023 and the nine months ended September 30, 2024, our revenue generated from our largest customer in each year/period accounted for 84.8%, 98.9% and 77.8% of our total revenue for the respective year/period. The following table summarizes information about all our largest customers and our revenue from them during each year/period of the Track Record Period.

Ranking	Customer	Revenue amount	% of total revenue	Commencement of business relationships	Products/ services purchased	Background
		RMB'000	%			
	For the nine months ended September 30, 2024					
1	BioNTech	1,137,266	77.8	2023	ADC candidate out-license	Biopharmaceutical company
2	Customer A	320,744	21.9	2023	ADC candidate out-license	A China-based biopharmaceutical company and a listed company on the Stock Exchange
3	Customer B	3,883	0.3	2022	ADC candidate out-license	A Europe-based biopharmaceutical company
4	Customer C	111	0.0	2024	Plasma stability study	A Europe-based biopharmaceutical company
Total		**1,462,004**	**100.0**			

Ranking	Customer	Revenue amount	% of total revenue	Commencement of business relationships	Products/ services purchased	Background
		RMB'000	*%*			
	For the year ended December 31, 2023					
1	BioNTech	1,766,133	98.9	2023	ADC candidate out-license	Biopharmaceutical company
2	Customer B	19,897	1.1	2022	ADC technology out-license	A Europe-based biopharmaceutical company
3	Customer D	283	0.0	2022	Pre-agreement biological materials provision	A China-based biopharmaceutical company
4	Customer E	227	0.0	2022	Pre-agreement biological materials provision	A Europe-based biopharmaceutical company
Total		**1,786,540**	**100.0**			

Ranking	Customer	Revenue amount	% of total revenue	Commencement of business relationships	Products/ services purchased	Background
		RMB'000	%			
	For the year ended December 31, 2022					
1	Customer B	1,356	84.8	2022	ADC candidate out-license	A Europe-based biopharmaceutical company
2	Customer F	159	9.9	2022	Pre-agreement biological materials provision	A China-based biopharmaceutical company
3	Customer G	85	5.3	2022	Pre-agreement biological materials provision	A China-based biopharmaceutical company and a listed company on the Stock Exchange
Total		**1,600**	**100.0**			

To the best knowledge of our Directors, none of our Directors, their respective associates or any of our Shareholders holding more than 5% of our issued share capital immediately following the completion of the [**REDACTED**] had an interest in any of our customers during the Track Record Period.

COMPETITION

The ADC industry is competitive and subject to rapid and significant change. While we believe the strength of our pipeline, technology platforms and R&D capability gives us competitive advantages, we face potential competition from many industry players, including MNCs and leading biotechnology companies, who have commercialized, or are pursuing the development of, ADC drugs that are similar to ours or target the same indications. Any ADC candidates that we successfully develop and commercialize will compete both with approved drugs and with any new drugs that may become available in the future. Our competitors may have substantially greater financial, technical, and other resources than we do, such as those with larger research and development staff and established marketing and manufacturing infrastructure. Collaborations, mergers and acquisitions in the biopharmaceutical industry may result in even more resources being concentrated in our competitors. As a result, these companies may be able to advance their drug candidates and obtain regulatory approval from the regulatory authorities more rapidly than we do, and become more effective in selling and marketing their products. For further details on market opportunities and competition in respect of our ADC candidates, see "— Our Pipeline" and "Industry Overview."

EMPLOYEES

As of September 30, 2024, we had 155 employees, a majority of whom were based in China. The following table sets forth the number of our employees by function as of the same date.

Function	Number of Employees	% of total
Research and development	119	76.8%
Administrative	15	9.7%
Management	12	7.7%
Manufacturing and quality control	4	2.6%
Business development	5	3.2%
Total	**155**	**100.0%**

The following table sets forth the number of our employees by location as of the same date.

Location	Number of Employees	% of total
China	134	86.5%
U.S.	21	13.5%
Total	**155**	**100.0%**

We recruit our employees primarily through online platforms, recruiting websites and headhunter referral. We conduct induction programs and periodic professional training for our employees.

We enter into individual employment contracts with our employees covering matters such as salaries, bonuses, employee benefits, confidentiality obligations, non-competition clauses, work product and intellectual property assignment clause and grounds for termination. The remuneration package of our employees includes salary and bonus, which are generally determined by their qualifications, performance review, and seniority. We also offer share incentives and promotion opportunities to motivate our employees.

We have not established a labor union. During the Track Record Period and up to the Latest Practicable Date, we did not experience any labor disputes or strikes that may have a material and adverse effect on our business, financial condition or results of operations.

INSURANCE

We maintain insurance policies that are required under PRC laws and regulations as well as based on our assessment of our operational needs and industry practice. Our existing insurance policies cover adverse events ("**AEs**") in our clinical trials, as well as supplementary commercial insurance plans for our employees. In line with industry practice in the PRC, we have elected not to maintain certain types of insurances, such as business interruption insurance or key man insurance. We believe our existing insurance coverage is adequate for our present operations and in line with the industry practice in the PRC. See also "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."

SOCIAL, HEALTH, WORK SAFETY AND ENVIRONMENTAL MATTERS

We believe our long-term success rests on our ability to make a positive impact on the society. As we continue to bring innovative and effective ADC drugs to patients in China and worldwide, we strive to build a sustainable ecosystem comprised of our employees, collaborators and business partners, physicians, and patient groups.

We are subject to various health, work safety and environmental laws and regulations and our operations are regularly inspected by local government authorities. During the Track Record Period and up to the Latest Practicable Date, we had been in compliance with health, work safety and environmental laws and regulations applicable to our operations in all material respects and had not been subject to any material claims, fines or other penalties due to non-compliance with health, work safety or environmental regulations that would materially and adversely affect our business, financial condition or results of operations.

Governance on ESG Matters

We have built a series of policies and procedures to contribute to social, health, work safety and environmental matters. Going forward, it is our objective to proactively identify and assess the actual and potential environmental, social and governance ("**ESG**") risks that may impact our business, strategy and financial performance, and integrate considerations of ESG issues into our business, strategic and financial planning, in compliance with the recommendations made by the Environmental, Social and Governance Reporting Guide in Appendix C2 to the Listing Rules.

We are committed to strengthening our ESG oversight mechanisms by thoroughly integrating environmental, social, and governance factors into our business operations and ensuring compliance with relevant environmental protection laws and regulations. Recognizing the risks and opportunities associated with ESG, we are dedicated to identifying and addressing these factors through environmental impact assessments and management. We are exploring various measures to mitigate ESG-related risks while striving to balance cost-effectiveness with sustainable development. Our emissions reduction targets are based on industry standards

and our specific circumstances, aiming to enhance our environmental performance in alignment with best practices. We plan to set up a timeline for achieving our ESG goals through a phased approach that ensures feasibility and traceability. Furthermore, we are committed to fostering a culture of compliance, with a goal to ensure that all employees are well-informed of and adhere to relevant ESG regulations and requirements through cross-departmental collaboration.

Our Board is responsible for monitoring and enhancing compliance with ESG laws and regulations. Our management regularly reports to the board on ESG matters, and the Board makes decisions regarding our policies and practices in alignment with ESG requirements. The Board will continue to monitor, evaluate, and address ESG issues, overseeing the implementation of policies that promote ESG practices.

Environmental Protection

We strive to conduct our operations in a manner that safeguards the environment associated with our operation.

Wastes

We have established waste management procedures to ensure compliance with relevant waste disposal regulations and to minimize environmental impact. The waste is categorized into hazardous waste (such as chemical waste and liquid waste) and non-hazardous waste (such as waste from general office operations). The wastewater and solid waste generated during our in-house research and development process are pre-treated by our team before being handled by qualified third-party medical waste treatment companies. We have implemented a comprehensive hazardous waste management system. This includes maintaining a hazardous waste ledger, completing and executing transfer documentation, and contracting with qualified institutions for hazardous waste disposal.

Greenhouse gas emission

Our greenhouse gas emissions consist of Scope 1 and Scope 2 emissions. Scope 1 direct emissions include the greenhouse gas emissions from our manufacturing facilities and other stationary combustion sources. Scope 2 energy indirect emissions primarily include the greenhouse gas emissions from our usage of purchased electricity. In response to the national carbon neutrality target, we are committed to actively reducing the greenhouse gas emissions produced in our operations.

Management of Environmental Protection Matters

We conduct environmental impact assessments to monitor emission levels. We use a range of metrics to evaluate the impact of environmental risks. Furthermore, we have set multiple objectives to reduce our environmental footprint and are actively pursuing significant measures to meet these targets. The following table sets forth the indicators related to our energy consumption and waste production during the Track Record Period.

	For the year ended December 31,		For the nine months ended September 30,
	2022	2023	2024
Energy consumption			
Electricity *(MWh)*	33.0	509.2	467.1
Water* *(tons)*	–	293.1	948.4
Waste			
Hazardous waste* *(tons)*	–	0.6	1.5

* In our Suzhou laboratory.

As our business grows and our candidates move closer to commercialization, we anticipate an increase in resource consumption and emissions. Nonetheless, we are dedicated to implementing a variety of measures to optimize resource use and reduce emissions. Simultaneously, we strive to cultivate a corporate culture that prioritizes environmental protection and work closely with our business partners to establish an eco-friendly ecosystem. Our commitment includes enhancing the environmental performance across our entire value chain, which encompasses office operations, supplier selection, laboratory activities, and waste management. We expect our energy consumption in 2024 to be approximately 200% of the level recorded in 2023, in line with our business growth.

Patient Data Protection and Prevention of Data Manipulation

We are committed to the protection of trial participant information in compliance with the applicable laws, regulations and industry standards. We generally require CROs to keep all documents, data, records, and information provided by us or generated during the contract strictly confidential. The CROs are also required to ensure that their employees, consultants, and other professionals who access this confidential information are bound by the same confidentiality obligations. Without our prior written consent, CROs are generally prohibited from disclosing, revealing, or disseminating any confidential information to third parties in any form. Additionally, to the extent possible, we require CROs to implement protective measures that are at least equivalent to those they use for their own confidential information, to prevent unauthorized use, disclosure, or leakage of the information provided by us or generated during the trial. Furthermore, our contracts with R&D employees contain confidentiality clauses, adding an extra layer of security for the confidential information. Through these measures, we maintain a high standard of confidentiality and data protection throughout the clinical trial process.

We have established comprehensive internal policies to protect data integrity and prevent data manipulation, specifically outlined in our Code of Business Conduct and Ethics, Data Protection Policy regarding detection and response to data breaches, tampering, and data loss, and the Compliance Disciplinary Policy. These policies establish clear guidelines for data handling and set forth consequences for policy violations. Together, they form a robust framework to safeguard the authenticity and reliability of our research and clinical data.

Manufacturing and Quality Management

We strive to align our manufacturing and quality management practices with ESG standards. We prioritize partnerships with suppliers who demonstrate strong environmental practices in their raw material sourcing and production processes. Meanwhile, we maintain a comprehensive quality management system which is developed and continuously refined to meet the stringent regulations and guidelines in China, the U.S., and Europe. We regularly audit and inspect CDMOs to verify that their processes align with our quality requirements and regulatory standards. See also "— Quality Management." Through the integration of rigorous quality standards and sustainable manufacturing practices, we strive to establish ourselves as a responsible participant in the ADC industry.

Management of Third-Party Relationships

We maintain strict compliance standards in our third-party engagements through a robust internal policy framework. Our procurement management system establishes clear protocols for supplier interactions, with specific anti-bribery and anti-corruption provisions. For healthcare professionals, we follow detailed guidelines that govern all professional engagements. Our Code of Business Conduct and Ethics provides additional safeguards against corruption, bribery, and unfair competition, while our third-party contracts incorporate specific compliance requirements.

Work Safety

We strive to provide a safe and healthy working environment for our employees. To achieve this, we have established stringent safety protocols. These protocols are reinforced by regular safety training initiatives that equip our employees with the necessary awareness and technical expertise to perform their duties safely and efficiently. Our safety measures encompass our operations as well as our primary operational sites. We have specific protocols in place for managing emergency matters. Regular meetings and periodic inspections are conducted to ensure continuous adherence to our safety standards. Through these efforts, we maintain a secure and productive working environment that supports the well-being of our employees and the success of our enterprise. During the Track Record Period and up to the Latest Practicable Date, we did not have any major workplace accidents.

Workplace Diversity

We are dedicated to fostering an inclusive and open workplace that values equality. Our recruitment practices are strictly merit-based, ensuring that all employees are provided with equal opportunities regardless of gender, age, race, religion, or any other social or personal attributes. As of September 30, 2024, over half of our total employees were female. We are committed to maintaining a fair and transparent employee management system and continuously strive to enhance the gender and age diversity of our workforce.

Animal Welfare

We typically engage CROs to conduct animal studies, and the CROs we engaged have obtained certification from the Association for Assessment and Accreditation of Laboratory Animal Care. This certification promotes compliance with key regulations regarding animal welfare, including the humane treatment of all animals, the promotion of psychological well-being, access to adequate veterinary care, ethical reviews of research protocols, proper training for personnel involved in animal care, and ongoing compliance monitoring to uphold high standards of animal welfare throughout the research process.

PROPERTIES

We have presence in Shanghai, Suzhou and Beijing in China, as well as in the U.S. We currently lease all of the properties used in our operations from Independent Third Parties. As of the Latest Practicable Date, we had eight property leases in Shanghai, Jiangsu Province, and Beijing for R&D and office use, with an aggregate GFA of approximately 4,365 m^2. Our employees based in the U.S., primarily including our overseas R&D, translational medicine and clinical operation personnel, work remotely from New Jersey and California.

Pursuant to the applicable PRC laws and regulations, property lease agreements must be registered with the local branch of the Ministry of Housing and Urban-Rural Development of the PRC. As of the Latest Practicable Date, our lease agreements in China had not been registered. Our PRC Legal Advisor are of the view that the non-registration of our lease agreements will not affect the validity of such lease agreements, but the relevant local housing administrative authorities may require us to complete registrations within a specified timeframe and we may be subject to a fine between RMB1,000 and RMB10,000 per lease for any delay in making these registrations. Therefore, we have the right to use such properties in accordance with the lease agreements, but we may be subject to the risks of fines if lease registration is not completed as required by the relevant local housing administrative authorities. During the Track Record Period and up to the Latest Practicable Date, we were not subject to any penalties arising from the non-registration of the lease agreements. See "Risk Factors — Risks Relating to Our Operations — Our leased properties may be subject to non-compliances or challenges that could potentially affect our future use of them" for details.

AWARDS AND RECOGNITION

The table below sets forth a summary of the major awards and recognition we received during the Track Record Period.

Awards or Recognitions	Year Granted	Granting Authority
Best New Drug Developer	2024	11th Annual World ADC Awards
Suzhou City 2022 "Unicorn" Cultivation Enterprise (2022年蘇州市「獨角獸」培育企業) . . .	2023	Suzhou Municipal People's Government (蘇州市人民政府)
Jiangsu Province 2022 "Potential Unicorn" Enterprise (2022年江蘇省「潛在獨角獸」企業)	2022	Productivity Center of Jiangsu Province (江蘇省生產力促進中心)

LICENSES, PERMITS AND APPROVALS

Our PRC Legal Advisor has advised us that, during the Track Record Period and up to the Latest Practicable Date, we had obtained all requisite licenses, approvals and permits from the relevant government authorities that are material for our business operations in the PRC.

RISK MANAGEMENT AND INTERNAL CONTROL

We have established and maintained risk management and internal control systems consisting of policies and procedures that we consider to be appropriate for our business operations.

Risk Management

We recognize that effective risk management is critical to the success of our business operations. The key operational risks we face include, among others, changes in the general market conditions and regulatory environment of the PRC and global biopharmaceutical markets, our ability to develop, manufacture, and commercialize our drug candidates, as well as our ability to compete with other biopharmaceutical companies. See "Risk Factors" for detailed discussion of the various risks and uncertainties we confront. We also encounter diverse market risks, including credit, liquidity, interest rate, and currency risks. See "Financial Information — Quantitative and Qualitative Disclosure about Market Risk".

To address these challenges, we have implemented a comprehensive set of risk management policies that establish a framework to identify, assess, evaluate, and continuously monitor the key risks associated with our strategic objectives. Risks identified by our management are analyzed based on likelihood and impact, and are then properly followed up, mitigated, and rectified by our Group, meanwhile reporting to our Board of Directors. Our Directors oversee the implementation of these risk management policies.

To monitor the ongoing implementation of risk management policies and corporate governance measures after the [**REDACTED**], we have adopted or will continue to adopt, among other things, the following risk management measures:

- Our Directors will oversee and manage the overall risks associated with our business operations by (i) reviewing and approving our risk management policy to ensure alignment with our corporate objectives; (ii) reviewing and approving the annual working plan and annual report on corporate risk management; (iii) monitoring the most significant risks related to our business operations and evaluating our management's handling of these risks; (iv) assessing our corporate risk in relation to our risk tolerance; and (v) ascertaining the appropriate application of our risk management framework across our Group.

- Our finance, legal, human resources and other relevant departments will be responsible for (i) developing our risk management policy and reviewing major risk management issues within our Company; (ii) creating the annual risk management plan and report; (iii) offering guidance on our risk management approach to relevant departments and supervising the implementation of our risk management policy; (iv) reviewing reports on key risks from relevant departments and providing feedback; and (v) conducting education and training related to risk management.

- Our finance, legal, human resources and other relevant departments will be responsible for implementing our risk management policy and conducting daily risk management activities. To standardize risk management across our Group and establish a common level of transparency and performance, these departments will (i) gather information about risks related to their operations or functions; (ii) conduct risk assessments, which include identifying, prioritizing, measuring, and categorizing all key risks that could potentially impact their objectives; (iii) continuously monitor key risks related to their operations or functions; (iv) implement appropriate risk responses as needed; (v) develop and maintain mechanisms to facilitate the application of our risk management framework; and (vi) promptly report any material risks to relevant departments.

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 of our Company and our major operating subsidiaries and to report factual findings on our Group's entity-level controls and internal controls of various processes, including financial reporting and disclosure controls, human resources and payroll management, general controls of IT system, taxation management, procurement management, and other procedures of our operations. The Internal Control Consultant performed the Internal Control Review in June 2024 and follow-up reviews in July 2024. As of the Latest Practicable Date, there were no material outstanding issues relating to our Group's internal control.

During the Track Record Period, we regularly reviewed and enhanced our internal control system. Below is a summary of the internal control policies, measures and procedures we have implemented or plan to implement:

- We have implemented a range of measures and procedures covering various aspects of our business operations, including related party transactions, risk management, intellectual property protection, environmental protection, and occupational health and safety. For more information, see "— Intellectual Property" and "— Social, Health, Work Safety and Environmental Matters." As part of our employee training program, we regularly provide training on these measures and procedures to our staff.

- Our Directors, who are responsible for overseeing the corporate governance of our Group, will, with assistance from our legal advisers, will periodically review our compliance status with all relevant laws and regulations following the [**REDACTED**].

- We have established an audit committee which (i) makes recommendations to our Directors on the appointment and removal of external auditors; and (ii) reviews the financial statements and renders advice in respect of financial reporting as well as oversees internal control procedures of our Group.

- We have engaged First Shanghai Capital Limited as our compliance adviser to provide advice to our Directors and management team until the end of the first fiscal year after the [**REDACTED**] regarding matters relating to the Listing Rules. Our compliance adviser is expected to ensure our use of funding complies with the section headed "Future Plans and [**REDACTED**]" in this document after the [**REDACTED**], as well as to provide support and advice regarding requirements of relevant regulatory authorities in a timely fashion.

You should read the following discussion and analysis in conjunction with our consolidated financial information, including the notes thereto, included in the Accountant's Report set out in Appendix I to this document. Our consolidated financial information has been prepared in accordance with International Financial Reporting Standards ("IFRSs").

The following discussion and analysis contain forward-looking statements that reflect our current views with respect to future events and financial performance that involve risks and uncertainties. These statements are based on assumptions and analysis made by us in light of our experience and perception of historical events, current conditions and expected future developments, as well as other factors we believe are appropriate under the circumstances. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of certain factors. We discuss factors that we believe could cause or contribute to these differences below and elsewhere in this document, including those set forth in "Risk Factors" and "Forward-Looking Statements" in this document.

OVERVIEW

We are a global player in ADC innovation, dedicated to the development of next-generation therapeutics in this fast-growing drug modality to treat cancer, autoimmune diseases, and beyond. Our pipeline comprises 12 in-house discovered assets, with seven in the clinical stage and five in the preclinical stage. Five of our clinical-stage assets had obtained IND approvals from both the FDA and the NMPA as of the Latest Practicable Date. We have seven ongoing global MRCTs across 17 countries and over 230 trial sites, with over 2,000 patients (more than 50% located in the U.S., EU and Australia) enrolled as of the Latest Practicable Date. In our short operating history, we have entered into several out-licensing and collaboration deals with leading industry players worldwide to date, including BioNTech (for DB-1303/BNT323, DB-1311/BNT324 and DB-1305/BNT325), BeiGene (for DB-1312), Adcendo (for ADC assets using our proprietary payload linkers), GSK (for DB-1324), and Avenzo (for DB-1418/AVZO-1418), with over US$6.0 billion in total deal value (of which approximately US$400 million had been received as of the Latest Practicable Date).

We currently have no products approved for commercial sales and was loss-making during the Track Record Period. We incurred losses of RMB387.1 million, RMB357.5 million and RMB566.5 million for the years ended December 31, 2022 and 2023 and the nine months ended September 30, 2024, respectively, which were primarily resulted from expenses in relation to R&D activities as well as fair value change of financial liabilities at fair value through profit or loss in relation to our Preferred Shares. For the years ended December 31, 2022 and 2023 and the nine months ended September 30, 2024, we recognized revenue of RMB1.6 million, RMB1,786.5 million and RMB1,462.0 million, respectively, substantially all of which were derived from our out-license and collaboration agreements.

We expect to incur significant expenses for at least the next several years as we continue to advance our preclinical research and clinical development plans, and to prepare for the commercialization of our drug candidates. Subsequent to the [**REDACTED**], our financial performance may fluctuate from period to period due to, among other factors, the development status of our drug candidates, regulatory approval timeline, and commercialization of our drug candidates after approval.

BASIS OF PREPARATION

Our historical financial information has been prepared in accordance with all applicable International Financial Reporting Standards issued by the International Accounting Standards Board ("**IFRS Accounting Standards**"). Our historical financial information has been prepared under the historical cost convention, except for financial liabilities measured at fair value through profit or loss. The preparation of historical financial information in conformity with IFRS Accounting Standards requires the use of certain critical accounting estimates. It also requires our management to exercise judgement in the process of applying our accounting policies. The areas involving a higher degree of judgement or complexity, or areas where assumptions and estimates are significant to our historical financial information are disclosed in note 4 to the Accountant's Report set out in Appendix I to this document. All effective standards, amendments to standards and interpretations, which are mandatorily effective for the financial year beginning on January 1, 2024, are consistently applied to us for the Track Record Period.

We had net current liabilities of RMB1,636.7 million as of September 30, 2024, of which the convertible preferred shares classified as current liabilities were RMB2,605.1 million and contract liabilities, which do not result in future cash payments, of RMB55.7 million. Our Directors of assessed our Group's liquidity by evaluating our ability to generate cash from operating activities, attract additional capital or other means of finance funding. Historically, we have relied principally on both operational sources of cash (e.g., revenue from out-licensing) and non-operational sources of financing from investors (e.g., convertible preferred shares) to fund our research and development activities.

Pursuant to the resolution passed by the Shareholders in September 2022, we shall redeem, at the option of any holder of outstanding convertible preferred shares, all of the outstanding convertible preferred shares held by the requesting holder, at any time after the earliest occurrence of failure to complete the qualified [**REDACTED**] within four years after April 23, 2021. In August 2024, we entered into supplemental agreements with respect to certain rights with the shareholders to suspend such redemption feature for a period commencing on the day immediately prior to the date of our first submission of the [**REDACTED**] application, until the earlier of: (a) the withdrawal of the [**REDACTED**] application by us; (b) the rejection of the [**REDACTED**] application; and (c) the expiration of 18 months after the first submission date.

Based on the above factors and our Group's historical performance and our management's operating and financing plans, our Directors believe the cash and cash equivalents and the operating and financing cash flows are sufficient to meet the cash requirements to fund our Group's planned operations, capital expenditures and other obligations for at least the next 12 months after September 30, 2024. Therefore, our historical financial information have been prepared on a going concern basis, which contemplates the realization of assets and settlement of liabilities in the normal course of business.

KEY FACTORS AFFECTING OUR RESULTS OF OPERATIONS

We believe that the most significant factors affecting our results of operations and financial condition include the following:

Our Ability to Successfully Develop and Commercialize Our Drug Candidates

The success of our business and results of operation relies on our ability to advance our drug development programs, demonstrate satisfactory safety and efficacy in clinical trials, obtain the necessary regulatory approvals, and launch our products in our target markets as planned. All of our ADC candidates are currently in the development stage. To date, we have built a pipeline comprising 12 in-house discovered assets, with seven in the clinical stage and five in the preclinical stage. See "Business — Our Pipeline" for more details.

Based on the expected approval timeline of each late-stage ADC candidate in our pipeline, which is subject to regulatory communications and marketing approval, we anticipate filing for accelerated approval with the FDA as early as 2025 for DB-1303 as a treatment for HER2-expressing EC. After our ADC candidates are commercialized, our business and results of operations will depend on the market acceptance and sales of our commercialized drugs. See also "Risk Factors — Risks Relating to the Development of Our Drug Candidates — We depend substantially on the success of our drug candidates. If we are unable to successfully complete clinical development, obtain regulatory approvals or achieve commercialization for our drug candidates, or if we experience significant delays or cost overruns in doing any of the foregoing, our business and prospects could be materially and adversely affected" for details.

Our Existing and Future License and Collaboration Arrangements

During the Track Record Period, we entered into a number of out-license and collaboration agreements for our ADC assets and technology, and generated revenue in relation to these agreements of RMB1,781.1 million, RMB1,674.6 million and RMB1,458.7 million in 2023 and the nine months ended September 30, 2023 and 2024, respectively. We are eligible to receive further payments upon the achievement of specified development, regulatory and commercial milestones, subject to terms and conditions of these agreements. Upon commercialization, we will also be eligible to receive royalties on net sales of the products. These strategic collaborations empower us to maximize the global value of our assets and provide capital support for our other pipeline assets and sustainable long-term growth. In

addition to these out-license and collaboration agreements, we are also required to pay certain milestone and royalty payments in relation to our in-licensing agreements based on terms of the agreements. See "Business — Our Collaboration and Licensing Arrangements" for details.

The timing and amounts of milestone payments and royalties differ by agreement and depend on the achievement of various milestones. Moreover, following the success of our existing out-license and collaboration partnerships, we may enter into new partnerships and collaborations depending on our development strategies. These factors will influence, and may result in fluctuations in, our revenue, profit and results of operations from period to period.

Our Cost Structure

Our cost structure during the Track Record Period primarily consisted of costs and expenses in relation to R&D activities and administrative expenses.

Our costs and expenses in relation to R&D activities, which represented our cost of revenue and research and development expenses, were the largest component of our cost structure during the Track Record Period. In 2022, 2023 and for the nine months ended September 30, 2023 and 2024, our costs and expenses in relation to R&D activities were RMB339.9 million, RMB986.7 million, RMB696.6 million and RMB1,404.4 million, respectively. Our costs and expenses in relation to R&D activities increased during the Track Record Period as we rapidly advanced multiple ADC programs in or towards the clinic, including our initiation of various clinical trials. Going forward, we expect to continue to incur significant R&D costs and expenses as we advance our ADC candidates towards commercialization or clinical stage.

In 2022 and 2023 and for the nine months ended September 30, 2024, costs and expenses in relation to R&D activities incurred for our Core Products were RMB137.0 million, RMB635.3 million and RMB878.9 million, respectively, accounting for 40.3%, 64.4% and 62.6% of our total costs and expenses in relation to R&D activities for the corresponding periods. In 2022, 2023 and for the nine months ended September 30, 2024, our research and development expenses accounted for 91.4%, 89.9% and 82.6% of our total operating expenses (which equals the sum of research and development expenses and administrative expenses), respectively. The decrease in the percentage of research and development expenses relative to total operating expenses in 2024 was primarily due to increase in administrative expenses caused by share incentive expenses and [**REDACTED**].

Our administrative expenses, which primarily consisted of professional services expenses and staff costs, amounted to RMB31.9 million, RMB62.6 million, RMB43.8 million and RMB126.8 million in 2022, 2023 and for the nine months ended September 30, 2023 and 2024, respectively. Our administrative expenses increased during the Track Record Period primarily because (i) our business grew and team expanded, (ii) our share incentive expenses increased, and (iii) we engaged professional services in relation to our out-license and collaboration agreements, equity financing and [**REDACTED**].

Going forward, our cost structure will evolve as we further develop our ADC candidates. As our ADC candidates progress through preclinical studies and clinical trials and advance towards commercialization, we expect to incur additional expenses related to research and development, sales and marketing, and regulatory affairs, among other activities. Additionally, we may also incur increased 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 equity financing and income from out-license and collaboration agreements. We expect to fund our future operations primarily with existing cash, income from our out-license and collaboration agreements, and [**REDACTED**] from the [**REDACTED**]. Upon the successful commercialization of one or more of our ADC candidates, we expect to fund our operations in part with income generated from sales of our commercialized drug products. As our business continues to expand, we may require further funding through equity offerings, debt financing, out-license and collaboration arrangements, and other sources. Changes in our ability to fund our operations may affect our cash flow and results of operations. See also "Risk Factors — Risks Relating to Our Financial Position and Need for Additional Capital — We may need to obtain substantial additional financing to fund our operations and expansion, and if we fail to do so, we may be unable to complete the development and commercialization of our drug candidates."

MATERIAL ACCOUNTING POLICIES AND SIGNIFICANT ACCOUNTING JUDGMENTS AND ESTIMATES

The preparation of our historical financial information requires our management to make judgments, estimates and assumptions that affect the reported amounts of revenues, expenses, assets and liabilities, and their accompanying disclosures, and the disclosure of contingent liabilities. Such judgments, estimates and assumptions are continually evaluated and are based on historical experience and various other factors, including expectations of future events, that are believed to be reasonable under the circumstances, from which our actual results may differ.

Set out below are material accounting policies, judgements and estimates which we believe are most important for understanding our results of operations and financial condition. See note 4 and other notes to the relevant financial line items or transactions to the Accountant's Report set out in Appendix I to this document for a detailed description of our material accounting policies, judgments and estimates.

Revenue Recognition

Revenue from contracts with customers is recognized when control of goods or services is transferred to the customers at an amount that reflects the consideration to which we expect to be entitled in exchange for those goods or services.

At contract inception, we assess the goods or services promised within each contract and determines those that are performance obligations and assesses whether each promised good or service is distinct.

We consider the terms of the contracts to determine the transaction price. When the consideration in a contract includes a variable amount, the amount of consideration is estimated to which we will be entitled in exchange for transferring the goods or services to the customer. The variable consideration is estimated at contract inception and constrained until it is highly probable that a significant revenue reversal in the amount of cumulative revenue recognized will not occur when the associated uncertainty with the variable consideration is subsequently resolved.

We recognize revenue only when it satisfies a performance obligation by transferring control of the promised goods or services. The transfer of control can occur over time or at a point in time. A performance obligation is satisfied over time if it meets one of the following criteria.

- The counterparty simultaneously receives and consumes the benefits provided by our performance as we perform.

- Our performance creates or enhances an asset that the counterparty controls as the asset is created or enhanced.

- Our performance does not create an asset with an alternative use to us and we have an enforceable right to payment for performance completed to date.

If control of the goods and services transfers over time, revenue is recognized over the period of the contract by reference to the progress towards complete satisfaction of that performance obligation. We adopt an appropriate method of measuring progress for the purpose of recognizing revenue. We evaluate the measure of progress at the end of each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

We enter into out-license and collaboration agreements for research, development, manufacturing and commercialization services. The terms of these arrangements typically include non-refundable upfront payments, reimbursements for costs incurred, milestone payments and royalties on net sales of licensed products. The contracts generally do not include a significant financing component.

As part of the accounting for these arrangements, we use the following significant judgements:

- ***Licenses of intellectual property.*** We assess whether the licensing of our intellectual property is distinct from the other performance obligations identified in the arrangements. For licenses determined to be distinct, we recognize revenue from non-refundable, upfront payments allocated to the license at a point in time, when the license is transferred to the licensee and the licensee is able to use and benefit from the license.

- ***Research and development services.*** For research and development services determined to be distinct, the portion of the reimbursements for costs incurred and other transaction price allocated to the performance obligations is recognized as revenue over time as delivery or performance of such services occurs.

- ***Milestone payments.*** At the inception of each arrangement that includes milestone payments, we assess whether the milestones are considered highly probable of being achieved and estimates the amount to be included in the transaction price using the most likely amount method. In making these assessments, we consider various factors such as the scientific, clinical, regulatory, commercial, and other risks that must be overcome to achieve a particular milestone. Milestone payments that are subject to regulatory approvals and commercialization stages are not considered highly probable of being achieved until those approvals are received or commercialization stages are achieved. The transaction price will be allocated to each performance obligation on a relative stand-alone selling price basis, for which we recognize revenue as or when the performance obligations are satisfied. At the end of each subsequent reporting period, we re-evaluate the probability of achievement of all milestones subject to constraint and, if necessary, adjusts our estimate of the overall transaction price.

- ***Royalties.*** For arrangements that include sales-based royalties, we recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

The excess of cumulative revenue recognized in profit or loss over the cumulative billings to customers is recognized as contract assets. The excess of cumulative billings to customers over the cumulative revenue recognized in profit or loss is recognized as contract liabilities.

Intangible Assets

Software

Computer software is recognized at historical cost and subsequently carried at cost less accumulated amortization and accumulated impairment losses. We amortized on a straight-line basis over their estimated useful lives of one to three years.

In-licenses

Certain intangible assets are for in-licenses of intellectual properties in development, with non-refundable upfront payment, milestone payment and royalty payment. Upfront payment is capitalized when paid. The milestone payment is capitalized as intangible assets when incurred, unless the payment is for outsourced research and development work which would follow the capitalization policy in note 16(b) to the Accountant's Report set out in Appendix I to this document. Royalty payment would be accrued for in line with the underlying sales and recognized as a cost of revenue. However, if the intangible asset is acquired in a business combination, it is measured at fair value at initial recognition.

In-licenses with finite useful life are amortized using the straight-line basis over the commercial lives of the underlying products, commencing from the date when the products are put into commercial production.

Intangible assets not ready for use are not subject to amortization and are tested annually for impairment, or more frequently if events or changes in circumstances indicate that they might be impaired. We obtained in-licenses and in-process research and development to continue research and development work and commercialize the products, which are classified as intangible assets not ready for use.

An impairment loss is recognized for the amount by which the asset's carrying amount exceeds its recoverable amount. The recoverable amount is the higher of an asset's fair value less costs of disposal and value in use. For the purposes of assessing impairment, assets are grouped at the lowest levels for which there are separately identifiable cash flows (cash-generating units).

Research and Development

We incur significant costs and efforts on research and development activities. Research expenditures are charged to the profit or loss as an expense in the period the expenditures are incurred. Development costs are recognized as assets if they can be directly attributable to a newly developed drug products and all the following can be demonstrated:

(i) the technical feasibility of completing the intangible assets so that it will be available for use or sale;

(ii) the intention to complete the intangible asset and use or sell it;

(iii) the ability to use or sell the intangible assets;

(iv) the intangible asset will generate probable future economic benefits;

(v) the availability of adequate technical, financial and other resources to complete the development and to use or sell the intangible asset; and

(vi) the ability to measure reliably the expenditure attributable to the intangible asset during its development.

All of our research expenditures during the Track Record Period were charged to the profit or loss.

Research and development expenses include costs paid to hospitals and third-party CROs. The estimate of accrual of research and development expenses is complex because billing terms under relevant contracts often do not coincide with the timing of when the work is performed, which in turn requires estimates of outstanding obligations as of the end of each year/period of the Track Record Period. These estimates are based on a number of factors, including management's knowledge of the R&D programs and activities associated with timelines, invoicing date, and the provisions in the contracts.

Financial Liabilities at Fair Value Through Profit or Loss

Preferred Shares issued by us are redeemable upon occurrence of certain future events. This instrument can be converted into Ordinary Shares at any time at the option of the holders or automatically converted into Ordinary Shares upon occurrence of an [**REDACTED**] of the Company.

We designated the Preferred Shares as financial liabilities at fair value through profit or loss. They are initially recognized at fair value. Subsequent to initial recognition, the Preferred Shares are carried at fair value with changes in fair value recognized in the consolidated statements of comprehensive loss. If our own credit risk results in fair value changes in financial liabilities designated as at fair value through profit or loss, they are recognized in other comprehensive loss.

The fair value of Preferred Shares that are not traded in an active market is determined by using valuation techniques. We applied back-solve method and the discounted cash flow approach to determine the underlying equity value of the Company and adopted option-pricing method and equity allocation model to determine the fair value of the Preferred Shares. Key assumptions such as discount rate, volatility and discount for lack of marketability are disclosed in note 24 to the Accountant's Report set out in Appendix I to this document.

Effective from January 1, 2024, "IAS 1 (Amendment) 'Classification of Liabilities as current or non-current'" requires a reclassification of convertible preferred shares from non-current liabilities to current liabilities, as the convertible preferred shares may be converted into ordinary shares at the option of the preferred shareholders at any time and the conversion feature does not meet "fixed-for-fixed" criteria. Such accounting policy change has been consistently applied to all the years presented in our historical financial information. This classification is applicable to us because we do not have an unconditional right to defer the settlement of these Preferred Shares for at least 12 months after the end of the Track Record Period.

As of December 31, 2022, our financial liabilities at fair value through profit or loss also included the convertible loans and advance payments issued in series B financing and series B+ financing, as transitional arrangements before the completion of certain onshore Renminbi investors' ODI registration obligation. See note 24 to the Accountant's Report set out in Appendix I to this document for details.

Share-based Compensation

We operate stock options granted to employees, under which we receive services from employees as consideration for equity instruments of us. The fair value of the employee services received in exchange for the grant of equity instruments (options) is recognized as an expense in the historical financial information. The total amount to be expensed is determined by reference to the fair value of the equity instruments granted:

- including any market performance conditions;
- excluding the impact of any service and non-market performance vesting conditions; (for example, the requirement for employees to serve);
- including the impact of any non-vesting conditions.

At the end of each year/period of the Track Record Period, we revise the estimates of the number of options that are expected to vest based on the non-market vesting performance and service conditions. We recognize the impact of the revision to original estimates, if any, in the consolidated statements of comprehensive loss, with a corresponding adjustment to equity.

We have engaged an independent valuer to determine the fair value of the options granted to employees, which is expensed over the vesting periods. Unobservable inputs, such as the risk-free interest rate, volatility and dividend yield, are used in determining the fair value of the share-based compensations.

For details, see note 13 to the Accountant's Report set out in Appendix I to this document.

DESCRIPTION OF SELECTED COMPONENTS OF THE CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

The following table sets forth a summary of our consolidated statements of comprehensive loss for the periods indicated. Our historical results presented below are not necessarily indicative of the results that may be expected for any future period.

	For the year ended December 31,		For the nine months ended September 30,	
	2022	2023	2023	2024
	(RMB'000)	*(RMB'000)*	*(RMB'000) (unaudited)*	*(RMB'000)*
Revenues	1,600	1,786,540	1,675,917	1,462,004
Cost of revenue	–	(427,655)	(324,161)	(802,456)
Gross profit	1,600	1,358,885	1,351,756	659,548
Research and development expenses	(339,890)	(558,997)	(372,391)	(601,930)
Administrative expenses	(31,921)	(62,567)	(43,800)	(126,836)
Other income	494	3,261	2,209	3,347
Other gains/(losses), net	1,134	40,773	38,847	(7,297)
Operating (loss)/profit	(368,583)	781,355	976,621	(73,168)
Finance income	3,268	34,483	24,160	38,809
Finance costs	(75)	(188)	(145)	(189)
Fair value change of financial liabilities at fair value through profit or loss	(21,700)	(1,017,899)	(959,200)	(501,351)
(Loss)/Profit before income tax	(387,090)	(202,249)	41,436	(535,899)
Income tax expense	–	(155,263)	(155,263)	(30,583)
Loss for the year/period attributable to the owners of the Company	**(387,090)**	**(357,512)**	**(113,827)**	**(566,482)**
Other comprehensive income/(loss):				
Items that will not be reclassified to profit or loss				
Exchange differences on translation[(1)]	(42,743)	(19,553)	(49,608)	28,828
Changes in fair value of financial liabilities from own credit risk	420	(1,688)	(87)	(216)

	For the year ended December 31,		For the nine months ended September 30,	
	2022	2023	2023	2024
	(RMB'000)	*(RMB'000)*	*(RMB'000) (unaudited)*	*(RMB'000)*
Other comprehensive loss for the year/period, net of tax	(42,323)	(21,241)	(49,695)	28,612
Total comprehensive loss for the year/period attributable to the owners of the Company	**(429,413)**	**(378,753)**	**(163,522)**	**(537,870)**

Note:

(1) The exchange differences on translation are primarily attributable to the discrepancy between the presentation currency of our historical financial information (RMB) and the functional currency of certain of our subsidiaries, including the Company, DualityBio HK Limited, and DualityBio Inc. (US dollar). As DualityBio HK Limited, and DualityBio Inc. share the same functional currency as the Company, they are not considered foreign operations. Consequently, we view the cumulative translation adjustment as part of other comprehensive income items, which will not be reclassified to profit or loss.

Revenue

During the Track Record Period, our revenue was primarily derived from our out-license and collaboration agreements, including income in relation to upfront payments, milestone payments, and reimbursement for R&D activities we undertake for our out-licensed candidates. See "Business — Our Collaboration and Licensing Arrangements" for details. The following table sets forth a breakdown of our revenue in absolute amounts and as percentages of the total revenue for the periods indicated.

	For the year ended December 31,				For the nine months ended September 30,			
	2022		2023		2023		2024	
	(RMB'000)	*%*	*(RMB'000)*	*%*	*(RMB'000) (unaudited)*	*%*	*(RMB'000)*	*%*
Revenue from the license and collaboration agreement	–	–	1,781,088	99.7	1,674,615	99.9	1,458,681	99.8
– Upfront	–	–	1,437,267	80.5	1,433,963	85.6	307,027	21.0
– Milestone	–	–	–	–	–	–	341,482	23.4
– Reimbursement	–	–	343,821	19.2	240,652	14.3	810,172	55.4
Others[(1)]	1,600	100.0	5,452	0.3	1,302	0.1	3,323	0.2
Total	**1,600**	**100.0**	**1,786,540**	**100.0**	**1,675,917**	**100.0**	**1,462,004**	**100.0**

The following table sets forth a breakdown of our revenue by drug candidates in absolute amounts and as percentages of the total revenue for the periods indicated.

	For the year ended December 31,				For the nine months ended September 30,			
	2022		2023		2023		2024	
	(RMB'000)	*%*	*(RMB'000)*	*%*	*(RMB'000)* *(unaudited)*	*%*	*(RMB'000)*	*%*
Revenue from the license and collaboration agreement	–	–	1,781,088	99.7	1,674,615	99.9	1,458,681	99.8
– DB-1303	–	–	699,567	39.2	620,298	37.0	645,116	44.1
– DB-1311	–	–	727,538	40.7	715,428	42.7	331,644	22.7
– DB-1305	–	–	339,027	19.0	323,933	19.3	160,506	11.0
– DB-1312	–	–	–	–	–	–	320,744	22.0
– DITAC platform	–	–	14,956	0.8	14,956	0.9	671	0.0
Others[(1)]	1,600	100.0	5,452	0.3	1,302	0.1	3,323	0.2
Total	**1,600**	**100.0**	**1,786,540**	**100.0**	**1,675,917**	**100.0**	**1,462,004**	**100.0**

Note:

(1) Primarily including the consideration paid by our business partners in exchange for biological materials to evaluate drug candidates in relation to the licensing deal.

Cost of Revenue

During the Track Record Period, our cost of revenue was primarily related to the R&D activities we conducted in accordance with our out-license and collaboration agreements. The costs were either incurred by us internally, or by third parties to whom we were obligated to make payments. In 2022 and 2023 and for the nine months ended September 30, 2023 and 2024, our cost of revenue was nil, RMB427.7 million, RMB324.2 million and RMB802.5 million, respectively.

Gross Profit and Gross Profit Margin

In 2022 and 2023 and for the nine months ended September 30, 2023 and 2024, our gross profit was RMB1.6 million, RMB1,358.9 million, RMB1,351.8 million and RMB659.5 million, respectively. For the same periods, our gross profit margin was 100.0%, 76.1%, 80.7% and 45.1%, respectively.

Research and Development Expenses

During the Track Record Period, our research and development expenses primarily consisted of (i) technical service expenses, primarily representing CRO and CDMO service fees, (ii) staff costs, including wages, bonus, social insurance and other welfare, as well as share incentive expenses in relation to Pre-[**REDACTED**] Equity Incentive Plan for our R&D personnel, see "Statutory and General Information — D. Share Incentive Plans" for details, (iii) depreciation of property, plant and equipment and right-of-use assets, (iv) asset impairment loss, representing impairment provision in relation to an in-licensed antibody, see "— Description of Selected Items from the Consolidated Balance Sheets — Intangible Assets" for details, and (v) others, including expenses for warehouse, logistics, insurance and miscellaneous items. The following table sets forth a breakdown of our research and development expenses in absolute amounts and as percentages of the total research and development expenses for the periods indicated.

	For the year ended December 31,				For the nine months ended September 30,			
	2022		2023		2023		2024	
	(RMB'000)	*%*	*(RMB'000)*	*%*	*(RMB'000)* *(unaudited)*	*%*	*(RMB'000)*	*%*
Technical service expenses	288,876	85.0	494,404	88.4	323,430	86.9	405,407	67.4
Staff costs	48,916	14.4	58,545	10.5	43,981	11.8	164,118	27.3
Depreciation of property, plant and equipment and right-of-use assets	162	–	1,848	0.3	1,186	0.3	3,057	0.5
Asset impairment loss	–	–	–	–	–	–	21,301	3.5
Others	1,936	0.6	4,200	0.8	3,794	1.0	8,047	1.3
Total	**339,890**	**100.0**	**558,997**	**100.0**	**372,391**	**100.0**	**601,930**	**100.0**

Administrative Expenses

During the Track Record Period, our administrative expenses primarily consisted of (i) staff costs, including wages, bonus, social insurance and other welfare, as well as share incentive expenses in relation to Pre-[**REDACTED**] Equity Incentive Plan for our administrative personnel, see "Statutory and General Information — D. Share Incentive Plans" for details, (ii) professional services expenses, primarily in relation to our equity financing and business collaboration activities, (iii) [**REDACTED**] expenses, (iv) depreciation of property,

plant and equipment and right-of-use assets, and (v) office, traveling and other expenses. The following table sets forth a breakdown of our administrative expenses in absolute amounts and as percentages of the total administrative expenses for the periods indicated.

	For the year ended December 31,				For the nine months ended September 30,			
	2022		2023		2023		2024	
	(RMB'000)	*%*	*(RMB'000)*	*%*	*(RMB'000)* *(unaudited)*	*%*	*(RMB'000)*	*%*
Staff costs	15,197	47.6	22,754	36.4	12,516	28.6	73,921	58.3
Professional services expenses	11,644	36.5	30,274	48.4	25,451	58.1	23,149	18.3
[**REDACTED**] expenses	–	–	–	–	–	–	19,819	15.6
Depreciation of property, plant and equipment and right-of-use assets	1,633	5.1	3,139	5.0	1,926	4.4	2,458	1.9
Office, traveling and other expenses	3,447	10.8	6,400	10.2	3,907	8.9	7,489	5.9
Total	**31,921**	**100.0**	**62,567**	**100.0**	**43,800**	**100.0**	**126,836**	**100.0**

Other Income

During the Track Record Period, our other income primarily consisted of (i) government grants, primarily representing government subsidies from government authorities in relation to our R&D activities, which were mainly one-off in nature, and (ii) others, primarily representing refunds in relation to individual income tax. The following table sets forth a breakdown of our other income in absolute amounts and as percentages of the total other income for the periods indicated.

	For the year ended December 31,				For the nine months ended September 30,			
	2022		2023		2023		2024	
	(RMB'000)	*%*	*(RMB'000)*	*%*	*(RMB'000)* *(unaudited)*	*%*	*(RMB'000)*	*%*
Government grants	444	89.9	3,154	96.7	2,102	95.2	3,143	93.9
Others	50	10.1	107	3.3	107	4.8	204	6.1
Total	**494**	**100.0**	**3,261**	**100.0**	**2,209**	**100.0**	**3,347**	**100.0**

Other Gains/(Losses), Net

During the Track Record Period, our net other gains/(losses) primarily consisted of net foreign exchange gains/(losses), as a result of fluctuations in currency exchange. The following table sets forth a breakdown of our net other gains/(losses) in absolute amounts and as percentages of the total net other gains/(losses) for the periods indicated.

	For the year ended December 31,				For the nine months ended September 30,			
	2022		2023		2023		2024	
	(RMB'000)	*%*	*(RMB'000)*	*%*	*(RMB'000)* *(unaudited)*	*%*	*(RMB'000)*	*%*
Foreign exchange gains/(losses), net	1,121	98.9	41,935	102.8	38,847	100.0	(8,688)	119.1
Others	13	1.1	(1,162)	(2.8)	–	–	1,391	(19.1)
Total	**1,134**	**100.0**	**40,773**	**100.0**	**38,847**	**100.0**	**(7,297)**	**100.0**

Finance Income

Our finance income represents interest income from bank deposits, which amounted to RMB3.3 million, RMB34.5 million, RMB24.2 million and RMB38.8 million in 2022, 2023 and the nine months ended September 30, 2023 and 2024, respectively.

Finance Costs

Our finance costs represent interest expenses on lease liabilities, which amounted to RMB75 thousand, RMB188 thousand, RMB145 thousand and RMB189 thousand in 2022, 2023 and the nine months ended September 30, 2023 and 2024, respectively.

Fair Value Change of Financial Liabilities at Fair Value through Profit or Loss

Our financial liabilities at fair value through profit or loss primarily represented our Preferred Shares issued in our previous equity financings. As of December 31, 2022, our financial liabilities at fair value through profit or loss also included the convertible loans and advanced payments issued in series B financing and series B+ financing. In our series B financing and series B+ financing, as transitional arrangements before the completion of certain onshore Renminbi investors' ODI registration obligation, we entered into convertible loan or advanced payment agreements with these onshore Renminbi investors. These investors provided convertible loans or advance payments with reference to their purchase consideration for our Preferred Shares to us, which we agreed to repay upon completion of ODI registration. At the same time, we issued warrants to these investors, allowing them to purchase our Preferred Shares once the ODI registration was completed. In 2023 we repaid the convertible

loans and advanced payments and issued Preferred Shares to these investors. See "History and Corporate Structure — Corporate History — Establishment and Major Shareholding Changes of Our Company — Series B and Series B+ Financing" and see "— Description of Selected Items from the Consolidated Balance Sheets — Financial Liabilities at Fair Value through Profit or Loss" for details.

The fair value changes of our financial liabilities are recognized in profit or loss unless they are related to our own credit risk, which are recognized in other comprehensive income/(loss). Our fair value change of financial liabilities at fair value through profit or loss amounted to loss of RMB21.7 million, RMB1,017.9 million, RMB959.2 million and RMB501.4 million in 2022, 2023 and for the nine months ended September 30, 2023 and 2024, respectively. For more details, please refer to note 24 to the Accountant's Report set out in Appendix I to this document.

Income Tax Expense

Our income tax expenses amounted to nil, RMB155.3 million, RMB155.3 million and RMB30.6 million in 2022, 2023 and the nine months ended September 30, 2023 and 2024, respectively. Our income tax expenses during the Track Record Period were mainly in relation to withholding tax on our overseas income. No deferred tax asset has been recognized in respect of the tax losses and temporary difference due to the unpredictability of future profit streams.

The current income tax charge is calculated on the basis of the tax laws enacted or substantively enacted at the end of the reporting period in the countries where we operate and generate taxable income. Our management periodically evaluates positions taken in tax returns with respect to situations in which applicable tax regulation is subject to interpretation and considers whether it is probable that a taxation authority will accept an uncertain tax treatment. We measure our tax balances either based on the most likely amount or the expected value, depending on which method provides a better prediction of the resolution of the uncertainty.

Our principal applicable taxes and tax rates are set out below.

Cayman Islands

Under the current laws of the Cayman Islands, our Company is not subject to tax on income or capital gains. Additionally, the Cayman Islands does not impose a withholding tax on payments of dividends to shareholders.

Hong Kong

Under the current Hong Kong Inland Revenue Ordinance, our subsidiary in Hong Kong is subject to Hong Kong profit tax on its taxable income generated from operations in Hong Kong at two-tiered profit tax rates, 8.25% for first HK$2 million of assessable profits and 16.5% for assessable profits above HK$2 million. Additionally, payments of dividends by the

subsidiary incorporated in Hong Kong to the Company are not subject to any Hong Kong withholding tax. No provision for Hong Kong profits tax has been provided for at the rate of 16.5% as our subsidiary in Hong Kong had no estimated assessable profit during the Track Record Period.

United States

DualityBio Inc. is incorporated in the United States and is subject to federal income tax at 21% and state and local income tax (generally ranges from 1% to 12%) where it has operation. DualityBio Inc. did not have any taxable income, therefore no income tax expense was accrued for the Track Record Period.

Mainland China

Duality Suzhou is subject to corporate income tax at a rate of 15% as its "High and New Technology Enterprises" certificate was obtained on November 19, 2024 with a valid period of three years. Duality Shanghai is subject to corporate income tax at a rate of 25%.

According to the CIT Law and the respective regulations, the income derived by a resident enterprise in China from the transfer of technology which meets certain prescribed criteria could be eligible for income tax incentives. The part of the annual income from the transfer of technology derived by a resident enterprise within RMB5.0 million shall be tax-exempt; and the remainder shall be subject to a 50% reduction in the enterprise income tax rate. During the year ended December 31, 2023 and the nine months ended September 30, 2024, Duality Suzhou incurred income of transfer of technology and applied for the above mentioned tax reduction and exemption incentives.

No provision for corporate income tax has been provided for at a rate of 15% or 25% pursuant to the CIT Law and the respective regulations, as we had no estimated assessable profits during the Track Record Period.

Withholding Tax

According to the CIT rules and regulations, distribution of profits earned by PRC companies is generally subject to a withholding tax of 10% upon the distribution of profits to overseas-incorporated immediate holding companies. Depending on the tax residency of the foreign shareholder, the withholding tax rate may be adjusted based on the relevant bilateral tax treaty. During the years ended December 31, 2022 and 2023 and nine months ended September 30, 2024, we did not have any profit distribution plan.

Withholding tax on revenue from out-licensing

We have entered into a number of out-license and collaboration agreements with certain overseas customers. According to the local income tax rules and regulations in the tax jurisdictions of the customers, a withholding tax might be triggered for the whole or part of the income arising from the license and collaboration agreements.

Loss for the Year/Period

As a result of the foregoing, we incurred losses of RMB387.1 million, RMB357.5 million, RMB113.8 million and RMB566.5 million for the years ended December 31, 2022 and 2023 and the nine months ended September 30, 2023 and 2024, respectively.

PERIOD-TO-PERIOD COMPARISON OF RESULTS OF OPERATIONS

Nine months ended September 30, 2024 Compared to Nine months ended September 30, 2023

Revenue

Our revenue decreased from RMB1,675.9 million for the nine months ended September 30, 2023 to RMB1,462.0 million for the nine months ended September 30, 2024, primarily because during the nine months ended September 30, 2023, we recognized higher revenue attributable to the upfront payments pursuant to the out-license and collaboration agreements with BioNTech. See "Business — Our Collaboration and Licensing Arrangements" for details.

Cost of Revenue

Our cost of revenue increased from RMB324.2 million for the nine months ended September 30, 2023 to RMB802.5 million for the nine months ended September 30, 2024, primarily in relation to the R&D activities we conducted in accordance with our out-license and collaboration agreements.

Gross Profit and Gross Profit Margin

Our gross profit decreased from RMB1,351.8 million for the nine months ended September 30, 2023 to RMB659.5 million for the nine months ended September 30, 2024. Our overall gross profit margin decreased from 80.7% for the nine months ended September 30, 2023 to 45.1% for the nine months ended September 30, 2024. The decreases in gross profit and gross profit margin are primarily because the revenue in the nine months ended September 30, 2023 was primarily derived from upfront payments, while the revenue in the nine months ended September 30, 2024 was primarily derived from reimbursement for R&D activities.

Research and Development Expenses

Our research and development expenses increased by 61.6% from RMB372.4 million for the nine months ended September 30, 2023 to RMB601.9 million for the nine months ended September 30, 2024, primarily due to (i) an increase of RMB120.1 million in staff costs mainly due to increase in share incentive expenses, as we recognized more expenses in accordance with the vesting conditions under our Pre-[**REDACTED**] Equity Incentive Plan during the nine months ended September 30, 2024, and (ii) an increase of RMB82.0 million in CRO and CDMO technical service expenses as we initiated several new trials in 2023 and 2024 and accordingly had more clinical trials in progress and more patients enrolled.

Administrative Expenses

Our administrative expenses increased by 189.6% from RMB43.8 million for the nine months ended September 30, 2023 to RMB126.8 million for the nine months ended September 30, 2024, primarily due to (i) an increase of RMB61.4 million in staff costs mainly due to increase in share incentive expenses, as we recognized more expenses in accordance with the vesting conditions under our Pre-[**REDACTED**] Equity Incentive Plan during the nine months ended September 30, 2024, and (ii) RMB19.8 million in [**REDACTED**] expenses.

Other Income

Our other income increased from RMB2.2 million for the nine months ended September 30, 2023 to RMB3.3 million for the nine months ended September 30, 2024, primarily due to an increase of RMB1.0 million in government grants.

Other Gains/(Losses), Net

We recorded net other gains of RMB38.8 million for the nine months ended September 30, 2023, while we recorded net other losses of RMB7.3 million for the nine months ended September 30, 2024. This is primarily because for the nine months ended September 30, 2023, we recorded net foreign exchange gains of RMB38.8 million due to the appreciation of the U.S. dollar against Renminbi and for the nine months ended September 30, 2024 we recorded net foreign exchange losses of RMB8.7 million due to the depreciation of the U.S. dollar against Renminbi in the third quarter of 2024.

Finance Income

Our finance income increased from RMB24.2 million for the nine months ended September 30, 2023 to RMB38.8 million for the nine months ended September 30, 2024, primarily because we had increased bank deposits as a result of increased cash derived from our out-license and collaboration agreements.

Finance Costs

Our finance costs increased from RMB145 thousand for the nine months ended September 30, 2023 to RMB189 thousand for the nine months ended September 30, 2024, primarily because we expanded the area of our leased properties during the nine months ended September 30, 2024 as we leased more space as our operations grew.

Fair Value Change of Financial Liabilities at Fair Value Through Profit or Loss

We recorded a fair value loss of financial liabilities at fair value through profit or loss of RMB959.2 million and RMB501.4 million for the nine months ended September 30, 2023 and 2024, respectively. The fair value change of financial liabilities at fair value through profit or loss was mainly in relation to changes in the fair value of our Preferred Shares.

Income Tax Expense

Our income tax expense decreased from RMB155.3 million for the nine months ended September 30, 2023 to RMB30.6 million for the nine months ended September 30, 2024 as we had less withholding tax during the nine months ended September 30, 2024.

Loss for the Period

For the reasons discussed above, we recorded loss for the period of RMB113.8 million and RMB566.5 million for the nine months ended September 30, 2023 and 2024, respectively.

Year Ended December 31, 2023 Compared with Year Ended December 31, 2022

Revenue

Our revenue was RMB1.6 million in 2022 and significantly increased to RMB1,786.5 million in 2023, primarily due to the increase in revenue from the out-license and collaboration agreements we entered into in 2023 with BioNTech and Adcendo, which was primarily derived from upfront payments from such collaborations and reimbursement for R&D activities we provided for clinical trials of DB-1303, DB-1305 and DB-1311. See "Business — Our Collaboration and Licensing Arrangements" for details.

Cost of Revenue

Our cost of revenue was nil in 2022 and increased to RMB427.7 million in 2023, primarily in relation to the R&D activities we conducted in accordance with our out-license and collaboration agreements.

Gross Profit and Gross Profit Margin

Our gross profit was RMB1.6 million in 2022 and significantly increased to RMB1,358.9 million in 2023, primarily due to the increase of revenue from the out-license and collaboration agreements we entered into. Our overall gross profit margin decreased from 100.0% in 2022 to 76.1% in 2023.

Research and Development Expenses

Our research and development expenses increased by 64.5% from RMB339.9 million in 2022 to RMB559.0 million in 2023, primarily due to (i) an increase of RMB205.5 million in CRO and CDMO technical service expenses as we had more clinical trials in progress in 2023, and (ii) an increase of RMB9.6 million in staff costs mainly as we granted more share options to new employees as we expanded our business scale.

Administrative Expenses

Our administrative expenses increased by 96.2% from RMB31.9 million in 2022 to RMB62.6 million in 2023, primarily due to (i) an increase of RMB18.6 million in professional service expenses which were mainly in relation to the professional services we engaged for our out-license and collaboration agreements and equity financing in 2023, and (ii) an increase of RMB7.6 million in staff costs mainly as we granted more share options to new employees as we expanded our business scale.

Other Income

Our other income increased significantly from RMB0.5 million in 2022 to RMB3.3 million in 2023, primarily due to an increase of RMB2.7 million in government grants.

Other Gains, Net

We recorded net other gains of RMB1.1 million in 2022, which increased to RMB40.8 million in 2023, primarily due to an increase in our cash reserves in U.S. dollars holdings in 2023 due to our revenue increase, coupled with the appreciation of the U.S. dollar against the Renminbi during the same period.

Finance Income

Our finance income increased significantly from RMB3.3 million in 2022 to RMB34.5 million in 2023, primarily because we had increased bank deposits as a result our increased cash derived from our out-license and collaboration agreements.

Finance Costs

Our finance costs increased by 150.7% from RMB75 thousand in 2022 to RMB188 thousand in 2023, primarily because our lease liabilities increased in 2023 as we leased more space as our operations grew.

Fair Value Change of Financial Liabilities at Fair Value Through Profit or Loss

We recorded a fair value loss of financial liabilities at fair value through profit or loss of RMB21.7 million and RMB1,017.9 million in 2022 and 2023, respectively. The fair value change of financial liabilities at fair value through profit or loss was primarily related to changes in the fair value of our Preferred Shares.

Income Tax Expense

We did not incur tax expense in 2022 and incurred tax expense of RMB155.3 million in 2023 mainly because we were subject to withholding tax in Germany and Denmark from our revenue in 2023.

Loss for the Year

For the reasons discussed above, our loss for the year decreased from RMB387.1 million in 2022 to RMB357.5 million in 2023, respectively.

DESCRIPTION OF SELECTED ITEMS FROM THE CONSOLIDATED BALANCE SHEETS

The following table sets forth a summary of our consolidated balance sheets as of the dates indicated.

	As of December 31,		As of September 30,
	2022	2023	2024
	(RMB'000)	*(RMB'000)*	*(RMB'000)*
Non-current assets			
Property, plant and equipment	2,511	12,313	13,105
Intangible assets	51,143	54,248	42,221
Right-of-use assets	4,568	5,445	3,744
Other non-current assets	635	94,008	112,358
Total non-current assets	**58,857**	**166,014**	**171,428**

	As of December 31,		As of September 30,
	2022	2023	2024
	(RMB'000)	*(RMB'000)*	*(RMB'000)*
Current assets			
Cash and cash equivalents	375,974	1,130,889	1,059,706
Restricted cash	–	42,645	43,656
Trade receivables	1,408	100,803	389,844
Prepayments and other receivables	4,913	27,024	20,691
Financial assets at fair value through profit or loss	–	–	60,199
Other current assets	22,585	32,534	59,551
Total current assets	**404,880**	**1,333,895**	**1,633,647**
Total assets	**463,737**	**1,499,909**	**1,805,075**
Current liabilities			
Financial liabilities at fair value through profit or loss	1,072,720	2,132,720	2,605,079
Trade payables	129,495	234,814	524,436
Other payables	25,974	34,674	81,966
Contract liabilities	–	156,132	55,698
Lease liabilities	2,591	2,906	3,207
Total current liabilities	**1,230,780**	**2,561,246**	**3,270,386**
Net current liabilities	**(825,900)**	**(1,227,351)**	**(1,636,739)**
Total assets less current liabilities	**(767,043)**	**(1,061,337)**	**(1,465,311)**
Non-current liabilities			
Contract liabilities	–	60,164	31,952
Lease liabilities	2,074	2,412	563
Total non-current liabilities	**2,074**	**62,576**	**32,515**
Total liabilities	**1,232,854**	**2,623,822**	**3,302,901**
Net liabilities	**(769,117)**	**(1,123,913)**	**(1,497,826)**

Property, Plant and Equipment

During the Track Record Period, our property, plant and equipment primarily consisted of equipment in our offices and facilities, leasehold improvements as well as construction in progress. Our property, plant and equipment increased from RMB2.5 million as of December 31, 2022 to RMB12.3 million as of December 31, 2023 and further increased to RMB13.1 million as of September 30, 2024, primarily due to the expansion of our business operations leading to the increase in the size and number of our offices and the improvement of laboratory.

Intangible Assets

During the Track Record Period, our intangible assets primarily consisted of (i) in-licenses and in-progress research and development, primarily in relation to certain antibodies we licensed in from third parties, see "Business — Our Collaboration and Licensing Arrangements" for details, and (ii) software. The following table sets forth the details of our intangible assets as of the dates indicated.

	As of December 31,		As of September 30,
	2022	2023	2024
	(RMB'000)	*(RMB'000)*	*(RMB'000)*
In-licenses and in-progress research and development	50,825	53,757	38,936
Software	318	491	3,285
Total	**51,143**	**54,248**	**42,221**

Our intangible assets increased from RMB51.1 million as of December 31, 2022 to RMB54.2 million as of December 31, 2023, and decreased to RMB42.2 million as of September 30, 2024. The decrease from December 31, 2023 to September 30, 2024 was primarily because (i) we suspended the development of a drug candidate and accordingly recorded a full allowance for the impairment of the in-licensed antibody used in its development, and (ii) certain amounts were recognized as cost of revenue in accordance with our out-licensing arrangements.

The intangible assets related to in-licenses and in-progress research and development are not ready for use and we are continuing their research and development. Impairment tests were performed in respect of these intangible assets 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 product level.

The impairment test was performed for each pipeline product by engaging an independent appraiser to estimate fair value less cost to sell as the recoverable amount of each pipeline product. The fair value was estimated using the multi-period excess earnings method and the Group estimated the forecast of profit for its pipeline products based on the timing of clinical development and regulatory approval, commercial ramp up to reach expected peak revenue potential, and the length of exclusivity for each pipeline product. The discount rate used is post-tax and reflects specific risks relating to the relevant products.

The following tables set forth details of the annual impairment tests for our key drug candidates with balances in in-licenses and in-progress research and development as of September 30, 2024.

DB-1310	As of December 31,		As of September 30,
	2022	2023	2024
Post-tax discount rate	16.1%	16.0%	16.0%
Revenue growth rate	-6% to 140%	-6% to 140%	-6% to 140%
Recoverable amount of CGU (in RMB'000)	39,492	84,406	113,207
Carrying amount of CGU (in RMB'000)	7,542	10,790	10,790

DB-1419	As of December 31,		As of September 30,
	2022	2023	2024
Post-tax discount rate	16.6%	16.0%	16.0%
Revenue growth rate	-8.7% to 218%	-8.7% to 218%	-8.7% to 218%
Recoverable amount of CGU (in RMB'000)	26,730	74,834	96,754
Carrying amount of CGU (in RMB'000)	3,349	3,349	10,077

DB-1311	As of December 31,		As of September 30,
	2022	2023	2024
Post-tax discount rate	16.1%	16.0%	16.0%
Revenue growth rate	-10% to 160%	-10% to 160%	-10% to 160%
Recoverable amount of CGU (in RMB'000)	55,394	140,526	202,705
Carrying amount of CGU (in RMB'000)	6,965	2,931	5,423

DB-1418	As of December 31,		As of September 30,
	2022	2023	2024
Post-tax discount rate	Not applicable	Not applicable	16.0%
Revenue growth rate	Not applicable	Not applicable	-5% to 333.9%
Recoverable amount of CGU (in RMB'000)	Not applicable	Not applicable	22,803
Carrying amount of CGU (in RMB'000)	Not applicable	Not applicable	6,703

DB-1324	As of December 31,		As of September 30,
	2022	2023	2024
Post-tax discount rate	Not applicable	Not applicable	16.0%
Revenue growth rate	Not applicable	Not applicable	-19.6% to 246.1%
Recoverable amount of CGU (in RMB'000)	Not applicable	Not applicable	12,605
Carrying amount of CGU (in RMB'000)	Not applicable	Not applicable	5,943

We also perform sensitivity test by increasing one percentage of post-tax discount rate or decreasing one percentage of revenue growth rate, which our management considers are the key assumptions to determine the recoverable amount of each intangible asset, with all other variables held constant.

For more details, please refer to note 16 to the Accountant's Report set out in Appendix I to this document.

Based on the result of the assessment, there was no impairment for the in-licenses and in-progress research and development as of December 31, 2022 and 2023. Considering there was sufficient headroom based on the assessment, our Directors and management believe that a reasonably possible change in any of the key assumptions would not cause the relevant carrying amount of the cash generating unit to exceed its recoverable amount, and that there was no impairment as of September 30, 2024, except that we suspended the development of a drug candidate and accordingly recorded a full allowance for the impairment of the in-licensed antibody used in its development.

Right-of-use Assets

During the Track Record Period, our right-of-use assets represents leases of offices and laboratory. Our right-of-use assets increased from RMB4.6 million as of December 31, 2022 to RMB5.4 million as of December 31, 2023, primarily because we had new leases in 2023. Our right-of-use assets decreased from RMB5.4 million as of December 31, 2023 to RMB3.7 million as of September 30, 2024, primarily due to the depreciation of the right-of-use assets.

Other Non-current Assets

During the Track Record Period, our other non-current assets primarily consisted of (i) withholding tax recoverable mainly in relation to the withholding tax deducted from payments made by our overseas collaboration partners in accordance with local regulations, a portion of

which may be refunded to us by virtue of the tax treaty between the local jurisdiction and China, and (ii) others, primarily representing non-current prepayments incurred during our business operation. The following table sets forth the details of our other non-current assets as of the dates indicated.

	As of December 31,		As of September 30,
	2022	2023	2024
	(RMB'000)	*(RMB'000)*	*(RMB'000)*
Tax deduction related to withholding tax	–	93,666	111,678
Others	635	342	680
Total	**635**	**94,008**	**112,358**

Our other non-current assets increased significantly from RMB0.6 million as of December 31, 2022 to RMB94.0 million as of December 31, 2023 and further increased to RMB112.4 million as of September 30, 2024, primarily due to the increase of withholding tax recoverable caused by the increase of our revenue from collaboration partners.

As of January 31, 2025, none of our withholding tax recoverable as of September 30, 2024 had been subsequently recovered. During the Track Record Period and up to the Latest Practicable Date, we had not encountered any recoverability issue in relation to our withholding tax recoverable.

Withholding tax receivables as of September 30, 2024 mainly represents RMB107,352,000 in withholding tax receivable from the Federal Central Tax Office, Germany, attributable to excess withholding tax withheld and paid by our overseas collaboration partner in Germany based on the normal statutory withholding tax rate of 15.825%. According to the double tax treaty between China and Germany, Duality Suzhou, as the recipient of the payment and a Chinese tax resident, is eligible to apply for a reduced withholding tax rate of 10%. Duality Suzhou has submitted an application for this treaty benefit and received a formal withholding tax exemption certificate issued by the Federal Central Tax Office. The certificate confirms that Duality Suzhou is entitled to the reduced withholding tax rate of 10% for license payments received. The refund process for the recoverable portion of withholding tax is currently ongoing. We do not anticipate material issues regarding the recoverability of the withholding tax recoverable.

As of January 31, 2025, our other non-current assets was RMB115.1 million, primarily representing tax deduction related to withholding tax.

Cash and Cash Equivalents

During the Track Record Period, our cash and cash equivalents primarily consisted of cash in bank and in hand, denominated on Renminbi, U.S. dollar and Euro. The following table sets forth the details of our cash in bank and on hand as of the dates indicated.

	As of December 31,		As of September 30,
	2022	2023	2024
	(RMB'000)	*(RMB'000)*	*(RMB'000)*
Cash in bank and on hand are denominated in:			
Renminbi	187,710	570,485	224,225
U.S. dollar	188,264	558,170	833,401
Euro	–	2,234	2,080
Total	**375,974**	**1,130,889**	**1,059,706**

Our cash and cash equivalents increased from RMB376.0 million as of December 31, 2022 to RMB1,130.9 million as of December 31, 2023 and further increased to RMB1,059.7 million as of September 30, 2024, primarily due to our increased revenue from out-license and collaboration agreements.

Financial Assets at Fair Value through Profit or Loss

As part of our cash management policy, we purchase wealth management products to better utilize our idle cash without interfering with our business operations or capital expenditures. During the Track Record Period, we purchased structured deposits issued by reputable commercial banks in the PRC, with a floating return being paid together with the principal on the maturity date, which were recognized as financial assets at fair value through profit or loss. As of December 31, 2022, December 31, 2023 and September 30, 2024, the balances of our financial assets at fair value through profit or loss were nil, nil and RMB60.2 million, respectively.

To monitor and control the investment risks associated with our financial assets at fair value through profit or loss, we have adopted a comprehensive set of internal policies and guidelines to manage our investment in financial assets at fair value through profit or loss. We make investment decisions based on our estimated capital requirements and our annual budget, taking into account the duration, expected returns and risks of the wealth management product. We generally limit our purchases to low-risk and short-term products which are redeemable on demand from reputable commercial banks.

After [**REDACTED**], we may continue to purchase low-risk wealth management products with a short maturity period based on our operational needs, strictly in accordance with our internal policies and measures and the requirements under Chapter 14 of the Listing Rules.

Restricted Cash

During the Track Record Period, our restricted cash represented the restricted deposits held in designated bank accounts mainly as security deposits for derivative financial instruments, denominated in U.S. dollars.

Trade Receivables

During the Track Record Period, our trade receivables consisted of receivables from our collaboration partners for payment obligations set out in the relevant agreements, primarily including reimbursement payments and a milestone payment as of the balance sheet dates. The following table sets forth the details of our trade receivables as of the dates indicated.

	As of December 31,		As of September 30,
	2022	2023	2024
	(RMB'000)	*(RMB'000)*	*(RMB'000)*
Trade receivables	1,410	100,888	390,356
Less: provision for impairment of trade receivables	(2)	(85)	(512)
Total	**1,408**	**100,803**	**389,844**

Our trade receivables increased significantly from RMB1.4 million as of December 31, 2022 to RMB100.8 million as of December 31, 2023 and further increased to RMB389.8 million as of September 30, 2024, generally in line with the R&D activities we conducted in relation to our out-license and collaboration programs.

The following table sets forth an aging analysis of our trade receivables presented based on the invoice date and net of expected credit losses as of the dates indicated.

	As of December 31,		As of September 30,
	2022	2023	2024
	(RMB'000)	*(RMB'000)*	*(RMB'000)*
Within 30 days	1,408	100,803	354,840
31 days to 60 days	–	–	35,004
Total trade receivables	**1,408**	**100,803**	**389,844**

As of January 31, 2025, RMB390.4 million, or 100.0%, of our trade receivables as of September 30, 2024 had been subsequently settled. There had been no material recoverability issue for our trade receivable balance during the Track Record Period and up to the Latest Practicable Date and we believe sufficient provision has been made.

As of January 31, 2025, our trade receivables amounted to RMB574.9 million, all of which aged less than 30 days.

Prepayments and Other Receivables

During the Track Record Period, our prepayments and other receivables primarily consisted of (i) prepayments to suppliers in our R&D activities, (ii) deposits for our leases and in relation to staff compensation, and (iii) deferred [**REDACTED**] expenses.

	As of December 31,		As of September 30,
	2022	2023	2024
	(RMB'000)	*(RMB'000)*	*(RMB'000)*
Prepayments to suppliers	1,685	21,746	11,552
Deposits	3,161	5,264	5,191
Deferred [**REDACTED**] expenses	–	–	3,902
Others	67	14	46
Total	**4,913**	**27,024**	**20,691**

Our prepayments and other receivables increased from RMB4.9 million as of December 31, 2022 to RMB27.0 million as of December 31, 2023 and decreased to RMB20.7 million as of September 30, 2024. The level of our prepayments and other receivables primarily depends on our R&D activities and business operation.

Other Current Assets

During the Track Record Period, our other current assets represent value-added tax recoverable. Our other current assets increased from RMB22.6 million as of December 31, 2022 to RMB32.5 million as of December 31, 2023 and further increased to RMB59.6 million as of September 30, 2024. This growth was primarily driven by the expansion of our operations and the resulting increase in procurement activities. Additionally, the amount of VAT we paid on inputs exceeded the VAT collected on sales, contributing to the rise in our VAT recoverable.

Financial Liabilities at Fair Value Through Profit or Loss

Our financial liabilities at fair value through profit or loss primarily represented the Preferred Shares issued in our previous equity financings. As of December 31, 2022, our financial liabilities at fair value through profit or loss also included the convertible loans and advanced payments issued in series B financing and series B+ financing. In our series B financing and series B+ financing, as transitional arrangements before the completion of certain onshore Renminbi investors' ODI registration obligation, these investors provided convertible loans or advanced payments with reference to their purchase consideration for our Preferred Shares to us, which we agreed to repay upon completion of ODI registration. At the

same time, we issued warrants to these investors, allowing them to purchase our Preferred Shares once the ODI registration was completed. In 2023 we repaid the convertible loans and advanced payments and issued Preferred Shares to these investors. See "History and Corporate Structure — Corporate History — Establishment and Major Shareholding Changes of Our Company — Series B and Series B+ Financing" for details.

Our Preferred Shares are recorded as financial liabilities at fair value through profit or loss (current). Effective from January 1, 2024, "IAS 1 (Amendment) 'Classification of Liabilities as current or non-current'" requires a reclassification of convertible preferred shares from non-current liabilities to current liabilities, as the convertible preferred shares may be converted into ordinary shares at the option of the preferred shareholders at any time and the conversion feature does not meet "fixed-for-fixed" criteria. See "— Material Accounting Policies and Significant Accounting Judgments and Estimates — Financial Liabilities at Fair Value Through Profit or Loss" for details. These Preferred Shares will be converted into Ordinary Shares upon [**REDACTED**], after which the amount of our financial liabilities at fair value through profit or loss will be derecognized from our liabilities and recorded as equity.

Our financial liabilities at fair value through profit or loss increased from RMB1.1 billion as of December 31, 2022 to RMB2.1 billion as of December 31, 2023, and further increased to RMB2.6 billion as of September 30, 2024 primarily due to the changes in fair value of our Preferred Shares.

Trade Payables

During the Track Record Period, our trade payables primarily consisted of payables in relation to our research and development activities. Our trade payables increased from RMB129.5 million as of December 31, 2022 to RMB234.8 million as of December 31, 2023 and further increased to RMB524.4 million as of September 30, 2024. The continuous increase of our trade payables was primarily due to the expanded scale of our R&D activities.

The following table sets forth an aging analysis of our trade payables presented based on the invoice date as of the dates indicated.

	As of December 31,		As of September 30,
	2022	2023	2024
	(RMB'000)	*(RMB'000)*	*(RMB'000)*
Within 6 months	123,980	234,476	523,475
6 months to 12 months	5,515	338	961
Total	**129,495**	**234,814**	**524,436**

As of January 31, 2025, RMB312.2 million, or 59.5%, of our trade payables as of September 30, 2024 had been subsequently settled.

Our Directors confirm that there has not been any material default on our part in the payment of trade payables during the Track Record Period and up to the date of this document.

Other Payables

During the Track Record Period, our other payables consisted of (i) staff salaries and welfare payables, (ii) payables for acquisition of property, plant and equipment and intangible assets, (iii) payables for [**REDACTED**] expenses, (iv) other taxes payable, (v) payables for financial and consulting services, (vi) recruitment services and other accrued expenses, and (vii) others. The following table sets forth the details of our other payables as of the dates indicated.

	As of December 31,		As of September 30,
	2022	2023	2024
	(RMB'000)	*(RMB'000)*	*(RMB'000)*
Staff salaries and welfare payables	16,829	23,587	24,027
Payables for acquisition of property, plant and equipment and intangible assets	6,965	7,408	33,538
Payables for [**REDACTED**] expenses	–	–	18,160
Other taxes payable	699	919	1,440
Payables for financial and consulting services	60	1,651	1,492
Recruitment services and other accrued expenses	807	–	455
Others	614	1,109	2,854
Total	**25,974**	**34,674**	**81,966**

Our other payables increased from RMB26.0 million as of December 31, 2022 to RMB34.7 million as of December 31, 2023, primarily due to an increase of RMB6.8 million in staff salaries and welfare payables as we had more employees. Our other payables further increased to RMB82.0 million as of September 30, 2024, primarily due to an increase of RMB26.1 million in payables for acquisition of property, plant and equipment and intangible assets, as well as the payables for [**REDACTED**] expenses. As of January 31, 2025, RMB47.9 million, or 58.4%, of our other payables as of September 30, 2024 had been subsequently settled.

Our Directors confirm that there has not been any material default on our part in the payment of other payables during the Track Record Period and up to the date of this document.

Contract Liabilities

Our contract liabilities primarily represented amounts paid by our collaboration partners in relation to our out-license and collaboration agreements before we fulfilled corresponding performance obligations. The excess of our cumulative billings to customers over the cumulative revenue recognized in profit or loss is recognized as contract liabilities. See "Business — Our Collaboration and Licensing Arrangements" for details. We did not incur any contract liabilities in 2022. Our contract liabilities amounted to RMB216.3 million as of December 31, 2023 and decreased to RMB87.7 million as of September 30, 2024, primarily because we fulfilled certain performance obligations. As of January 31, 2025, RMB27.7 million, or 31.6%, of our contract liabilities as of September 30, 2024 had been recognized as revenue.

Lease Liabilities

Our lease liabilities primarily consisted of leases of offices and laboratory. During the Track Record Period, our lease liabilities increased from RMB4.7 million as of December 31, 2022 to RMB5.3 million as of December 31, 2023, as we entered into new leases in 2023. Our lease liabilities decreased from RMB5.3 million as of December 31, 2023 to RMB3.8 million as of September 30, 2024, primarily because we continued paying rent under our lease contracts.

LIQUIDITY AND CAPITAL RESOURCES

Our primary uses of cash during the Track Record Period were to fund our research and development activities. During the Track Record Period, we conducted series B and B+ financing and also generated cash inflow from our out-license and collaboration agreements. We recorded net cash from operating activities of RMB816.3 million and RMB20.4 million for the year ended December 31, 2023 and the nine months ended September 30, 2024, respectively. As of January 31, 2025, being the latest practicable date for determining our indebtedness, we had cash and cash equivalents, term deposits with initial term over three months (principal-protected and available for early withdrawal at any time), restricted cash and financial assets at fair value through profit or loss of RMB1,801.4 million.

Current Assets and Liabilities

	As of December 31,		As of September 30,	As of January 31,
	2022	2023	2024	2025
	(RMB'000)	*(RMB'000)*	*(RMB'000)*	*(RMB'000) (Unaudited)*
Current assets				
Cash and cash equivalents	375,974	1,130,889	1,059,706	1,503,769
Restricted cash	–	42,645	43,656	45,155
Term deposits with initial term over three months	–	–	–	182,478
Trade receivables	1,408	100,803	389,844	574,933
Prepayments and other receivables	4,913	27,024	20,691	24,573
Contract assets	–	–	–	29,502
Financial assets at fair value through profit or loss	–	–	60,199	70,000
Other current assets	22,585	32,534	59,551	1,985
Total current assets	**404,880**	**1,333,895**	**1,633,647**	**2,432,395**
Current liabilities				
Financial liabilities at fair value through profit or loss	1,072,720	2,132,720	2,605,079	3,057,035
Trade payables	129,495	234,814	524,436	715,465
Other payables	25,974	34,674	81,966	70,309
Contract liabilities	–	156,132	55,698	82,949
Lease liabilities	2,591	2,906	3,207	2,686
Total current liabilities	**1,230,780**	**2,561,246**	**3,270,386**	**3,928,444**
Net current (liabilities)/assets	**(825,900)**	**(1,227,351)**	**(1,636,739)**	**(1,496,049)**

We recorded net current liabilities during the Track Record Period primarily because our Preferred Shares issued to Pre-[**REDACTED**] investors are recorded as current liabilities under financial liabilities at fair value through profit or loss. These Preferred Shares will be converted into Ordinary Shares upon [**REDACTED**], after which the amount of our financial liabilities at fair value through profit or loss, which were recorded as our current liabilities during the Track Record Period, will be derecognized from our liabilities and recorded as equity, which can result in the Group turning into net current assets and net assets position. See "— Description of Selected Items from the Consolidated Balance Sheets — Financial Liabilities at Fair Value through Profit or Loss" for details.

We expect to continue to incur significant expenses for the foreseeable future as we advance our ADC candidates, which will be funded by a combination of our cash on hand, our income from out-license and collaboration agreements, and [**REDACTED**] from the [**REDACTED**].

Working Capital Sufficiency

Although we recorded significant net current liabilities during the Track Record Period, our Directors are of the view that we have sufficient working capital to cover at least 125% of our costs, including research and development expenses and administrative expenses (including any production costs), for at least the next 12 months from the date of this document, primarily for the reasons set out below:

- ***Cash on hand and cash inflow from our operations.*** We had cash and cash equivalents, restricted cash and financial assets at fair value through profit or loss together amounting to RMB1,163.6 million as of September 30, 2024. We expect to receive milestone payments from our out-license and collaboration agreements in the future, and intend to utilize them to fund our operations, subject to the achievement of certain milestones and other terms of these agreements. See "Business — Our Collaboration and Licensing Arrangements" for details. Furthermore, upon the successful commercialization of one or more of our ADC candidates, we expect to fund our operations in part with income generated from sales of our commercialized drugs.

- ***Conversion of Preferred Shares upon*** [**REDACTED**]**.** As of September 30, 2024, we recorded RMB2,605.1 million in financial liabilities at fair value through profit or loss, which were attributable to the Preferred Shares we issued to Pre-[**REDACTED**] Investors. These Preferred Shares will be converted into Ordinary Shares upon [**REDACTED**], after which our financial liabilities at fair value through profit or loss, which were recorded as current liabilities during the Track Record Period, will be derecognized from our liabilities and recorded as equity, which can result in the Group turning into net current assets and net assets position. See "— Description of Selected Items from the Consolidated Balance Sheets — Financial Liabilities at Fair Value through Profit or Loss" for details.

- ***Cash burn rate.*** Our cash burn rate refers to the average monthly amount of cash used in operating activities, payment for property, plant and equipment and payment for intangible assets, without taking into account the cash inflow from out-licensing and collaboration agreements. We estimate that we will receive [**REDACTED**] of approximately HK$[**REDACTED**] million in the [**REDACTED**], assuming an [**REDACTED**] of HK$[**REDACTED**] per Share, being the low end of the indicative [**REDACTED**] range stated in this document. Assuming an average cash burn rate going forward of 1.2 times the level in 2023, we estimate that (i) our cash and cash equivalents as of September 30, 2024 will be able to maintain our financial viability for [**REDACTED**] months, (ii) if we take into account [**REDACTED**]% of the

estimated [**REDACTED**] from the [**REDACTED**] (namely, the portion allocated for our working capital and other general corporate purposes), [**REDACTED**] months, or, (iii) if we take into account all estimated [**REDACTED**] from the [**REDACTED**], [**REDACTED**] months. We will continue to monitor our cash flows from operations closely and expect to raise our next round of financing no earlier than six months after the completion of the [**REDACTED**].

Cash Flows

The following table sets forth the components of our consolidated statements of cash flows for the periods indicated:

	For the year ended December 31,		For the nine months ended September 30,	
	2022	**2023**	**2023**	**2024**
	(RMB'000)	*(RMB'000)*	*(RMB'000)* *(unaudited)*	*(RMB'000)*
Operating cash flows before movement in working capital	(360,877)	790,947	978,381	140,242
Changes in working capital	58,139	239,834	215,349	(110,230)
Income tax paid	–	(248,929)	(248,929)	(48,398)
Interest received	3,268	34,483	24,160	38,809
Net cash (used in)/from operating activities	(299,470)	816,335	968,961	20,423
Net cash (used in) investing activities	(22,200)	(78,550)	(33,479)	(80,839)
Net cash (used in)/from financing activities	451,461	10,817	12,954	(3,312)
Net increase/(decrease) in cash and cash equivalents	129,791	748,602	948,436	(63,728)
Cash and cash equivalents at beginning of year/period	227,762	375,974	375,974	1,130,889
Effect of foreign exchange rate changes	18,421	6,313	15,388	(7,455)
Cash and cash equivalents at the end of year/period	375,974	1,130,889	1,339,798	1,059,706

Net Cash (Used in)/From Operating Activities

For the nine months ended September 30, 2024, we had net cash from operating activities of RMB20.4 million, which was primarily attributable to our loss before taxation of RMB535.9 million adjusted by certain non-cash and working capital items, including (i) positive adjustments, which primarily included fair value losses on financial liabilities at fair value through profit or loss of RMB501.4 million, increase in trade and other payables of RMB327.8 million and share-based compensation expenses of RMB164.0 million, and (ii) negative adjustments, which primarily included increase in trade, other receivables and prepayments of RMB282.4 million, decrease in contract liability of RMB128.6 million.

For the year ended December 31, 2023, we had net cash from operating activities of RMB816.3 million, which was primarily attributable to our loss before taxation of RMB202.2 million adjusted by certain non-cash and working capital items, including (i) positive adjustments, which primarily included fair value losses on financial liabilities at fair value through profit or loss of RMB1,017.9 million and an increase of RMB216.3 million in contract liabilities, and (ii) negative adjustments, which primarily included an increase of RMB121.0 million in trade, other receivables and prepayments, net foreign exchange gains of RMB41.9 million and finance income of RMB34.5 million.

For the year ended December 31, 2022, we had net cash used in operating activities of RMB299.5 million, which was primarily attributable to our loss before taxation of RMB387.1 million adjusted by certain non-cash and working capital items, including (i) positive adjustments, which primarily included an increase of RMB71.0 million in trade and other payables and fair value losses on financial liabilities at fair value through profit or loss of RMB21.7 million, and (ii) negative adjustments, which primarily included an increase of RMB12.2 million in other current assets and finance income of RMB3.3 million.

Net Cash Used in Investing Activities

For the nine months ended September 30, 2024, we had net cash used in investing activities of RMB80.8 million, primarily attributable to (i) net increase in financial assets of RMB60.0 million, (ii) purchase of intangible assets of RMB17.9 million, (iii) purchase of property, plant and equipment of RMB3.2 million, (iv) interest received on financial assets of RMB1.3 million, and (v) changes in restricted cash balances of RMB1.0 million.

For the year ended December 31, 2023, we had net cash used in investing activities of RMB78.6 million, primarily attributable to (i) purchase of intangible assets of RMB24.6 million, (ii) purchase of property, plant and equipment of RMB11.3 million, and (iii) changes in restricted cash balances of RMB42.6 million.

For the year ended December 31, 2022, we had net cash used in investing activities of RMB22.2 million, primarily attributable to (i) purchase of intangible assets of RMB19.7 million, and (ii) purchase of property, plant and equipment of RMB2.5 million.

Net Cash (Used in)/From Financing Activities

For the nine months ended September 30, 2024, we had net cash used in financing activities of RMB3.3 million, primarily attributable to (i) principal component of lease payments of RMB2.2 million, and (ii) payment of [**REDACTED**] of RMB0.9 million.

For the year ended December 31, 2023, we had net cash from financing activities of RMB10.8 million, primarily attributable to proceeds from issuance of Preferred Shares issued of RMB151.1 million; partially offset by (i) repayments of loans with warrants to purchase Series B-2 Preferred Shares from holders of Preferred Shares of RMB135.2 million, see "— Description of Selected Items from the Consolidated Balance Sheets — Financial Liabilities at Fair Value through Profit or Loss" for details, (ii) settlement of financial assets at fair value through profit or loss of RMB1.2 million, and (iii) principal component of lease payments of RMB3.5 million.

For the year ended December 31, 2022, we had net cash from financing activities of RMB451.5 million, primarily attributable to (i) proceeds from issuance of Preferred Shares issued of RMB318.6 million and (ii) proceeds from loans with warrants to purchase Series B-2 Preferred Shares from holders of Preferred Shares of RMB135.2 million, see "— Description of Selected Items from the Consolidated Balance Sheets — Financial Liabilities at Fair Value through Profit or Loss" for details; partially offset by (i) principal component of lease payments of RMB1.4 million, and (ii) interests elements of lease payments of RMB75 thousand.

CASH OPERATING COSTS

The following table sets forth our cash operating costs for the periods indicated:

	For the year ended December 31,		For the nine months ended September 30,
	2022	2023	2024
	(RMB'000)	*(RMB'000)*	*(RMB'000)*
Costs relating to research and development of our Core Products			
Clinical costs	20,798	237,700	361,953
Nonclinical costs	69,065	155,074	182,121
In-license costs	–	84,670	–
Subtotal	89,863	477,444	544,074

	For the year ended December 31,		For the nine months ended September 30,
	2022	2023	2024
	(RMB'000)	*(RMB'000)*	*(RMB'000)*
Costs relating to research and development of our other drug candidates			
Clinical costs	15,967	72,953	119,028
Nonclinical costs	142,982	231,799	181,171
In-license costs	–	8,554	12,779
Subtotal	158,949	313,306	312,978
Labor cost for research and development staff	28,594	79,806	93,646
Total	**277,406**	**870,556**	**950,698**
Labor cost for non-research and development staff	8,912	13,865	21,973
Operating cost	15,999	43,690	39,558

INDEBTEDNESS

As of December 31, 2022 and 2023, September 30, 2024, and January 31, 2025, being the most recent practicable date for determining our indebtedness, except as disclosed in the table below, we did not have any material indebtedness.

	As of December 31,		As of September 30,	As of January 31,
	2022	2023	2024	2025
	(RMB'000)	*(RMB'000)*	*(RMB'000)*	*(RMB'000)* *(Unaudited)*
Current				
Lease liabilities	2,591	2,906	3,207	2,686
Financial liabilities at fair value through profit or loss	1,072,720	2,132,720	2,605,079	3,057,035
Non-current				
Lease liabilities	2,074	2,412	563	2,179
Total	**1,077,385**	**2,138,038**	**2,608,849**	**3,061,900**

Except as discussed above, we did not have any other 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 the Latest Practicable Date. 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 material 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.

As of the Latest Practicable Date, we had unutilized banking facilities of RMB600.0 million. Our Directors confirm that there have been no material changes in our indebtedness since January 31, 2025, being the latest practicable date for determining our indebtedness, up to the date of this document.

CAPITAL EXPENDITURES

In 2022 and 2023 and the nine months ended September 30, 2024, we incurred capital expenditures of RMB29.2 million, RMB35.9 million and RMB28.6 million, respectively, primarily in connection with the intangible assets and purchase of property, plant and equipment. These purchases were primarily for our R&D and business operation. The following table sets forth the details of our capital expenditure for the periods indicated.

	For the year ended December 31,		For the nine months ended September 30,
	2022	2023	2024
	(RMB'000)	*(RMB'000)*	*(RMB'000)*
Purchases of property, plant and equipment	2,482	11,284	3,189
Purchases of intangible assets	26,683	24,621	25,453
Total	**29,165**	**35,905**	**28,642**

We plan to finance our future capital expenditures primarily with our existing cash as well as [**REDACTED**] from the [**REDACTED**]. See the section "Future Plans and [**REDACTED**]" in the document for more details. We may reallocate the funds to be utilized on capital expenditures based on our ongoing business needs.

CONTRACTUAL COMMITMENTS

Capital Commitments

As of December 31, 2022 and 2023 and September 30, 2024, our capital expenditure contracted for but not yet incurred is related to property, plant and equipment, amounting to RMB5.1 million, RMB0.5 million and RMB1.2 million.

CONTINGENT LIABILITIES

As of December 31, 2022 and 2023 and September 30, 2024, we did not have any contingent liabilities. Our Directors confirm that there has been no material change in our contingent liabilities since September 30, 2024 to the date of this document.

OFF-BALANCE SHEET COMMITMENTS AND ARRANGEMENTS

We did not have, during the years or periods presented, and we do not currently have, any off-balance sheet arrangements such as relationships with unconsolidated entities or financial partnerships, which are often referred to as structured finance or special purpose entities, established for the purpose of facilitating financing transactions that are not required to be reflected on our balance sheets.

KEY FINANCIAL RATIOS

The following table sets forth our key financial ratios as of the dates indicated:

	As of December 31,		As of September 30,
	2022	2023	2024
Current ratio[(1)]	0.3	0.5	0.5

Note:

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

Our current ratio increased from 0.3 as of December 31, 2022 to 0.5 as of December 31, 2023 and further increased to 0.5 as of September 30, 2024, primarily because our cash and cash equivalents continuously increased during the Track Record Period, partially offset by the increase in our financial liabilities at fair value through profit or loss.

MATERIAL RELATED PARTY TRANSACTIONS

We did not have any material related party transactions during the Track Record Period. See note 30 in the Accountant's Report set out in Appendix I of this document for details on our transactions with related parties during the Track Record Period.

QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

Our activities expose us to a variety of financial risks: market risk (including foreign exchange, cash flow and fair value interest rate risk), credit risk and liquidity risk. Our overall risk management program focuses on the unpredictability of financial markets and seeks to minimize potential adverse effects on our financial performance. Risk management is carried out by our management. For further details, see note 3 in the Accountant's Report set out in Appendix I of this document.

Market Risk

Foreign Exchange Risk

Foreign exchange risk arises when future commercial transactions or recognized assets and liabilities are denominated in a currency that is not our entities' functional currency. Our Company's functional currency is U.S. dollar. Our primary subsidiaries were incorporated in the PRC and these subsidiaries considered Renminbi as their functional currency.

We operate mainly in the PRC. There are certain cash and bank balances, trade receivables, other non-current assets, and other payables denominated in a currency that is not the functional currency. We constantly review the economic situation and our foreign exchange risk profile, and will consider appropriate hedging measures, as may be necessary. For further details, see note 3.1.1 of the Accountant's Report set out in Appendix I to this document.

Cash Flow and Fair Value Interest Rate Risk

Interest rate risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in market interest rates. Our exposure to the risk of changes in market interest rates relates primarily to our interest-bearing cash and cash equivalents. When cash and cash equivalents obtained at variable rates expose us to cash flow interest-rate risk. We have not hedged cash flow or fair value interest-rate risk. The cash and cash equivalents are disclosed in note 17 in the Accountant's Report set out in Appendix I of this document.

We have no significant interest-bearing assets except for cash and cash equivalents, details of which have been disclosed in note 17 in the Accountant's Report set out in Appendix I of this document.

Credit Risk

Credit risk arises from cash and cash equivalents, trade receivables as well as other receivables. The carrying amount of each class of the above financial assets represents our maximum exposure to credit risk in relation to the corresponding class of financial assets.

To manage this risk, cash and cash equivalents are mainly deposited with state-owned or reputable financial institutions in the PRC and reputable international financial institutions outside of the PRC. There has been no recent history of default in relation to these financial institutions.

For trade receivables, management applies the IFRS 9 simplified approach to measuring expected credit losses which uses a lifetime expected loss allowance for all trade receivables. Our Directors believe that there is no material credit risk inherent in the our outstanding balance of trade receivables, details of which have been disclosed in note 19 in the Accountant's Report set out in Appendix I of this document.

For other receivables and other non-current assets, our management has assessed that during the years ended December 31, 2022 and 2023 and nine months ended September 30, 2024, other receivables and other non-current assets have not had a significant increase in credit risk since initial recognition. Thus, a 12-month expected credit loss approach that results from possible default event within 12 months of each reporting date is adopted by management. We do not expect any losses from non-performance by the counterparties of other receivables and no loss allowance provision for other receivables and other non-current assets was recognized.

To measure the expected credit losses, other receivables have been grouped based on shared credit risk characteristics and the days past due. As of December 31, 2022 and 2023 and September 30, 2024, we have assessed that the expected loss rate for other receivables was immaterial. Thus no loss allowance provision for other receivables was recognized as of December 31, 2022 and 2023 and September 30, 2024.

Liquidity Risk

We aim to maintain sufficient cash and cash equivalents or have available facility through an adequate amount of available financing to meet our daily operating working capital. For further details, see note 3.1.3 of the Accountant's Report set out in Appendix I to this document.

DIVIDENDS

We did not declare or pay dividends on our Shares during the Track Record Period. We currently expect to retain all future earnings for use in operation and expansion of our business, and do not anticipate paying cash dividends in the foreseeable future. Our board of directors has complete discretion as to whether to distribute dividends, subject to certain restrictions under Cayman Islands law. In addition, our Shareholders may by ordinary resolution declare a dividend, but no dividend may exceed the amount recommended by our board of directors. Even if our board of directors decides to declare and pay dividends, the timing, amount and form of future dividends, if any, will depend on our future results of operations and cash flow, our capital requirements and surplus, the amount of distributions, if any, received by us from our subsidiaries, our financial condition, contractual restrictions and other factors deemed relevant by our board of directors. Currently, we do not have any dividend policy or intention to declare or pay any dividends in the near future. As advised by our legal advisor as to Cayman Islands law, notwithstanding that the Company may have accumulated losses, the Company may declare dividend (a) out of profits of the Company if the Company has sufficient profits, realized or unrealized, unless such is contrary to the accounting principles adopted by the Company or (b) out of the share premium of the Company if following the date on which the dividend is proposed to be paid, the Company is able to pay its debts as they fall due in the ordinary course of business. In determining whether to declare a dividend, our Board will need to be satisfied that the declaration of dividend is in the best interest of the Company and may make provision for losses. [**REDACTED**] should not purchase our Shares with the expectation of receiving cash dividends.

[**REDACTED**]

[**REDACTED**] to be borne by us are estimated to be approximately HK$[**REDACTED**] million (assuming an [**REDACTED**] of HK$[**REDACTED**] per Share, being the [**REDACTED**] of the indicative [**REDACTED**] range of HK$[**REDACTED**] to HK$[**REDACTED**] per Share), representing approximately [**REDACTED**]% of the estimate [**REDACTED**] from the [**REDACTED**] assuming no Shares are issued pursuant to the [**REDACTED**]. The [**REDACTED**] consist of (i) [**REDACTED**]-related expenses, including [**REDACTED**] commission, of approximately HK$[**REDACTED**] million, and (ii) non-[**REDACTED**]-related expenses of approximately HK$[**REDACTED**] million, comprising (a) fees and expenses of our legal advisors and reporting accountants of approximately HK$[**REDACTED**] million, and (b) other fees and expenses of approximately HK$[**REDACTED**] million. During the Track Record Period, [**REDACTED**] of RMB19.8 million was charged to our consolidated statements of profit or loss. After the Track Record Period, approximately HK$[**REDACTED**] million is expected to be charged to our consolidated statements of profit or loss, and approximately HK$[**REDACTED**] million is expected to be accounted for as a deduction from equity upon the [**REDACTED**]. The [**REDACTED**] above are the latest practicable estimate for reference only, and the actual amount may differ from this estimate.

UNAUDITED [REDACTED] FINANCIAL INFORMATION

The following unaudited [**REDACTED**] statement of adjusted consolidated net tangible assets of our Group prepared in accordance with Rule 4.29 of the Listing Rules is for illustrative purposes only, and is set out below to illustrate the effect of the [**REDACTED**] on the net tangible assets of our Group attributable to the owners of our Company as of September 30, 2024 as if the [**REDACTED**] had taken place on September 30, 2024.

This unaudited [**REDACTED**] statement of adjusted consolidated net tangible assets has been prepared for illustrative purposes only and because of its hypothetical nature, it may not give a true picture of the consolidated net tangible assets of our Group as of September 30, 2024 or at any future dates following the [**REDACTED**].

[**REDACTED**]

[**REDACTED**]

NO MATERIAL ADVERSE CHANGE

After performing sufficient due diligence work which our Directors consider appropriate and after due and careful consideration, our Directors confirm that, except as disclosed in "Summary — Recent Developments and No Material Adverse Change" and up to the date of this document, there has been no material adverse change in our financial or [**REDACTED**] position or prospects since September 30, 2024, which is the end date of the periods reported on in the Accountant's Report included in Appendix I to this document, and there is no event since September 30, 2024 that would materially affect the information as set out in the Accountant's Report included in Appendix I to this document.

DISCLOSURE UNDER RULES 13.13 TO 13.19 OF THE LISTING RULES

Our Directors confirm that, as of the Latest Practicable Date, they were not aware of any circumstance that would give rise to a disclosure requirement under Rules 13.13 to 13.19 of the Listing Rules.

AUTHORIZED AND ISSUED SHARE CAPITAL

The following is a description of the authorized share capital of our Company as of the Latest Practicable Date and the issued share capital of our Company in issue and to be issued as fully paid or credited as fully paid immediately after the [**REDACTED**]. All Preferred Shares shall be automatically and immediately converted into Ordinary Shares on a one-to-one basis upon [**REDACTED**].

1. Share Capital as of the Latest Practicable Date

(i) Authorized Share Capital

Description of Shares	Number of Shares	Approximate aggregate nominal value of Shares	Approximate percentage of authorized share capital
		(US$)	*(%)*
Ordinary Shares with a par value of US$0.0001 each	139,895,836	13,989.58	69.95
Series Seed Preferred Shares with a par value of US$0.0001 each	5,000,000	500.00	2.50
Series A-1 Preferred Shares with a par value of US$0.0001 each	12,333,333	1,233.33	6.17
Series A-2 Preferred Shares with a par value of US$0.0001 each	2,666,667	266.67	1.33
Series B-1 Preferred Shares with a par value of US$0.0001 each	16,666,666	1,666.67	8.33
Series B-2 Preferred Shares with a par value of US$0.0001 each	23,437,498	2,343.75	11.72
Total	**200,000,000**	**20,000**	**100.00**

(ii) Issued Share Capital

Description of Shares	Number of Shares	Approximate aggregate nominal value of Shares	Approximate percentage of issued share capital
		(US$)	*(%)*
Ordinary Shares with a par value of US$0.0001 each	8,000,000	800.00	11.75
Series Seed Preferred Shares with a par value of US$0.0001 each	5,000,000	500.00	7.34
Series A-1 Preferred Shares with a par value of US$0.0001 each	12,333,333	1,233.33	18.11
Series A-2 Preferred Shares with a par value of US$0.0001 each	2,666,667	266.67	3.92
Series B-1 Preferred Shares with a par value of US$0.0001 each	16,666,666	1,666.67	24.47
Series B-2 Preferred Shares with a par value of US$0.0001 each	23,437,498	2,343.75	34.41
Total	**68,104,164**	**6,810.42**	**100.00**

2. Share capital immediately following the completion of the [REDACTED] (assuming the [REDACTED] is not exercised)

Authorized Share Capital

Description of Shares	Number of Shares	Approximate aggregate nominal value of Shares
		(US$)
Ordinary shares with a par value of US$0.0001 each	200,000,000	20,000.000

Issued Share Capital

Description of Shares	Number of Shares	Aggregate nominal value of Shares	Approximate percentage of issued share capital
		(US$)	*(%)*
Shares in issue as of the Latest Practicable Date	68,104,164	6,810.42	[**REDACTED**]
Shares to be issued pursuant to the [**REDACTED**]	[**REDACTED**]	[**REDACTED**]	[**REDACTED**]
Total	[**REDACTED**]	[**REDACTED**]	**100.00**

ASSUMPTIONS

The above tables assume that the [**REDACTED**] becomes unconditional, that Shares are issued pursuant to the [**REDACTED**], and that the Preferred Shares are converted into Shares on a one-to-one basis. The above tables do not take into account any additional Shares which may be issued pursuant to the Pre-[**REDACTED**] Equity Incentive Plan, or any Shares which may be issued or repurchased by the Company under the general mandates granted to our Directors as referred to below.

RANKING

The [**REDACTED**] are Shares in the share capital of our Company and rank equally in all respects with all Shares currently in issue or to be issued (including all Preferred Shares to be converted into 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.

POTENTIAL CHANGES TO SHARE CAPITAL

Circumstances Under Which General Meetings and Class Meetings Are Required

Upon [**REDACTED**], our Company will have only one class of shares, namely Ordinary Shares, each of which ranks *pari passu* with the other Shares.

A company may, by an ordinary resolution of its members, if so authorized by its articles of association, alter the conditions of its memorandum of association to (a) increase its share capital by new shares of such amount as it thinks expedient provided that an exempted company having no shares of a fixed amount may increase its share capital by such number of shares without nominal or par value, or may increase the aggregate consideration for which such shares may be issued, as it thinks expedient; (b) consolidate and divide all or any of its share capital into shares of larger amount than its existing shares; (c) convert all or any of its paid-up shares into stock, and reconvert that stock into paid-up shares of any denomination; (d)

subdivide its shares or any of them, into shares of an amount smaller than that fixed by the memorandum of association so, however, that in the subdivision the proportion between the amount paid and the amount, if any, unpaid on each reduced share shall be the same as it was in case of the share from which the reduced share is derived; and (e) cancel shares which, at the date of the passing of the resolution in that behalf, 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 cancelled or, in the case of shares without nominal or par value, diminish the number of shares into which its capital is divided. Subject to the provisions of the Companies Act and to confirmation by the Cayman Islands Court, a company limited by shares may, if so authorized by its articles of association, by special resolution, reduce its share capital in any way. Please see "Summary of the Constitution of our Company and Cayman Islands Company Law" in Appendix III to this document for details.

As a matter of the Companies Act, an exempted company is not required by law to hold any general meetings or class meetings. The holding of general meetings or class meetings is prescribed for under the Articles of Association. Accordingly, our Company will hold general meetings and class meetings as prescribed for under the Articles of Association, a summary of which is set forth in the paragraph headed "Summary of the Constitution of our Company and Cayman Islands Company Law" in Appendix III to this document.

General Mandate to Issue Shares

Subject to the [**REDACTED**] becoming unconditional, our Directors [have been] granted a general mandate to allot, issue and deal with (including the sale or transfer of Treasury Shares) any Shares or securities convertible into Shares of not more than the sum of:

(a) [20%] of the total number of Shares in issue (excluding Treasury Shares) immediately following completion of the [**REDACTED**] (but excluding any Shares which may be issued pursuant to the exercise of the [**REDACTED**]); and

(b) the total number of Shares repurchased by our Company pursuant to the authority referred to in "— General Mandate to Repurchase Shares" below.

This general mandate to issue Shares will remain in effect until the earliest of:

(a) the conclusion of the next annual general meeting of our Company unless, by ordinary resolution passed at that meeting, the authority is renewed, either unconditionally or subject to condition;

(b) the expiration of the period within which the next annual general meeting of our Company is required to be held under any applicable laws of the Cayman Islands or the Memorandum and Articles of Association; and

(c) the passing of an ordinary resolution by Shareholders in a general meeting revoking or varying the authority.

General Mandate to Repurchase Shares

Subject to the [**REDACTED**] becoming unconditional, our Directors [have been] granted a general mandate to repurchase our own Shares up to 10% of the total number of Shares in issue (excluding Treasury Shares) immediately following completion of the [**REDACTED**] (excluding any Shares which may be allotted and issued pursuant to the exercise of the [**REDACTED**], if any).

This repurchase mandate only relates to repurchases on the Stock Exchange or on any other stock exchange on which the securities of our Company may be [**REDACTED**] and which is recognized by the SFC and the Stock Exchange for this purpose, and in accordance with all applicable laws and the requirements under the Listing Rules or equivalent rules or regulations of any other stock exchange as amended from time to time.

This general mandate to repurchase Shares will remain in effect until the earliest of:

(a) the conclusion of the next annual general meeting of our Company unless, by ordinary resolution passed at that meeting, the authority is renewed, either unconditionally or subject to condition;

(b) the expiration of the period within which the next annual general meeting of our Company is required to be held under any applicable laws of the Cayman Islands or the Memorandum and Articles of Association; and

(c) the passing of an ordinary resolution by our Shareholders in a general meeting revoking or varying the authority.

See "Statutory and General Information — A. Further Information about Our Company — 4. Resolutions of Shareholders of Our Company Passed on [●], 2025" in Appendix IV for further details of the general mandate to issue and repurchase Shares.

SHARE INCENTIVE SCHEMES

As of the Latest Practicable Date, we had one share incentive scheme, namely the Pre-[**REDACTED**] Equity Incentive Plan, the terms of which are not subject to the provisions of Chapter 17 of the Listing Rules. For the purpose of the [**REDACTED**], our Company [adopted] the Post-[**REDACTED**] Share Incentive Plan on [●], 2025, the terms of which comply with the requirements of Chapter 17 of the Listing Rules. For further details of the share incentive schemes, please see "Statutory and General Information — D. Share Incentive Plans" in Appendix IV to this document.

So far as is known to our Directors, immediately after the [**REDACTED**], assuming the [**REDACTED**] is not exercised, the following persons are expected to have an interest and/or short positions in our Shares or underlying Shares of our Company which would fall to be disclosed to us pursuant to the provisions of Divisions 2 and 3 of Part XV of the SFO, or, who are, directly or indirectly, is entitled to exercise, or control the exercise of, 10% or more of the voting power at any meeting of our Company or any other member of our Group:

		Shares held as of the Latest Practicable Date		**Shares held immediately after the [REDACTED] (assuming the [REDACTED] is not exercised)**	
Name	**Nature of interest**	**Number of Shares[1]**	**Approximate percentage of interest in our Company**	**Number of Shares[1]**	**Approximate percentage of interest in our Company**
LAV Fund VI, L.P. ("**LAV Fund VI**")[2] . . .	Beneficial owner	11,272,321	16.55%	11,272,321	[REDACTED]%
LAV Fund VI Opportunities, L.P. ("**LAV Opportunities**") .	Beneficial owner	5,000,000[3]	7.34%	5,000,000	[REDACTED]%
King Star Med LP ("**King Star Med**")[4] . .	Beneficial owner	6,589,554	9.68%	6,589,554	[REDACTED]%
Founder Holdco[5]	Beneficial owner	6,500,000	9.54%	6,500,000	[REDACTED]%
	Interest of a party to an agreement	2,000,000[3]	2.94%	–	–
Shanghai Yingjia Enterprise Management Partnership (Limited Partnership) (上海楹伽企業管理合夥企業(有限合夥)) ("**Shanghai Yingjia**")[6]	Beneficial owner	6,387,649	9.38%	6,387,649	[REDACTED]%

Notes:

(1) All interests stated are long positions.

(2) LAV Fund VI is a Cayman Islands exempted limited partnership whose general partner is LAV GP VI, L.P. The general partner of LAV GP VI, L.P. is LAV Corporate VI GP, Ltd., a Cayman Islands exempted company wholly owned by Dr. SHI Yi. Therefore, under the SFO, each of LAV GP VI, L.P., LAV Corporate VI GP, Ltd. and Dr. SHI Yi is deemed to be interested in the Shares held by LAV Fund VI.

LAV Opportunities is a Cayman Islands exempted limited partnership whose general partner is LAV GP VI Opportunities, L.P. The general partner of LAV GP VI Opportunities, L.P. is LAV Corporate VI GP Opportunities, Ltd., a Cayman Islands exempted company wholly owned by Dr. SHI Yi. Therefore, under the SFO, each of LAV GP VI Opportunities, L.P., LAV Corporate VI GP, Ltd. and Dr. SHI Yi is deemed to be interested in the Shares held by LAV Opportunities.

For details of LAV Fund VI and LAV Opportunities, see "History and Corporate Structure — Pre-[**REDACTED**] Investments — Information regarding the Pre-[**REDACTED**] Investors."

(3) Founder Holdco is entitled to exercise the voting rights attached to 2,000,000 Ordinary Shares held by LAV Opportunities pursuant to the Voting Rights Proxy Agreement, which will terminate upon completion of the [**REDACTED**]. For details, see "History and Corporate Structure — Voting Rights Proxy Agreement".

(4) King Star Med is a Cayman Islands exempted limited partnership. The general partner and manager of King Star Med, namely King Star Med Management Limited and King Star Consulting Limited are both indirectly held by Ace Treasure Trust and Superb Outcome Trust (the "**Trusts**") as to 40.0% and 30.0%, respectively. Dr. LIN Xianghong is the settlor, the protector and one of the beneficiaries of the Trusts. Therefore, under the SFO, Dr. LIN Xianghong, the Trusts, King Star Consulting Limited and King Star Med Management Limited is deemed to be interested in the Shares held by King Star Med. For details of King Star Med, see "History and Corporate Structure — Pre-[**REDACTED**] Investments — Information regarding the Pre-[**REDACTED**] Investors."

(5) Founder Holdco is a company with limited liability incorporated under the laws of BVI and is wholly owned by our founder, Dr. ZHU Zhongyuan. Therefore, under the SFO, Dr. ZHU is deemed to be interested in the Shares held by Founder Holdco.

(6) Shanghai Yingjia is a limited partnership incorporated in the PRC whose general partner is Xiamen Yinglian Health Industry Management Partnership (Limited Partnership) (廈門楹聯健康產業管理合夥企業(有限合夥)) ("**Yinglian Management**"). Yinglian Management is controlled by Xiamen Yinglian Health Industry Investment Management Co. (廈門楹聯健康產業投資管理有限公司) ("**Yinglian Health**"), which is ultimately beneficially owned by LUO Jing. Therefore, under the SFO, each of Yinglian Management, Yinglian Health and LUO Jing is deemed to be interested in the Shares held by Shanghai Yingjia. For details of Shanghai Yingjia, see "History and Corporate Structure — Pre-[**REDACTED**] Investments — Information regarding the Pre-[**REDACTED**] Investors."

Except as disclosed above, our Directors are not aware of any persons who will, immediately following completion of the [**REDACTED**] (assuming that the [**REDACTED**] is not exercised), have any interests and/or short positions in the Shares or underlying Shares of our Company which would fall to be disclosed to the Company and the Stock Exchange under the provisions of Divisions 2 and 3 of Part XV of the SFO or, will be, directly or indirectly, is entitled to exercise, or control the exercise of, 10% or more of the voting power at any meeting of our Company or any other member of our Group.

BOARD OF DIRECTORS

Our Board consists of eight Directors, comprising three executive Directors, two non-executive Directors and three independent non-executive Directors. The following table sets forth the key information about our Directors as of the Latest Practicable Date.

Name	Age	Positions	Roles and responsibilities	Date of joining our Group	Date of appointment as a Director
Dr. ZHU Zhongyuan (朱忠遠)	54	Chairman of the Board, executive Director and chief executive officer	Responsible for strategic vision, corporate management and business planning of our Group	January 1, 2020	February 19, 2020
Mr. ZHANG Shaoren (張韶壬)	39	Executive Director and vice president of finance	Responsible for the overall financial strategy, corporate finance, capital management and investor relations of our Group	May 1, 2020	April 23, 2021
Ms. SI Wen (司文)	45	Executive Director and executive director (執行總監) of human resources	Responsible for the management of human resources affairs of our Group	October 21, 2020	April 23, 2021
Mr. CAI Zhiyang (蔡志洋)	42	Non-executive Director	Responsible for overseeing Board affairs and providing strategic advice and guidance on the business operations of our Group	July 22, 2024	July 22, 2024
Dr. YU Tao (余濤)	39	Non-executive Director	Responsible for overseeing Board affairs and providing strategic advice and guidance on the business operations of our Group	April 23, 2021	April 23, 2021

Name	Age	Positions	Roles and responsibilities	Date of joining our Group	Date of appointment as a Director
Mr. XIE Dong (謝東)*(Note)*. . .	44	Independent non-executive Director	Responsible for providing independent advice and judgment to our Board	August 12, 2024	August 12, 2024
Mr. GAO Fengyong (高鳳勇)*(Note)* .	54	Independent non-executive Director	Responsible for providing independent advice and judgment to our Board	August 12, 2024	August 12, 2024
Ms. CHUAI Shuyin (揣姝茵)*(Note)* .	48	Independent non-executive Director	Responsible for providing independent advice and judgment to our Board	August 12, 2024	August 12, 2024

Note: Mr. XIE Dong (謝東), Mr. GAO Fengyong (高鳳勇) and Ms. CHUAI Shuyin (揣姝茵) have been appointed by the Board as our independent non-executive Directors, effective from the [**REDACTED**].

Executive Directors

Dr. ZHU Zhongyuan (朱忠遠), aged 54, is our founder, chairman of the Board, executive Director and chief executive officer of our Company. He also holds directorships and managerial positions across our subsidiaries. Dr. ZHU was re-designated as our executive Director on August 12, 2024. He is primarily responsible for strategic vision, corporate management and business planning of our Group.

Dr. ZHU is a sophisticated and resourceful veteran in China's biotech industry with strong scientific and business acumen. He brings in over 20 years of experience bridging the realms of biotech entrepreneurship and venture investment. Dr. ZHU has been instrumental in investing in and incubating a number of notable emerging biotech companies, including CStone Pharmaceuticals (2616.HK), RemeGen (9995.HK), Gan & Lee Pharmaceuticals (603087. SH), and BGI Genomics (300676. SH). Throughout his career, Dr. ZHU has focused on value creation, and has established a reputation of driving growth and innovation, navigating market dynamics while managing operational risks. He developed company building acumen at two leading biotech venture investment firms, including 6 Dimensions Capital, where he served as a Partner from 2018 to 2019, and Wuxi Healthcare Ventures, where he also held the position of Partner from 2015 to 2017. Prior to these roles, Dr. ZHU held various senior roles at Mingxin Capital, SIG Asia Investment Fund, Greenwoods Investment and HighLight Capital, from 2008 to 2015.

In addition, Dr. ZHU held multiple non-executive directorships at various portfolio companies, including a non-executive director of Phoenix Healthcare Group Co., Ltd. (currently known as China Resources Medical Holdings Company Limited (1515. HK)), from September 2013 to July 2014, and a non-executive director of CStone Pharmaceuticals (2616. HK), from April 2016 to August 2018. In 2006, he was the senior director at Shanghai Genomics, Inc. (上海睿星基因技術有限公司), which was later acquired by GNI Group Ltd, an integrated multinational biopharma.

Dr. ZHU obtained a bachelor's degree in molecular biology from Nankai University (南開大學) in the PRC in July 1992, a Ph.D. in biomedical science from the University of Massachusetts at Worcester in the United States in June 2001, and an MBA from the University of California at Berkeley in the United States in December 2005. In July 2020, Dr. ZHU was honored with "14th Jinji Lake Leading Scientific Talent of Suzhou Industrial Park" (蘇州工業園區第十四屆金雞湖科技領軍人才) by the Suzhou Industrial Park Administrative Committee (蘇州工業園區管委會).

Mr. ZHANG Shaoren (張韶壬), aged 39, is our executive Director and vice president of finance. Mr. ZHANG has been our Director since April 23, 2021, and re-designated as our executive Director on August 12, 2024. He is primarily responsible for the overall financial strategy, corporate finance, capital management and investor relations of our Group. Mr. ZHANG served as various senior positions within our Group previously, including a director (總監) from May 2020 to July 2021, and an executive director (執行總監) from August 2021 to February 2024.

Mr. ZHANG's extensive financial management, strategic investment, and financing experience spans over 15 years. He honed his expertise during his tenure as manager at PricewaterhouseCoopers Zhong Tian LLP (普華永道中天會計師事務所(特殊普通合夥)) from September 2008 to November 2015, with his last position as manager at the audit department where he was primarily responsible for providing audit services to multiple clients. From December 2015 to June 2017, Mr. ZHANG served as the deputy general manager for Shanghai Yikang Medical Laboratory Co., Ltd. (上海億康醫學檢驗所有限公司), a company dedicated to the R&D of single-cell whole genome amplification and sequencing technology for the field of eugenics and early cancer diagnosis, responsible for overseeing financial and operational management. From February 2017 to December 2019, Mr. ZHANG served as the deputy general manager of Shanghai Shihao International Logistics Co., Ltd. (上海世灝國際物流有限公司), a logistics service company and an affiliate of Y.U.D. Yangtze River Investment Industry Co., Ltd. (長發集團長江投資實業股份有限公司), a comprehensive logistics company listed on Shanghai Stock Exchange (stock code: 600119), where he was responsible for the company's overall operations.

Mr. ZHANG obtained a bachelor's degree in international accounting from Shanghai Institute of Foreign Trade (上海對外貿易學院) (currently known as Shanghai University of International Business and Economics (上海對外經貿大學)) in July 2008, and a Finance MBA

from China Europe International Business School (中歐國際工商學院) in November 2022, both in the PRC. He was accredited as a non-practicing Certified Public Accountant by Shanghai Institute of Certified Public Accountants (上海市註冊會計師協會) in December 2015.

Ms. SI Wen (司文), aged 45, is our executive Director and executive director (執行總監) of human resources. Ms. SI first joined our Group as director of human resources in October 2020. She has been our Director since April 23, 2021 and was re-designated as our executive Director on August 12, 2024. Ms. SI is primarily responsible for the management of human resources affairs of our Group.

Ms. SI's career demonstrates a consistent dedication to human resources expertise. With over 20 years of industry experience spanning diverse sectors, including, among others, pharmacology, chemicals, and healthcare, she has established herself as a human resources trailblazer. Ms. SI began her career honing her operational expertise at Kentucky Fried Chicken (Guangdong) Co., Ltd. (廣東肯德基有限公司) (currently known as Yum! Restaurants (Guangdong) Co., Ltd. (百勝餐飲(廣東)有限公司)), an affiliate of Yum China Holdings, Inc. (百勝中國控股有限公司), a restaurant company listed on both the Stock Exchange (stock code: 9987) and the New York Stock Exchange (ticker symbol: YUMC), from January 2002 to November 2002.

Prior to joining our Group, Ms. SI served as various positions in several companies, including but not limited to:

- at Wrigley Confectionery (China) Limited (箭牌糖果(中國)有限公司) (currently known as Mars Wrigley Confectionery (China) Limited (瑪氏箭牌糖果(中國)有限公司)), from December 2002 to April 2006;

- at the China-based subsidiaries of Novartis AG, a medicines company listed on both the New York Stock Exchange (ticker symbol: NVS) and the SIX Swiss Exchange (ticker symbol: NOVN), from January 2009 to November 2011;

- at Tecan (Shanghai) Trading Co., Ltd. (帝肯(上海)貿易有限公司) (currently known as Tecan (Shanghai) Laboratory Equipment Co., Ltd. (帝肯(上海)實驗器材有限公司)), an associate of Tecan Group AG, a healthcare company listed on the SIX Swiss Exchange (ticker symbol: TECN), from December 2011 to November 2013, and from August 2014 to December 2018, respectively, being, among others, its director of human resources;

- at Dow Chemical (China) Investment Company Limited (陶氏化學(中國)投資有限公司), an associate of Dow Inc., a global materials science company listed on the New York Stock Exchange (ticker symbol: DOW), from November 2013 to August 2014; and

- at Shanghai Fosun Pharmaceutical Industrial Development Co., Ltd. (上海復星醫藥產業發展有限公司), a wholly-owned subsidiary Shanghai Fosun Pharmaceutical (Group) Co., Ltd. (上海復星醫藥(集團)股份有限公司), a pharmaceutical manufacturing company listed on both the Stock Exchange (stock code: 2196) and Shanghai Stock Exchange (stock code: 600196), from December 2018 to October 2020, being its senior director of human resources.

Ms. SI obtained a bachelor's degree in economics from Southwest University of Science and Technology (西南科技大學) in the PRC in June 2001, and a postgraduate diploma in managerial psychology from the Institute for China Business, School of Professional and Continuing Education of the University of Hong Kong in November 2023.

Non-executive Directors

Mr. CAI Zhiyang (蔡志洋), aged 42, has been appointed as a Director on July 22, 2024 and re-designated as our non-executive Director on August 12, 2024. He is mainly responsible for overseeing Board affairs and providing strategic advice and guidance on the business operations of our Group.

For more than ten years, Mr. CAI has been focusing on the private equity and M&A practices, spearheading investment sourcing, management, consulting and execution. He is the partner of Suzhou Qingtan Private Fund Management Partnership (Limited Partnership) (蘇州青檀私募基金管理合夥企業(有限合夥)), since January 2023. From April 2012 to July 2016, he served at Fountain Investment Consulting (Shanghai) Co., Ltd. (方源投資顧問(上海)有限公司) with his last position as the vice president of investment, primarily responsible for the evaluation and post-investment management of investment projects. Subsequently, from March 2017 to December 2022, he was a partner at Suzhou Kington Capital Co., Ltd. (蘇州翼樸股權投資基金管理有限公司).

Mr. CAI obtained a bachelor's degree in economics from Fudan University (復旦大學) in the PRC in July 2004 and an MBA from the Wharton School of the University of Pennsylvania in the United States in May 2009.

Dr. YU Tao (余濤), aged 39, has been our Director since April 23, 2021 and re-designated as our non-executive Director on August 12, 2024. He is mainly responsible for overseeing Board affairs and providing strategic advice and guidance on the business operations of our Group.

Dr. YU's career exemplifies the application of strategic ingenuity to the biotechnology sector. He has been serving as managing director at Lilly Asia Ventures, a biomedical venture capital firm focused on healthcare investment, since February 2025, where he also served as principal from March 2018 to February 2025. Dr. YU's early career, from July 2015 to February 2018, was with McKinsey & Company, where he served as an engagement manager as his last position.

Dr. YU obtained a bachelor's degree in biological science from Peking University (北京大學) in the PRC in July 2008 and a Ph.D. in biomedical engineering from Johns Hopkins University in the United States in May 2015.

Independent Non-executive Directors

Mr. XIE Dong (謝東), aged 44, has been appointed as an independent non-executive Director with effect from the [**REDACTED**]. He is mainly responsible for providing independent advice and judgment to our Board.

Mr. XIE has nearly 19 years of professional experience in sectors of financial management, auditing, investment and financing, and capital markets. He has served as the (i) chief financial officer and director of QuantaSing Group Limited, a Chinese leading online service provider listed on the Nasdaq (ticker symbol: QSG), since January 2021 and June 2022, respectively; and (ii) independent non-executive director of China BlueChemical Ltd. (中海石油化學股份有限公司), a state-owned chemical fertilizer producer and leading methanol producer listed on the Stock Exchange (stock code: 3983), since May 2021.

Prior to the above positions, from October 2006 to October 2007, Mr. XIE worked as a staff accountant of the auditing department of Ernst & Young Hua Ming LLP (安永華明會計師事務所(特殊普通合夥)). From April 2010 to September 2010, he was appointed as vice president of CCB International (China) Limited (建銀國際(中國)有限公司). From October 2010 to August 2014, he served as associate director at Deloitte China. From September 2014 to December 2018, he served as the chief financial officer and company secretary of FinUp Finance Technology Group (Holding) Limited. From January 2019 to March 2020, he served as the director and chief financial officer of Renmai Technology Group (Holding) Limited (任買科技集團(控股)有限公司).

Mr. XIE obtained a bachelor's degree in economics and a master's degree in world economics from Nankai University in June 2003 and June 2006, respectively. He is a holder of Chinese Institute of Certified Public Accountants (CICPA), Certified Internal Auditor (CIA), Certified Tax Agent (CTA) and Chinese Legal Professional Qualification.

Mr. GAO Fengyong (高鳳勇), aged 54, has been appointed as an independent non-executive Director with effect from the [**REDACTED**]. He is mainly responsible for providing independent advice and judgment to our Board.

Since the nineties, Mr. GAO has been engaged in investment and financing activities. Concurrently outside our Group, Mr. GAO is (i) the founder and director of Shanghai Leading Investment Management Co., Ltd. (上海力鼎投資管理有限公司) since July 2007, (ii) the founder, partner and chairman of the board of Shanghai Blue Ocean Capital Co., Ltd. (上海灤海投資管理有限公司) since September 2012, and (iii) a supervisor of Wuhan Guide Technology Co., Ltd. (武漢港迪技術股份有限公司), a company specializing in development, production and sales in industrial automation, since January 2022. In his early career, Mr. GAO worked at Southern Securities Co., Ltd. (南方證券有限公司), engaged in underwriting and

sponsorship activities, and Bridge Trust Co., Ltd. (百瑞信託有限責任公司), an affiliate of SPIC Industry-Finance Holdings Co., Ltd. (國家電投集團產融控股股份有限公司), a company listed on Shenzhen Stock Exchange (stock code: 000958), with his last position being vice president.

Mr. GAO has been holding and held directorships or supervisory roles in the following listed companies:

- a director of Henan BCCY Environmental Energy Co., Ltd (河南百川暢銀環保能源股份有限公司), an environmentally-focused technology enterprise listed on Shenzhen Stock Exchange (stock code: 300614), since January 2016;

- an independent director of CNFinance Holdings Limited, a leading home equity loan service provider listed on both the New York Stock Exchange (ticker symbol: CNF), since November 2018;

- an independent director of Nanjing Xinjiekou Department Store Co., Ltd. (南京新街口百貨商店股份有限公司), a company listed on Shanghai Stock Exchange (stock code: 600682), since December 2019;

- a supervisor of Shaanxi Construction Machinery Co., Ltd. (陝西建設機械股份有限公司), a company listed on Shanghai Stock Exchange (stock code: 600984), from October 2015 to November 2017;

- an independent director of China Haisum Engineering Co., Ltd. (中國海誠工程科技股份有限公司), a comprehensive engineering service company listed on Shenzhen Stock Exchange (stock code: 002116), from August 2016 to May 2023; and

- an independent director of Great Wall Movie and Television Co., Ltd. (長城影視股份有限公司), a company previously listed on Shenzhen Stock Exchange (stock code: 002071) and delisted in May 2021, from February 2017 to April 2020.

Mr. GAO obtained both his bachelor's degree and master's degree in finance from Nankai University in July 1992 and January 2002, respectively.

Ms. CHUAI Shuyin (揣姝茵), aged 48, has been appointed as an independent non-executive Director with effect from the [**REDACTED**]. She is mainly responsible for providing independent advice and judgment to our Board.

Ms. CHUAI is the founder of Shanghai Meishen Enterprise Management Consulting Co., Ltd. (上海美深企業管理諮詢有限公司), also known as Mission Consulting (使命諮詢), acting as its executive director. From January 2007 to May 2008, she was employed by the Shanghai branch of Zhirui Enterprise Consulting (Shenzhen) Co., Ltd. (智睿企業諮詢(深圳)有限公司) (currently known as Zhirui Zhuocai Enterprise Consulting (Shanghai) Co., Ltd. (智睿卓才企業諮詢(上海)有限公司)). From May 2008 to December 2008, she was recruited by Hewitt

Consulting (Shanghai) Co., Ltd. (currently known as Aon Enterprise Services (Shanghai) Co., Ltd. (怡安企業服務(上海)有限公司)). From March 2009 to April 2010, she worked for Shanghai Maizhi Enterprise Management Consulting Office (上海邁智企業管理諮詢事務所). Later from December 2011 to April 2016, she was employed by McKinsey & Consulting Company Inc., Shanghai (麥肯錫(上海)諮詢有限公司).

Ms. CHUAI obtained a bachelor's degree in Korean language and culture and a master's degree in Asian and African languages and literatures from Peking University in July 1998 and June 2001, respectively. She also obtained a master's degree in art and in human resources and industrial relations from the University of Illinois at Urbana-Champaign in the United States in May 2003 and December 2004, respectively. She is now the honorary president of the Shanghai Alumni Chapter of the University of Illinois Urbana-Champaign.

SENIOR MANAGEMENT

Our senior management is responsible for the day-to-day management of our business. The following table sets forth the key information about our senior management as of the Latest Practicable Date.

Name	Age	Positions	Roles and responsibilities	Date of joining our Group	Date of appointment as a senior management
Dr. ZHU Zhongyuan (朱忠遠)	54	Chairman of the Board, executive Director and chief executive officer	Responsible for strategic vision, corporate management and business planning of our Group	January 1, 2020	January 1, 2020
Mr. ZHANG Shaoren (張韶壬)	39	Executive Director and vice president of finance	Responsible for the overall financial strategy, corporate finance, capital management and investor relations of our Group	May 1, 2020	April 23, 2021
Ms. SI Wen (司文)	45	Executive Director and executive director (執行總監) of human resources	Responsible for the management of human resources affairs of our Group	October 16, 2020	April 23, 2021

Name	Age	Positions	Roles and responsibilities	Date of joining our Group	Date of appointment as a senior management
Dr. QIU Yang (邱楊)	52	Chief scientific officer	Responsible for directing the R&D, providing scientific insights and leadership, and progressing key assets of our Group	July 19, 2021	July 19, 2021
Ms. GU Wei (顧薇)	53	Chief medical officer	Responsible for leading clinical development team and developing clinical development strategies of our Group	July 18, 2022	July 18, 2022
Mr. WANG Xin (王昕)	53	Senior vice president of strategy and business development	Responsible for the business development, external cooperation and licensing strategies of our Group	June 27, 2022	June 27, 2022
Dr. HUA Haiqing (花海清)	44	Senior vice president and head of drug discovery	Responsible for the pipeline development strategies, new drug discovery and R&D of our Group	July 1, 2021	July 1, 2021
Mr. YU Xin (于鑫)	42	Vice president and head of regulatory affairs	Responsible for overseeing regulatory affairs and product registration operations of our Group	August 1, 2021	August 1, 2021
Dr. SHI Rong (施榕)	43	Vice president of development science	Responsible for leading team of clinical pharmacologists and bioanalysis of our Group	February 24, 2022	February 24, 2022

Name	Age	Positions	Roles and responsibilities	Date of joining our Group	Date of appointment as a senior management
Dr. CHU Ruiyin (儲瑞銀)	63	Vice president of translational medicine	Responsible for management of the translational medicine department of our Group	July 24, 2023	July 24, 2023
Ms. ZHOU Lan (周嵐)	54	Vice president of commercial strategy	Responsible for the product commercialization strategy and government relationship of our Group	May 1, 2024	May 1, 2024

Dr. ZHU Zhongyuan (朱忠遠), aged 54, is our chief executive officer. For his biography, see "— Board of Directors — Executive Directors" in this section.

Mr. ZHANG Shaoren (張韶壬), aged 39, is our vice president of finance. For his biography, see "— Board of Directors — Executive Directors" in this section.

Ms. SI Wen (司文), aged 45, is our executive director (執行總監) of human resources. For her biography, see "— Board of Directors — Executive Directors" in this section.

Dr. QIU Yang (邱楊), aged 52, first joined our Group as senior vice president of translational medicine in July 2021 and was then promoted to our chief scientific officer in March 2022. Dr. QIU is also the general manager of Duality U.S. She is mainly responsible for directing the R&D, providing scientific insights and leadership, and progressing key assets of our Group.

Dr. QIU brings over 20 years of global leadership experience in the biopharmaceutical industry, with a demonstrated track record of success in drug discovery, translational medicine and early clinical development. Prior to joining our Group, from March 2004 to December 2015, Dr. QIU worked at the China-based subsidiaries of GlaxoSmithKline plc., a global healthcare company listed on both the London Stock Exchange (stock code: GSK) and the New York Stock Exchange (ticker symbol: GSK), with her last position being a director, leading the progress of early drug discovery. From April 2016 to May 2019, Dr. QIU joined Johnson & Johnson (China) Investment Ltd. (強生(中國)投資有限公司), a subsidiary of Johnson & Johnson, whose shares are listed on the New York Stock Exchange (ticker symbol: JNJ). During her tenure, she worked at the division Janssen (China) Research & Development Center (楊森(中國)研發中心) as its director of biomarker research, where she was responsible for the

design and delivery of multiple biomarker studies in clinical development programs of the company's oncology portfolio. From May 2019 to July 2021, Dr. QIU served at a pharmaceutical company Daiichi Sankyo Inc., an affiliate of Daiichi Sankyo Company, Limited, which is listed on Tokyo Stock Exchange (stock code: 4568), where she was responsible for the development of global translational medicine and early development strategy for ADC programs.

Dr. QIU obtained a master's degree and a Ph.D. from University of Texas at Austin in the United States in December 1994 and December 1997, respectively.

Ms. GU Wei (顧薇), aged 53, is our chief medical officer. She is mainly responsible for leading clinical development team and developing clinical development strategies of our Group.

Ms. GU possesses more than 10 years of experience in clinical trial management and research. Her career began as a resident physician and then an attending physician at Huadong Hospital Affiliated to Fudan University (復旦大學附屬華東醫院) from July 1996 to August 2002. From September 2002 to April 2004, Ms. GU worked for Quintiles Medical Development (Shanghai) Co., Ltd. (昆泰醫藥發展(上海)有限公司) with positions including clinical research associate. From April 2004 to August 2010, Ms. GU worked at Boehringer Ingelheim International Trading (Shanghai) Co., Ltd. (勃林格殷格翰國際貿易(上海)有限公司). During August 2010 to July 2012, Ms. GU served as a director of clinical development at AstraZeneca Global R&D (China) Co., Ltd. (阿斯利康全球研發(中國)有限公司), a subsidiary of AstraZeneca plc, a biotechnology company listed on London Stock Exchange, Nasdaq Stockholm and the Nasdaq Global Select Market under the stock symbol "AZN", mainly responsible for operations of clinical programs in Mainland China and Hong Kong. From July 2012 to September 2015, Ms. GU served as a senior director at Sino-American Shanghai Squibb Pharmaceuticals Ltd. (中美上海施貴寶製藥有限公司), an affiliate of Shanghai Pharmaceuticals Holding Co., Ltd. (上海醫藥集團股份有限公司), whose shares are listed on both the Stock Exchange (stock code: 2607) and Shanghai Stock Exchange (stock code: 601607). From December 2015 to September 2016, Ms. GU worked for Shanghai Greenvalley Pharmaceutical Co., Ltd. (上海綠谷製藥有限公司). From October 2016 to January 2018, Ms. GU served as a vice president at Shanghai Haihe Biopharma Co., Ltd. (上海海和藥物研究開發股份有限公司), a biotechnology company focusing on innovative anti-tumor therapies. Later from January 2018 to July 2022, Ms. GU worked for Shanghai Baili Jiasheng Pharmaceutical Technology Co. (上海百利佳生醫藥科技有限公司) (currently known as Novotel Pharmaceutical Technology (Shanghai) Co., Ltd. (諾為泰醫藥科技(上海)有限公司)) with positions including head of clinical development and regulatory and China chief medical officer.

Ms. GU obtained a bachelor's degree in clinical medicine and a master's degree in internal medicine from Shanghai Medical University (上海醫科大學) (currently known as Shanghai Medical College, Fudan University (復旦大學上海醫學院)) in the PRC in July 1994 and July 1996, respectively.

Mr. WANG Xin (王昕), Chartered Financial Analyst, aged 53, is our senior vice president of strategy and business development. He is mainly responsible for the business development, external cooperation and licensing strategies of our Group.

Mr. WANG brings nearly 20 years of experience in healthcare research and banking, accumulating from his tenure successively as an assistant scientist II, scientist I and then associate scientist at Schering-Plough Research Institute from October 1997 to December 2001. Mr. WANG joined the equity research team of Thomas Weisel Partners LLC as an associate in January 2003 and then joined UBS Securities LLC in May 2004 as an associate research analyst in equities. In March 2007, Mr. WANG joined Mizuho Bank, Ltd. as a vice president, primarily responsible for researching and analyzing industries including healthcare, pharmaceuticals and biotechnology, and held positions including director, senior vice president with his last position as executive director when his journey with Mizuho Bank, Ltd. came to a close in September 2021.

Mr. WANG obtained a bachelor's degree in microbiology from Nankai University in the PRC in July 1994, a master's degree in biochemistry from University of British Columbia in Canada in November 1996, and an MBA in finance and marketing from New York University in the United States in January 2003. In September 2023, he received the Community Service Excellence Award at the 2023 Sino-American Pharmaceutical Professionals Association Annual Conference.

Dr. HUA Haiqing (花海清), aged 44, first joined our Group as our vice president and head of drug discovery in July 2021 and was further promoted as senior vice president and head of drug discovery in March 2024. He is mainly responsible for the pipeline development strategies, new drug discovery and R&D of our Group.

Dr. HUA's career in the field of drug discovery and development spans for nearly 15 years. Dr. HUA had his postdoctoral training focusing on stem cell and gene therapy at Columbia University Medical Center from 2009 to January 2014. From January 2014 to February 2018, he served as a principal scientist at the Lilly China Research and Development Co., Ltd. (禮來(中國)研發有限公司), an affiliate of Eli Lilly, a company listed on the New York Stock Exchange (ticker symbol: LLY). From February 2018 to June 2021, Dr. HUA worked for Shanghai Hansoh BioMedical Co., Ltd. (上海翰森生物醫藥科技有限公司), an indirect wholly-owned subsidiary of Hansoh Pharmaceutical Group Company Limited (翰森製藥集團有限公司), whose shares are listed on the Stock Exchange (stock code: 3692).

Dr. HUA obtained a bachelor's degree in biological science from Tsinghua University (清華大學) in the PRC in July 2003, recognized as a doctor of natural sciences by University of Zurich in Switzerland in July 2009. Dr. HUA was elected as a talent in Jiangsu Province High-Level Creative Talent Strategic Plan (江蘇省高層次創新創業人才引進計劃) in July 2019.

Mr. YU Xin (于鑫), aged 42, first joined our Group as head of regulatory affairs in August 2021 and was also appointed as our vice president in September 2022. He is mainly responsible for overseeing regulatory affairs and product registration operations of our Group.

Mr. YU is a seasoned biotechnology professional with nearly 20 years' experience in pharmaceutical industry. In August 2004, he began his career at the Center for Drug Evaluation of the NMPA (國家藥品監督管理局藥品審評中心), where he obtained a pharmacist qualification in September 2006. Mr. YU's career further expanded through his senior roles in several pharmaceutical companies, with the focus staying at drug regulatory affairs and novel drug development, including (i) an officer at Shanghai Roche Pharmaceutical Co., Ltd. (上海羅氏製藥有限公司) from October 2006 to December 2007, responsible for imported drugs registration in the PRC, (ii) the director of R&D center as his last position at Beijing Fresenius Kabi Pharmaceutical Co., Ltd. (北京費森尤斯卡比醫藥有限公司), a company mainly engaged in R&D and production in the fields of infusion, blood transfusion, clinical nutrition, pharmaceuticals and medical device, from July 2009 to November 2016, managing the drug registration affairs and the center's development, and (iii) a vice president at Alpha Biopharma (Jiangsu) Co., Ltd. (江蘇晨泰醫藥科技有限公司), a drug innovation specializer, from December 2017 to July 2021, responsible for the R&D management and registration of innovative drugs R&D.

Mr. YU obtained a bachelor's degree in pharmaceutical engineering, and a master's degree in pharmacy (pharmaceutical administration) from Shenyang Pharmaceutical University (沈陽藥科大學) in the PRC.

Dr. SHI Rong (施榕), aged 43, is our vice president of development science. She is mainly responsible for leading team of clinical pharmacologists and bioanalysis of our Group.

Dr. SHI brings approximately 13 years of experience in global clinical research. From February 2012 to January 2018, Dr. SHI served as a clinical pharmacologist of oncology at E.R. Squibb & Sons LLC, a subsidiary of Bristol-Myers Squibb Company, a pharmaceutical company listed on the New York Stock Exchange (ticker symbol: BMY), Dr. SHI joined Genentech Inc., a biotechnology company and subsidiary of Roche Holding AG, and Daiichi Sankyo Inc. in January 2018 and February 2020, respectively.

Dr. SHI obtained a bachelor's degree in pharmaceutical engineering from Zhejiang University of Technology (浙江工業大學) in the PRC in June 2004, a master's degree of science in chemistry from Missouri University of Science and Technology in the United States in December 2006, and a Ph.D. from University of Florida in the United States in May 2011. Dr. SHI was a participant in the research participation program at the Center for Drug Evaluation and Research of FDA from May 2011 to January 2012.

Dr. CHU Ruiyin (儲瑞銀), aged 63, is our vice president of translational medicine. He is mainly responsible for management of the translational medicine department of our Group.

Dr. CHU brings over 20 years of experience in the global pharmaceutical industry. In July 2000, Dr. CHU joined Sanofi, a global pharmaceutical products manufacturer. During more than ten years of service for Sanofi, he held positions including principal research investigator and associate director, and led and advanced various early-stage discovery projects. He later joined Hengrui USA, Ltd. in August 2021, a subsidiary of Jiangsu Hengrui Pharmaceuticals Co., Ltd., leading its biomarker programs as a director of biomarker program leader (oncology). Subsequently before joining us, in August 2022, Dr. CHU joined Cogent Biosciences, Inc., a solution provider of genetically driven diseases listed on the Nasdaq (ticker symbol: COGT) as a senior director of translational medicine.

Dr. CHU obtained a master's degree and a Ph.D. from Chinese Academy of Agricultural Sciences (中國農業科學院) in the PRC in November 1986 and October 1990, respectively. Dr. CHU completed a postdoctoral fellowship at Peking University in March 1992 and later furthered his studies at Northwestern University in the United States.

Ms. ZHOU Lan (周嵐), aged 54, is our vice president of commercial strategy. She is mainly responsible for the product commercialization strategy and government relationship of our Group.

Ms. ZHOU brings nearly 17 years of experience in the healthcare and biotechnology sectors. From August 2007 to December 2011, she worked for Shanghai branch of Eisai China Inc. (衛材(中國)藥業有限公司), which is indirectly wholly owned by Eisai Co., Ltd., a Japanese pharmaceutical company listed on the Tokyo Stock Exchange (stock code: 4523). From January 2012 to May 2018, she worked for Shanghai Roche Pharmaceuticals Limited (上海羅氏製藥有限公司). From May 2018 to October 2020, she worked for Innovent Biologics Technology Co., Ltd. (信達生物科技有限公司), an indirect wholly-owned subsidiary of Innovent Biologics, Inc. (信達生物製藥), a biopharmaceutical company listed on the Stock Exchange (stock code: 1801). Subsequently from November 2020 to November 2023, Ms. ZHOU worked within the group of I-Mab, a company listed on the Nasdaq (ticker symbol: IMAB) with her last position as vice president of operations.

Ms. ZHOU obtained an MBA from University of Leicester in the United Kingdom in July 2001 and an EMBA from Washington University in St. Louis in the United States in July 2020.

OTHER INFORMATION IN RELATION TO OUR DIRECTORS AND SENIOR MANAGEMENT

Dr. ZHU Zhongyuan held positions in the following entities, each of which had dissolved by deregistration under the relevant laws and regulations:

Name of company	Place of incorporation	Principal business immediately prior to cessation of business	Roles	Reasons of dissolution
Jiayu Investment Management (Hubei) Co. Ltd. (嘉毓投資管理(湖北)有限公司) . . .	PRC	Investment management	Executive director and general manager	Voluntary dissolution
Suzhou Yucheng Investment Management Co. Ltd. (蘇州毓承投資管理有限公司) .	PRC	Investment management	Executive director and general manager	Voluntary dissolution

Dr. ZHU Zhongyuan confirmed that to the best of his knowledge, (i) there was no wrongful act on his part leading to the deregistration; (ii) each of the above companies was solvent immediately prior to its deregistration and had no outstanding claim or liabilities arising from any material non-compliance incidents; (iii) he has not received any notification in respect of penalty, action or proceeding from relevant PRC or Hong Kong authorities as a result of the deregistration; and (iv) he is not aware of any actual or potential claim which has been or will be made against him as a result of the deregistration.

Save as disclosed above, to the best knowledge, information and belief of the Directors having made all reasonable inquiries, there are no other material matters relating to their appointment as a Director that need to be brought to the attention of our Shareholders and there is no other information in relation to his or her appointment which is required to be disclosed pursuant to Rule 13.51(2) of the Listing Rules as of the Latest Practicable Date.

Save as disclosed above, none of the Directors and senior management held any other directorships in any other company listed in Hong Kong or overseas during the three years immediately preceding the date of this document.

None of our Directors and senior management is related to other Directors and senior management.

JOINT COMPANY SECRETARIES

Ms. YUAN Jiali (袁佳麗), aged 38, is our head of legal and compliance and has been appointed as one of the joint company secretaries of our Company with effect from the [**REDACTED**].

Ms. YUAN has been dedicating in legal services for over 15 years. Prior to joining our Group, from September 2022 to July 2023, she served as the head of legal in Taizhou EOC Jing'ang Pharmaceutical Co., Ltd. (泰州億騰景昂藥業股份有限公司). From November 2017 to August 2022, she was employed within the group of Fosun International Limited (復星國際有限公司), whose shares are listed on the Stock Exchange (stock code: 656), and Shanghai Fosun Pharmaceutical (Group) Co., Ltd. (上海復星醫藥(集團)股份有限公司), a company listed on both the Stock Exchange (stock code: 2196) and Shanghai Stock Exchange (stock code: 600196), successively serving as legal director, senior legal director, legal executive director and general manager assistant. From April 2011 to May 2017, Ms. YUAN served as an attorney in Beijing Dentons (Shanghai) Law Office (北京大成(上海)律師事務所), focusing on domestic and outbound investment, financing, merger and acquisitions, and commercial dispute resolution. From August 2009 to February 2011, she worked in Rolmax Law Offices.

Ms. YUAN obtained a bachelor's degree in international economics law from Shanghai Institute of Foreign Trade (上海對外貿易學院) (currently known as Shanghai University of International Business and Economics (上海對外經貿大學)) in June 2009, and a master's degree in public policy from the University of Tokyo in Japan in June 2017.

Ms. TSANG Wing Man (曾穎雯) ("**Ms. Tsang**") was appointed as one of the joint company secretaries of our Company with effect from August 12, 2024. Ms. Tsang holds a bachelor's degree in business administration from City University of Hong Kong. She currently serves as a manager of SWCS Corporate Services Group (Hong Kong) Limited and has over 10 years of experience in company secretarial matters. She is an associate member of The Chartered Governance Institute and The Hong Kong Chartered Governance Institute.

BOARD COMMITTEES

Our Company has established three committees under the Board pursuant to the corporate governance practice requirements under the Listing Rules, including the Audit Committee, Remuneration Committee and Nomination Committee.

Audit Committee

We have established an Audit Committee in compliance with Rule 3.21 of the Listing Rules and the Corporate Governance Code set out in Appendix C1 to the Listing Rules. The primary duties of the Audit Committee are to (i) review and supervise our financial reporting process and internal control system, risk management and internal audit of our Group; (ii) provide advice and comments to our Board in respect of financial risk, risk management and internal control matters; and (iii) perform other duties and responsibilities as may be assigned by the Board.

The Audit Committee comprises three independent non-executive Directors, namely, Mr. XIE Dong (謝東), Mr. GAO Fengyong (高鳳勇) and Ms. CHUAI Shuyin (揣姝茵), Mr. XIE Dong (謝東) is the chairperson of the Audit Committee. He holds the appropriate professional qualifications as required under Rules 3.10(2) and 3.21 of the Listing Rules.

Remuneration Committee

We have established a Remuneration Committee in compliance with Rule 3.25 of the Listing Rules and the Corporate Governance Code set out in Appendix C1 to the Listing Rules. 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; and (ii) reviewing and approving matters relating to share schemes of our Company.

The Remuneration Committee comprises one executive Director and two independent non-executive Directors, namely, Ms. CHUAI Shuyin (揣姝茵), Mr. GAO Fengyong (高鳳勇) and Ms. SI Wen (司文). Ms. CHUAI Shuyin (揣姝茵) is the chairperson of the Remuneration Committee.

Nomination Committee

We have established a Nomination Committee in compliance with Rule 3.27A of the Listing Rules and the Corporate Governance Code set out in Appendix C1 to the Listing Rules. The primary duties of the Nomination Committee include, but are not limited to, (i) reviewing the structure, size and composition of our Board on a regular basis and make recommendations to the Board regarding any proposed changes to the composition of our Board; (ii) identifying, selecting or making recommendations to our Board on the selection of individuals nominated for directorship, and ensuring the diversity of our Board members; (iii) performing review on the contributions made by our Directors (including our independent non-executive Directors) and the sufficiency of time devoted to perform their duties; (iv) assessing the independence of our independent non-executive Directors; and (v) making recommendations to our Board on relevant matters relating to the appointment, re-appointment and removal of our Directors.

The Nomination Committee comprises one executive Director and two independent non-executive Directors, namely, Dr. ZHU Zhongyuan (朱忠遠), Ms. CHUAI Shuyin (揣姝茵) and Mr. XIE Dong (謝東). Dr. ZHU Zhongyuan (朱忠遠) is the chairperson of the Nomination Committee.

DIRECTORS' AND SENIOR MANAGEMENT'S REMUNERATION

Our Directors and senior management receive remuneration, including salaries, discretionary bonus, share-based compensation expenses, pension costs and other benefits. The aggregate amount of remuneration for the five highest paid individuals of our Group, who is neither a Director nor chief executive of the Company, for the two years ended December 31, 2023 and the nine months ended September 30, 2024 was approximately RMB14.4 million, RMB22.4 million and RMB49.4 million, respectively.

The aggregate amount of remuneration for our Directors for the two years ended December 31, 2023 and the nine months ended September 30, 2024 was approximately RMB11.8 million, RMB22.0 million and RMB78.9 million, respectively.

The significant increase in the aggregate amount of remuneration paid or payable to our Directors and five highest paid individuals during the nine months ended September 30, 2024 was primarily due to the increase in the share-based payments resulting from the grant of share options and the increase of [**REDACTED**] probability in the corresponding period. For further details, see Notes 7 and 31 to the Accountant's Report set out in Appendix I to this document.

According to existing effective arrangements, the total amount of remuneration (excluding any possible payment of discretionary bonus and share-based compensation expenses) shall be paid by us to Directors for the financial year ending December 31, 2025 is expected to be approximately RMB15.5 million.

Save as disclosed above, no other payments have been paid or are payable by our Company to our Directors or senior management for the Track Record Period.

Save as disclosed in this document, no bonuses were paid or receivable by our Directors which were discretionary or were based on our Company's, our Group's or any member of our Group's performance for the Track Record Period.

No remuneration was paid to our Directors or the five highest paid individuals as an inducement to join, or upon joining, our Group. No compensation was paid to, or receivable by, our Directors or past directors for the Track Record Period for the loss of office as director or any member of our Group or of any other office in connection with the management of the affairs of any member of our Group. None of our Directors waived any emoluments during the Track Record Period.

COMPLIANCE ADVISOR

We have appointed First Shanghai Capital Limited as our Compliance Advisor pursuant to Rule 3A.19 of the Listing Rules. Our Compliance Advisor will provide us with guidance and advice as to compliance with the Listing Rules and applicable Hong Kong laws. Pursuant to Rule 3A.23 of the Listing Rules, our Compliance Advisor will advise our Company in certain circumstances including:

(i) before the publication of any regulatory announcement, circular, or financial report;

(ii) where a transaction, which might be a notifiable or connected transaction, is contemplated, including share issues, sales or transfers of treasury shares and share repurchases; and

(iii) where we propose to use the [**REDACTED**] of the [**REDACTED**] in a manner different from that detailed in this document or where the business activities, development or results of our Group deviate from any forecast, estimate or other information in this document; and where the Stock Exchange makes an inquiry to our Company regarding unusual movements in the [**REDACTED**] or [**REDACTED**] of its [**REDACTED**] securities or any other matters in accordance with Rule 13.10 of the Listing Rules.

Pursuant to Rule 3A.24 of the Listing Rules, the Compliance Advisor will, on a timely basis, inform our Company of any amendment or supplement to the Listing Rules that are announced by the Stock Exchange. The Compliance Advisor will also inform our Company of any new or amended law, regulation or code in Hong Kong applicable to us, and advise us on the applicable requirements under the Listing Rules and laws and regulations.

The term of appointment of our Compliance Advisor shall commence on the [**REDACTED**] and is expected to end 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**].

CORPORATE GOVERNANCE CODE

Our Directors recognize the importance of incorporating elements of good corporate governance in the management structures and internal control procedures of our Group to achieve effective accountability. Our Company intends to comply with all code provisions in the Part 2 of the Corporate Governance Code as set out in Appendix C1 to the Listing Rules after the [**REDACTED**] except for code provision C.2.1 of Part 2 of the Corporate Governance Code, which provides that the roles of chairman of the board and chief executive should be separate and should not be performed by the same individual.

The roles of chairman and chief executive officer of our Company are currently performed by Dr. ZHU. In view of Dr. ZHU's substantial contribution to our Group since our establishment and his extensive experience, we consider that having Dr. ZHU acting as both

our chairman and chief executive officer will provide strong and consistent leadership to our Group and facilitate the efficient execution of our business strategies. We consider it appropriate and beneficial to our business development and prospects that Dr. ZHU continues to act as both our chairman and chief executive officer after the [**REDACTED**], and therefore currently do not propose to separate the functions of chairman and chief executive officer. While this would constitute a deviation from code provision C.2.1 of Part 2 of the Corporate Governance Code, the Board believes that this structure will not impair the balance of power and authority between the Board and the management of our Company, given that: (i) there are sufficient checks and balances in the Board, as a decision to be made by our Board requires approval by at least a majority of our Directors, and our Board comprises three independent non-executive Directors, which is in compliance with the requirement under the Listing Rules; (ii) Dr. ZHU and the other Directors are aware of and undertake to fulfill their fiduciary duties as Directors, which require, among other things, that he acts for the benefit and in the best interests of our Company and will make decisions for our Group accordingly; and (iii) the balance of power and authority is ensured by the operations of the Board which comprises experienced and high caliber individuals who meet regularly to discuss issues affecting the operations of our Company. Moreover, the overall strategic and other key business, financial, and operational policies of our Group are made collectively after thorough discussion at both Board and senior management levels. The Board will continue to review the effectiveness of the corporate governance structure of our Group in order to assess whether the separation of the roles of chairman and chief executive officer is necessary.

MANAGEMENT PRESENCE

According to Rule 8.12 of the Listing Rules, we must have sufficient management presence in Hong Kong. This normally means that at least two of our executive Directors must be ordinarily resident in Hong Kong. Since the principal business operations of our Group are conducted in Mainland China, members of our senior management are, and are expected to continue to be, based in Mainland China. Further, as our executive Directors have a vital role in our Group's operations, it is crucial for them to remain in close proximity to our Group's central management located in Mainland China. Our Company does not and, for the foreseeable future, will not have a sufficient management presence in Hong Kong. We have applied for, and the Stock Exchange [has granted], a waiver from compliance with Rule 8.12 of the Listing Rules. For further details, see "Waivers from Strict Compliance with the Listing Rules and Exemptions from the Companies (Winding Up and Miscellaneous Provisions) Ordinance — Management Presence in Hong Kong."

BOARD DIVERSITY POLICY

Our Board has adopted a board diversity policy which sets out the approach to achieve diversity on our Board. Our Company recognizes and embraces the benefits of having a diverse Board and sees increasing diversity at the Board level as an essential element in supporting the attainment of our Company's strategic objectives and sustainable development. Our Company seeks to achieve Board diversity through the consideration of a number of factors, including but not limited to talent, skills, gender, age, cultural and educational background, ethnicity,

professional experience, independence, knowledge and length of service. We will select potential Board candidates based on merit and their potential contribution to our Board while taking into consideration our own business model and specific needs from time to time. All Board appointments will be based on meritocracy and candidates will be considered against objective criteria, having due regard to the benefits of diversity on our Board.

Our Board has a balanced mix of knowledge, skills and experience. They completed studies in various majors including but without limitation to molecular biology, biochemistry and polymer biology, business administration, international accounting, economics, managerial psychology, science, biomedical engineering, Korean language and culture, Asian and African languages and literatures, art and human resources and industrial relations. We have three independent non-executive Directors who have different industry backgrounds. Furthermore, our Directors are of a wide range of age, from 38 to 54 years old. Taking into account our business model and specific needs as well as the presence of two female Directors out of a total of eight Board members, we consider that the composition of our Board satisfies our board diversity policy.

We recognize the particular importance of gender diversity on our Board. We have taken and will continue to take steps to promote and enhance gender diversity at all levels of our Company, including but without limitation at our Board and senior management levels. Our board diversity policy provides that our Board shall take opportunities when selecting and making recommendations on suitable candidates for Board appointments with the aim of increasing the proportion of female members over time after [**REDACTED**]. In particular, taking into account the business needs of our Group and changing circumstances that may affect our business plans, we will actively identify and select several female individuals with a diverse range of skills, experience and knowledge in different fields from time to time, and maintain a list of such female individuals who possess qualities to become our Board members, which will be periodically reviewed by our Nomination Committee in order to develop a pipeline of potential successors to our Board and promote gender diversity. Additionally, female representatives of our investors are also considered as potential candidates for Board appointments. We will also ensure that there is gender diversity when recruiting staff at the mid- to senior- levels so that we have a pipeline of female senior management and potential successors to our Board going forward. We plan to offer well-rounded trainings to female employees whom we consider have the requisite experience, skills and knowledge of our operation and business, on topics including but not limited to business operation, management, accounting and finance, and legal compliance. We are of the view that such strategies will provide our Board with ample opportunities to identify capable female employees to be nominated as Directors in the future, fulfilling our aim to develop a pipeline of female candidates to achieve greater gender diversity in our Board in the long run. We believe that such a merit-based selection process with reference to our diversity policy and the nature of our business will be in the best interests of our Company and our Shareholders as a whole. It is our objective to maintain an appropriate balance of gender diversity with reference to the stakeholders' expectations and international and local recommended best practices.

Our Nomination Committee is responsible for ensuring the diversity of our Board members. After [**REDACTED**], our Nomination Committee will review our board diversity policy and its implementation annually to monitor its continued effectiveness and we will disclose the implementation of our board diversity policy, including any measurable objectives set for implementing the board diversity policy and the progress on achieving these objectives, in our corporate governance report on an annual basis.

KEY TERMS OF EMPLOYMENT CONTRACTS

We normally enter into employment contracts, confidentiality agreements and non-competition agreements with our senior management members and other key personnel. Below sets forth the key terms of these contracts we enter into with our senior management and other key personnel.

Non-competition

Within two years from the date of the employee's departure and during the course of employment by our Group, he/she shall not, among others, directly or indirectly engage in any business activities which are similar or competitive with the business of our Group. In addition, the employee shall not work for nor provide any financial assistance, guarantees or advice to any other entities that may compete with our Group.

Confidentiality

The employee shall keep in confidence and shall not disclose our trade secrets, including but not limited to our business strategy and approaches, marketing or pricing activities, business development plans, customer information, financial information, various research data, other information that is deemed as confidential by our Group or our business partners and should be kept in confidence by our Group, and other information, that is disclosed to or obtained by the employee directly or indirectly from our Company or other members of our Group during the term of their employment.

Service Invention

The intellectual property rights in any invention, work, design, copyrights or any other intellectual property that is (i) resulted from performing employee duties, (ii) produced from other tasks assigned by our Company, (iii) developed within one year from the date of the employee's departure and related to his/her previous duties or tasks in our Group, or (iv) developed mainly using our material, technologies and information, shall belong to us.

CONFIRMATIONS FROM OUR DIRECTORS

Rule 8.10 of the Listing Rules

Each of our Directors confirms that as of the Latest Practicable Date, they 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.

From time to time our non-executive Directors may serve on the boards of both private and public companies within the broader healthcare and biopharmaceutical industries. However, as these non-executive Directors are not members of our executive management team, we do not believe that their interests in such companies as directors would render us incapable of carrying on our business independently from the other companies in which these non-executive Directors may hold directorships from time to time.

Rule 3.09D of the Listing Rules

Each of our Directors confirms that they (i) have obtained the legal advice referred to under Rule 3.09D of the Listing Rules on July 29, 2024, July 31, 2024 or August 1, 2024, and (ii) understand their obligations as a director of a [**REDACTED**] issuer under the Listing Rules.

Rule 3.13 of the Listing Rules

Each of the independent non-executive Directors has confirmed (i) their independence as regards each of the factors referred to in Rules 3.13(1) to (8) of the Listing Rules, (ii) they have no past or present financial or other interest in the business of our Company or its subsidiaries or any connection with any core connected person of our Company under the Listing Rules as of the Latest Practicable Date, and (iii) that there are no other factors that may affect their independence at the time of their appointments.

FUTURE PLANS AND PROSPECTS

See "Business — Our Business Strategies" for a detailed description of our future plans.

[**REDACTED**]

We estimate that we will receive [**REDACTED**] from the [**REDACTED**] of approximately HK$[**REDACTED**] million, after deducting [**REDACTED**], fees and estimated expenses payable by us in connection with the [**REDACTED**], and assuming an [**REDACTED**] of HK$[**REDACTED**] per Share, being the [**REDACTED**] of the indicative [**REDACTED**] range stated in this document. If the [**REDACTED**] is set at HK$[**REDACTED**] per Share, being the [**REDACTED**] of the indicative [**REDACTED**] range, the [**REDACTED**] from the [**REDACTED**] will increase by approximately HK$[**REDACTED**] million. If the [**REDACTED**] is set at HK$[**REDACTED**] per Share, being the [**REDACTED**] of the indicative [**REDACTED**] range, the [**REDACTED**] from the [**REDACTED**] will decrease by approximately HK$[**REDACTED**] million.

Assuming an [**REDACTED**] at the [**REDACTED**] of the indicative [**REDACTED**] range and that the [**REDACTED**] is not exercised, we currently intend to apply these [**REDACTED**] for the following purposes:

- Approximately [**REDACTED**]%, or HK$[**REDACTED**] million, will be used for the research, development and commercialization of our Core Products, namely, DB-1303 and DB-1311 in our retained territory:

  — approximately [**REDACTED**]%, or HK$[**REDACTED**] million, will be used for the ongoing and planned clinical trials of DB-1303/BNT323, including approximately [**REDACTED**]%, or HK$[**REDACTED**] million for HER2-expressing EC, approximately [**REDACTED**]%, or HK$[**REDACTED**] million for HR+/HER2-low BC, approximately [**REDACTED**]%, or HK$[**REDACTED**] million for HER2+ BC (2L+), approximately [**REDACTED**]%, or HK$[**REDACTED**] million for HER2+ BC (1L, in combination with Pertuzumab) and approximately [**REDACTED**]%, or HK$[**REDACTED**] million for other solid tumors such as OC, CRC and esophageal cancer;

  For details of DB-1303's clinical development plan, see "Business — Our Pipeline — Overview" and "Business — Our Pipeline — ADC Assets Developed from DITAC Technology Platform — DB-1303/BNT323, a late clinical stage HER2 ADC candidate, our Core Product — Clinical Development Plan." For competitive landscape of HER2 ADCs, see "Business — Our Pipeline — ADC Assets Developed from DITAC Technology Platform — DB-1303/BNT323, a late clinical stage HER2 ADC candidate, our Core Product — Market Opportunity and Competition."

We anticipate using over [**REDACTED**]% of the [**REDACTED**] allocated for the ongoing and planned clinical trials of DB-1303 within 24 months following the [**REDACTED**].

— approximately [**REDACTED**]%, or HK$[**REDACTED**] million, will be used for the ongoing and planned clinical trials of DB-1311/BNT324, including approximately [**REDACTED**]%, or HK$[**REDACTED**] million for SCLC, approximately [**REDACTED**]%, or HK$[**REDACTED**] million for CRPC, approximately [**REDACTED**]%, or HK$[**REDACTED**] million for ESCC and approximately [**REDACTED**]%, or HK$[**REDACTED**] million for other solid tumors such as NSCLC;

For details of DB-1311's clinical development plan, see "Business — Our Pipeline — Overview" and "Business — Our Pipeline — ADC Assets Developed from DITAC Technology Platform — DB-1311/BNT324, a B7-H3 ADC candidate with global market potential, our Core Product — Clinical Development Plan." For competitive landscape of B7-H3 ADCs, see "Business — Our Pipeline — ADC Assets Developed from DITAC Technology Platform — DB-1311/BNT324, a B7-H3 ADC candidate with global market potential, our Core Product — Market Opportunity and Competition."

We anticipate using over [**REDACTED**]% of the [**REDACTED**] allocated for the ongoing and planned clinical trials of DB-1311 within 24 months following the [**REDACTED**].

— approximately [**REDACTED**]%, or HK$[**REDACTED**] million, will be used for the commercialization, registration filings and other regulatory matters for DB-1303 and DB-1311;

We anticipate using over [**REDACTED**]% of the [**REDACTED**] allocated for the commercialization, registration filings and other regulatory matters for DB-1303 and DB-1311 within 24 months following the [**REDACTED**].

• Approximately [**REDACTED**]%, or HK$[**REDACTED**] million, will be used for the research and development of our key products, including:

— approximately [**REDACTED**]%, or HK$[**REDACTED**] million, will be used for the ongoing and planned clinical trials for DB-1310, including approximately [**REDACTED**]%, or HK$[**REDACTED**] million for EGFRm NSCLC, approximately [**REDACTED**]%, or HK$[**REDACTED**] million for KRASm NSCLC, approximately [**REDACTED**]%, or HK$[**REDACTED**] million for HER2+ BC and approximately [**REDACTED**]%, or HK$[**REDACTED**] million for other solid tumors, such as CRPC, HNSCC, ESCC and BTC;

For details of DB-1310's clinical development plan, see "Business — Our Pipeline — Overview" and "Business — Our Pipeline — ADC Assets Developed from DITAC Technology Platform — DB-1310, a HER3 ADC candidate in phase 1/2a trial, our Key Product — Next Steps." For competitive landscape of HER3 ADCs, see "Business — Our Pipeline — ADC Assets Developed from DITAC Technology Platform — DB-1310, a HER3 ADC candidate in phase 1/2a trial, our key product — Market Opportunity and Competition."

We anticipate using over [**REDACTED**]% of the [**REDACTED**] allocated for the ongoing and planned clinical trials for DB-1310 within 24 months following the [**REDACTED**].

— approximately [**REDACTED**]%, or HK$[**REDACTED**] million, will be used for the ongoing and planned clinical trials for DB-1305/BNT325, in our retained territory, including approximately [**REDACTED**]%, or HK$[**REDACTED**] million for OC, approximately [**REDACTED**]%, or HK$[**REDACTED**] million for NSCLC (2L+), and approximately [**REDACTED**]%, or HK$[**REDACTED**] million for other solid tumors, and approximately [**REDACTED**]%, or HK$[**REDACTED**] million for combination studies in NSCLC, OC, CC and TNBC patients;

For details of DB-1305's clinical development plan, see "Business — Our Pipeline — Overview." For competitive landscape of TROP2 ADCs, see "Business — Our Pipeline — ADC Assets Developed from DITAC Technology Platform — DB-1305/BNT325, a TROP2 ADC candidate with potential as a frontline backbone therapy, our key product — Market Opportunity and Competition."

We anticipate using over [**REDACTED**]% of the [**REDACTED**] allocated for the ongoing and planned clinical trials for DB-1305 within 24 months following the [**REDACTED**].

— approximately [**REDACTED**]%, or HK$[**REDACTED**] million, will be used to advance the ongoing and planned clinical trials for DB-1419;

For details of DB-1419's clinical development plan, see "Business — Our Pipeline — Overview" and "Business — Our Pipeline — ADC Assets Developed from DITAC Technology Platform — DB-2304, Potential First-in-class Autoimmune ADC for SLE/CLE, our Key Product — Next Steps." For competitive landscape of ADCs for autoimmune diseases, see "Business — Our Pipeline — ADC Assets Developed from DITAC Technology Platform — DB-2304, Potential First-in-class Autoimmune ADC for SLE/CLE, our Key Product — Market Opportunity and Competition."

We anticipate using over [**REDACTED**]% of the [**REDACTED**] allocated for the clinical development of DB-1419 within 24 months following the [**REDACTED**].

— approximately [**REDACTED**]%, or HK$[**REDACTED**] million, will be used to advance the clinical development of DB-2304 for SLE and CLE. We have submitted IND applications to both the FDA and NMPA for DB-2304 and, subject to regulatory approval, expect to complete DB-2304's phase 1 global trial in 2026;

For details of DB-2304's clinical development plan, see "Business — Our Pipeline — Overview" and "Business — Our Pipeline — ADC Assets Developed from DITAC Technology Platform — DB-1419, Potential Global First-in-class B7-H3xPD-L1 BsADC Candidate — Next Steps." For competitive landscape of BsADCs, see "Industry Overview — Overview of Bispecific ADCs."

We anticipate using over [**REDACTED**]% of the [**REDACTED**] allocated for the clinical development of DB-2304 within 24 months following the [**REDACTED**].

- Approximately [**REDACTED**]%, or HK$[**REDACTED**] million, will be used to fund the continued development of our ADC technology platforms, advance our other pipeline assets, and explore and develop new drug assets; and

  Our research in the next few years will focus on novel payloads and linkers to broaden the therapeutic index of our ADCs. We are actively exploring new mechanism of action and formats to achieve new heights in terms of safety, potency and activity, and have a number of prototypes under development with promising broad-spectrum anti-tumor activity and potent bystander killing effects. We believe these innovations will redefine ADC functionality and chart the course for a new revolution of the ADC modality. In addition, we plan to leverage the power of AI to systematically optimize every stage of our R&D, from target identification, ADC design and engineering to biomarker discovery, enabling us to fine-tune our engineering of next generation ADC candidates to prioritize high-potential targets and indications. For details on our strategies on ADC technology innovation, see "Business — Our Business Strategies — Continue technology innovation to unlock the full potential of ADCs and disrupt treatment landscape."

  We anticipate using over [**REDACTED**]% of the [**REDACTED**] allocated to fund the continued development of our ADC technology platforms, advance our other pipeline assets, and explore and develop new drug assets within 24 months following the [**REDACTED**].

- Approximately [**REDACTED**]%, or HK$[**REDACTED**] million, will be used for working capital and other general corporate purposes.

The above allocation of the [**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 [**REDACTED**] of the indicative [**REDACTED**] range stated in this document.

If the [**REDACTED**] is exercised in full, the [**REDACTED**] that we will receive will be approximately HK$[**REDACTED**] million, assuming an [**REDACTED**] of HK$[**REDACTED**] per Share (being the [**REDACTED**] of the indicative [**REDACTED**] range). In the event that the [**REDACTED**] is exercised in full, we intent to apply the additional [**REDACTED**] to the above purposes in the proportions stated above.

To the extent that the [**REDACTED**] from the [**REDACTED**] are not immediately used for the purposes described above and to the extent permitted by the relevant laws and regulations, they will be [**REDACTED**] in short-term interest-bearing accounts at licensed commercial banks and/ or other authorized financial institutions (as defined under the Securities and Futures Ordinance or the 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**]

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The following is the text of a report set out on pages I-[●] to I-[●], received from the Company's reporting accountant, PricewaterhouseCoopers, Certified Public Accountants, Hong Kong, for the purpose of incorporation in this document. It is prepared and addressed to the directors of the Company and to the Joint Sponsors pursuant to the requirements of HKSIR 200, Accountants' Reports on Historical Financial Information in Investment Circulars issued by the Hong Kong Institute of Certified Public Accountants.

[DRAFT]

[To insert the firm's letterhead]

ACCOUNTANT'S REPORT ON HISTORICAL FINANCIAL INFORMATION TO THE DIRECTORS OF DUALITY BIOTHERAPEUTICS, INC. AND MORGAN STANLEY ASIA LIMITED, JEFFERIES HONG KONG LIMITED AND CITIC SECURITIES (HONG KONG) LIMITED

Introduction

We report on the historical financial information of Duality Biotherapeutics, Inc. (the "Company") and its subsidiaries (together, the "Group") set out on pages [I-[●] to [I-[●]], which comprises the consolidated balance sheets as at 31 December 2022 and 2023 and 30 September 2024, the balance sheets of the Company as at 31 December 2022 and 2023 and 30 September 2024, and the consolidated statements of comprehensive loss, the consolidated statements of changes in equity and the consolidated statements of cash flows for each of the years ended 31 December 2022 and 2023 and the nine months ended 30 September 2024 (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-[●]] to [I-[●]] forms an integral part of this report, which has been prepared for inclusion in the document of the Company dated [document date] (the "Document") in connection with the initial [**REDACTED**] of shares of the Company on the Main Board of The Stock Exchange of Hong Kong Limited.

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 2.1 to the Historical Financial Information, and for such internal control as the directors determine is necessary to enable the preparation of Historical Financial Information that is free from material misstatement, whether due to fraud or error.

Reporting accountant's responsibility

Our responsibility is to express an opinion on the Historical Financial Information and to report our opinion to you. We conducted our work in accordance with Hong Kong Standard on Investment Circular Reporting Engagements 200, *Accountants' Reports on Historical Financial Information in Investment Circulars* issued by the Hong Kong Institute of Certified Public Accountants ("HKICPA"). This standard requires that we comply with ethical standards and plan and perform our work to obtain reasonable assurance about whether the Historical Financial Information is free from material misstatement.

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 accountant's 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 accountant considers 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 2.1 to the Historical Financial Information in order to design procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control. Our work also included evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by the directors, as well as evaluating the overall presentation of the Historical Financial Information.

We believe that the evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Opinion

In our opinion, the Historical Financial Information gives, for the purposes of the accountant's report, a true and fair view of the financial position of the Company as at 31 December 2022 and 2023 and 30 September 2024 and the consolidated financial position of the Group as at 31 December 2022 and 2023 and 30 September 2024 and of its consolidated financial performance and its consolidated cash flows for the Track Record Period in accordance with the basis of preparation set out in Note 2.1 to the Historical Financial Information.

Review of stub period comparative financial information

We have reviewed the stub period comparative financial information of the Group which comprises the consolidated statements of comprehensive loss, the consolidated statements of changes in equity and the consolidated statements of cash flows for the nine months ended 30 September 2023 and other explanatory information (the "Stub Period Comparative Financial Information"). The directors of the Company are responsible for the presentation and preparation of the Stub Period Comparative Financial Information in accordance with the basis of preparation set out in Note 2.1 to the Historical Financial Information. Our responsibility is to express a conclusion on the Stub Period Comparative Financial Information based on our review. We conducted our review in accordance with International Standard on Review Engagements 2410, *Review of Interim Financial Information Performed by the Independent Auditor of the Entity* issued by the International Auditing and Assurance Standards Board ("IAASB"). A review consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion. Based on our review, nothing has come to our attention that

causes us to believe that the Stub Period Comparative Financial Information, for the purposes of the accountant's report, is not prepared, in all material respects, in accordance with the basis of preparation set out in Note 2.1 to the Historical Financial Information.

Report on matters under the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited (the "Listing Rules") 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-[●]] have been made.

Dividends

We refer to note 27 to the Historical Financial Information which states that no dividends have been paid by the Company in respect of the Track Record Period.

No statutory financial statements for the Company

No statutory financial statements have been prepared for the Company since its date of incorporation.

PricewaterhouseCoopers
Certified Public Accountants
Hong Kong
[Date]

I 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 accountant's report.

The financial statements of the Group for the Track Record Period, on which the Historical Financial Information is based, were audited by PricewaterhouseCoopers in accordance with International Standards on Auditing ("ISAs") issued by the International Auditing and Assurance Standards Board ("Underlying Financial Statements").

The Historical Financial Information is presented in Renminbi ("RMB") and all amounts are rounded to the nearest thousand (RMB'000) except when otherwise stated.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

	Notes	Year ended 31 December		Nine months ended 30 September	
		2022	2023	2023	2024
		RMB'000	*RMB'000*	*RMB'000 (Unaudited)*	*RMB'000*
Revenues	*5*	1,600	1,786,540	1,675,917	1,462,004
Cost of revenue	*6*	–	(427,655)	(324,161)	(802,456)
Gross Profit		1,600	1,358,885	1,351,756	659,548
Research and development expenses	*6*	(339,890)	(558,997)	(372,391)	(601,930)
Administrative expenses	*6*	(31,921)	(62,567)	(43,800)	(126,836)
Other income	*8*	494	3,261	2,209	3,347
Other gains/(losses), net	*9*	1,134	40,773	38,847	(7,297)
Operating (loss)/profit		(368,583)	781,355	976,621	(73,168)
Finance income	*10*	3,268	34,483	24,160	38,809
Finance costs	*10*	(75)	(188)	(145)	(189)
Fair value change of financial liabilities at fair value through profit or loss	*24*	(21,700)	(1,017,899)	(959,200)	(501,351)
(Loss)/profit before income tax		(387,090)	(202,249)	41,436	(535,899)
Income tax expense	*11*	–	(155,263)	(155,263)	(30,583)
Loss for the year/period attributable to the owners of the Company		(387,090)	(357,512)	(113,827)	(566,482)
Other comprehensive income/(loss):					
Items that will not be reclassified to profit or loss					
Exchange differences on translation		(42,743)	(19,553)	(49,608)	28,828
Changes in fair value of financial liabilities from own credit risk		420	(1,688)	(87)	(216)
Other comprehensive (loss)/income for the year/period, net of tax		(42,323)	(21,241)	(49,695)	28,612
Total comprehensive loss for the year/period attributable to the owners of the Company		(429,413)	(378,753)	(163,522)	(537,870)
Loss per share for the loss attributable to owners of the Company					
Basic and diluted loss per share (in RMB)	*12*	(48.4)	(44.7)	(14.2)	(70.8)

CONSOLIDATED BALANCE SHEETS

	Notes	As at 31 December		As at 30 September
		2022	2023	2024
		RMB'000	*RMB'000*	*RMB'000*
ASSETS				
Non-current assets				
Property, plant and equipment	*14*	2,511	12,313	13,105
Intangible assets	*16*	51,143	54,248	42,221
Right-of-use assets	*15*	4,568	5,445	3,744
Other non-current assets	*21*	635	94,008	112,358
Total non-current assets		58,857	166,014	171,428
Current assets				
Cash and cash equivalents	*17*	375,974	1,130,889	1,059,706
Restricted cash	*18*	–	42,645	43,656
Trade receivables	*19*	1,408	100,803	389,844
Prepayments and other receivables	*20*	4,913	27,024	20,691
Financial assets at fair value through profit or loss	*24*	–	–	60,199
Other current assets	*21*	22,585	32,534	59,551
Total Current assets		404,880	1,333,895	1,633,647
Total assets		463,737	1,499,909	1,805,075
DEFICITS				
Share capital	*22*	6	6	6
Other reserves	*23*	(16,085)	31,861	224,430
Accumulated losses		(753,038)	(1,155,780)	(1,722,262)
Deficits attributable to the owners of the Company		(769,117)	(1,123,913)	(1,497,826)
Total deficits		(769,117)	(1,123,913)	(1,497,826)
LIABILITIES				
Non-current liabilities				
Contract liabilities	*5*	–	60,164	31,952
Lease liabilities		2,074	2,412	563
Total non-current liabilities		2,074	62,576	32,515
Current liabilities				
Financial liabilities at fair value through profit or loss	*24*	1,072,720	2,132,720	2,605,079
Trade payables	*25*	129,495	234,814	524,436
Other payables	*26*	25,974	34,674	81,966
Contract liabilities	*5*	–	156,132	55,698
Lease liabilities		2,591	2,906	3,207
Total current liabilities		1,230,780	2,561,246	3,270,386
Net current liabilities		825,900	1,227,351	1,636,739
Total liabilities		1,232,854	2,623,822	3,302,901
Total deficits and liabilities		463,737	1,499,909	1,805,075

THE COMPANY BALANCE SHEETS

	Notes	As at 31 December		As at 30 September
		2022	2023	2024
		RMB'000	*RMB'000*	*RMB'000*
ASSETS				
Non-current assets				
Investments in subsidiaries	*32*	772,428	994,762	1,146,008
Total non-current assets		772,428	994,762	1,146,008
Current assets				
Cash and cash equivalents	*17*	41,775	6,201	5,061
Prepayments and other receivables		–	2,937	3,902
Total Current assets		41,775	9,138	8,963
Total assets		814,203	1,003,900	1,154,971
DEFICITS				
Share capital	*22*	6	6	6
Other reserves	*23*	12,788	29,155	209,347
Accumulated losses		(136,149)	(1,158,101)	(1,678,088)
Deficits attributable to the owners of the Company		(123,355)	(1,128,940)	(1,468,735)
Total deficits		(123,355)	(1,128,940)	(1,468,735)
LIABILITIES				
Current liabilities				
Financial liabilities at fair value through profit or loss	*24*	937,529	2,132,720	2,605,079
Other payables	*26*	29	120	18,627
Total current liabilities		937,558	2,132,840	2,623,706
Net current liabilities		895,783	2,123,702	2,614,743
Total liabilities		937,558	2,132,840	2,623,706
Total deficits and liabilities		814,203	1,003,900	1,154,971

CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

	Attributable to the owners of the Company			
	Share capital	Other reserves	Accumulated losses	Total deficits
	RMB'000	*RMB'000*	*RMB'000*	*RMB'000*
Balances at 1 January 2022	6	19,206	(365,948)	(346,736)
Comprehensive loss				
Loss for the year	–	–	(387,090)	(387,090)
Other comprehensive loss				
Items that will not be reclassified to profit or loss				
Exchange differences on translation	–	(42,743)	–	(42,743)
Changes in fair value of financial liabilities from own credit risk	–	420	–	420
Transactions with owners in their capacity as owner:				
Share-based compensation expense	–	7,032	–	7,032
Balances at 31 December 2022	6	(16,085)	(753,038)	(769,117)
Comprehensive loss				
Loss for the year	–	–	(357,512)	(357,512)
Surplus reserves	–	45,230	(45,230)	–
Other comprehensive loss				
Items that will not be reclassified to profit or loss				
Exchange differences on translation	–	(19,553)	–	(19,553)
Changes in fair value of financial liabilities from own credit risk	–	(1,688)	–	(1,688)
Transactions with owners in their capacity as owner:				
Share-based compensation expense	–	23,957	–	23,957
Balance at 31 December 2023	6	31,861	(1,155,780)	(1,123,913)

	Attributable to the owners of the Company			
	Share capital	Other reserves	Accumulated losses	Total deficits
	RMB'000	*RMB'000*	*RMB'000*	*RMB'000*
(Unaudited)				
Balance at 31 December 2022	6	(16,085)	(753,038)	(769,117)
Comprehensive loss				
Loss for the period	–	–	(113,827)	(113,827)
Other comprehensive loss				
Items that will not be reclassified to profit or loss				
Exchange differences on translation	–	(49,608)	–	(49,608)
Changes in fair value of financial liabilities from own credit risk	–	(87)	–	(87)
Transactions with owners in their capacity as owner:				
Share-based compensation expense	–	16,139	–	16,139
Balances at 30 September 2023	6	(49,641)	(866,865)	(916,500)
Balance at 31 December 2023	6	31,861	(1,155,780)	(1,123,913)
Comprehensive loss				
Loss for the period	–	–	(566,482)	(566,482)
Other comprehensive loss				
Items that will not be reclassified to profit or loss				
Exchange differences on translation	–	28,828	–	28,828
Changes in fair value of financial liabilities from own credit risk	–	(216)	–	(216)
Transactions with owners in their capacity as owner:				
Share-based compensation expense	–	163,957	–	163,957
Balance at 30 September 2024	6	224,430	(1,722,262)	(1,497,826)

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Notes	For the year ended 31 December		Nine months ended 30 September	
		2022	2023	2023	2024
		RMB'000	*RMB'000*	*RMB'000* (Unaudited)	*RMB'000*
Cash flows from operating activities					
Cash (used in)/generated from operating activities	*28*	(302,738)	1,030,781	1,193,730	30,012
Income tax paid		–	(248,929)	(248,929)	(48,398)
Interest received		3,268	34,483	24,160	38,809
Net cash (outflow)/inflow from operating activities		(299,470)	816,335	968,961	20,423
Cash flows from investing activities					
Purchase of property, plant and equipment		(2,482)	(11,284)	(8,858)	(3,189)
Purchase of intangible assets		(19,718)	(24,621)	(24,621)	(17,930)
Payments for financial assets at fair value through profit or loss		–	–	–	(1,129,000)
Redemption of financial assets		–	–	–	1,069,000
Interest received on financial assets		–	–	–	1,291
Changes in restricted cash balances		–	(42,645)	–	(1,011)
Net cash outflow from investing activities		(22,200)	(78,550)	(33,479)	(80,839)
Cash flows from financing activities					
Proceeds from issuance of convertible preferred shares	*24*	318,593	151,101	151,101	–
Proceeds of loans with warrants to purchase B-2 Preferred Shares from convertible preferred shareholders	*24*	135,191	–	–	–
Repayments of loans with warrants to purchase Series B-2 Preferred Shares from convertible preferred shareholders	*24*	–	(135,191)	(135,191)	–

	Notes	For the year ended 31 December		Nine months ended 30 September	
		2022	2023	2023	2024
		RMB'000	*RMB'000*	*RMB'000* *(Unaudited)*	*RMB'000*
Settlement of financial assets at fair value through profit or loss		–	(1,162)	–	–
Deposits in relation to lease agreements		(815)	(244)	(214)	(27)
Principal element of lease payments		(1,433)	(3,499)	(2,597)	(2,237)
Interests elements of lease payments		(75)	(188)	(145)	(189)
Payment of [**REDACTED**]		–	–	–	(859)
Net cash inflow from financing activities		451,461	10,817	12,954	(3,312)
Net increase/(decrease) in cash and cash equivalents		129,791	748,602	948,436	(63,728)
Cash and cash equivalents at the beginning of year/period		227,762	375,974	375,974	1,130,889
Effect of foreign exchange rate changes on cash and cash equivalents		18,421	6,313	15,388	(7,455)
Cash and cash equivalents at end of year/period		375,974	1,130,889	1,339,798	1,059,706

II NOTES TO THE HISTORICAL FINANCIAL INFORMATION

1 GENERAL INFORMATION

Duality Biotherapeutics, Inc. (the "Company") was incorporated on 3 July 2019 in the Cayman Islands with limited liabilities under the Companies Law Cap. 22 of the Cayman Islands. The address of the Company's registered office is at the offices of Aequitas International Management Ltd., Grand Pavilion Commercial Centre, Suite 24, 802 West Bay Road, P.O. Box 10281, Grand Cayman KY1-1003, Cayman Islands.

The Company is an investment holding company. The Company and its subsidiaries (hereinafter collectively referred to as the "Group") are a global clinical-stage biopharmaceutical company discovering, developing next generation Antibody-Drug Conjugate therapeutics in the People's Republic of China (the "PRC") and United States of America (the "US").

2 BASIS OF PREPARATION AND NEW OR AMENDED STANDARDS OR INTERPRETATIONS

2.1 Basis of preparation

The Historical Financial Information have been prepared in accordance with all applicable International Financial Reporting Standards issued by the International Accounting Standards Board ("IFRS Accounting Standards"). The Historical Financial Information have been prepared under the historical cost convention, except for financial assets and financial liabilities measured at fair value through profit or loss.

The preparation of the Historical Financial Information in conformity with IFRS Accounting Standards requires the use of certain critical accounting estimates. It also requires management to exercise its judgment in the process of applying the Group's accounting policies. The areas involving a higher degree of judgment or complexity, or areas where assumptions and estimates are significant to the Historical Financial Information are disclosed in Note 4.

The accounting policies applied in the preparation of the Historical Financial Information have been consistently applied to the Track Record Period, unless otherwise stated.

Other than those material accounting policies information as disclosed in the notes to the relevant financial line items or transactions in this Historical Financial Information, a summary of the other accounting policies information has been set out in Note 34 to this Historical Financial Information.

The Group had net current liabilities of RMB1,636.7 million as at 30 September 2024, of which the convertible preferred shares classified as current liabilities were RMB2,605.1 million and contract liabilities were RMB55.7 million, which do not result in future cash payments. The Group had net liabilities of RMB1,497.8 million as at 30 September 2024, of which the convertible preferred shares classified as liabilities were RMB2,605.1 million and contract liabilities were RMB87.7 million, which do not result in future cash payments. The directors of the Company assessed the Group's liquidity by evaluating its ability to generate cash from operating activities, attract additional capital or other means of finance funding. Historically, the Group has relied principally on both operational sources of cash (e.g. revenue from out-licensing) and non-operational sources of financing from investors (e.g. convertible preferred shares) to fund its research and development activities.

Pursuant to the resolution passed by the shareholders of the Company in September 2022, the Company shall redeem, at the option of any holder of outstanding convertible preferred shares, all of the outstanding convertible preferred shares held by the requesting holder, at any time after the earliest occurrence of failure to complete the qualified [**REDACTED**] within four years after 23 April 2021, which was the date of Initial USD Closing as defined in Series B share purchase agreements and a few other specified events. Please refer to Note 24 for details. In August 2024, the Company entered into supplemental agreements with respect to certain rights with the shareholders to suspend such redemption feature for a period commencing on the day immediately prior to the date of the Company's first submission of the [**REDACTED**] application, until the earlier of:

(a) the withdrawal of the [**REDACTED**] application by the Company;

(b) the rejection of the [**REDACTED**] application by the Hong Kong Stock Exchange; and

(c) the expiration of eighteen months after the first submission date.

Based on the above factors and the Group's historical performance and management's operating and financing plans, the directors of the Company believe the cash and cash equivalents and the operating and financing cash flows are sufficient to meet the cash requirements to fund the Group's planned operations, capital expenditures and other obligations for at least the next twelve months after 30 September 2024. Therefore, the Historical Financial Information have been prepared on a going concern basis, which contemplates the realization of assets and settlement of liabilities in the normal course of business.

2.2 New or amended standards or interpretations

All effective standards, amendments to standards and interpretations, which are mandatorily effective for the financial year beginning on 1 January 2024, are consistently applied to the Group for the Track Record Period.

New standards amendments and interpretations not yet adopted

Standards, amendments and interpretations that have been issued but not yet effective and not been early adopted by the Group during the Track Record Period are as follows:

Standards	Key requirements	Effective for annual periods beginning on or after
Amendments to IAS 21	Lack of exchangeability	1 January 2025
Amendments to IFRS 9 and IFRS 7	Amendments to the classification and measurement of financial instruments	1 January 2026
Annual improvements project	Annual improvements to IFRS Accounting Standards — volumes 11	1 January 2026
IFRS 18	Presentation and disclosure in financial statements	1 January 2027
IFRS 19	Subsidiaries without public accountability: disclosures	1 January 2027
Amendments to IFRS 10 and IAS 28	Sale or contribution of assets between an investor and its associate or joint venture	To be determined

The Group has already commenced an assessment of the impact of these new or revised standards and amendments, certain of which are relevant to the Group's operations. According to the preliminary assessment made by the directors, these standards and amendments are not expected to have a significant impact on the Group's financial performance and position.

3 FINANCIAL RISK MANAGEMENT

3.1 Financial risk factors

The Group's activities expose it to a variety of financial risks: market risk (including foreign exchange risk, cash flow and fair value interest rate risk), credit risk and liquidity risk. The Group's overall risk management programme focuses on the unpredictability of financial markets and seeks to minimize potential adverse effects on the Group's financial performance. Risk management is carried out by the management of the Group.

3.1.1 Market risk

(i) Foreign exchange risk

Foreign exchange risk arises when future commercial transactions or recognized assets and liabilities are denominated in a currency that is not the Group entities' functional currency. The Company's functional currency is USD. The Company's primary subsidiaries were incorporated in the PRC and these subsidiaries considered RMB as their functional currency.

The Group operates mainly in the PRC. There are certain cash and bank balances, trade receivables, other non-current assets and other payables denominated in a currency that is not the functional currency. The Group constantly reviews the economic situation and its foreign exchange risk profile, and will consider appropriate hedging measures, as may be necessary.

At 31 December 2022 and 2023 and 30 September 2024, if the USD strengthened/weakened by 5% against the RMB with all other variables held constant, net loss for the years would have been RMB579,000 lower/higher, RMB18,492,000 lower/higher and RMB37,196,000 lower/higher, respectively.

At 31 December 2022 and 2023 and 30 September 2024, if the Euro strengthened/weakened by 5% against the RMB with all other variables held constant, net loss for the years would have been RMB nil lower/higher, RMB3,430,000 lower/higher and RMB4,246,000 lower/higher, respectively.

(ii) Cash flow and fair value interest rate risk

Interest rate risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in market interest rates. The Group's exposure to the risk of changes in market interest rates relates primarily to the Group's interest-bearing cash and cash equivalents. When cash and cash equivalents obtained at variable rates expose the Group to cash flow interest-rate risk. The Group has not hedged its cash flow or fair value interest-rate risk. The cash and cash equivalents are disclosed in Note 17.

The Group has no significant interest-bearing assets except for cash and cash equivalents, details of which have been disclosed in Note 17.

3.1.2 Credit risk

Credit risk arises from cash and cash equivalents, trade receivables as well as other receivables. The carrying amount of each class of the above financial assets represents the Group's maximum exposure to credit risk in relation to the corresponding class of financial assets.

To manage this risk, cash and cash equivalents are mainly deposited with state-owned or reputable financial institutions in the PRC and reputable international financial institutions outside of the PRC. There has been no recent history of default in relation to these financial institutions.

For trade receivables, management applies the IFRS 9 simplified approach to measuring expected credit losses which uses a lifetime expected loss allowance for all trade receivables. The directors of the Group believe that there is no material credit risk inherent in the Group's outstanding balance of trade receivables, details of which have been disclosed in Note 19.

For other receivables and other non-current assets, management has assessed that during the years ended 31 December 2022 and 2023 and the nine months ended 30 September 2024, other receivables and other non-current assets have not had a significant increase in credit risk since initial recognition. Thus, a 12-month expected credit loss approach that results from possible default event within 12 months of each reporting date is adopted by management. The Group does not expect any losses from non-performance by the counterparties of other receivables and no loss allowance provision for other receivables and other non-current assets was recognized.

To measure the expected credit losses, other receivables have been grouped based on shared credit risk characteristics and the days past due. As at 31 December 2022 and 2023 and 30 September 2024, the Group has assessed that the expected loss rate for other receivables was immaterial. Thus no loss allowance provision for other receivables was recognized as at 31 December 2022 and 2023 and 30 September 2024.

3.1.3 Liquidity risk

The Group aims to maintain sufficient cash and cash equivalents or have available facility through an adequate amount of available financing to meet its daily operating working capital.

The table below analyzes the Group's non-derivative financial liabilities that will be settled into relevant maturity grouping based on the remaining period at each balance sheet date to the contractual maturity date. The amounts disclosed in the table are the contractual undiscounted cash flows.

The following table presents the Group's contractual maturities of financial liabilities at 30 September 2024:

	Less than 1 year	Between 1 and 2 years	Between 2 and 5 years	Over 5 years	Total
	RMB'000	*RMB'000*	*RMB'000*	*RMB'000*	*RMB'000*
Trade payables	524,436	–	–	–	524,436
Other payables (excluding salaries and welfare payables and VAT and other taxes payables)	56,499	–	–	–	56,499
Lease liabilities	3,315	481	102	–	3,898
	584,250	481	102	–	584,833

The following table presents the Group's contractual maturities of financial liabilities at 31 December 2023:

	Less than 1 year	Between 1 and 2 years	Between 2 and 5 years	Over 5 years	Total
	RMB'000	*RMB'000*	*RMB'000*	*RMB'000*	*RMB'000*
Trade payables	234,814	–	–	–	234,814
Other payables (excluding salaries and welfare payables and VAT and other taxes payables)	10,168	–	–	–	10,168
Lease liabilities	3,119	2,082	408	–	5,609
	248,101	2,082	408	–	250,591

The following table presents the Group's contractual maturities of financial liabilities at 31 December 2022:

	Less than 1 year	Between 1 and 2 years	Between 2 and 5 years	Over 5 years	Total
	RMB'000	*RMB'000*	*RMB'000*	*RMB'000*	*RMB'000*
Trade payables	129,495	–	–	–	129,495
Other payables (excluding salaries and welfare payables and VAT and other taxes payables)	8,446	–	–	–	8,446
Lease liabilities	2,643	1,424	728	–	4,795
	140,584	1,424	728	–	142,736

The Group recognizes the convertible preferred shares liabilities and loans with warrants to purchase Series B-2 Preferred Shares at fair value through profit or loss. Accordingly, these liabilities are managed on a fair value basis rather than by maturing dates (Note 24).

3.2 Capital management

The Group's objectives when managing capital are to safeguard the Group's ability to continue as a going concern in order to provide returns for shareholders and benefits for other stakeholders and to maintain an optimal capital structure to reduce the cost of capital.

In order to maintain or adjust the capital structure, the Group may adjust the amount of dividends paid to shareholders, issue new shares or sell assets to reduce debt.

The Group monitors capital (including share capital and convertible preferred shares on an as-if-converted basis) by regularly reviewing the capital structure. As a part of this review, the Company considers the cost of capital and the risks associated with the issued share capital. In the opinion of the directors of the Company, the Group's capital risk is low.

As at 31 December 2022 and 2023 and 30 September 2024, the Group was in a net cash position, hence it is not meaningful to present the gearing ratio.

3.3 Fair value estimation

Fair value hierarchy

This section explains the judgments and estimates made in determining the fair values of the financial instruments that are recognized and measured at fair value in the financial statements. To provide an indication about the reliability of the inputs used in determining fair value, the Group has classified its financial instruments into the three levels prescribed under the accounting standards.

Level 1: The fair value of financial instruments traded in active markets (such as publicly traded derivatives, and equity securities) is based on quoted market prices at the end of the reporting period. The quoted market price used for financial assets held by the Group is the current bid price.

Level 2: The fair value of financial instruments that are not traded in an active market is determined using valuation techniques which maximize the use of observable market data and rely as little as possible on entity-specific estimates. If all significant inputs required to fair value an instrument are observable, the instrument is included in level 2.

Level 3: If one or more of the significant inputs is not based on observable market data, the instrument is included in level 3.

The following table presents the Group's assets and liabilities that were measured at fair value at 30 September 2024:

	Level 1	Level 2	Level 3	Total
	RMB'000	*RMB'000*	*RMB'000*	*RMB'000*
Assets				
Financial assets at fair value through profit or loss	–	–	60,199	60,199
	–	–	60,199	60,199
Liabilities				
Financial liabilities at fair value through profit or loss	–	–	2,605,079	2,605,079
	–	–	2,605,079	2,605,079

The following table presents the Group's liabilities that were measured at fair value at 31 December 2023:

	Level 1	Level 2	Level 3	Total
	RMB'000	*RMB'000*	*RMB'000*	*RMB'000*
Liabilities				
Financial liabilities at fair value through profit or loss	–	–	2,132,720	2,132,720
	–	–	2,132,720	2,132,720

The following table presents the Group's liabilities that were measured at fair value at 31 December 2022:

	Level 1	Level 2	Level 3	Total
	RMB'000	*RMB'000*	*RMB'000*	*RMB'000*
Liabilities				
Financial liabilities at fair value through profit or loss	–	–	1,072,720	1,072,720
	–	–	1,072,720	1,072,720

(i) Valuation techniques used to determine fair values

Specific valuation techniques used to value financial instruments mainly include binomial option-pricing model or discounted cash flow analysis.

There were no changes in valuation techniques for the years ended 31 December 2022 and 2023 and the nine months ended 30 September 2024.

(ii) Valuation processes

The Group's finance team manages the valuation of level 3 instruments for financial reporting purposes. The team manages the valuation exercise of the relevant instruments on a case by case basis. At least once a year, the team uses valuation techniques to determine the fair value of the Group's level 3 instruments. External valuers will be involved when necessary.

The summary of significant unobservable inputs to the valuation of financial instruments together with a quantitative sensitivity analysis was disclosed in Note 24.

4 CRITICAL ACCOUNTING ESTIMATES AND JUDGMENTS

The preparation of the Historical Financial Information requires the use of accounting estimates which, by definition, will seldom equal the actual results. Management also needs to exercise judgment in applying the Group's accounting policies.

Estimates and judgments are continually evaluated. They are based on historical experience and other factors, including expectations of future events that may have a financial impact on the entity and that are believed to be reasonable under the circumstances.

(i) Impairment of non-current assets

The Group assesses impairment based on its subjective judgment and determines the separate cash flows of a specific group of assets, useful lives of assets and the future possible income and expenses arising from the assets depending on how assets are utilized and industrial characteristics. Any changes of economic circumstances or estimates due to the change of Group strategy might cause material impairment on assets in the future.

Intangible assets not ready for use are not subject to amortization and are tested annually for impairment, or more frequently if events or changes in circumstances indicate that they might be impaired. The Group obtained in-licenses and In-Process Research and Development "IPR&D" to continue research and development work and commercialize the products, which are classified as intangible assets not ready for use.

An impairment loss is recognized for the amount by which the asset's carrying amount exceeds its recoverable amount. The recoverable amount is the higher of an asset's fair value less costs of disposal and value in use. For the purposes of assessing impairment, assets are grouped at the lowest levels for which there are separately identifiable cash flows (cash-generating units ("CGU")).

(ii) Fair value of convertible preferred shares

The fair value of convertible preferred shares that are not traded in an active market is determined by using valuation techniques. The Group applied the back-solve method and discounted cash flow approach to determine the underlying equity value of the Company and adopted option-pricing method and equity allocation model to determine the fair value of the convertible preferred shares. Key assumptions such as discount rate, volatility and discount for lack of marketability ("DLOM") are disclosed in Note 24.

(iii) Share-based compensation

The Group has granted share options to the Group's employees. The Company has engaged an independent valuer to determine the fair value of the options granted to employees, which is expensed over the vesting periods. Unobservable inputs such as the risk-free interests rate, volatility and dividend yield, etc. are used in determining the fair value of the share-based compensations.

(iv) Accrual of research and development expenses

Research and development expenses include costs paid to hospitals and third-party contract research organizations (CROs). The estimate of accrual of research and development expenses is complex because billing terms under relevant contracts often do not coincide with the timing of when the work is performed, which in turn requires estimates of outstanding obligations as of period end. These estimates are based on a number of factors, including management's knowledge of the research and development ("R&D") programs and activities associated with timelines, invoicing date, and the provisions in the contracts.

5 SEGMENT AND REVENUE INFORMATION

Management has determined the operating segments based on the reports reviewed by the chief operating decision-maker ("CODM"). The CODM, who is responsible for allocating resources and assessing performance of the operating segment, has been identified as the executive directors of the Group.

(a) Description of segments and principal activities

The Group is principally engaged in the research and development of new drugs. The CODM reviews the operating results of the business as one operating segment to make decisions about resources to be allocated. Therefore, the CODM regards that there is only one segment which is used to make strategic decisions.

(b) License and collaboration agreements with customers

The Group entered into a number of license and collaboration agreements with certain customers during the Track Record Period. Under the terms of these agreements, the Group agreed to grant licenses of certain intellectual properties and to provide research and development services in relation to certain licensed products to the relevant customers. The considerations of these agreements generally consist of non-refundable upfront payment, reimbursements for research and development costs incurred, and variable considerations including milestone payments and royalties on net sales of the licensed products.

(c) Disaggregated revenue information is as follows:

	For the year ended 31 December		For the nine months ended 30 September	
	2022	2023	2023	2024
	RMB'000	*RMB'000*	*RMB'000* (Unaudited)	*RMB'000*
Type of revenue				
Revenue from the license and collaboration agreement	–	1,781,088	1,674,615	1,458,681
Others	1,600	5,452	1,302	3,323
	1,600	1,786,540	1,675,917	1,462,004
Timing of revenue recognition				
Over time	–	356,924	250,451	831,437
At a point in time	1,600	1,429,616	1,425,466	630,567
	1,600	1,786,540	1,675,917	1,462,004

(d) Liabilities related to contracts with customers

The Group has recognized the following liabilities related to contracts with customers:

	As at 31 December		As at 30 September
	2022	2023	2024
	RMB'000	*RMB'000*	*RMB'000*
Contract liabilities	–	216,296	87,650

During the Track Record Period, revenue recognized in relation to contract liabilities that was included in the contract liabilities at the beginning of the year is as follows:

	As at 31 December		As at 30 September
	2022	2023	2024
	RMB'000	*RMB'000*	*RMB'000*
Revenue recognized that was included in the contract liabilities at beginning of the year	–	–	128,562

The unsatisfied performance obligations arising from the contracts with customers, is as follows:

	As at 31 December		As at 30 September
	2022	2023	2024
	RMB'000	*RMB'000*	*RMB'000*
Within one year	–	156,132	55,698
Above one year	–	60,164	31,952
	–	216,296	87,650

(e) Accounting policy of revenue recognition

Revenue from contracts with customers is recognized when control of goods or services is transferred to the customers at an amount that reflects the consideration to which the Group expects to be entitled in exchange for those goods or services.

At contract inception, the Group assesses the goods or services promised within each contract and determines those that are performance obligations and assesses whether each promised good or service is distinct.

The Group considers the terms of the contracts to determine the transaction price. When the consideration in a contract includes a variable amount, the amount of consideration is estimated to which the Group will be entitled in exchange for transferring the goods or services to the customer. The variable consideration is estimated at contract inception and constrained until it is highly probable that a significant revenue reversal in the amount of cumulative revenue recognized will not occur when the associated uncertainty with the variable consideration is subsequently resolved.

The Group recognizes revenue only when it satisfies a performance obligation by transferring control of the promised goods or services. The transfer of control can occur over time or at a point in time. A performance obligation is satisfied over time if it meets one of the following criteria.

- The counterparty simultaneously receives and consumes the benefits provided by the Group's performance as the Group performs.

- The Group's performance creates or enhances an asset that the counterparty controls as the asset is created or enhanced.

- The Group's performance does not create an asset with an alternative use to the Group and the Group has an enforceable right to payment for performance completed to date.

If control of the goods and services transfers over time, revenue is recognized over the period of the contract by reference to the progress towards complete satisfaction of that performance obligation. The Group adopts an appropriate method of measuring progress for the purpose of recognizing revenue. The Group evaluates the measure of progress at the end of each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

The Group enters into license and collaboration agreements for research, development, manufacturing and commercialisation services. The terms of these arrangements typically include non-refundable upfront payments, reimbursements for costs incurred, milestone payments and royalties on net sales of licensed products. The contracts generally do not include a significant financing component.

Licenses of intellectual property: The Group assesses whether the licensing of the Group's intellectual property is distinct from the other performance obligations identified in the arrangements. For licenses determined to be distinct, the Group recognizes revenue from non-refundable, upfront payments allocated to the license at a point in time, when the license is transferred to the licensee and the licensee is able to use and benefit from the license.

Research and development services: For research and development services determined to be distinct, the portion of the reimbursements for costs incurred and other transaction price allocated to the performance obligations is recognized as revenue over time as delivery or performance of such services occurs.

The Group uses judgment to determine whether milestones or other variable consideration should be included in the transaction price.

Milestone payments: At the inception of each arrangement that includes milestone payments, the Group assesses whether the milestones are considered highly probable of being achieved and estimates the amount to be included in the transaction price using the most likely amount method.

In making these assessments, the Group considers various factors such as the scientific, clinical, regulatory, commercial, and other risks that must be overcome to achieve a particular milestone. Milestone payments that are subject to regulatory approvals and commercialisation stages are not considered highly probable of being achieved until those approvals are received or commercialisation stages are achieved.

The transaction price will be allocated to each performance obligation on a relative stand-alone selling price basis, for which the Group recognizes revenue as or when the performance obligations are satisfied. At the end of each subsequent reporting period, the Group re-evaluates the probability of achievement of all milestones subject to constraint and, if necessary, adjusts its estimate of the overall transaction price.

Royalties: For arrangements that include sales-based royalties, the Group recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

The excess of cumulative revenue recognized in profit or loss over the cumulative billings to customers is recognized as contract assets. The excess of cumulative billings to customers over the cumulative revenue recognized in profit or loss is recognized as contract liabilities.

6 EXPENSES BY NATURE

	Year ended 31 December		Nine months ended 30 September	
	2022	2023	2023	2024
	RMB'000	*RMB'000*	*RMB'000 (Unaudited)*	*RMB'000*
Technical services expenses	292,317	883,272	623,931	1,153,790
Employee benefit expenses *(Note 7)*	64,113	117,234	80,147	282,952
Impairment of intangible assets *(Note 16)*	–	–	–	21,301
Professional services expenses	7,920	28,247	23,477	22,221
[**REDACTED**] expenses	–	–	–	19,819
Warehouse, logistics and insurance service expenses	1,861	8,208	5,269	16,395
Auditors' remuneration	283	300	225	600
Depreciation and amortization	1,795	4,987	3,112	5,515
Traveling expenses	523	2,759	1,810	3,291
Other expenses	2,999	4,212	2,381	5,338
	371,811	1,049,219	740,352	1,531,222

7 EMPLOYEE BENEFIT EXPENSES

	Year ended 31 December		Nine months ended 30 September	
	2022	2023	2023	2024
	RMB'000	*RMB'000*	*RMB'000 (Unaudited)*	*RMB'000*
Share-based compensation expenses *(Note 13)*	7,032	23,957	16,139	163,957
Wages, salaries and bonus	52,320	84,729	57,497	106,208
Social insurance *(a)*	4,681	8,268	6,290	12,322
Other welfare for employees	80	280	221	465
	64,113	117,234	80,147	282,952

(a) Social insurance

The employees of the Group's subsidiaries participate in various government-sponsored defined contribution pension plans and various government supervised housing funds, medical insurance and other employee social insurance plan under which these subsidiaries are required to make monthly contributions to these plans at certain percentages of the employee's monthly salaries and wages subject to certain ceilings. During the years ended 31 December 2022 and 2023 and the nine months ended 30 September 2023 and 2024, the Group had no forfeited contributions under these plans which may be utilized by the Group to reduce its contributions for the current year/period.

The Group has no other material obligation for the payment of retirement benefit associated with these schemes beyond the annual contribution described above.

(b) Five highest paid individuals

The five individuals whose emoluments were the highest in the Group include 1 director for the years ended 31 December 2022 and 2023 and for the nine months ended 30 September 2023 and 2024, whose emoluments are reflected in the analysis shown in Note 31. The emoluments payable to the remaining individuals during the year/period are as follows:

	Year ended December 31		Nine months ended 30 September	
	2022	2023	2023	2024
	RMB'000	*RMB'000*	*RMB'000 (Unaudited)*	*RMB'000*
Share-based compensation expenses	1,053	5,628	2,796	37,301
Wages, salaries and bonus	12,502	15,432	11,558	11,073
Social insurance	746	891	756	735
Other welfare for employees	124	404	288	266
	14,425	22,355	15,398	49,375

The emoluments fell within the following bands:

	Year ended December 31		Nine months ended 30 September	
	2022	2023	2023	2024
			(Unaudited)	
Emolument bands				
HKD3,000,001 to HKD3,500,000	2	–	2	–
HKD3,500,001 to HKD4,000,000	1	1	1	–
HKD4,000,001 to HKD4,500,000	–	1	–	–
HKD5,000,001 to HKD5,500,000	–	1	–	–
HKD6,000,001 to HKD6,500,000	1	–	–	–
HKD6,500,001 to HKD7,000,000	–	–	1	1
HKD7,500,001 to HKD8,000,000	–	–	–	1
HKD11,000,001 to HKD11,500,000	–	1	–	–
HKD14,500,001 to HKD15,000,000	–	–	–	1
HKD25,000,001 to HKD25,500,000	–	–	–	1
	4	4	4	4

8 OTHER INCOME

Grants from the government are recognized at their fair value where there is a reasonable assurance that the subsidies will be received and the Group will comply with all attached conditions.

	Year ended 31 December		Nine months ended 30 September	
	2022	2023	2023	2024
	RMB'000	*RMB'000*	*RMB'000* *(Unaudited)*	*RMB'000*
Government grants	444	3,154	2,102	3,143
Others	50	107	107	204
	494	3,261	2,209	3,347

9 OTHER GAINS/(LOSSES), NET

	Year ended 31 December		Nine months ended 30 September	
	2022	2023	2023	2024
	RMB'000	*RMB'000*	*RMB'000* *(Unaudited)*	*RMB'000*
Foreign exchange gains/(loss), net	1,121	41,935	38,847	(8,688)
Others	13	(1,162)	–	1,391
	1,134	40,773	38,847	(7,297)

10 FINANCE INCOME

	Year ended 31 December		Nine months ended 30 September	
	2022	2023	2023	2024
	RMB'000	*RMB'000*	*RMB'000* *(Unaudited)*	*RMB'000*
Finance income:				
Finance income from bank deposits	3,268	34,483	24,160	38,809
Finance costs:				
Interest expense on lease liabilities	(75)	(188)	(145)	(189)
Finance income – net	3,193	34,295	24,015	38,620

11 INCOME TAX EXPENSE

Current income tax

The current income tax charge is calculated on the basis of the tax laws enacted or substantively enacted at the end of the reporting period in the countries where the Company and its subsidiaries operate and generate taxable income. Management periodically evaluates positions taken in tax returns with respect to situations in which applicable tax regulation is subject to interpretation and considers whether it is probable that a taxation authority will accept an uncertain tax treatment. The Group measures its tax balances either based on the most likely amount or the expected value, depending on which method provides a better prediction of the resolution of the uncertainty.

The Group's principal applicable taxes and tax rates are as follows:

(a) Cayman Islands

Under the current laws of the Cayman Islands, the Company is not subject to tax on income or capital gains. Additionally, the Cayman Islands does not impose a withholding tax on payments of dividends to shareholders.

(b) Hong Kong

Under the current Hong Kong Inland Revenue Ordinance, the Group's subsidiary in Hong Kong is subject to Hong Kong profit tax on its taxable income generated from operations in Hong Kong at two-tiered profits tax rates, 8.25% for first 2 million HKD of assessable profits and 16.5% for assessable profits above 2 million HKD. Additionally, payments of dividends by the subsidiary incorporated in Hong Kong to the Company are not subject to any Hong Kong withholding tax. No provision for Hong Kong profits tax has been provided for at the rate of 16.5% as the Group's subsidiary in Hong Kong has no estimated assessable profit during the Track Record Period.

(c) United States

DualityBio Inc. is incorporated in the United States and is subject to federal income tax at 21% and state and local income tax (generally ranges from 1% to 12%) where it has operation. DualityBio Inc. did not have any taxable income, therefore no income tax expense was accrued for the Track Record Period.

(d) Mainland China

Duality Biologics (Suzhou) Co., Ltd. incorporated in the PRC is subject to Corporate Income Tax at a rate of 15% as the "High and New Technology Enterprises" certificate was obtained on 19 November 2024 with a valid period of three years. Duality Biologics (Shanghai) Co., Ltd. incorporated in the PRC is subject to Corporate Income Tax at a rate of 25%.

According to the Corporate Income Tax Law of the PRC and the respective regulations, the income derived by a resident enterprise in China from the transfer of technology which meets certain prescribed criteria could be eligible for income tax incentives. The part of the annual income from the transfer of technology derived by a resident enterprise within RMB5 million shall be tax-exempt; and the remainder shall be subject to a 50% reduction in the enterprise income tax rate. During the year ended 31 December 2023 and the nine months ended 30 September 2024, Duality Biologics (Suzhou) Co., Ltd has incurred income of transfer of technology and applied for the above mentioned tax reduction and exemption incentives.

No provision for corporate income tax has been provided for at a rate of 15% or 25% pursuant to the Corporate Income Tax Law of the PRC and the respective regulations (the "CIT Law"), as the Group has no estimated assessable profits during the Track Record Period.

(e) Withholding tax

According to the CIT rules and regulations, distribution of profits earned by PRC companies is generally subject to a withholding tax of 10% upon the distribution of profits to overseas-incorporated immediate holding companies. Depending on the tax residency of the foreign shareholder, the withholding tax rate may be adjusted based on the relevant bilateral tax treaty. During the years ended 31 December 2022 and 2023 and nine months ended 30 September 2024, the Group does not have any profit distribution plan.

Withholding tax on revenue from out-licensing

The Group entered into a number of license and collaboration agreements with certain overseas customers. According to the local income tax rules and regulations in the tax jurisdictions of the customers, a withholding tax might be triggered for the whole or part of the income arising from the license and collaboration agreements.

The tax on the Group's (loss)/profit before income tax differs from the theoretical amount that would arise using the statutory tax rate applicable to loss of the consolidated entities as follows:

	Year ended 31 December		Nine months ended 30 September	
	2022	2023	2023	2024
	RMB'000	*RMB'000*	*RMB'000* *(Unaudited)*	*RMB'000*
(Loss)/profit before income tax	(387,090)	(202,249)	41,436	(535,899)
Income tax expenses calculated at applicable tax rates	(96,018)	215,130	291,622	36,351
Withholding tax	–	155,263	155,263	30,583
Additional deduction of research and development expense	(54,149)	(83,331)	(45,675)	(55,242)
Expenses not deductible for tax purposes	75	14,031	42	82
Tax exempted interest income	(128)	(906)	(792)	(258)
Taxable income reduction or exemption arising from technology transfer income	–	(171,560)	(158,904)	(53,624)
Deductible temporary differences for which no deferred tax asset was recognized	–	14,630	72	3,657
Utilisation of previously unrecognized deductible temporary differences	–	–	–	(5,316)
Utilisation of previously unrecognized tax losses	–	(32,395)	(128,068)	–
Tax losses for which no deferred income tax asset was recognized, net	150,220	44,401	41,703	74,350
Income tax expense	–	155,263	155,263	30,583

No deferred tax asset has been recognized in respect of the tax losses and deductible temporary difference due to the unpredictability of future profit streams.

12 LOSS PER SHARE

(a) Basic loss per share

Basic loss per share is calculated by dividing the loss of the Group attributable to the equity holders of the Company by weighted average number of ordinary shares outstanding during the Track Record Period.

	For the year ended 31 December		For the nine months ended 30 September	
	2022	2023	2023	2024
			(Unaudited)	
Loss attributable to the ordinary equity holders of the Company (RMB'000)	(387,090)	(357,512)	(113,827)	(566,482)
Weighted average number of ordinary shares in issue (in thousands)	8,000	8,000	8,000	8,000
Basic loss per share (RMB)	(48.4)	(44.7)	(14.2)	(70.8)

(b) Diluted loss per share

Diluted loss per share is calculated by adjusting the weighted average number of ordinary shares outstanding to assume conversion of all dilutive potential ordinary shares.

For the years ended 31 December 2022 and 2023 and the nine months ended 30 September 2024, the Company had two categories of potential ordinary shares, namely the stock options granted to employees and convertible preferred shares of the Company. As the Group incurred losses for the years ended 31 December 2022 and 2023 and the nine months ended 30 September 2024, the potential ordinary shares were not included in the calculation of diluted loss per share as their inclusion would be anti-dilutive.

Accordingly, diluted loss per share for the years ended 31 December 2022 and 2023 and the nine months ended 30 September 2024 are the same as basic loss per share.

13 SHARE-BASED COMPENSATION

Accounting policy for share-based compensation

The Group operates stock options granted to employees, under which the Group receives services from employees as consideration for equity instruments of the Group. The fair value of the employee services received in exchange for the grant of equity instruments (options) is recognized as an expense during the Track Record Period. The total amount to be expensed is determined by reference to the fair value of the equity instruments granted:

- including any market performance conditions;
- excluding the impact of any service and non-market performance vesting conditions; (for example, the requirement for employees to serve)
- including the impact of any non-vesting conditions.

At the end of each reporting period, the Group revises its estimates of the number of options that are expected to vest based on the non-market vesting performance and service conditions. It recognizes the impact of the revision to original estimates, if any, in the consolidated statements of comprehensive loss, with a corresponding adjustment to equity.

(i) Employee share option

The Group adopted a number of employee share option plans to provide long-term incentives for its employees and directors of the Group to deliver long-term shareholder returns. Under the plans, participants are granted options which only vest if certain conditions are met. Participation in the plan is at the board of directors' discretion.

For the years ended 31 December 2022 and 2023, the Company granted 5,309,044 and 5,221,959 options at nil consideration to certain employees of the Group, of which 1,140,244 and 2,731,959 were granted to the founder of the Group.

For the nine months ended 30 September 2023 and 2024, the Company granted 3,981,959 and 1,538,500 options at nil consideration to certain employees of the Group, of which no options were granted to the founder of the Group.

Pursuant to relevant award agreements, the abovementioned options were generally divided in several tranches and to be "temporarily owned" by the grantees with the following schedules:

(a) 25% of the share options on the first anniversary of the grant date and the remaining 75% monthly thereafter in 36 equal monthly instalments; or

(b) 33% of the share options immediately on the grant date and the remaining 67% over a period of around two years on a case-by-case basis.

Except for the share options granted to certain key management personnel, for substantially all the abovementioned share options granted, in the event of termination of service prior to the [**REDACTED**] of the Company ("[**REDACTED**]"), the grantees may only retain certain percentage of the abovementioned "temporarily owned" share options. The remaining portion of these share options shall be forfeited immediately. The retention ratio shall be determined as follows:

Years of service upon termination of service	Retention ratio
Less than 3 years	–
3 – 4 years	40%
4 – 5 years	50%
More than 5 years	60%

Substantially all the share options granted shall not be exercisable until the [**REDACTED**]. The expiry dates of the share options granted are the tenth anniversary of the grant dates.

The following table summarizes the movements in the number of share options granted and their related weighted average exercise price during the years ended 31 December 2022 and 2023.

	Year ended 31 December 2022		Year ended 31 December 2023	
	Average exercise price per option	Number of options	Average exercise price per option	Number of options
	USD		*USD*	
At beginning of the year	0.37	6,387,500	0.53	11,149,044
Granted	0.73	5,309,044	0.89	5,221,959
Forfeited	0.58	(547,500)	0.72	(130,000)
At end of the year	0.53	11,149,044	0.65	16,241,003

The following table summarizes the movements in the number of share options granted and their related weighted average exercise price during the nine months ended 30 September 2023 and 2024.

(Unaudited)

	Nine months ended 30 September 2023		Nine months ended 30 September 2024	
	Average exercise price per option	Number of options	Average exercise price per option	Number of options
	USD		*USD*	
At beginning of the period	0.53	11,149,044	0.65	16,241,003
Granted	0.89	3,981,959	0.90	1,538,500
Forfeited	0.72	(130,000)	0.80	(320,000)
At end of the period	0.62	15,001,003	0.67	17,459,503

(ii) Fair value of share options granted

At the grant date, the assessed fair value of above options granted during the years ended 31 December 2022 and 2023 and the nine months ended 30 September 2023 and 2024 was as follows:

		Weighted average fair value per option	
	Number of options	[REDACTED] as non-market performance condition*	[REDACTED] as non-vesting condition*
		USD	*USD*
Share options granted in the year ended 31 December 2022	5,309,044	2.03	0.61
Share options granted in the year ended 31 December 2023	5,221,959	5.04	2.27
Share options granted in the nine months ended 30 September 2023 *(Unaudited)*	3,981,959	5.03	2.01
Share options granted in the nine months ended 30 September 2024	1,538,500	5.08	2.79

* For the portion of share options that cannot be retained in the event of termination of service prior to the [**REDACTED**], [**REDACTED**] is regarded as non-market performance condition. For the remaining portion that can be retained even in the event of termination of service prior to the [**REDACTED**], [**REDACTED**] is regarded as non-vesting condition.

As a private company with no quoted market price of the Company's equity instruments, the Company needs to estimate the fair value of the Group's equity interests at the relevant grant date.

The directors of the Company estimated the risk-free interest rate based on the yield of US Treasury Bond with a maturity life close to the option life of the share option. Expected volatility was estimated at grant date based on average of historical volatilities of the comparable companies with length commensurable to the time to maturity of the share option.

The fair value of the share options granted have been valued by an independent qualified valuer using the binomial valuation model as at the relevant grant date. Key assumptions are set as below:

	Risk-free interest rate	Expected volatility	Dividend yield
Share options granted in the year ended 31 December 2022	4.1%	56.9%	0.0%
Share options granted in the year ended 31 December 2023	3.8%-4.5%	57.3-58%	0.0%
Share options granted in the nine months ended 30 September 2023 *(Unaudited)*	3.8%-4.5%	57.3%	0.0%
Share options granted in the nine months ended 30 September 2024	4.2%-4.5%	56.5%-58%	0.0%

(iii) Expenses arising from share-based payment transactions

Expenses for the share-based compensation have been charged to the consolidated statements of comprehensive loss as follows:

	Year ended 31 December		Nine months ended 30 September	
	2022	2023	2023	2024
	RMB'000	*RMB'000*	*RMB'000 (Unaudited)*	*RMB'000*
Research and development expenses	4,310	15,662	10,203	112,275
Administrative expenses	2,722	8,295	5,936	51,682
	7,032	23,957	16,139	163,957

Before 2024, management expected [**REDACTED**] was not probable as no [**REDACTED**] plan was in anticipation. Hence, for the portion of share options that cannot be retained in the event of termination of service prior to the [**REDACTED**], management considered that the [**REDACTED**] was a performance condition and thus no share-based compensation expense was recorded for the years ended 31 December 2022 and 2023.

For certain portion of share options that can be retained in the event of termination of service prior to the [**REDACTED**] and are exercisable only if an [**REDACTED**] occurs, [**REDACTED**] was a non-vesting condition for the years ended 31 December 2022 and 2023 and it was considered in the grant-date fair value.

As of 30 September 2024, management updated their expectation and considered [**REDACTED**] became probable to occur and the Group re-assessed whether [**REDACTED**] is non-vesting condition or non-market performance condition as well as re-estimated the number of share options that are expected to vest, probability of meeting this non-market performance condition.

Accordingly, the Group determined the cumulative share-based compensation expenses as at 30 September 2024 and all changes in the cumulative expenses between the beginning and end of the period were recognized in profit or loss during the nine months ended 30 September 2024.

14 PROPERTY, PLANT AND EQUIPMENT

Accounting policy for property, plant and equipment

(i) Recognition and subsequent measurement

Property, plant and equipment, comprising office equipment, electronic equipment, laboratory equipment and leasehold improvement are stated at historical cost less depreciation and impairment losses, if any. Historical cost includes expenditure that is directly attributable to the acquisition of the items.

Subsequent costs are included in the asset's carrying amount or recognized as a separate asset, as appropriate, only when it is probable that future economic benefits associated with the item will flow to the Group and the cost of the item can be measured reliably. The carrying amount of any component accounted for as a separate asset is derecognized when replaced. All other repairs and maintenance are charged to profit or loss during the reporting period in which they are incurred.

Depreciation is calculated using the straight-line method to allocate their cost or revalued amounts, net of their residual values, over their estimated useful lives as follows:

	Estimated useful lives
Office equipment	5 years
Electronic equipment	3 years
Laboratory equipment	5 years
Leasehold improvement	2-5 years

The assets' residual values and useful lives are reviewed, and adjusted if appropriate, at the end of each reporting period.

An asset's carrying amount is written down immediately to its recoverable amount if the asset's carrying amount is greater than its estimated recoverable amount.

Gains and losses on disposals are determined by comparing proceeds with carrying amount. These are included in the consolidated statement of comprehensive loss. When revalued assets are sold, it is group policy to transfer any amounts included in other reserves in respect of those assets to retained earnings.

(ii) Impairment

Property, plant and equipment are tested for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. An impairment loss is recognized for the amount by which the asset's carrying amount exceeds its recoverable amount. The recoverable amount is the higher of an asset's fair value less costs of disposal and value in use. For the purposes of assessing impairment, assets are grouped at the lowest levels for which there are separately identifiable cash inflows which are largely independent of the cash inflows from other assets or groups of assets (CGU). Non-financial assets that suffered an impairment are reviewed for possible reversal of the impairment at the end of each reporting period.

Group

Non-current	Office equipment	Electronic equipment	Laboratory equipment	Leasehold improvement	Construction in progress	Total
	RMB'000	*RMB'000*	*RMB'000*	*RMB'000*	*RMB'000*	*RMB'000*
At 1 January 2022						
Cost	99	260	–	–	–	359
Accumulated amortization	(16)	(84)	–	–	–	(100)
Net book amount	83	176	–	–	–	259
Year ended 31 December 2022						
Opening net book amount	83	176	–	–	–	259
Additions	22	248	–	220	1,992	2,482
Depreciation charge	(20)	(132)	–	(78)	–	(230)
Closing net book amount	85	292	–	142	1,992	2,511
At 31 December 2022						
Cost	121	508	–	220	1,992	2,841
Accumulated amortization	(36)	(216)	–	(78)	–	(330)
Net book amount	85	292	–	142	1,992	2,511

Non-current	Office equipment	Electronic equipment	Laboratory equipment	Leasehold improvement	Construction in progress	Total
	RMB'000	*RMB'000*	*RMB'000*	*RMB'000*	*RMB'000*	*RMB'000*
At 1 January 2023						
Cost	121	508	–	220	1,992	2,841
Accumulated amortization	(36)	(216)	–	(78)	–	(330)
Net book amount	85	292	–	142	1,992	2,511
Year ended 31 December 2023						
Opening net book amount	85	292	–	142	1,992	2,511
Transfers	7	–	1,624	2,872	(4,503)	–
Additions	120	858	4,373	3,236	2,697	11,284
Depreciation charge	(26)	(237)	(464)	(755)	–	(1,482)
Closing net book amount	186	913	5,533	5,495	186	12,313
At 31 December 2023						
Cost	248	1,366	5,997	6,328	186	14,125
Accumulated amortization	(62)	(453)	(464)	(833)	–	(1,812)
Net book amount	186	913	5,533	5,495	186	12,313

(Unaudited)

Non-current	Office equipment	Electronic equipment	Laboratory equipment	Leasehold improvement	Construction in progress	Total
	RMB'000	*RMB'000*	*RMB'000*	*RMB'000*	*RMB'000*	*RMB'000*
At 1 January 2023						
Cost	121	508	–	220	1,992	2,841
Accumulated amortization	(36)	(216)	–	(78)	–	(330)
Net book amount	85	292	–	142	1,992	2,511
For the nine months ended 30 September 2023						
Opening net book amount	85	292	–	142	1,992	2,511
Transfers	7	–	1,623	2,643	(4,273)	–
Additions	9	370	2,941	2,917	2,621	8,858
Depreciation charge	(16)	(161)	(215)	(442)	–	(834)
Closing net book amount	85	501	4,349	5,260	340	10,535
At 30 September 2023						
Cost	137	878	4,564	5,780	340	11,699
Accumulated amortization	(52)	(377)	(215)	(520)	–	(1,164)
Net book amount	85	501	4,349	5,260	340	10,535

Non-current	Office equipment	Electronic equipment	Laboratory equipment	Leasehold improvement	Construction in progress	Total
	RMB'000	*RMB'000*	*RMB'000*	*RMB'000*	*RMB'000*	*RMB'000*
At 1 January 2024						
Cost	248	1,366	5,997	6,328	186	14,125
Accumulated amortization	(62)	(453)	(464)	(833)	–	(1,812)
Net book amount	186	913	5,533	5,495	186	12,313
For the nine months ended 30 September 2024						
Opening net book amount	186	913	5,533	5,495	186	12,313
Transfers	–	–	905	432	(1,337)	–
Additions	–	540	1,366	132	1,151	3,189
Depreciation charge	(34)	(357)	(979)	(1,027)	–	(2,397)
Closing net book amount	152	1,096	6,825	5,032	–	13,105
At 30 September 2024						
Cost	248	1,906	8,268	6,892	–	17,314
Accumulated amortization	(96)	(810)	(1,443)	(1,860)	–	(4,209)
Net book amount	152	1,096	6,825	5,032	–	13,105

Depreciation of the Group charged to consolidated statements of comprehensive loss is analyzed as follows:

	Year ended December 31		Nine months ended 30 September	
	2022	2023	2023	2024
	RMB'000	*RMB'000*	*RMB'000 (Unaudited)*	*RMB'000*
Administrative expenses	98	318	277	173
Research and development expense	132	1,164	557	2,224
	230	1,482	834	2,397

15 RIGHT-OF-USE ASSETS

Group

The Group leases offices and laboratory for its own use. Information about leases for which the Group is a lessee is presented below:

	Offices and laboratory
	RMB'000
As at 1 January 2022	
Cost	2,289
Accumulated depreciation	(982)
Net book amount	**1,307**
For the year ended 31 December 2022	
Opening net book amount	1,307
Additions	4,766
Depreciation charge	(1,505)
Closing net book amount	**4,568**
As at 31 December 2022	
Cost	7,055
Accumulated depreciation	(2,487)
Net book amount	**4,568**

	Offices and laboratory
	RMB'000
As at 1 January 2023	
Cost	7,055
Accumulated depreciation	(2,487)
Net book amount	**4,568**
For the year ended 31 December 2023	
Opening net book amount	4,568
Additions	4,152
Depreciation charge	(3,275)
Closing net book amount	**5,445**
As at 31 December 2023	
Cost	11,207
Accumulated depreciation	(5,762)
Net book amount	**5,445**

(Unaudited)

	Offices and laboratory
	RMB'000
As at 1 January 2023	
Cost	7,055
Accumulated depreciation	(2,487)
Net book amount	**4,568**
For the nine months ended 30 September 2023	
Opening net book amount	4,568
Additions	1,456
Depreciation charge	(2,115)
Closing net book amount	**3,909**
As at 30 September 2023	
Cost	8,511
Accumulated depreciation	(4,602)
Net book amount	**3,909**

	Offices and laboratory
	RMB'000
As at 1 January 2024	
Cost	11,207
Accumulated depreciation	(5,762)
Net book amount	**5,445**
For the nine months ended 30 September 2024	
Opening net book amount	5,445
Additions	689
Depreciation charge	(2,390)
Closing net book amount	**3,744**
As at 30 September 2024	
Cost	11,896
Accumulated depreciation	(8,152)
Net book amount	**3,744**

(i) Amounts recognized in the consolidated statement of comprehensive loss

The consolidated statements of comprehensive loss contain the following amounts relating to leases:

	Year ended 31 December		Nine months ended 30 September	
	2022	2023	2023	2024
	RMB'000	*RMB'000*	*RMB'000 (Unaudited)*	*RMB'000*
Depreciation charge of right-to-use assets				
Offices and laboratory	1,505	3,275	2,115	2,390
Interest expenses	75	188	145	189
Expenses relating to short-term leases (included in administrative expenses and research and development expenses)	–	19	8	30

The total cash outflow for leases in the years ended 31 December 2022 and 2023 were RMB1,508,000 and RMB3,706,000 respectively.

The total cash outflow for leases in the nine months ended 30 September 2023 and 2024 were RMB2,750,000 and RMB2,456,000 respectively.

16 INTANGIBLE ASSETS

Accounting policy for intangible assets

(i) Recognition and subsequent measurement

(a) Software

Computer software is recognized at historical cost and subsequently carried at cost less accumulated amortization and accumulated impairment losses. The Group amortized on a straight-line basis over their estimated useful lives of 1-3 years.

(b) Licenses

Certain intangible assets are for license of intellectual properties in development, with non-refundable upfront payment, milestone payment and royalty payment. Upfront payment is capitalized when paid. The milestone payment is capitalized as intangible assets when incurred, unless the payment is for outsourced research and development work which would follow the capitalization policy in Note 16 (c). Royalty payment would be accrued for in line with the underlying sales and recognized as a cost of sales. However, if the intangible asset is acquired in a business combination, it is measured at fair value at initial recognition.

In-licenses with finite useful life are amortized using the straight-line basis over the commercial lives of the underlying products, commencing from the date when the products are put into commercial production.

(c) Research and development

The Group incurs significant costs and efforts on research and development activities. Research expenditures are charged to the profit or loss as an expense in the period the expenditures are incurred. Development costs are recognized as assets if they can be directly attributable to a newly developed drug products and all the following can be demonstrated:

(i) the technical feasibility of completing the intangible assets so that it will be available for use or sale;

(ii) the intention to complete the intangible asset and use or sell it;

(iii) the ability to use or sell the intangible assets;

(iv) the intangible asset will generate probable future economic benefits;

(v) the availability of adequate technical, financial and other resources to complete the development and to use or sell the intangible asset; and

(vi) the ability to measure reliably the expenditure attributable to the intangible asset during its development.

The cost of an internally generated intangible asset is the sum of the expenditures incurred from the date the asset meets the recognition criteria above to the date when it is available for use. The costs capitalized in connection with the intangible asset include costs of materials and services used or consumed, employee costs incurred in the creation of the asset and an appropriate portion of relevant overheads. The Group generally considers capitalization criteria for internally generated intangible assets is met when obtaining regulatory approval of new drug license.

Capitalized development expenditures are amortized using the straight-line method over the life of the related drug products. Amortization shall begin when the asset is available for use. Subsequent to initial recognition, internally generated intangible assets are reported as cost less accumulated amortization and accumulated impairment losses (if any).

Development expenditures not satisfying the above criteria are recognized in the profit or loss as incurred and development expenditures previously recognized as an expense are not recognized as an asset in a subsequent period.

(ii) Impairment

Expenditure to acquire In-licenses and IPR&D is capitalised at fair value at the acquisition date. Intangible assets that have an indefinite useful life are not subject to amortization and are tested annually for impairment, or more frequently if events or changes in circumstances indicate that they might be impaired. An impairment loss is recognized for the amount by which the asset's carrying amount exceeds its recoverable amount. The recoverable amount is the higher of an asset's fair value less costs of disposal and value in use. For the purposes of assessing impairment, assets are grouped at the lowest levels for which there are separately identifiable cash inflows which are largely independent of the cash inflows from other assets or groups of assets (CGU). Non-financial assets that suffered an impairment are reviewed for possible reversal of the impairment at the end of each reporting period.

Group

	In-licenses and IPR&D	Software	Total
	RMB'000	*RMB'000*	*RMB'000*
At 1 January 2022	23,342	–	23,342
Additions	26,305	378	26,683
Amortization charges	–	(60)	(60)
Currency translation	1,178	–	1,178
At 31 December 2022	50,825	318	51,143
At 31 December 2022			
Cost	50,825	378	51,203
Accumulated amortization and impairment	–	(60)	(60)
Net book amount	50,825	318	51,143
At 1 January 2023	50,825	318	51,143
Additions	24,218	403	24,621
Amortization charges	–	(230)	(230)
License out	(21,421)	–	(21,421)
Currency translation	135	–	135
At 31 December 2023	53,757	491	54,248
As at 31 December 2023			
Cost	53,757	781	54,538
Accumulated amortization and impairment	–	(290)	(290)
Net book amount	53,757	491	54,248

(Unaudited)

	In-licenses and IPR&D	Software	Total
	RMB'000	*RMB'000*	*RMB'000*
At 1 January 2023	50,825	318	51,143
Additions	24,218	403	24,621
Amortization charges	–	(163)	(163)
License out	(21,356)	–	(21,356)
Currency translation	401	–	401
At 30 September 2023	54,088	558	54,646
As at 30 September 2023			
Cost	54,088	781	54,869
Accumulated amortization and impairment	–	(223)	(223)
Net book amount	54,088	558	54,646

	In-licenses and IPR&D	Software	Total
	RMB'000	*RMB'000*	*RMB'000*
At 1 January 2024	53,757	491	54,248
Additions	21,931	3,522	25,453
Amortization charges	–	(728)	(728)
License out	(15,439)	–	(15,439)
Impairment	(21,301)	–	(21,301)
Currency translation	(12)	–	(12)
At 30 September 2024	38,936	3,285	42,221
As at 30 September 2024			
Cost	59,959	4,303	64,262
Accumulated amortization and impairment	(21,023)	(1,018)	(22,041)
Net book amount	38,936	3,285	42,221

The intangible assets related to in-license and IPR&D are not ready for use and the Group is continuing research and development work.

Impairment tests were performed in respect of these intangible assets based on the recoverable amount of the cash-generating unit ("CGU") to which the intangible asset is related. The appropriate CGU is at the product level.

The impairment test was performed for each pipeline product by engaging an independent appraiser to estimate fair value less cost to sell as the recoverable amount of each pipeline product. The fair value was based on the multi-period excess earnings method and the Group estimated the forecast of profit for its pipeline products based on the timing of clinical development and regulatory approval, commercial ramp up to reach expected peak revenue potential, and the length of exclusivity for each pipeline product. The discount rate used is post-tax and reflects specific risks relating to the relevant products.

The annual impairment test was performed by engaging an independent valuer to estimate the fair value less cost to sell as the recoverable amount. The fair value is based on the multi-periods excessive earning method with key assumptions as below, and certain pipeline products are not applicable to impairment tests during the stub period, given that they were out-licensed already:

DB-1202	**As at 31 December**		**As at 30 September,**
	2022	**2023**	**2024**
Post-tax discount rate	16.1%	16.0%	Not applicable
Revenue growth rate	-5% to 52%	-5% to 68%	Not applicable
Recoverable amount of CGU (in RMB'000)	46,066	43,226	Not applicable
Carrying amount of CGU (in RMB'000)	20,893	21,248	–

DB-1312	**As at 31 December**		**As at 30 September,**
	2022	**2023**	**2024**
Post-tax discount rate	16.1%	16.0%	Not applicable
Revenue growth rate	-10% to 199.8%	-10% to 199.8%	Not applicable
Recoverable amount of CGU (in RMB'000)	158,746	202,777	Not applicable
Carrying amount of CGU (in RMB'000)	12,076	15,439	–

DB-1310	As at 31 December		As at 30 September,
	2022	2023	2024
Post-tax discount rate	16.1%	16.0%	16.0%
Revenue growth rate	-6% to 140%	-6% to 140%	-6% to 140%
Recoverable amount of CGU (in RMB'000)	39,492	84,406	113,207
Carrying amount of CGU (in RMB'000)	7,542	10,790	10,790

DB-1419	As at 31 December		As at 30 September,
	2022	2023	2024
Post-tax discount rate	16.6%	16.0%	16.0%
Revenue growth rate	-8.7% to 218%	-8.7% to 218%	-8.7% to 218%
Recoverable amount of CGU (in RMB'000)	26,730	74,834	96,754
Carrying amount of CGU (in RMB'000)	3,349	3,349	10,077

DB-1311	As at 31 December		As at 30 September,
	2022	2023	2024
Post-tax discount rate	16.1%	16.0%	16.0%
Revenue growth rate	-10% to 160%	-10% to 160%	-10% to 160%
Recoverable amount of CGU (in RMB'000)	55,394	140,526	202,705
Carrying amount of CGU (in RMB'000)	6,965	2,931	5,423

DB-1418	As at 31 December		As at 30 September
	2022	2023	2024
Post-tax discount rate	Not applicable	Not applicable	16.0%
Revenue growth rate	Not applicable	Not applicable	-5% to 333.9%
Recoverable amount of CGU (in RMB'000)	Not applicable	Not applicable	22,803
Carrying amount of CGU (in RMB'000)	Not applicable	Not applicable	6,703

DB-1324	As at 31 December		As at 30 September
	2022	2023	2024
Post-tax discount rate	Not applicable	Not applicable	16.0%
Revenue growth rate	Not applicable	Not applicable	-19.6% to 246.1%
Recoverable amount of CGU (in RMB'000)	Not applicable	Not applicable	12,605
Carrying amount of CGU (in RMB'000)	Not applicable	Not applicable	5,943

Impairment test-sensitivity

The Company performed sensitivity test by increasing 1 percentage point of post-tax discount rate or decreasing 1 percentage point of revenue growth rate, which management considers are the key assumptions in determining the recoverable amount of each intangible asset, with all other variables held constant. The impacts on the amount (in RMB thousand) by which the intangible asset's recoverable amount above its carrying amount (headroom) are as below:

DB-1202	As at 31 December		As at 30 September,
	2022	2023	2024
Headroom	25,173	21,978	Not applicable
Impact by increasing post-tax discount rate	(24,612)	(16,194)	Not applicable
Impact by decreasing revenue growth rate	(24,914)	(19,353)	Not applicable

DB-1312	As at 31 December		As at 30 September,
	2022	2023	2024
Headroom	146,670	187,338	Not applicable
Impact by increasing post-tax discount rate	(68,990)	(80,015)	Not applicable
Impact by decreasing revenue growth rate	(39,966)	(47,233)	Not applicable

DB-1310	As at 31 December		As at 30 September,
	2022	2023	2024
Headroom	31,950	73,616	102,417
Impact by increasing post-tax discount rate	(30,155)	(32,146)	(27,561)
Impact by decreasing revenue growth rate	(20,325)	(23,873)	(22,072)

DB-1419	As at 31 December		As at 30 September,
	2022	2023	2024
Headroom	23,381	71,485	86,677
Impact by increasing post-tax discount rate	(21,575)	(26,473)	(24,555)
Impact by decreasing revenue growth rate	(11,656)	(14,653)	(13,989)

DB-1311	As at 31 December		As at 30 September,
	2022	2023	2024
Headroom	48,429	137,595	197,282
Impact by increasing post-tax discount rate	(37,714)	(44,266)	(38,712)
Impact by decreasing revenue growth rate	(27,979)	(33,000)	(30,476)

DB-1418	As at 31 December		As at 30 September
	2022	2023	2024
Headroom	Not applicable	Not applicable	16,100
Impact by increasing post-tax discount rate	Not applicable	Not applicable	(15,283)
Impact by decreasing revenue growth rate	Not applicable	Not applicable	(8,215)

DB-1324	As at 31 December		As at 30 September
	2022	2023	2024
Headroom	Not applicable	Not applicable	6,662
Impact by increasing post-tax discount rate	Not applicable	Not applicable	(5,550)
Impact by decreasing revenue growth rate	Not applicable	Not applicable	(2,692)

Based on the result of the above assessment, there was no impairment for the in-licenses and IPR&D as at 31 December 2022 and 2023. Considering there was sufficient headroom based on the assessment, except for DB-1202 which was terminated and fully impaired due to change in market condition during the nine months period ended 30 September 2024, the directors and management believe that a reasonably possible change in any of the key assumptions would not cause the relevant carrying amount of the CGU to exceed its recoverable amount, and there was no impairment as at 30 September 2024.

17 CASH AND BANK BALANCES

Group

	As at 31 December		As at 30 September
	2022	2023	2024
	RMB'000	*RMB'000*	*RMB'000*
Cash in bank and on hand *(a)*	375,974	1,130,889	1,059,706

(a) All cash in bank are deposits with original maturity within 3 months. The Group earns interest on cash in bank.

	As at 31 December		As at 30 September
	2022	2023	2024
	RMB'000	*RMB'000*	*RMB'000*
Cash in bank and on hand are denominated in:			
RMB	187,710	570,485	224,225
USD	188,264	558,170	833,401
EUR	–	2,234	2,080
	375,974	1,130,889	1,059,706

Company

	As at 31 December		As at 30 September
	2022	2023	2024
	RMB'000	*RMB'000*	*RMB'000*
Cash in bank and on hand *(a)*	41,775	6,201	5,061

(a) All cash in bank are deposits with original maturity within 3 months. The Group earns interest on cash in bank.

	As at 31 December		As at 30 September
	2022	2023	2024
	RMB'000	*RMB'000*	*RMB'000*
Cash in bank and on hand are denominated in:			
USD	41,775	6,201	5,061

18 RESTRICTED CASH

As at 31 December 2023 and 30 September 2024, all the restricted deposits were denominated in USD and held in designated bank accounts mainly as security deposits for derivative financial instruments.

19 TRADE RECEIVABLES

Group

	As at 31 December		As at 30 September
	2022	2023	2024
	RMB'000	*RMB'000*	*RMB'000*
Trade receivables	1,410	100,888	390,356
Less: provision for impairment of trade receivables	(2)	(85)	(512)
Trade receivables – net	1,408	100,803	389,844

Customers are generally granted with credit terms ranging from 7 to 30 days.

As at 31 December 2022 and 2023 and 30 September 2024, the ageing analysis of trade receivables based on invoices date and net of expected credit losses is as follows:

	As at 31 December		As at 30 September
	2022	2023	2024
	RMB'000	*RMB'000*	*RMB'000*
Within 30 days	1,408	100,803	354,840
31 days to 60 days	–	–	35,004
	1,408	100,803	389,844

The carrying amounts of the Group's trade receivables are denominated in RMB and approximate their fair values.

The credit loss allowance as at 31 December 2022 and 2023 and 30 September 2024 was determined as follows for trade receivables:

	As at 31 December		As at 30 September
	2022	2023	2024
Provision on collective basis			
Expected credit loss rate	0.14%	0.08%	0.13%
Gross carrying amount (RMB'000)	1,410	100,888	390,356
Credit loss allowance (RMB'000)	(2)	(85)	(512)

Impairment losses on trade receivables are presented as credit loss allowance within operating loss. Subsequent recoveries of amounts previously written off are credited against the same line item. Movements on the Group's credit loss allowance for trade receivables are as follows:

	As at 31 December		As at 30 September
	2022	2023	2024
	RMB'000	*RMB'000*	*RMB'000*
Loss allowance			
At beginning of the year	–	2	85
Increase in loss allowance recognized in the consolidated statements of profit or loss	2	83	427
At end of the year	2	85	512

Trade receivables are written off when there is no reasonable expectation of recovery. Indicators that there is no reasonable expectation of recovery include, amongst others, the failure of a debtor to engage in a repayment plan with the Group, and a failure to make contractual payment.

20 PREPAYMENTS AND OTHER RECEIVABLES

Group

	As at 31 December		As at 30 September
	2022	2023	2024
	RMB'000	*RMB'000*	*RMB'000*
Prepayments to suppliers	1,685	21,746	11,552
Deposits	3,161	5,264	5,191
Deferred [**REDACTED**] expenses	–	–	3,902
Others	67	14	46
	4,913	27,024	20,691

21 OTHER CURRENT ASSETS AND OTHER NON-CURRENT ASSETS

Group

	As at 31 December		As at 30 September
	2022	2023	2024
	RMB'000	*RMB'000*	*RMB'000*
Other current assets			
Value-added tax recoverable	22,585	32,534	59,551
Other non-current assets			
Tax deduction related to withholding tax *(i)*	–	93,666	111,678
Others	635	342	680
	635	94,008	112,358

(i) The overseas income made by the Group's PRC subsidiaries will normally be subject to withholding tax. During the Track Record Period, certain overseas customers withheld excessive tax without considering the relevant bilateral tax treaties. The receivables in relation to such excessive withholding tax are RMB93,666,000 and RMB111,678,000 as at 31 December 2023 and 30 September 2024, respectively.

The Group considers it probable that the tax deduction will be available and has calculated the current tax expense on this basis. The Group has submitted the application for deduction to respective tax bureau in September 2023 and July 2024 and the process is still ongoing. If the application is not consentient, this would increase the Group's current tax payable and Current tax expense by RMB93,666,000 and RMB111,678,000 as at 31 December 2023 and 30 September 2024, respectively.

22 SHARE CAPITAL

Group and Company

Authorized

	Number of Ordinary Shares	Number of Series Seed Preferred Shares	Number of Series A-1 Preferred Shares	Number of Series A-2 Preferred Shares	Number of Series B-1 Preferred Shares	Number of Series B-2 Preferred Shares	Equivalent Nominal Value
							RMB'000
At 1 January 2022	146,183,037	5,000,000	12,333,333	2,666,667	18,749,999	15,066,964	137
Adjustment of authorised Series B-1 Preferred Shares	2,083,333	–	–	–	(2,083,333)	–	–
Reclassification and re-designation upon issuance of the Series B-2 Preferred Shares	(8,370,534)	–	–	–	–	8,370,534	–
At 31 December 2022, 2023 and 30 September 2024	139,895,836	5,000,000	12,333,333	2,666,667	16,666,666	23,437,498	137

Issued

The Company was incorporated in the Cayman Islands as an exempted company registered under the laws of the Cayman Islands on 3 July 2019. Upon incorporation of the Company, one share was issued at par value of USD0.0001.

	Number of Ordinary Shares	Equivalent Nominal Value of Ordinary Shares
		RMB'000
At 31 December 2021, 2022 and 2023 and 30 September 2024	8,000,000	6

23 OTHER RESERVES

Group

	Translation reserve	Share-based compensation	Surplus reserves	Credit risk of convertible preferred shares	Total
	RMB'000	*RMB'000*	*RMB'000*	*RMB'000*	*RMB'000*
At 1 January 2022	8,511	3,592	–	7,103	19,206
Other comprehensive loss – resulted from change of credit risk of convertible preferred shares	–	–	–	420	420
Currency translation loss	(42,743)	–	–	–	(42,743)
Share-based compensation	–	7,032	–	–	7,032
At 31 December 2022	(34,232)	10,624	–	7,523	(16,085)
Surplus reserves	–	–	45,230	–	45,230
Other comprehensive loss – resulted from change of credit risk of convertible preferred shares	–	–	–	(1,688)	(1,688)
Currency translation loss	(19,553)	–	–	–	(19,553)
Share-based compensation	–	23,957	–	–	23,957
At 31 December 2023	(53,785)	34,581	45,230	5,835	31,861

(Unaudited)

	Translation reserve	Share-based compensation	Surplus reserves	Credit risk of convertible preferred shares	Total
	RMB'000	*RMB'000*	*RMB'000*	*RMB'000*	*RMB'000*
At 31 December 2022	(34,232)	10,624	–	7,523	(16,085)
Other comprehensive loss – resulted from change of credit risk of convertible preferred shares	–	–	–	(87)	(87)
Currency translation loss	(49,608)	–	–	–	(49,608)
Share-based compensation	–	16,139	–	–	16,139
At 30 September 2023	(83,840)	26,763	–	7,436	(49,641)
At 31 December 2023	(53,785)	34,581	45,230	5,835	31,861
Other comprehensive loss – resulted from change of credit risk of convertible preferred shares	–	–	–	(216)	(216)
Currency translation gain	28,828	–	–	–	28,828
Share-based compensation	–	163,957	–	–	163,957
At 30 September 2024	(24,957)	198,538	45,230	5,619	224,430

Company

	Translation reserve	Share-based compensation	Credit risk of convertible preferred shares	Total
	RMB'000	*RMB'000*	*RMB'000*	*RMB'000*
At 1 January 2022	6,319	3,592	7,103	17,014
Other comprehensive loss – resulted from change of credit risk of convertible preferred shares	–	–	420	420
Currency translation loss	(11,678)	–	–	(11,678)
Share-based compensation	–	7,032	–	7,032
At 31 December 2022	(5,359)	10,624	7,523	12,788
Other comprehensive loss – resulted from change of credit risk of convertible preferred shares	–	–	(1,688)	(1,688)
Currency translation loss	(5,902)	–	–	(5,902)
Share-based compensation	–	23,957	–	23,957
At 31 December 2023	(11,261)	34,581	5,835	29,155

(Unaudited)

	Translation reserve	Share-based compensation	Credit risk of convertible preferred shares	Total
	RMB'000	*RMB'000*	*RMB'000*	*RMB'000*
At 31 December 2022	(5,359)	10,624	7,523	12,788
Other comprehensive loss – resulted from change of credit risk of convertible preferred shares	–	–	(87)	(87)
Issuance of convertible preferred shares *(Note 24)*	–	–	–	–
Currency translation loss	(35,221)	–	–	(35,221)
Share-based compensation	–	16,139	–	16,139
At 30 September 2023	(40,580)	26,763	7,436	(6,381)
At 31 December 2023	(11,261)	34,581	5,835	29,155
Other comprehensive loss – resulted from change of credit risk of convertible preferred shares	–	–	(216)	(216)
Issuance of convertible preferred shares *(Note 24)*	–	–	–	–
Currency translation gain	16,451	–	–	16,451
Share-based compensation	–	163,957	–	163,957
At 30 September 2024	5,190	198,538	5,619	209,347

24 FINANCIAL ASSETS/LIABILITIES AT FAIR VALUE THROUGH PROFIT OR LOSS

Financial assets at fair value through profit or loss

Fair value measurement of financial assets includes the following:

Group

	As at 31 December		As at 30 September
	2022	2023	2024
	RMB'000	*RMB'000*	*RMB'000*
Structured deposits	–	–	60,199
	–	–	60,199

The following table gives information about how the fair values of Level 3 financial assets are determined:

Unobservable inputs	31 December 2022	31 December 2023	30 September 2024	Relationship of unobservable inputs to fair value
Expected rate of return	Not applicable	Not applicable	0.95%-2.7%	The higher the expected rate of return, the higher the fair value.

If the fair values of the structured deposits measured at fair value through profit or loss held by the Group had been 0.5% higher/ lower, the loss before income tax for the years ended December 31, 2022, 2023 and the nine months ended September 30, 2024 would have been approximately nil, nil and RMB301,000 lower/higher, respectively.

The structured deposits are purchased from creditworthy commercial banks in Chinese Mainland. They were mandatorily classified as financial assets at fair value through profit or loss as their contractual cash flows are not solely payments of principal and interest. The interest rates fluctuate within the range of 0.95% to 2.7%, hooked onto EUR/USD exchange rate.

Financial liabilities at fair value through profit or loss

Convertible preferred shares issued by the Company are redeemable upon occurrence of certain future events. This instrument can be converted into ordinary shares of the Company at any time at the option of the holders or automatically converted into ordinary shares upon occurrence of an [**REDACTED**] of the Company.

The Group designated the convertible preferred shares as financial liabilities at fair value through profit or loss. They are initially recognized at fair value. Subsequent to initial recognition, the convertible preferred shares are carried at fair value with changes in fair value recognized in the consolidated statements of comprehensive loss.

If the Company's own credit risk results in fair value changes in financial liabilities designated as at fair value through profit or loss, they are recognized in other comprehensive loss.

Group

	As at 31 December		As at 30 September
	2022	2023	2024
	RMB'000	*RMB'000*	*RMB'000*
Loans with warrants to purchase Series B-2 Preferred Shares *(a)*	135,191	–	–
Series Seed Preferred Shares	66,129	166,600	216,189
Series A-1 Preferred Shares	171,517	417,219	533,634
Series A-2 Preferred Shares	37,077	90,203	115,380
Series B-1 Preferred Shares	328,501	600,614	722,504
Series B-2 Preferred Shares	334,305	858,084	1,017,372
	1,072,720	2,132,720	2,605,079

As at 1 January 2022, 5,000,000 Series Seed Preferred Shares, 12,333,333 Series A-1 Preferred Shares, 2,666,667 Series A-2 Preferred Shares and 16,666,666 Series B-1 Preferred Shares were issued and remained outstanding.

Through April to September 2022, the Company issued 16,071,428 Series B-2 Preferred Shares to a number of investors at a cash consideration of USD48,000,000 (RMB318,593,000).

Through March to April 2023, the Company further issued 7,366,070 Series B-2 Preferred Shares to certain onshore investors at a cash consideration of USD22,000,000 (RMB151,101,000), via the following arrangement.

(a) Loans with warrants to purchase Series B-2 Preferred Shares

Prior to investing in the Company, onshore investors shall obtain requisite overseas direct investment approvals ("ODI approval"). In the Series B-2 financing, prior to obtaining ODI approval, these onshore investors entered into loan agreements with the Group in 2022 whereby these onshore investors agreed to provide loans to Duality Biologics (Suzhou) Co., Ltd. (the "WFOE"), a subsidiary of the Company that incorporated in PRC, and the Company agreed to issue Series B-2 Preferred Share Purchase Warrants (the "Warrants") to these investors.

Once these onshore investors obtain ODI approval, the WFOE shall return these onshore investors the principal amount of loans, and such amount shall be paid by these onshore investors to the Company as part of purchase consideration for Series B-2 Preferred Shares.

These abovementioned loans were designated as financial liabilities at fair value through profit or loss, which are initially recognized at fair value. The component of fair value changes relating to the Company's own credit risk is recognized in other comprehensive income/(loss). Amounts recorded in other comprehensive income/(loss) related to credit risk are not subject to recycling in profit or loss, but are transferred to retained earnings when realized. Fair value changes relating to market risk are recognized in profit or loss.

During the year ended 31 December 2022, the WFOE received loans with a total amount of RMB135,191,000, with Warrants issued to purchase 7,366,070 Series B-2 Preferred Shares accordingly. In 2023, these loans were repaid and the abovementioned Warrants were all exercised with 7,366,070 Series B-2 Preferred Shares issued. As at 31 December 2022, the fair value of the unexercised Warrants were immaterial.

(b) Convertible preferred shares of the Company

The rights, preferences and privileges of the above convertible preferred shares are as follows:

(i) Conversion feature

Each convertible preferred share may, at the option of the holder thereof, be converted at any time after the date of issuance of such convertible preferred shares into ordinary shares, or shall automatically be converted into ordinary shares upon the closing of a [**REDACTED**] of the Company.

The conversion ratio for the convertible preferred shares to the ordinary shares is 1:1 if no adjustments to conversion price have occurred. As at 30 September 2024, each convertible preferred share is convertible into one ordinary share.

(ii) Liquidation preferences

Each holder of convertible preferred shares shall be entitled to receive for each series of convertible preferred shares he or it holds on the preferential basis, prior and in preference to any distribution of any of the assets or surplus funds of the Company to the holders of other series of convertible preferred shares and ordinary shares or any other class or series of shares by reason of their ownership of such shares, the amount equal to one hundred percent (100%) of the respective applicable issue price, plus (a) all interest that would accrue on the applicable issue price during the period from the relevant issue date to the date of receipt by the holder thereof of the full liquidation amount at a rate of 10% per annum, plus (b) accrued or declared but unpaid dividends on such convertible preferred shares, respectively.

If the assets and funds available for distribution shall be insufficient to permit the payment to such holders of the full preferred preference amount, the liquidation preference amount will be paid to the holders of convertible preferred shares in the following order: first to holders of Series B-1 and B-2 Preferred Shares ("Series B Preferred Shares"), second to holders of Series A Preferred Shares, third to holders of Series Seed Preferred Shares, and lastly to the holders of ordinary shares. After distributing or paying in full the liquidation preference amount to all of the holders of convertible preferred shares, the remaining assets of the Company available for distribution to members, if any, shall be distributed to the holders of the ordinary shares on a pro rata basis.

(iii) Redemption feature

The shareholders of Series B Preferred Shares, Series A Preferred Shares and Series Seed Preferred Shares may give a written notice to the Company at any time or from time to time requesting redemption of all or part of their convertible preferred shares under certain conditions as provided in the article of association. These conditions substantially include the following:

(a) the Company fails to complete a [**REDACTED**] within four (4) years after 23 April 2021, which was the date of Initial USD Closing as defined in Series B share purchase agreements;

(b) the Company fails to obtain the occurrence a deemed liquidation event within four years after the Initial USD Closing;

(c) other than as approved by the board, the founder terminates his full-time employment relationship with the Group within four years after the Initial USD Closing;

(d) other than as approved by the board, the founder transfers two thirds or more of the ordinary shares directly or indirectly held by him as of the Initial USD Closing within four years after the Initial USD Closing;

(e) the Group fails to maintain, obtain or renew any permits, authorizations, approvals, consents or licenses necessary to the principal business; or

(f) the occurrence of a material breach, violation or misconduct by the Group or founder parities in its performance of the relevant transaction documents.

The redemption price payable on each of the abovementioned convertible preferred shares is the applicable purchase price for each share, plus (a) all interest that would accrue on applicable purchase price during the period from the relevant issue date to the date of receipt by the holder thereof of the full redemption amount at a rate of 10% or 30% per annum, minus (b) minus any dividends already paid on each share.

The directors of the Group believes that due to the conversion feature of the convertible preferred shares, the financial liabilities at fair value through profit or loss will not result in cash payment in the future.

The movement of financial liabilities at fair value through profit or loss is set out below:

	Total
	RMB'000
At 1 January 2022	531,669
Issuance of convertible preferred shares	318,593
Issuance of loans with warrants to purchase Series B Preferred Shares	135,191
Changes in fair value – profit or loss	21,700
Changes in fair value – other comprehensive loss	(420)
Currency translation difference	65,987
At 31 December 2022	1,072,720
Issuance of convertible preferred shares *(1)*	151,101
Repayments of loans with warrants to purchase Series B Preferred Shares	(135,191)
Changes in fair value – profit or loss	1,017,899
Changes in fair value – other comprehensive loss	1,688
Currency translation difference	24,503
At 31 December 2023	2,132,720
(Unaudited)	
At 31 December 2022	1,072,720
Issuance convertible preferred shares	151,101
Repayments of loans with warrants to purchase Series B Preferred Shares	(135,191)
Changes in fair value – profit or loss	959,200
Changes in fair value – other comprehensive loss	87
Currency translation difference	55,687
At 30 September 2023	2,103,604
At 31 December 2023	2,132,720
Changes in fair value – profit or loss	501,351
Changes in fair value – other comprehensive loss	216
Currency translation difference	(29,208)
At 30 September 2024	2,605,079

(1) Through March to April 2023, the Company received total consideration of USD22,000,000 (RMB151,101,000) by issuance of the 7,366,070 Series B-2 Preferred Shares with Warrants exercised (Note 24(a)). The fair value change in relation with these Warrants before the issuance dates of Series B-2 Preferred Shares were approximately USD10,309,000 (RMB70,807,000).

With the assistance from an external valuer appointed by the Group, the Group applied the back-solve method and discounted cash flow method to determine the underlying equity value of the Company and adopted option-pricing method and equity allocation model to determine the fair value of the financial instruments issued to investors. Key assumptions are set out as below:

Unobservable inputs	31 December 2022	31 December 2023	30 September 2024	Relationship of unobservable inputs to fair value
Discount rate	Not applicable	15.0%	15.0%	The higher the discount rate, the lower the fair value of financial instrument to investors.
Volatility	56.1%	57.7%	48.7%	Nonlinear relationships
DLOM	27.0%	22.0%	12.0%	The higher the DLOM, the lower the fair value of financial instrument to investors.

As of 31 December 2022, increasing/decreasing expected volatility by 5% would decrease/increase the fair value of financial instruments by RMB841,000 and RMB856,000 respectively. Increasing/Decreasing DLOM by 1% would decrease/increase the fair value by RMB3,651,000 and RMB3,651,000 respectively.

As of 31 December 2023, increasing/decreasing expected volatility by 5% would increase/decrease the fair value of financial instruments by RMB845,000 and RMB941,000 respectively. Increasing/Decreasing discount rate by 1% would decrease/increase the fair value by RMB34,068,000 and RMB34,881,000 respectively. Increasing/Decreasing DLOM by 1% would decrease/increase the fair value by RMB5,799,000 and RMB5,799,000 respectively.

As of 30 September 2024, increasing/decreasing expected volatility by 5% would increase/decrease the fair value of financial instruments by RMB260,000 and RMB220,000 respectively. Increasing/Decreasing discount rate by 1% would decrease/increase the fair value by RMB33,361,000 and RMB34,077,000 respectively. Increasing/Decreasing DLOM by 1% would decrease/increase the fair value by RMB3,497,000 and RMB3,497,000 respectively.

Company

	As at 31 December		As at 30 September
	2022	2023	2024
	RMB'000	*RMB'000*	*RMB'000*
Series Seed Preferred Shares	66,129	166,600	216,189
Series A-1 Preferred Shares	171,517	417,219	533,634
Series A-2 Preferred Shares	37,077	90,203	115,380
Series B-1 Preferred Shares	328,501	600,614	722,504
Series B-2 Preferred Shares	334,305	858,084	1,017,372
	937,529	2,132,720	2,605,079

	Total
	RMB'000
At 1 January 2022	531,669
Issuance of convertible preferred shares	318,593
Changes in fair value – profit or loss	21,700
Changes in fair value – other comprehensive loss	(420)
Currency translation difference-recognize in equity	65,987
At 31 December 2022	937,529
Issuance of convertible preferred shares	151,101
Changes in fair value – profit or loss	1,017,899
Changes in fair value – other comprehensive loss	1,688
Currency translation difference-recognize in equity	24,503
At 31 December 2023	2,132,720
(Unaudited)	
At 31 December 2022	937,529
Issuance of convertible preferred shares	151,101
Changes in fair value – profit or loss	959,200
Changes in fair value – other comprehensive loss	87
Currency translation difference-recognize in equity	55,687
At 30 September 2023	2,103,604
At 31 December 2023	2,132,720
Changes in fair value – profit or loss	501,351
Changes in fair value – other comprehensive loss	216
Currency translation difference-recognize in equity	(29,208)
At 30 September 2024	2,605,079

25 TRADE PAYABLES

Group

As at 31 December 2022 and 2023 and 30 September 2024, the ageing analysis of trade payables based on invoice date is as follows:

	As at 31 December		As at 30 September
	2022	2023	2024
	RMB'000	*RMB'000*	*RMB'000*
Within 6 months	123,980	234,476	523,475
6 months to 12 months	5,515	338	961
	129,495	234,814	524,436

26 OTHER PAYABLES

Group

	As at 31 December		As at 30 September
	2022	2023	2024
	RMB'000	*RMB'000*	*RMB'000*
Payables for acquisition of property, plant and equipment and intangible assets	6,965	7,408	33,538
Staff salaries and welfare payables	16,829	23,587	24,027
Payables for [**REDACTED**] expenses	–	–	18,160
Payables for financial and consulting services	60	1,651	1,492
Other taxes payable	699	919	1,440
Recruitment services and other accrued expenses	807	–	455
Others	614	1,109	2,854
	25,974	34,674	81,966

The carrying amounts of accruals and other payables of the Group are denominated in the following currencies:

	As at 31 December		As at 30 September
	2022	2023	2024
	RMB'000	*RMB'000*	*RMB'000*
USD	6,979	8,090	46,710
RMB	18,995	26,584	35,256
Total	25,974	34,674	81,966

Company

	As at 31 December		As at 30 September
	2022	2023	2024
	RMB'000	*RMB'000*	*RMB'000*
Payables for [**REDACTED**] expenses	–	–	16,570
Others	29	120	2,057
	29	120	18,627

The carrying amounts of accruals and other payables of the Company are denominated in the following currencies:

	As at 31 December		As at 30 September
	2022	2023	2024
	RMB'000	*RMB'000*	*RMB'000*
USD	29	120	16,062
RMB	–	–	2,565
Total	29	120	18,627

27 DIVIDENDS

No dividend has been paid or declared by the Company or the companies now comprising the Group during each of the years ended 31 December 2022 and 2023 and for the nine months ended 30 September 2024.

28 CASH FLOW INFORMATION

(a) Reconciliation of (loss)/profit for the year/period to net cash used in operations

	Year ended 31 December		Nine months ended 30 September	
	2022	2023	2023	2024
	RMB'000	*RMB'000*	*RMB'000 (Unaudited)*	*RMB'000*
(Loss)/profit before income tax	(387,090)	(202,249)	41,436	(535,899)
Adjustments for:				
– Depreciation of property, plant and equipment	230	1,482	834	2,397
– Impairment of intangible assets	–	–	–	21,301
– Amortization of intangible assets	60	230	163	728
– Share-based compensation expenses	7,032	23,957	16,139	163,957
– Depreciation of right-of-use assets	1,505	3,275	2,115	2,390
– Finance income	(3,268)	(34,483)	(24,160)	(38,809)
– Finance cost	75	188	145	189
– Net foreign exchange (gains)/loss	(1,121)	(41,935)	(38,847)	8,688
– Fair value losses on financial liabilities at fair value through profit or loss	21,700	1,017,899	959,200	501,351
– Losses on disposal of financial assets at fair value through profit or loss	–	1,162	–	–
– Investment income	–	–	–	(1,490)
– License out of intangible assets	–	21,421	21,356	15,439
Changes in working capital:				
– Increase in trade, other receivables and prepayments	(747)	(120,969)	(174,525)	(282,357)
– Increase in other current assets	(12,156)	(9,949)	(10,087)	(27,017)
– Increase/(decrease) in contract liabilities	–	216,296	225,361	(128,646)
– Increase in trade and other payables	71,042	154,456	174,600	327,790
Cash (used in)/generated from operating activities	(302,738)	1,030,781	1,193,730	30,012

(b) Reconciliation of liabilities arising from financing activities

	Lease liabilities	Financial liabilities at fair value through profit or loss	Total
	RMB'000	*RMB'000*	*RMB'000*
Net debt as at 1 January 2022	(1,332)	(531,669)	(533,001)
Cash flows	1,508	(453,784)	(452,276)
Acquisition-leases	(4,766)	–	(4,766)
Other changes	(75)	(21,280)	(21,355)
Foreign exchange adjustments	–	(65,987)	(65,987)
Net debt as at 31 December 2022	(4,665)	(1,072,720)	(1,077,385)
Cash flows	3,687	(15,910)	(12,223)
Acquisition-leases	(4,152)	–	(4,152)
Other changes	(188)	(1,019,587)	(1,019,775)
Foreign exchange adjustments	–	(24,503)	(24,503)
Net debt as at 31 December 2023	(5,318)	(2,132,720)	(2,138,038)

	Lease liabilities	Financial liabilities at fair value through profit or loss	Total
	RMB'000	*RMB'000*	*RMB'000*
(Unaudited)			
Net debt as at 1 January 2023	(4,665)	(1,072,720)	(1,077,385)
Cash flows	2,742	(15,910)	(13,168)
Acquisition-leases	(1,456)	–	(1,456)
Other changes	(145)	(959,287)	(959,432)
Foreign exchange adjustments	–	(55,687)	(55,687)
Net debt as at 30 September 2023	(3,524)	(2,103,604)	(2,107,128)
Net debt as at 1 January 2024	(5,318)	(2,132,720)	(2,138,038)
Cash flows	2,426	–	2,426
Acquisition-leases	(689)	–	(689)
Other changes	(189)	(501,567)	(501,756)
Foreign exchange adjustments	–	(29,208)	(29,208)
Net debt as at 30 September 2024	(3,770)	(2,605,079)	(2,608,849)

29 COMMITMENTS

(a) Capital commitments

Capital expenditure contracted for by the Group at the balance sheet date but not yet incurred is as follows:

	As at 31 December		As at 30 September
	2022	2023	2024
	RMB'000	*RMB'000*	*RMB'000*
Property, plant and equipment	5,136	519	1,204
	5,136	519	1,204

30 RELATED PARTY TRANSACTIONS

Parties are considered to be related in one party has the ability, directly or indirectly, to control the other part or exercise significant influence over the other party in making financial and operation decisions. Parties are also considered to be related if they are subject to common control. The following is a summary of the significant transactions carried out between the Group and its related parties in the ordinary course of business during the years ended 31 December 2022 and 2023 and the nine months ended 30 September 2024 respectively.

(a) Key management compensation

Compensations for key management other than those for directors as disclosed in Note 31 is set out below.

	Year ended 31 December		Nine months ended 30 September	
	2022	2023	2023	2024
	RMB'000	*RMB'000*	*RMB'000* *(Unaudited)*	*RMB'000*
Share-based compensation expenses	1,390	5,968	3,143	44,101
Wages, salaries and bonus	17,914	23,406	16,555	17,924
Social insurance	916	1,476	284	435
Other welfare for employees	151	480	1,069	1,273
	20,371	31,330	21,051	63,733

31 DIRECTORS' BENEFITS AND INTERESTS

(a) Directors' and senior management's emoluments

Directors and chief executives' emoluments for the years ended 31 December 2022 and 2023 are set out as follows:

	Fees	Salary	Discretionary bonus	Share-based compensation expenses	Pension costs	Other benefits	Total
	RMB'000	*RMB'000*	*RMB'000*	*RMB'000*	*RMB'000*	*RMB'000*	*RMB'000*
Year ended December 31, 2022							
Executive directors							
Dr. Zhongyuan Zhu *(i)*	–	2,334	1,300	4,321	133	95	8,183
Mr. Shaoren Zhang *(ii)*	–	1,267	583	226	133	13	2,222
Ms. Wen Si *(iii)*	–	911	350	20	133	13	1,427
Non-executive directors							
Dr. Tao Yu *(iv)*	–	–	–	–	–	–	–
Ms. Xianghong Lin *(v)*	–	–	–	–	–	–	–
	–	4,512	2,233	4,567	399	121	11,832

	Fees	Salary	Discretionary bonus	Share-based compensation expenses	Pension costs	Other benefits	Total
	RMB'000	*RMB'000*	*RMB'000*	*RMB'000*	*RMB'000*	*RMB'000*	*RMB'000*
Year ended December 31, 2023							
Executive directors							
Dr. Zhongyuan Zhu *(i)*	–	2,334	1,260	14,665	143	142	18,544
Mr. Shaoren Zhang *(ii)*	–	1,364	402	150	143	13	2,072
Ms. Wen Si *(iii)*	–	933	297	18	143	13	1,404
Non-executive directors							
Dr. Tao Yu *(iv)*	–	–	–	–	–	–	–
Ms. Xianghong Lin *(v)*	–	–	–	–	–	–	–
	–	4,631	1,959	14,833	429	168	22,020

Directors and chief executives' emoluments for the nine months ended 30 September 2023 and 2024 are set out as follows:

(Unaudited)

	Fees	Salary	Discretionary bonus	Share-based compensation expenses	Pension costs	Other benefits	Total
	RMB'000	*RMB'000*	*RMB'000*	*RMB'000*	*RMB'000*	*RMB'000*	*RMB'000*
Period ended 30 September 2023							
Executive directors							
Dr. Zhongyuan Zhu *(i)*	–	1,751	945	10,513	106	106	13,421
Mr. Shaoren Zhang *(ii)*	–	1,023	301	125	106	10	1,565
Ms. Wen Si *(iii)*	–	700	223	104	106	10	1,143
Non-executive directors							
Dr. Tao Yu *(iv)*	–	–	–	–	–	–	–
Ms. Xianghong Lin *(v)*	–	–	–	–	–	–	–
	–	3,474	1,469	10,742	318	126	16,129

	Fees	Salary	Discretionary bonus	Share-based compensation expenses	Pension costs	Other benefits	Total
	RMB'000	*RMB'000*	*RMB'000*	*RMB'000*	*RMB'000*	*RMB'000*	*RMB'000*
Period ended 30 September 2024							
Executive directors							
Dr. Zhongyuan Zhu *(i)*	–	1,808	858	68,372	108	112	71,258
Mr. Shaoren Zhang *(ii)*	–	1,167	328	3,114	108	10	4,727
Ms. Wen Si *(iii)*	–	741	206	1,809	108	10	2,874
Non-executive directors							
Dr. Tao Yu *(iv)*	–	–	–	–	–	–	–
Mr. Zhiyang Cai *(vi)*	–	–	–	–	–	–	–
	–	3,716	1,392	73,295	324	132	78,859

(i) Dr. Zhongyuan Zhu, as the founder, was appointed as executive director on 19 February 2020.

(ii) Mr. Shaoren Zhang was appointed as executive director on 23 April 2021.

(iii) Ms. Wen Si was appointed as executive director on 23 April 2021.

(iv) Dr. Tao Yu was appointed as a non-executive director on 23 April 2021.

(v) Ms. Xianghong Lin was appointed as a non-executive director on 13 May 2020 and resigned on 22 July 2024.

(vi) Mr. Zhiyang Cai was appointed as a non-executive director on 12 August 2024.

(b) Directors' retirement benefits

None of the directors received or will receive any retirement benefits during the years ended 31 December 2022 and 2023 and the nine months ended 30 September 2024.

(c) Directors' termination benefits

None of the directors received or will receive any termination benefits during the years ended 31 December 2022 and 2023 and the nine months ended 30 September 2024.

(d) Consideration provided to third parties for making available directors' services

During the years ended 31 December 2022 and 2023 and the nine months ended 30 September 2024, the Company did not pay consideration to any third parties for making available directors' services.

(e) Information about loans, quasi-loans and other dealings in favor of directors, bodies corporate controlled by or entities connected with directors

Save as disclosed in Note 10, there were no loans, quasi-loans and other dealings in favor of directors, controlled bodies corporate by and connected entities with such directors during the years ended 31 December 2022 and 2023 and the nine months ended 30 September 2024.

(f) Directors' material interests in transactions, arrangements or contracts

No significant transactions, arrangements and contracts in relation to the Group's business to which the Company 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 years or at any time during the years ended 31 December 2022 and 2023 and the nine months ended 30 September 2024.

32 SUBSIDIARIES

The details of the subsidiaries of the Group are set out below:

Name	Place and date of incorporation	Principal activities	Paid-in-capital/Reserve			Percentage of attributable equity interest to the Company			
			As at 31 December		As at 30 September	As at 31 December		As at 30 September	
			2022	2023	2024	2022	2023	2024	As at the date of this report
			(RMB'000)	*(RMB'000)*	*(RMB'000)*				*(Unaudited)*
DualityBio HK Limited *(a)*	Hong Kong, 21 January 2020	Investment holding	USD1	USD1	USD1	100%	100%	100%	100%
Duality Biologics (Suzhou) Co., Ltd. *(b)*	PRC, 23 March 2020	Investment holding and pharmaceuticals research, development and production	USD60,000	USD73,000	USD73,000	100%	100%	100%	100%
Duality Biologics (Shanghai) Co., Ltd. *(b)*	PRC, 26 April 2020	Pharmaceuticals research, development and production	RMB55,000	RMB70,000	RMB90,000	100%	100%	100%	100%
DualityBio Inc. *(c)*	United States, 3 May 2021	Pharmaceuticals research, development and production	–	–	–	100%	100%	100%	100%

Notes:

(a) The statutory auditor of the subsidiary of the Group for the years ended 31 December 2022 and 2023 was AYC CPA Limited, certified public accountants registered in the Hong Kong.

(b) The statutory auditor of the subsidiaries of the Group for the years ended 31 December 2022 and 2023 were Suzhou Genhood C.P.A Co., Ltd, certified public accountants registered in the PRC.

(c) No audited financial statements have been prepared for these companies for the years ended 31 December 2022 and 2023, as these entities were not subject to any statutory audit requirements under the relevant rules and regulations in the jurisdiction of incorporation.

33 SUBSEQUENT EVENTS

There are no material subsequent events undertaken by the Duality Biotherapeutics Group after 30 September 2024.

34 SUMMARY OF OTHER ACCOUNTING POLICIES

34.1 Principles of consolidation and equity accounting

34.1.1 Subsidiaries

Subsidiaries are all entities (including structured entities) over which the Group has control. The Group controls an entity when the Group is exposed to, or has rights to, variable returns from its involvement with the entity and has the ability to affect those returns through its power to direct the activities of the entity. Subsidiaries are consolidated from the date on which control is transferred to the Group. They are deconsolidated from the date that control ceases.

Inter-company transactions, balances and unrealized gains on transactions between group companies are eliminated. Unrealized losses are also eliminated unless the transaction provides evidence of an impairment of the transferred asset. Accounting policies of subsidiaries have been changed where necessary to ensure consistency with the policies adopted by the Group.

34.2 Foreign currency translation

34.2.1 Functional and presentation currency

Items included in the financial statements of each of the Group's entities are measured using the currency of the primary economic environment in which the entity operates (the "functional currency"). The Company's functional currency is USD; however the Historical Financial Information are presented in RMB. As the major operations of the Group are within the PRC, the Group determined to present the Historical Financial Information in RMB (unless otherwise stated).

34.2.2 Transactions and balances

Foreign currency transactions are translated into the functional currency using the exchange rates prevailing at the dates of the transactions or valuation where items are re-measured. Foreign exchange gains and losses resulting from the settlement of such transactions are recognized in consolidated statements of comprehensive loss in the period in which they arise.

Monetary assets and liabilities denominated in foreign currencies at the year end are re-translated at the exchange rates prevailing at the balance sheet date. Exchange differences arising upon re-translation at the balance sheet date are recognized in profit or loss.

All foreign exchange gains and losses are presented in the consolidated statements of comprehensive loss within "Other gains/losses — net".

34.2.3 Group companies

The results and balance sheet of all the Group entities (none of which has the currency of a hyperinflationary economy) that have a functional currency different from the presentation currency are translated into the presentation currency as follows:

- Assets and liabilities for each statement of financial position are translated at the closing rate;
- Income and expenses for each statement of profit or loss and statement of comprehensive income are translated at average exchange rate; and
- All resulting exchange differences are recognized in other comprehensive income and accumulated as "Other reserves" in equity.

34.3 Prepayments and other receivables

Prepayments mainly represent upfront cash payments made to testing companies. Prepayments to testing companies will be subsequently recorded as research and development expenses in accordance with the applicable performance requirements.

Prepayments are generally due for settlement within one year or less and therefore are all classified as current assets.

Other receivables are recognized initially at fair value and subsequently measured at amortized cost using the effective interest method, less allowance for impairment.

34.4 Cash and cash equivalents

For the purpose of presentation in the statement of cash flows, cash and cash equivalents includes cash on hand, deposits held at call with financial institutions, other short-term, highly liquid investments with original maturities of three months or less that are readily convertible to known amounts of cash and which are subject to an insignificant risk of changes in value.

34.5 Share capital

Ordinary shares are classified as equity. Convertible preferred shares issued to investors are classified as liabilities based on the respective contract terms (see Note 24).

Incremental costs directly attributable to the issue of new shares are shown in equity as a deduction, net of tax, from the proceeds.

34.6 Trade and other payables

Trade and other payables mainly represent the obligations to pay for services that have been acquired in the ordinary course of business from hospitals and clinical trial companies. Trade and other payables are presented as current liabilities unless payment is not due within one year or less after the reporting period.

Trade and other payables are recognized initially at their fair value and subsequently measured at amortized cost using the effective interest method.

34.7 Income tax

The income tax expense or credit for the period is the tax payable on the current period's taxable income based on the applicable income tax rate for each jurisdiction adjusted by changes in deferred tax assets and liabilities attributable to temporary differences and to unused tax losses.

Deferred income tax

Deferred income tax is provided in full, using the liability method, on temporary differences arising between the tax bases of assets and liabilities and their carrying amounts in the Historical Financial Information. However, deferred tax liabilities are not recognized if they arise from the initial recognition of goodwill. Deferred income tax is also not accounted for if it arises from initial recognition of an asset or liability in a transaction other than a business combination that at the time of the transaction affects neither accounting nor taxable profit or loss and does not give rise to equal taxable and deductible temporary differences. Deferred income tax is determined using tax rates (and laws) that have been enacted or substantively enacted by the end of the reporting period and are expected to apply when the related deferred income tax asset is realized or the deferred income tax liability is settled.

Deferred tax assets are recognized only if it is probable that future taxable amounts will be available to utilise those temporary differences and losses.

Deferred tax liabilities and assets are not recognized for temporary differences between the carrying amount and tax bases of investments in foreign operations where the company is able to control the timing of the reversal of the temporary differences and it is probable that the differences will not reverse in the foreseeable future.

Deferred tax assets and liabilities are offset where there is a legally enforceable right to offset current tax assets and liabilities and where the deferred tax balances relate to the same taxation authority. Current tax assets and tax liabilities are offset where the entity has a legally enforceable right to offset and intends either to settle on a net basis, or to realize the asset and settle the liability simultaneously.

Current and deferred tax is recognized in profit or loss, except to the extent that it relates to items recognized in other comprehensive income or directly in equity. In this case, the tax is also recognized in other comprehensive income or directly in equity, respectively.

34.8 Employee benefits

34.8.1 Pension obligations

In accordance with the rules and regulations in the PRC, the PRC based employees of the Group participate in various defined contribution retirement benefit plans organised by the relevant municipal and provincial governments in the PRC under which the Group and the employees are required to make monthly contributions to these plans calculated as a percentage of the employees' salaries, subject to certain ceiling. The municipal and provincial governments undertake to assume the retirement benefit obligations of all existing and future retired PRC based employees payable under the plans described above. Other than the monthly contributions, the Group has no further obligation for the payment of retirement and other post-retirement benefits of its employees. The assets of these plans are held separately from those of the Group in an independent fund managed by the PRC government. The Group's contributions to these plans are expensed as incurred.

34.8.2 Housing funds, medical insurances and other social insurances

The PRC employees of the Group are entitled to participate in various government-supervised housing funds, medical insurance and other employee social insurance plan. The Group contributes on a monthly basis to these funds based on certain percentages of the salaries of the employees, subject to certain ceiling. The Group's liability in respect of these funds is limited to the contributions payable in each period.

34.8.3 Short-term obligations

Liabilities for wages and salaries, including non-monetary benefits that are expected to be settled wholly within 12 months after the end of the period in which the employees render the related service are recognized in respect of employees' services up to the end of the reporting period and are measured at the amounts expected to be paid when the liabilities are settled. The liabilities are presented as current employee benefit obligations in the balance sheet.

34.8.4 Employee leave entitlement

Employee entitlement to annual leave are recognized when they have accrued to employees. A provision is made for the estimated liability for annual leave as a result of services rendered by employees up to the end of the reporting period. Employees entitlement to sick leave and maternity leave are not recognized until the time of leave.

34.8.5 Bonus plan

The expected cost of bonus is recognized as a liability when the Group has a present legal or constructive obligation for payment of bonus as a result of services rendered by employees and a reliable estimate of the obligation can be made. Liabilities for bonus plans are expected to be settled within 12 months and are measured at the amounts expected to be paid when they are settled.

34.9 Government grants

Government grants are recognized at their fair value where there is a reasonable assurance that the grant will be received and the Group will comply with all the attached conditions.

Government grants relating to costs are deferred and recognized in consolidated statements of comprehensive loss over the period necessary to match them with the costs that they are intended to compensate.

Government grants relating to property, plant and equipment are included in non-current liabilities as deferred income and are credited to consolidated statements of comprehensive loss over the estimated useful lives of the related assets using the straight-line method.

34.10 Leases as lessee

The Group leases various properties. Rental contracts are typically made for fixed periods of 1 to 2 years. Lease terms are negotiated on an individual basis and contain a wide range of different terms and conditions. The lease agreements do not impose any covenants, but leased assets may not be used as security for borrowing purposes.

Leases are recognized as a right-of-use asset and a corresponding liability at the date at which the leased asset is available for use by the Group. Each lease payment is allocated between the liability and finance cost. The finance cost is charged to consolidated statements of comprehensive loss over the lease period so as to produce a constant periodic rate of interest on the remaining balance of the liability for each period. The right-of-use asset is depreciated over the shorter of the asset's useful life and the lease term on a straight-line basis.

Assets and liabilities arising from a lease are initially measured on a present value basis. Lease liabilities include the net present value of the following lease payments:

- fixed payments (including in-substance fixed payments), less any lease incentives receivable; and
- the lease payments are discounted using the interest rate implied in the lease, if that rate can be determined, or the respective incremental borrowing rate.

Right-of-use assets are measured at cost comprising the following:

- the amount of the initial measurement of lease liabilities;
- payments associated with short-term leases are recognized on a straight-line basis as an expense in consolidated statements of comprehensive loss. Short-term leases are leases with a lease term of 12 months or less.

III SUBSEQUENT FINANCIAL STATEMENTS

No audited financial statements have been prepared for the Company or any of the companies comprising the Group in respect of any period subsequent to 30 September 2024 and up to the date of this report. No dividend or distribution has been declared, made or paid by the Company or any of the companies comprising the Group in respect of any period subsequent to 30 September 2024.

[**REDACTED**]

[**REDACTED**]

[**REDACTED**]

[**REDACTED**]

[**REDACTED**]

Set out below is a summary of certain provisions of the constitution of the Company and certain aspects of the company laws of the Cayman Islands.

The Company was incorporated in the Cayman Islands as an exempted company with limited liability on July 3, 2019 under the Companies Act. The Company's constitutional documents consist of the Memorandum of Association and the Articles of Association.

1. MEMORANDUM OF ASSOCIATION

The Memorandum provides, *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 therefore include acting as an investment holding company) and that 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.

2. ARTICLES OF ASSOCIATION

The Articles were conditionally adopted on [●] and will become effective on the [**REDACTED**]. A summary of certain provisions of the Articles is set out below.

2.1 Shares

(a) Classes of Shares

The share capital of the Company consists of a single class of ordinary shares.

(b) 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 of Shares 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 with the consent in writing of the holders of at least three-fourths of the issued Shares of that class, or with the approval of a resolution passed by at least three-fourths of the votes cast by the holders of the Shares of that class present and voting in person (whether physically or by virtual attendance with the use of technology) or by proxy at a separate meeting of such holders. The provisions of the Articles relating to general meetings shall apply *mutatis mutandis* to every such separate meeting, except that the necessary quorum shall be two persons together holding (or, in the case of a member being a corporation, by its duly authorised representative), or representing by proxy, at least one-third of the issued Shares of that class. Every holder of Shares of the class shall be entitled on a poll to one vote for every such Share held by him, and any holder of Shares of the class present in person (whether physically or by virtual attendance with the use of technology), or, by proxy may demand a poll.

For the purposes of a separate class meeting, the Board may treat two or more classes of Shares as forming one class of Shares if the Board considers that such classes of Shares would be affected in the same way by the proposals under consideration, but in any other case shall treat them as separate classes of Shares.

Any rights conferred upon the holders of Shares of any class shall not, unless otherwise expressly provided in the rights attaching to 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.

(c) Alteration of Capital

The Company may by ordinary resolution:

(i) increase its share capital by the creation of new Shares of such amount and with such rights, priorities and privileges attached to such Shares as it may determine;

(ii) consolidate and divide all or any of its share capital into Shares of a larger amount than its existing Shares. On any consolidation of fully paid Shares and division into Shares of a larger amount, the Board may settle any difficulty which may arise as it thinks 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 a 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 Board for that purpose and the person so appointed may transfer the Shares so sold to the purchaser(s) thereof and the validity of such transfer shall not be questioned, and 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;

(iii) sub-divide its Shares or any of them into Shares of an amount smaller than that fixed by the Memorandum; and

(iv) cancel any Shares which, as at the date of passing of the 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 cancelled.

The Company may by special resolution reduce its share capital or any undistributable reserve, subject to the provisions of the Companies Act.

(d) Transfer of Shares

Subject to the terms of the Articles, any member of the Company may transfer all or any of his Shares by an instrument of transfer. If the Shares in question were issued in conjunction with rights, options, warrants or units issued pursuant to the Articles on terms that one cannot be transferred without the other, the Board shall refuse to register the transfer of any such Share without evidence satisfactory to it of the like transfer of such right, option, warrant or unit.

Subject to the Articles and the requirements of the Stock Exchange, all transfers of Shares shall be effected by an instrument of transfer in the usual or common form or in such other form as the Board may approve and may be under hand or, if the transferor or transferee is a recognised clearing house or its nominee(s), under hand or by machine imprinted signature, or by such other manner of execution as the Board may approve from time to time.

Execution of the instrument of transfer shall be by or on behalf of the transferor and the transferee, provided that the Board may dispense with the execution of the instrument of transfer by the transferor or transferee or accept mechanically executed transfers. The transferor shall be deemed to remain the holder of a Share until the name of the transferee is entered in the register of members of the Company in respect of that Share.

Subject to the provisions of the Companies Act, if the Board considers it necessary or appropriate, the Company may establish and maintain a branch register or registers of members at such location or locations within or outside the Cayman Islands as the Board thinks fit. The Board may, in its absolute discretion, at any time transfer any Share on the principal register to any branch register or any Share on any branch register to the principal register or any other branch register.

The Board may, in its absolute discretion, decline to register a transfer of any Share (not being a fully paid Share) to a person of whom it does not approve or on which the Company has a lien, or a transfer of any Share issued under any share option scheme upon which a restriction on transfer subsists or a transfer of any Share to more than four joint holders. It may also decline to recognise any instrument of transfer if the proposed transfer does not comply with the Articles or any requirements of the Listing Rules.

The Board may decline to recognise any instrument of transfer unless a certain fee, up to such maximum sum as the Stock Exchange may determine to be payable, is paid to the Company, the instrument of transfer is properly stamped (if applicable), is in respect of only one class of Share and is lodged at the relevant registration office or the place at which the principal register is located accompanied by the relevant share certificate(s) and such other evidence as the Board may reasonably require is provided to show the right of the transferor to make the transfer (and if the instrument of transfer is executed by some other person on his behalf, the authority of that person so to do).

The register of members may, subject to the Listing Rules and the relevant section of the Companies Ordinance, be closed at such time or for such period not exceeding in the whole 30 days in each year as the Board may determine (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).

Fully paid Shares shall be free from any restriction on transfer (except when permitted by the Stock Exchange) and shall also be free from all liens.

(e) Redemption of Shares

Subject to the provisions of the Companies Act, the Listing Rules and any rights conferred on the holders of any Shares or attaching to any class of Shares, the Company may issue Shares that are to be redeemed or are liable to be redeemed at the option of the members or the Company. The redemption of such Shares shall be effected in such manner and upon such other terms as the Company may by special resolution determine before the issue of such Shares.

(f) Power of the Company to Purchase its own Shares

Subject to the Companies Act, or any other law or so far as not prohibited by any law and subject to any rights conferred on the holders of any class of Shares, the Company shall have the power to purchase or otherwise acquire all or any of its own Shares (which includes redeemable Shares), provided that the manner and terms of purchase have first been authorised by ordinary resolution and that any such purchase shall only be made in accordance with the relevant code, rules or regulations issued from time to time by the Stock Exchange and/or the Securities and Futures Commission of Hong Kong from time to time in force.

(g) Power of any Subsidiary of the Company to own Shares in the Company

There are no provisions in the Articles relating to the ownership of Shares in the Company by a subsidiary.

(h) Calls on Shares and Forfeiture of Shares

Subject to the terms of allotment and issue of any Shares (if any), the Board may, from time to time, make such calls as it thinks fit upon the members in respect of any monies unpaid on the Shares held by them (whether in respect of par value or share premium). A member who is the subject of the call shall (subject to receiving at least 14 clear days' notice specifying the time or times for payment) pay to the Company at the time or times so specified the amount called on his Shares. A call may be made payable either in one sum or by instalments, and shall be deemed to have been made at the time when the resolution of the Board authorising such call was passed. The joint holders of a Share shall be severally as well as jointly liable for the payment of all calls and instalments due in respect of such Share.

If a call remains unpaid after it has become due and payable, the member from whom the sum is due shall pay interest on the unpaid amount at such rate as the Board shall determine (together with any expenses incurred by the Company as a result of such non-payment) from the day it became due and payable until it is paid, but the Board may waive payment of such interest or expenses in whole or in part.

If a member fails to pay any call or instalment of a call after it has become due and payable, the Board may, for so long as any part of the call or instalment remains unpaid, give to such member not less than 14 clear days' notice requiring payment of the unpaid amount together with any interest which may have accrued and which may still accrue up to the date of payment (together with any expenses incurred by the Company as a result of such non-payment). The notice shall specify a further day on or before which the payment required by the notice is to be made. The notice shall also state that, in the event of non-payment at or before the appointed time, 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 the notice was given may, before the payment required by the notice has been made, be forfeited by a resolution of the Board. Such forfeiture shall include all dividends, other distributions and other monies payable in respect of the forfeited Share and not paid before the forfeiture.

A person whose Shares have been forfeited shall cease to be a member in respect of the forfeited Shares, shall surrender to the Company for cancellation the certificate(s) for the Shares forfeited and shall remain liable to pay to the Company all monies which, as at the date of forfeiture, were payable by him to the Company in respect of the Shares together with (if the Board shall in its discretion so require) interest thereon from the date of forfeiture until the date of payment as the Board may determine and any expenses incurred by the Company as a result of such non-payment.

2.2 Directors

(a) Appointment, Retirement and Removal

The Company may by ordinary resolution of the members elect any person to be a Director. The Board may also appoint any person to be a Director at any time, either to fill a casual vacancy or as an additional Director subject to any maximum number fixed by the members in general meeting or the Articles. Any Director so appointed shall hold office only until the first annual general meeting of the Company after his appointment and shall then be eligible for re-election at such meeting. Any Director so appointed by the Board shall not be taken into account in determining the Directors or the number of Directors who are to retire by rotation at an annual general meeting.

There is no shareholding qualification for Directors nor is there any specified age limit for Directors.

The members may by ordinary resolution remove any Director (including a managing or executive Director) before the expiration of his term of office, notwithstanding anything in the Articles or any agreement between the Company and such Director, and may by ordinary resolution elect another person in his stead. Nothing shall be taken as depriving a Director so removed of any 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 office of a Director shall be vacated if:

(i) the Director gives notice in writing to the Company that he resigns from his office as Director;

(ii) the Director is absent, 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 Board, and the Board passes a resolution that he has by reason of such absence vacated his office;

(iii) the Director becomes bankrupt or has a receiving order made against him or suspends payment or compounds with his creditors generally;

(iv) the Director dies or an order is made by any competent court or official on the grounds that he is or may be suffering from mental disorder or is otherwise incapable of managing his affairs and the Board resolves that his office be vacated;

(v) the Director is prohibited from being or ceases to be a Director by operation of law;

(vi) the Director has been required by the Stock Exchange to cease to be a Director or no longer qualifies to be a Director pursuant to the Listing Rules; or

(vii) the Director is removed from office by notice in writing served upon him 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 (including himself) then in office.

At each annual general meeting, one-third of the Directors for the time being shall retire from office by rotation. If the number of Directors is not a multiple of three, then the number nearest to but not less than one-third shall be the number of retiring Directors, provided that every Director shall be subject to retirement by rotation at least once every three years. The Directors to retire at each annual general meeting shall be those who have been in office longest since their last re-election or appointment and, as between persons who became or were last re-elected Directors on the same day, those to retire shall (unless they otherwise agree among themselves) be determined by lot.

(b) Power to Allot and Issue Shares and other Securities

Subject to the provisions of the Companies Act, the Memorandum and Articles and, where applicable, the Listing Rules, and without prejudice to any rights or restrictions for the time being attached to any Shares, the Board may allot, issue, grant options over or otherwise dispose of Shares with or without preferred, deferred or other rights or restrictions, whether with regard to dividend, voting, return of capital or otherwise, to such persons, at such times, for such consideration and on such terms and conditions as it in its absolute discretion thinks fit, provided that no Shares shall be issued at a discount to their par value.

The Company may issue rights, options, warrants or convertible securities or securities of a similar nature conferring the right upon the holders thereof to subscribe for, purchase or receive any class of Shares or other securities in the Company on such terms as the Board may from time to time determine.

Neither the Company nor the Board shall be obliged, when making or granting any allotment of, offer of, option over or disposal of Shares, to make, or make available, any such allotment, offer, option or Shares to members or others whose registered addresses are in any particular territory or territories where, in the absence of a registration statement or other special formalities, this is or may, in the opinion of the Board, be unlawful or impracticable. However, no member affected as a result of the foregoing shall be, or be deemed to be, a separate class of members for any purpose whatsoever.

(c) Power to Dispose of the Assets of the Company or any of its Subsidiaries

Subject to the provisions of the Companies Act, the Memorandum and Articles and any directions given by special resolution of the Company, the Board may exercise all powers and do all acts and things which may be exercised or done by the Company to dispose of the assets of the Company or any of its subsidiaries. No alteration to the Memorandum or Articles and no direction given by special resolution of the Company shall invalidate any prior act of the Board which would have been valid if such alteration or direction had not been made or given.

(d) Borrowing Powers

The Board may exercise all the powers of the Company to raise or borrow money, secure the payment of any sum or sums of money for the purposes of the Company, mortgage or charge all or any part of its undertaking, property and uncalled capital of the Company, and, subject to the Companies Act, issue debentures, debenture stock, bonds and other securities, whether outright or as collateral security for any debt, liability or obligation of the Company or of any third party.

(e) Remuneration

A Director shall be entitled to receive such sums as shall from time to time be determined by the Board or the Company in general meetings. The Directors shall also be entitled to be repaid all expenses reasonably incurred by them in connection with attendance at meetings of the Board or committees of the Board, 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 and the discharge of their duties as Directors, and/or to receive fixed allowances in respect thereof as may be determined by the Board.

The Board or the Company in general meetings may also approve additional remuneration to any Director for any services which in the opinion of the Board or the Company in general meetings go beyond such Director's ordinary routine work as a Director.

(f) Compensation or Payments for Loss of Office

There are no provisions in the Articles relating to compensation or payment for loss of office.

(g) Loans to Directors

There are no provisions in the Articles relating to making of loans to Directors.

(h) Disclosure of Interest in Contracts with the Company or any of its Subsidiaries

With the exception of the office of auditor of the Company, a Director may hold any other office or place of profit with the Company in conjunction with his office of Director for such period and upon such terms as the Board may determine, and may be paid such extra remuneration for that other office or place of profit, in whatever form, in addition to any remuneration provided for by or pursuant to the Articles. A Director may be or become a director, officer or member of any other company in which the Company may be interested, and shall not be liable to account to the Company or the members for any remuneration or other benefits received by him as a director, officer or member of such other company.

No person shall be disqualified from the office of Director or alternate Director or prevented by such office from contracting with the Company, nor shall any such contract or any other contract or transaction entered into by or on behalf of the Company in which any Director or alternate Director is 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 such office or of the fiduciary relationship established by it, provided that the nature of interest of any Director or alternate Director in any such contract or transaction shall be disclosed by such Director or alternate Director at or prior to the consideration and vote thereon.

A Director shall not vote on (or be counted in the quorum in relation to) any resolution of the Board in respect of any contract or arrangement or other proposal in which he or any of his close associate(s) has/have a material interest, and if he shall do so his vote shall not be counted and he shall not be counted in the quorum for such resolution. This prohibition shall not apply to any of the following matters:

(i) the giving of any security or indemnity to the Director or his close associate(s) 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 his close associate(s) has/have himself/themselves assumed responsibility in whole or in part 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 his close associate(s) 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 the adoption, modification or operation of (A) any employees' share scheme or any share incentive or share option scheme under which the Director or his close associate(s) may benefit or (B) any 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 his close associate(s) 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 his close associate(s) is/are interested in the same manner as other holders of Shares, debentures or other securities of the Company by virtue only of his/their interest in those Shares, debentures or other securities.

2.3 Proceedings of the Board

The Board may meet anywhere in the world for the despatch of business and may adjourn and otherwise regulate its meetings as it thinks fit. Unless otherwise determined, two Directors shall be a quorum. Questions arising at any meeting shall be determined by a majority of votes. In the case of an equality of votes, the chairman of the meeting shall have a second or casting vote.

2.4 Alterations to the Constitutional Documents and the Company's Name

The Memorandum and Articles may only be altered or amended, and the name of the Company may only be changed, by special resolution of the Company.

2.5 Meetings of Members

(a) Special and Ordinary resolutions

A special resolution must be passed by a majority of not less than two-thirds (other than in relation to any resolution approving changes to the Company's constitutional documents or a voluntary winding up of the Company, in which case a special resolution must be passed by a majority of not less than three-fourths) of the voting rights held by such members as, being entitled so to do, vote in person (whether physically or by virtual attendance with the use of technology), or by proxy or, in the case of any members which is a corporation, by its duly authorised representative(s) or by proxy, at a general meeting of which notice specifying the intention to propose the resolution as a special resolution has been duly given. A special resolution may also be approved in writing by all the members entitled to vote at a general meeting in one or more instruments each signed by one or more of such members.

An ordinary resolution, in contrast, is a resolution passed by a simple majority of the voting rights held by such members as, being entitled to do so, vote in person (whether physically or by virtual attendance with the use of technology), or by proxy or, in the case of any member which is a corporation, by its duly authorised representative(s) or by proxy, at a general meeting. An ordinary resolution may also be approved in writing by all the members entitled to vote at a general meeting in one or more instruments each signed by one or more of such members.

The provisions of special resolutions and ordinary resolutions shall apply *mutatis mutandis* to any resolutions passed by the holders of any class of shares.

(b) Voting Rights and Right to Demand a Poll

Subject to any rights, restrictions or privileges as to voting for the time being attached to any class or classes of Shares, at any general meeting: (a) on a poll every member present in person (whether physically or by virtual attendance with the use of technology), or, in the case of a member being a corporation, by its duly authorised representative or by proxy shall have one vote for every Share and (b) on a show of hands every member who is present in person (whether physically or by virtual attendance with the use of technology), or, in the case of a member being a corporation, by its duly authorised representative or by proxy shall have one vote. For the avoidance of doubt, votes may be cast by members by electronic means.

In the case of joint holders, the vote of the senior holder who tenders a vote, whether in person or by proxy shall be accepted to the exclusion of the votes of the other join 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.

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 the relevant Shares have been paid.

At any general meeting a resolution put to the vote of the meeting shall be decided by way of poll save that the chairman of the meeting may, pursuant to the Listing Rules, allow a resolution which relates purely to a procedural or administrative matter to be voted on by a show of hands (whether physically or by virtual attendance with the use of technology).

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 or by power of attorney, 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 or other non-natural person could exercise as if it were a natural person member of the Company.

If a recognised clearing house or its nominee(s) is a member of the Company, it may appoint proxies or authorise such person or persons as it thinks fit to act as its representative(s), who enjoy rights equivalent to the rights of other members, at any meeting of the Company (including but not limited to general meetings and creditors meetings) or at any meeting of any class of members of the Company, provided that if more than one person is so authorised, the authorisation shall specify the number and class of Shares in respect of which each such person is so authorised. A person so authorised shall be entitled to exercise the same rights and powers on behalf of the recognised clearing house or its nominee(s) as if such person were a natural person member of the Company, including the right to speak and vote individually on a show of hands or on a poll (whether physically or by virtual attendance with the use of technology).

All members of the Company (including a member which is a recognised clearing house (or its nominee(s))) shall have the right to (i) speak at a general meeting and (ii) and vote at a general meeting (whether physically or virtual attendance with the use of technology), except where a member is required by the Listing Rules to abstain from voting to approve the matter under consideration. 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.

(c) Annual General Meetings and Extraordinary General Meetings

The Company must hold a general meeting as its annual general meeting in each financial year. Such meeting shall be specified as such in the notices calling it, and must be held within six months after the end of the Company's financial year. A meeting of the members or any class thereof may be held by telephone, tele-conferencing or other electronic means, provided that all participants can attend the meeting virtually with the use of technology and are able to communicate contemporaneously with one another, and participation in a meeting in such manner shall constitute presence at such meetings.

The Board may convene an extraordinary general meeting whenever it thinks fit. In addition, one or more members holding, as at the date of deposit of the requisition, in aggregate not less than one-tenth of the voting rights (on a one vote per Share basis) in the share capital of the Company may make a requisition to convene an extraordinary general meeting and/or add resolutions to the agenda of a meeting. Such requisition, which must state the objects and the resolutions to be added to the agenda of the meeting and must be signed by the requisitionists, shall be deposited at the principal place of business of the Company in Hong Kong or, in the event the Company ceases to have such a principal place of business, the registered office of the Company. If the Board does not within 21 days from the date of deposit of such requisition duly proceed to convene a general meeting to be held within the following 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 such meeting so convened shall be held no later than the day falling 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 the Board, and all reasonable expenses incurred by the requisitionists shall be reimbursed to the requisitionists by the Company.

(d) Notices of Meetings and Business to be Conducted

An annual general meeting of the Company shall be called by at least 21 days' notice in writing, and any other general meeting of the Company shall be called by at least 14 days' notice in writing. The notice 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, and must specify the date, time, place and agenda of the meeting, the particulars of the resolution(s) to be considered at the meeting, the general nature of the business to be considered at the meeting and details for members to attend the meeting virtually with the use of technology.

Except where otherwise expressly stated, any notice or document (including a share certificate) to be given or issued under the Articles shall be in writing, and may be served by the Company on any member personally, by post to such member's registered address, (to the extent permitted by the Listing Rules and all applicable laws and regulations) by electronic means or (in the case of a notice) by advertisement published in the manner prescribed under the Listing Rules and all applicable laws, rules and regulations, or by sending or otherwise making it available to the relevant person through such other means, whether electronically or otherwise, to the extent permitted by and in accordance with the Listing Rules and all applicable laws, rules and regulations.

Notwithstanding that a meeting of the Company is called by shorter notice than as specified above, if permitted by the Listing Rules, such meeting may be deemed to have been duly called if it is so agreed:

(i) in the case of an annual general meeting, by all members of the Company entitled to attend and vote thereat; and

(ii) 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 holding not less than 95% of the total voting rights held by such members.

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 Board in its 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, it may change or postpone the meeting to another date, time and place.

The Board also has the power to provide in every notice calling a general meeting that in the event of a gale warning, a black rainstorm warning or extreme conditions is/are in force at any time on the day of the general meeting (unless such warning is cancelled at least a minimum period of time prior to the general meeting as the Board 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, a black rainstorm warning or extreme conditions being in force on the day of the general meeting;

(B) the Board shall determine the date, time, place and details for members to attend virtually with the use of technology for the reconvened meeting and at least seven clear days' notice shall be given for the reconvened meeting. Such notice shall specify the date, time and place at which the postponed meeting will be reconvened, details for members to attend such postponed meeting virtually with the use of technology 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 considered at the reconvened meeting, and notice given for the reconvened meeting does not need to specify the business to be considered at the reconvened meeting, nor shall any accompanying documents be required to be recirculated. Where any new business is to be considered at such reconvened meeting, the Company shall give a fresh notice for such reconvened meeting in accordance with the Articles.

(e) Quorum for Meetings and Separate Class Meetings

No business shall be considered at any general meeting unless a quorum is present when the meeting proceeds to business, and continues to be present until the conclusion of the meeting.

The quorum for a general meeting shall be two members present in person (whether physically or by virtual attendance with the use of technology), or in the case of a member being a corporation, by its duly authorised representative or by proxy and entitled to vote. In respect of a separate class meeting (other than an adjourned meeting) convened to approve the variation of class rights, the necessary quorum shall be two persons holding or representing by proxy not less than one-third of the issued Shares of that class.

(f) Proxies

Any member of the Company (including a member which is a recognised clearing house (or its nominee(s))) entitled to attend and vote at a meeting of the Company is entitled to appoint another person (being a natural person) as his proxy to attend and vote in his place. A member who is the holder of two or more Shares may appoint more than one proxy to represent him and vote on his behalf at a general meeting of the Company or at a class meeting. A proxy need not be a member of the Company and shall be entitled to exercise the same powers on behalf of a member who is a natural person and for whom he acts as proxy as such member could exercise. In addition, a proxy shall be entitled to exercise the same powers on behalf of a member which is a corporation and for which he acts as proxy as such member could exercise as if it were a natural person member present in person (whether physically or by virtual attendance with the use of technology) at any general meeting. On a poll or on a show of hands, votes may be given either personally (or, in the case of a member being a corporation, by its duly authorised representative) or by proxy.

The instrument appointing a proxy shall be in writing and 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, either under its seal or under the hand of a duly authorised representative.

The Board shall, in the notice convening any meeting or adjourned meeting, or in an instrument of proxy sent out by the Company, specify the manner by which the instrument appointing a proxy shall be deposited and the place and time (being no later than the time appointed for the commencement of the meeting or adjourned meeting to which the instrument of proxy relates) at which such instrument shall be deposited.

Every instrument of proxy, whether for a specified meeting or otherwise, shall be in such form that complies with the Listing Rules as the Board may from time to time approve. Any form issued to a member for appointing a proxy to attend and vote at a general meeting at which any business is to be considered shall be such as to enable the member, according to his intentions, to instruct the proxy to vote in favour of or against (or, in default of instructions, to exercise the discretion of the proxy in respect of) each resolution dealing with any such business.

2.6 Accounts and Audit

The Board shall cause to be 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 in accordance with the Companies Act.

The books of accounts of the Company shall be kept at the principal place of business of the Company in Hong Kong or, subject to the provisions of the Companies Act, at such other place or places as the Board thinks fit and shall always be open to inspection by any Director. No member (not being a Director) or other person shall have any right to inspect any account, book or document of the Company except as conferred by the Companies Act or ordered by a court of competent jurisdiction or as authorised by the Board or the Company in general meeting.

The Board shall cause to be prepared and 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 and the Listing Rules.

The members shall at each annual general meeting appoint auditor(s) to hold office by ordinary resolution of the members until the conclusion of the next annual general meeting on such terms and with such duties as may be agreed with the Board. The auditors' remuneration shall be fixed by the members at the annual general meeting at which they are appointed by ordinary resolution of the members or in any other manner as specified in such ordinary resolution. The members may, at any general meeting convened and held in accordance with the Articles, remove the auditors by ordinary resolution at any time before the expiration of the term of office and shall, by ordinary resolution, at that meeting appoint new auditors in their place for the remainder of the term.

The accounts of the Company shall be prepared and audited based on the generally accepted accounting principles of Hong Kong, the International Accounting Standards or such other standards as may be permitted by the Stock Exchange.

2.7 Dividends and other Methods of Distribution

Subject to the Companies Act and the Articles, the Company may by ordinary resolution resolve to declare dividends and other distributions on Shares in issue in any currency and authorise payment of the dividends or distributions out of the funds of the Company lawfully available therefor, provided that (i) no dividends shall exceed the amount recommended by the Board, and (ii) no dividends or distributions shall be paid except out of the realised or unrealised profits of the Company, out of the share premium account or as otherwise permitted by law.

The Board may from time to time pay to the members of the Company such interim dividends as appear to the Board to be justified by the financial conditions and the profits of the Company. In addition, the Board may from time to time declare and pay special dividends on Shares of such amounts and on such dates as it thinks 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 the period in respect of which the dividends and distributions are paid. No amount paid up on a Share in advance of calls shall for this purpose be treated as paid up on the Share.

The Board may deduct from any dividends or other distributions payable to any member of the Company all sums of money (if any) then payable by him to the Company on account of calls or otherwise. The Board may retain any dividends or distributions 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 dividends or other distributions payable by the Company on or in respect of any Share shall carry interest against the Company.

Where the Board or the Company in general meeting has resolved that a dividend should be paid or declared, the Board may further resolve:

(a) that such dividend be satisfied in whole or in part in the form of an allotment of Shares credited as fully paid on the basis that the Shares so allotted shall be of the same class as the class already held by the allottee, provided that the members 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 entitled to such dividend will be entitled to elect to receive an allotment of Shares credited as fully paid in lieu of the whole or such part of the dividend as the Board may think fit on the basis that the Shares so allotted shall be of the same class as the class already held by the allottee.

Upon the recommendation of the Board, the Company may by ordinary resolution resolve in respect of any one particular dividend of the Company determine 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 to elect to receive such dividend in cash in lieu of such allotment.

Any dividends, distributions or other monies payable in cash in respect of Shares may be paid by wire transfer to the holder of such Shares or by cheque or warrant sent by post to the registered address of such 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. Any one of two or more joint holders may give effectual receipts for any dividends, distributions or other monies payable in respect of the Shares held by them as joint holders.

Whenever the Board or the Company in general meeting has resolved that a dividend be paid or declared, the Board may further resolve that such dividend be satisfied in whole or in part by the distribution of specific assets of any kind.

Any dividends or other distributions which remain unclaimed for six years from the date on which such dividends or distributions become payable shall be forfeited and shall revert to the Company.

2.8 Inspection of Corporate Records

For so long as any part of the share capital of the Company is [**REDACTED**] on the Stock Exchange, any member may inspect any register of members of the Company maintained in Hong Kong (except when the register of members is closed in accordance with the Companies Ordinance) without charge and require the provision to him of copies or extracts of such register in all respects as if the Company were incorporated under and were subject to the Companies Ordinance.

2.9 Rights of Minorities in relation to Fraud or Oppression

There are no provisions in the Articles concerning the rights of minority members in relation to fraud or oppression. However, certain remedies may be available to members of the Company under the Cayman Islands laws, as summarised in paragraph 3.6 below.

2.10 Procedures on Liquidation

Subject to the Companies Act, the members of the Company may by special resolution resolve to wind up the Company voluntarily or by the court.

Subject to any rights, privileges or restrictions as to the distribution of available surplus assets on liquidation for the time being attached to any class or classes of Shares:

(a) if the assets available for distribution among the members of the Company are 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 *pari passu* among such members in proportion to the amount paid up on the Shares held by them at the commencement of the winding up; and

(b) if the assets available for distribution among the members of the Company are 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 in proportion to the capital paid up, or ought to be paid up, on the Shares held by them at the commencement of the winding up.

If the Company is wound up (whether the liquidation is voluntary or compelled by the court), the liquidator may, with the approval of a special resolution and any other approval required by the Companies Act, divide among the members in kind the whole or any part of the assets of the Company, whether the assets consist of property of one kind or different kinds, and the liquidator may, for such purpose, set such value as he deems fair upon any one or more class or classes of property to be so divided and may determine how such division shall be carried out as between the members or different classes of members and the members within each class. The liquidator may, with the like approval, vest any part of the assets in trustees upon such trusts for the benefit of the members as the liquidator thinks fit, provided that no member shall be compelled to accept any shares or other property upon which there is a liability.

3. COMPANY LAWS OF THE CAYMAN ISLANDS

The Company was incorporated in the Cayman Islands as an exempted company on 3 July 2019 subject to the Companies Act. Certain provisions of the company laws of the Cayman Islands are set out below but this section does not purport to contain all applicable qualifications and exceptions or to be a complete review of all matters of the company laws of the Cayman Islands, which may differ from equivalent provisions in jurisdictions with which interested parties may be more familiar.

3.1 Company Operations

An exempted company such as the Company must conduct its operations mainly outside the Cayman Islands. An exempted company is also 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 amount of its authorised share capital.

3.2 Share Capital

Under the Companies Act, a Cayman Islands company may issue ordinary, preference or redeemable shares or any combination thereof. Where a company issues shares at a premium, whether for cash or otherwise, a sum equal to the aggregate amount or value of the premium on those shares shall be transferred to an account, to be called the share premium account. At the option of a company, these provisions may not apply to premium on shares of that company allotted pursuant to any arrangements in consideration of the acquisition or cancellation of shares in any other company and issued at a premium. The share premium account may be applied by the 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, the following:

(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) any manner provided in section 37 of the Companies Act;

(d) writing-off the preliminary expenses of the company; and

(e) writing-off the expenses of, or the commission paid or discount allowed on, any issue of shares or debentures of the company.

Notwithstanding the foregoing, 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.

Subject to confirmation by the court, a company limited by shares or a company limited by guarantee and having a share capital may, if authorised to do so by its articles of association, by special resolution reduce its share capital in any way.

3.3 Financial Assistance to Purchase Shares of a Company or its Holding Company

There are no statutory prohibitions in the Cayman Islands on the granting of financial assistance by a company to another person for the purchase of, or subscription for, its own, its holding company's or a subsidiary's shares. Therefore, a company may provide financial assistance provided the directors of the company, when proposing to grant such financial assistance, discharge their duties of care and act in good faith, for a proper purpose and in the interests of the company. Such assistance should be on an arm's-length basis.

3.4 Purchase of Shares and Warrants by a Company and its Subsidiaries

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 member and, for the avoidance of doubt, it shall be lawful for the rights attaching to any shares to be varied, subject to the provisions of the company's articles of association, so as to provide that such shares are to be or are liable to be so redeemed. In addition, such a company may, if authorised to do so by its articles of association, purchase its own shares, including any redeemable shares; an ordinary resolution of the company approving the manner and terms of the purchase will be required if the articles of association do not authorise the manner and terms of such purchase. A company may not redeem or purchase its shares unless they are fully paid. Furthermore, 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 issued shares of the company other than shares held as treasury shares. In addition, 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.

Shares that have been purchased or redeemed by a company or surrendered to the company shall not be treated as cancelled but shall be classified as treasury shares if held in compliance with the requirements of section 37A(1) of the Companies Act. Any such shares shall continue to be classified as treasury shares until such shares are either cancelled or transferred pursuant to the Companies Act.

A Cayman Islands company may be able to purchase its own warrants subject to and in accordance with the terms and conditions of the relevant warrant instrument or certificate. Thus there is no requirement under the Cayman Islands laws that a company's memorandum or articles of association contain a specific provision enabling such purchases. The directors of a company may under the general power contained in its memorandum of association be able to buy, sell and deal in personal property of all kinds.

A subsidiary may hold shares in its holding company and, in certain circumstances, may acquire such shares.

3.5 Dividends and Distributions

Subject to a solvency test, as prescribed in the Companies Act, and the provisions, if any, of the company's memorandum and articles of association, a company may pay dividends and distributions out of its share premium account. In addition, based upon English case law which is likely to be persuasive in the Cayman Islands, dividends may be paid out of profits.

For so long as a company holds treasury shares, no dividend may be declared or paid, and no other distribution (whether in cash or otherwise) of the company's assets (including any distribution of assets to members on a winding up) may be made, in respect of a treasury share.

3.6 Protection of Minorities and Shareholders' Suits

It can be expected that the Cayman Islands courts will ordinarily follow English case law precedents (particularly the rule in the case of *Foss vs. Harbottle* and the exceptions to that rule) which permit a minority member to commence a representative action against or derivative actions in the name of the company to challenge acts which are ultra vires, illegal, fraudulent (and performed by those in control of the Company) against the minority, or represent an irregularity in the passing of a resolution which requires a qualified (or special) majority which has not been obtained.

Where a company (not being a bank) is one which has a share capital divided into shares, the court 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 the affairs of the company and, at the direction of the court, to report on such affairs. In addition, any member of a company may petition the court, 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.

In general, claims against a company by its members must be based on the general laws of contract or tort applicable in the Cayman Islands or be based on potential violation of their individual rights as members as established by a company's memorandum and articles of association.

3.7 Disposal of Assets

There are no specific restrictions on the power of directors to dispose of assets of a company, however, the directors are expected to exercise certain duties of care, diligence and skill to the standard that a reasonably prudent person would exercise in comparable circumstances, in addition to fiduciary duties to act in good faith, for proper purpose and in the best interests of the company under English common law (which the Cayman Islands courts will ordinarily follow).

3.8 Accounting and Auditing Requirements

A company must cause proper records of accounts to be kept with respect to: (i) all sums of money received and expended by it; (ii) all sales and purchases of goods by it; and (iii) its assets and liabilities.

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.

If a company keeps its books of account at any place other than at its registered office or any other place within the Cayman Islands, it shall, upon service of an order or notice by the Tax Information Authority pursuant to the Tax Information Authority Act (2021 Revision) of the Cayman Islands, make available, in electronic form or any other medium, at its registered office copies of its books of account, or any part or parts thereof, as are specified in such order or notice.

3.9 Exchange Control

There are no exchange control regulations or currency restrictions in effect in the Cayman Islands.

3.10 Taxation

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 for certain stamp duties which may be applicable, from time to time, on certain instruments.

3.11 Stamp Duty on Transfers

No stamp duty is payable in the Cayman Islands on transfers of shares of Cayman Islands companies save for those which hold interests in land in the Cayman Islands.

3.12 Loans to Directors

There is no express provision prohibiting the making of loans by a company to any of its directors. However, the company's articles of association may provide for the prohibition of such loans under specific circumstances.

3.13 Inspection of Corporate Records

The members of a company have no general right 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.

3.14 Register of Members

A Cayman Islands exempted company may maintain its principal register of members and any branch registers in any country or territory, whether within or outside the Cayman Islands, as the company may determine from time to time. There is no requirement for an exempted company to make any returns of members to the Registrar of Companies in 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. However, an exempted company shall make available at its registered office, in electronic form or any other medium, such register of members, including any branch register of member, as may be required of it upon service of an order or notice by the Tax Information Authority pursuant to the Tax Information Authority Act (2021 Revision) of the Cayman Islands.

3.15 Register of Directors and Officers

Pursuant to the Companies Act, the Company is required to maintain at its registered office a register of directors, alternate directors and officers. The Registrar of Companies shall make available the list of the names of the current directors of the Company (and, where applicable, the current alternate directors of the Company) for inspection by any person upon payment of a fee by such person. A copy of the register of directors and officers must be filed with the Registrar of Companies in the Cayman Islands, and any change must be notified to the Registrar of Companies within 30 days of any change in such directors or officers, including a change of the name of such directors or officers.

3.16 Winding up

A Cayman Islands company may be wound up by: (i) an order of the court; (ii) voluntarily by its members; or (iii) under the supervision of the court.

The court has authority to order winding up in a number of specified circumstances including where, in the opinion of the court, it is just and equitable that such company be so wound up.

A voluntary winding up of a company (other than a limited duration company, for which specific rules apply) occurs where the company resolves by special resolution that it be wound up voluntarily or where the company in general meeting resolves that it be wound up voluntarily because it is unable to pay its debt as they fall due. In the case of a voluntary winding up, the company is obliged to cease to carry on its business from the commencement of its winding up except so far as it may be beneficial for its winding up. Upon appointment of a voluntary liquidator, all the powers of the directors cease, except so far as the company in general meeting or the liquidator sanctions their continuance.

In the case of a members' voluntary winding up of a company, one or more liquidators are appointed for the purpose of winding up the affairs of the company and distributing its assets.

As soon as the affairs of a company are fully wound up, the liquidator must make a report and an account of the winding up, showing how the winding up has been conducted and the property of the company disposed of, and call a general meeting of the company for the purposes of laying before it the account and giving an explanation of that account.

When a resolution has been passed by a company to wind up voluntarily, the liquidator or any contributory or creditor may apply to the court for an order for the continuation of the winding up under the supervision of the court, on the grounds that: (i) the company is or is likely to become insolvent; or (ii) the supervision of the court will facilitate a more effective, economic or expeditious liquidation of the company in the interests of the contributories and creditors. A supervision order takes effect for all purposes as if it was an order that the company be wound up by the court except that a commenced voluntary winding up and the prior actions of the voluntary liquidator shall be valid and binding upon the company and its official liquidator.

For the purpose of conducting the proceedings in winding up a company and assisting the court, one or more persons may be appointed to be called an official liquidator(s). The court may appoint to such office such person or persons, either provisionally or otherwise, as it thinks fit, and if more than one person is appointed to such office, the court shall declare whether any act required or authorised to be done by the official liquidator is to be done by all

or any one or more of such persons. The court may also determine whether any and what security is to be given by an official liquidator on his appointment; if no official liquidator is appointed, or during any vacancy in such office, all the property of the company shall be in the custody of the court.

3.17 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 members 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.

3.18 Mergers and Consolidations involving a Foreign Company

Where the merger or consolidation involves a foreign company, the procedure is similar, save that with respect to the foreign company, the directors of the Cayman Islands exempted company are required to make a declaration to the effect that, having made due enquiry, they are of the opinion that the requirements set out below have been met: (i) that the merger or consolidation is permitted or not prohibited by the constitutional documents of the foreign company and by the laws of the jurisdiction in which the foreign company is incorporated, and that those laws and any requirements of those constitutional documents have been or will be complied with; (ii) that no petition or other similar proceeding has been filed and remains outstanding or order made or resolution adopted to wind up or liquidate the foreign company in any jurisdictions; (iii) that no receiver, trustee, administrator or other similar person has been appointed in any jurisdiction and is acting in respect of the foreign company, its affairs or its property or any part thereof; (iv) that no scheme, order, compromise or other similar arrangement has been entered into or made in any jurisdiction whereby the rights of creditors of the foreign company are and continue to be suspended or restricted.

Where the surviving company is the Cayman Islands exempted company, the directors of the Cayman Islands exempted company are further required to make a declaration to the effect that, having made due enquiry, they are of the opinion that the requirements set out below have been met: (i) that the foreign company is able to pay its debts as they fall due and that the merger or consolidated is bona fide and not intended to defraud unsecured creditors of the foreign company; (ii) that in respect of the transfer of any security interest granted by the foreign company to the surviving or consolidated company (a) consent or approval to the transfer has been obtained, released or waived; (b) the transfer is permitted by and has been approved in accordance with the constitutional documents of the foreign company; and (c) the laws of the jurisdiction of the foreign company with respect to the transfer have been or will be complied with; (iii) that the foreign company will, upon the merger or consolidation becoming effective, cease to be incorporated, registered or exist under the laws of the relevant foreign jurisdiction; and (iv) that there is no other reason why it would be against the public interest to permit the merger or consolidation.

3.19 Reconstructions and Amalgamations

Reconstructions and amalgamations may be approved by (i) 75% in value of the members or class of members or (ii) a majority in number representing 75% in value of the creditors or class of creditors, in each case 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 member has the right to express to the court his view that the transaction for which approval is being sought would not provide the members with a fair value for their shares, it can be expected that the court would approve the transaction if it is satisfied that (i) the company is not proposing to act illegally or beyond the scope of our corporate authority and the statutory provisions as to majority vote have been complied with, (ii) the members have been fairly represented at the meeting in question, (iii) the transaction is such as a businessman would reasonable approve and (iv) the transaction is not one that would more properly be sanctioned under some other provisions of the Companies Act or that would amount to a "fraud on the minority".

If the transaction is approved, no dissenting member would have any rights comparable to the appraisal rights (namely the right to receive payment in cash for the judicially determined value of his shares), which may be available to dissenting members of corporations in other jurisdictions.

3.20 Takeovers

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 that four-month period, by notice require the dissenting members to transfer their shares on the terms of the offer. A dissenting member may apply to the Cayman Islands courts within one month of the notice objecting to the transfer. The burden is on the dissenting member to show

that the 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 members.

3.21 Indemnification

The Cayman Islands laws do not limit the extent to which a company's articles of association may provide for indemnification of officers and directors, save to the extent any such provision may be held by the court to be contrary to public policy, for example, where a provision purports to provide indemnification against the consequences of committing a crime.

3.22 Economic Substance

The Cayman Islands enacted the International Tax Co-operation (Economic Substance) Act (2024 Revision) together with the Guidance Notes published by the Cayman Islands Tax Information Authority from time to time. If a company is considered to be a "relevant entity" and is conducting one or more of the nine "relevant activities", then such company will be required to comply with the economic substance requirements in relation to the relevant activity from 1 July 2019. All companies whether a relevant entity or not is required to file an annual report with the Registrar of Companies of the Cayman Islands confirming whether or not it is carrying on any relevant activities and if it is, it must satisfy an economic substance test.

4. GENERAL

Harney Westwood & Riegels, the Company's legal adviser on Cayman Islands laws, has sent to the Company a letter of advice summarising the aspects of the Companies Act set out in section 3 above. This letter, together with copies of the Companies Act, the Memorandum and the Articles, is on display on the websites of the Stock Exchange and the Company as referred to in the paragraph headed "Documents Delivered to the Registrar of Companies and Available on Display — Documents Available on Display" in Appendix V. Any person wishing to have a detailed summary of the Companies Act or advice on the differences between it and the laws of any jurisdiction with which he is more familiar is recommended to seek independent legal advice.

A. FURTHER INFORMATION ABOUT OUR COMPANY

1. Incorporation of Our Company

Our Company was incorporated in the Cayman Islands under Cayman Companies Act as an exempted company with limited liability on July 3, 2019. Our registered office is at the offices of Aequitas International Management Ltd., Grand Pavilion Commercial Centre, Suite 24, 802 West Bay Road, P.O. Box 10281, Grand Cayman KY1-1003, Cayman Islands. Accordingly, our corporate structure and the Memorandum and Articles of Association are subject to the relevant laws of the Cayman Islands. A summary of certain aspects of the Cayman Islands company law and a summary of certain provisions of our Memorandum and Articles of Association are set out in the section headed "Summary of the Constitution of Our Company and Cayman Islands Company Law" in Appendix III to this document.

Our principal place of business in Hong Kong is at 40/F, Dah Sing Financial Centre, 248 Queen's Road East, Wanchai, Hong Kong. We have registered as a non-Hong Kong Company under Part 16 of the Companies Ordinance on September 2, 2024. Ms. TSANG Wing Man, one of our joint company secretaries, has been appointed as the authorized representative of our Company for the acceptance of the service of process on behalf of our Company in Hong Kong. The address for the service of process is the same as our principal place of business in Hong Kong.

2. Changes in Share Capital of Our Company

Save as disclosed in "History and Corporate Structure — Corporate History — Establishment and Major Shareholding Changes of Our Company," there has been no other alteration in the share capital of our Company during the two years immediately preceding the date of this document.

3. Changes in the Share Capital of Our Subsidiaries

There has been no other alteration in the registered capital of any of our subsidiaries within the two years immediately preceding the date of this document. For details of the list of our subsidiaries, see Note 32 to the Accountant's Report as set out in Appendix I to this document.

4. Resolutions of Shareholders of Our Company Passed on [●], 2025

Written resolutions of our Shareholders were passed on [●], 2025, pursuant to which, among others:

(i) all of the Preferred Shares (whether issued or unissued) be re-designated and reclassified as Shares of US$0.0001 each on a one-for-one basis before the completion of the [**REDACTED**] was approved;

(ii) the Memorandum and Articles of Association was approved and adopted conditional upon [**REDACTED**];

(iii) conditional upon all the conditions set out in "Structure of the [**REDACTED**] — Conditions of the [**REDACTED**]" being fulfilled:

(a) the [**REDACTED**] and the granting of the [**REDACTED**] was approved;

(b) the Board (or any of its duly authorized committee or person thereof) was authorized to allot and issue the [**REDACTED**] pursuant to the [**REDACTED**] and the [**REDACTED**];

(c) the Board (or any of its duly authorized committee or person thereof) was authorized to agree to the [**REDACTED**] with the [**REDACTED**];

(d) a general unconditional mandate was granted to our Directors to allot, issue and deal with Shares (including the resale or transfer of Treasury Shares by our Company) or securities convertible into Shares or options, warrants or similar rights to subscribe for Shares or such convertible securities and to make or grant offers, agreements or options (including but not limited to warrants, bonds, debentures, notes and other securities convertible into Shares) which would or might require the exercise of such powers, provided that the aggregate nominal value of Shares allotted or agreed conditionally or unconditionally to be allotted by our Directors other than pursuant to (A) a rights issue, (B) any scrip dividend scheme or similar arrangement providing for the allotment and issuance of Shares in lieu of the whole or part of a dividend on Shares in accordance with the Articles of Association, (C) the exercise of any subscription or conversion rights attaching to any warrants or securities which are convertible into Shares or in issue prior to the date of passing the relevant resolution or (D) a specific authority granted by the Shareholders in general meeting, shall not exceed the aggregate of (1) 20% of the total nominal value of the share capital of our Company in issue (excluding Treasury Shares, if any) immediately following the completion of and the [**REDACTED**] (assuming the [**REDACTED**] is not exercised and the outstanding share options granted under the Pre-[**REDACTED**] Equity Incentive Plan are not exercised) and (2) the total nominal value of the share capital of our Company repurchased by our Company (if any) under the general mandate to repurchase Shares referred to in paragraph (e) below, such mandate to remain in effect during the period from the passing of the resolution until the earliest of the conclusion of our next annual general meeting, the end of the period within which we are required by any applicable law or the Articles of Association to hold our next annual general meeting or the date on which the resolution is varied or revoked by an ordinary resolution of the Shareholders in general meeting (the "**Applicable Period**");

(e) a general unconditional mandate was granted to our Directors to exercise all powers of our Company to repurchase Shares on the Stock Exchange or on any other stock exchange on which the securities of our Company may be [**REDACTED**] and which is recognized by the SFC and the Stock Exchange for this purpose with a total nominal value of not more than 10% of the total nominal value of the share capital of our Company in issue (excluding Treasury Shares, if any) immediately following completion of the [**REDACTED**] (assuming the [**REDACTED**] is not exercised and the outstanding share options granted under the Pre-[**REDACTED**] Equity Incentive Plan are not exercised), such mandate to remain in effect during the Applicable Period (the "**Repurchase Mandate**"); and

(f) the general unconditional mandate mentioned in paragraph (d) above be extended by the addition to the aggregate nominal value of the share capital of our Company which may be allotted, issued or dealt with or agreed conditionally or unconditionally to be allotted, issued or dealt with by our Directors pursuant to such general mandate of an amount representing the aggregate nominal value of the share capital of our Company repurchased by our Company pursuant to the mandate to repurchase Shares referred to in paragraph (e) above, provided that such extended amount shall not exceed 10% of the aggregate nominal value of our Company's share capital in issue (excluding Treasury Shares, if any) immediately following completion of the [**REDACTED**] (assuming the [**REDACTED**] is not exercised and the outstanding share options granted under the Pre-[**REDACTED**] Equity Incentive Plan are not exercised).

(iv) the Post-[**REDACTED**] Share Incentive Plan as described in details in "— D. Share Incentive Plans — 2. Post-[**REDACTED**] Share Incentive Plan" in this Appendix, was approved and adopted with effective upon the [**REDACTED**].

5. Restrictions on Repurchase of Our Own Securities

This paragraph contains information required by the Stock Exchange to be included in this document concerning the repurchase by our Company of our own securities. Our Directors confirm that neither the explanatory statement of the Share Repurchase Mandate nor the proposed share repurchase has any unusual features.

(i) Provisions of the Listing Rules

The Listing Rules permit companies with a primary listing on the Stock Exchange to repurchase their own Shares on the Stock Exchange subject to certain restrictions, the most important of which are summarized below:

(a) Shareholders' Approval

All proposed repurchase 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, either by way of general mandate or by specific approval of a particular transaction.

Pursuant to a resolution passed by our then Shareholders on [●], 2025, the Repurchase Mandate was given to our Directors authorizing any repurchase by our Company of Shares on the Stock Exchange or on any other stock exchange on which the securities may be listed and which is recognized by the SFC and the Stock Exchange for this purpose, of not more than 10% of the aggregate number of our Company's share capital in issue (excluding Treasury Shares, if any) immediately following the completion of the [**REDACTED**] (assuming the [**REDACTED**] is not exercised and the outstanding share options granted under the Pre-[**REDACTED**] Equity Incentive Plan are not exercised). For details, see "— A. Further Information about Our Company — 4. Resolutions of Shareholders of Our Company Passed on [●], 2025" in this Appendix.

(b) Source of Funds

Any repurchases of Shares by us must be paid out of funds legally available for the purpose in accordance with our Articles of Association, the Listing Rules and the Cayman Companies Act. We are not permitted to repurchase our Shares 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 law, any purchases by our Company may be made out of profits or out of proceeds of a new issue of shares made for the purpose of the purchase 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 purchase 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.

(c) 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 a maximum of 10% of the aggregate number of shares in issue (excluding treasury shares, if any) immediately after the completion of its listing. A company may not (A) issue or announce a proposed issue of

new securities, or (B) sell or transfer or announce a proposed sale or transfer of treasury shares, in compliance with the Listing Rules, for a period of 30 days immediately following a repurchase without the prior approval of the Stock Exchange. Such restriction does not apply to (A) a new issue of Shares, or a sale or transfer of treasury shares under a capitalization issue; (B) a grant of share awards or options under a share scheme that complies with Chapter 17 of the Listing Rules or a new issue of Shares or a transfer of treasury shares upon vesting or exercise of shares awards or options under the share scheme that complies with Chapter 17 of the Listing Rules; and (C) a new issue of Shares or a transfer of treasury shares pursuant to the exercise of warrants, share options or similar instruments requiring our Company to issue Shares or transfer treasury shares, which were outstanding prior to the purchase of its own Shares. 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 listed 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.

(d) Status of Repurchased Shares

Pursuant to the Listing Rules, the shares repurchased by an issuer shall be held as treasury shares or cancelled. The listing of all shares which are held as treasury shares shall be retained. The issuer shall ensure that treasury shares are appropriately identified and segregated. The listing of all repurchased securities (whether on the Stock Exchange or otherwise) but not held as treasury shares is automatically cancelled upon repurchase and our Company must apply for listing of any further Shares in the normal way. The relative certificates must be cancelled and destroyed as soon as reasonably practicable following settlement of any such repurchase. However, the purchase of shares will not be taken as reducing the amount of the authorized share capital of our Company under the Cayman Companies Act.

(e) Suspension of Repurchase

A listed company may not make any repurchase of securities at any time after insider information has come to its knowledge until such information has been made publicly available. In particular, during the period of 30 days 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 publication of an announcement of a listed company's 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 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 the Stock Exchange considers the listed company has breached the Listing Rules.

(f) 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 following any day on which the listed company may take a purchase of securities. The report must state the total number of shares purchased the previous day, the purchase price per share or the highest and lowest prices paid for such purchases. In addition, a listed company's annual report is required to disclose details regarding repurchases of securities made during the year, including a monthly analysis of the number of securities repurchased, the purchase price per share or the highest and lowest price paid for all such repurchases, where relevant, and the aggregate prices paid.

(g) 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 our Company or any of its subsidiaries or a close associate of any of them (as defined in the Listing Rules) and a core connected person shall not knowingly sell his/her/its securities to our Company.

(ii) Reasons for Repurchase

Our Directors believe that it is in the best interest of us and our Shareholders for our Directors to have general authority from the Shareholders to enable us to repurchase Shares in the market. Repurchases may, depending on the circumstances, result in an increase in the net assets and/or earnings per Share. The Directors have sought the grant of a general mandate to repurchase Shares to give our Company the flexibility to do so if and when appropriate. The number of Shares to be repurchased on any occasion and the price and other terms upon which the same are repurchased will be decided by the Directors at the relevant time having regard to the circumstances then pertaining. Repurchases of Shares will only be made when our Directors believe that such repurchases will benefit our Company and our Shareholders and our Company will be able to pay our debts as they fall due in the ordinary course of business.

(iii) Funding of Repurchases

In repurchasing securities, we may only apply funds legally available for such purpose in accordance with the Memorandum and Articles of Association, the Cayman Companies Act or other applicable laws of Cayman Islands and the Listing Rules. On the basis of our current financial condition as disclosed in this document and taking into account our current working

capital position, our Directors consider that, if the Repurchase Mandate were to be exercised in full, it might have a material adverse effect on our working capital and/or our gearing position as compared with the position disclosed in this document. 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 our working capital requirements or the gearing levels which in the opinion of our Directors are from time to time appropriate for us.

The exercise in full of the Repurchase Mandate, on the basis of [**REDACTED**] Shares in issue (excluding Treasury Shares, if any) immediately following completion of the [**REDACTED**] (assuming the [**REDACTED**] is not exercised and the outstanding share options granted under the Pre-[**REDACTED**] Equity Incentive Plan are not exercised), could accordingly result in up to [**REDACTED**] Shares being repurchased by our Company during the period prior to:

(a) the conclusion of the next annual general meeting of our Company;

(b) the expiry of the period within which our Company is required by the Articles of Association or any applicable law to hold our annual general meeting; or

(c) the variation or revocation by an ordinary resolution of the Shareholders passed in a general meeting,

whichever is the earliest.

(iv) General

None of our Directors nor, to the best of their knowledge having made all reasonable enquiries, any of their close associates (as defined in the Listing Rules) currently intends to sell any Shares to us or our subsidiaries.

Our Directors have undertaken with the Stock Exchange that, so far as the same may be applicable, they will exercise the Repurchase Mandate in accordance with the Listing Rules, the Articles of Association, the Cayman Companies Act or any other applicable laws of the Cayman Islands. Our Company has not repurchased any Shares since our incorporation.

Subject to the applicable requirements under the Listing Rules, our Company may cancel the repurchased Shares following settlement of any such repurchase or hold them as Treasury Shares, subject to, for example, market conditions and its capital management needs at the relevant time of the repurchases.

Should our Company decide to hold repurchased Shares as Treasury Shares, we will, upon completion of the Share repurchase, withdraw the repurchased Shares from [**REDACTED**] and register the Treasury Shares in our Company's name. We may re-deposit our Treasury Shares into [**REDACTED**] only if we have an imminent plan to resell these Treasury Shares on the Stock Exchange and will complete such resale as soon as possible. We will have appropriate

measures to ensure that it would not exercise any Shareholders' rights or receive any entitlements which would otherwise be suspended under the relevant laws with respect to Treasury Shares. These measures include, for example, an approval by the Board that (i) our Company should procure its broker not to give any instructions to [**REDACTED**] to vote at general meetings for the Treasury Shares deposited with [**REDACTED**]; and (ii) in the case of dividends or distributions, our Company should withdraw the Treasury Shares from [**REDACTED**], and either re-register them in our Company's name as Treasury Shares or cancel them, in each case before the record date for the dividends or distributions. Holders of Treasury Shares (if any) shall abstain from voting on matters that require Shareholders' approval at our Company's general meetings.

If, as a result of a repurchase of our Shares pursuant to the Repurchase Mandate, a Shareholder's proportionate interest in our voting rights is increased, such increase will be treated as an acquisition for the purpose of the Takeovers Code. Accordingly, a Shareholder or a group of Shareholders acting in concert could obtain or consolidate control of us and become obliged to make a mandatory offer in accordance with Rule 26 of the Takeovers Code. Save as aforesaid, our Directors are not aware of any consequences which would arise under the Takeovers Code as a consequence of any repurchases pursuant to the Repurchase Mandate.

Any repurchase of Shares which results in the number of Shares held by the public being reduced to less than 25% of our Shares than in issue could only implemented with the approval of the Stock Exchange to waive the Listing Rules requirements regarding the public shareholding 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, as defined in the Listing Rules, has notified us that he/she/it has a present intention to sell Shares to us, or has undertaken not to do so, if the Repurchase Mandate is exercised.

B. FURTHER INFORMATION ABOUT OUR BUSINESS

1. Summary of Material Contract

We have entered into the following contract (not being contracts entered into in the ordinary course of business) within the two years immediately preceding the date of this document that is or may be material:

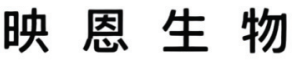
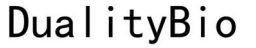
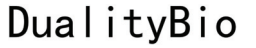
(i) the [**REDACTED**].

2. Intellectual Property Rights

(i) Trademarks

(a) Registered Trademarks

As of the Latest Practicable Date, we had registered the following trademarks which we consider to be or may be material to our business:

No.	Trademark	Owner	Class	Place of Registration	Expiry Date	Registration Number
1. . .	 	Duality Shanghai	5, 35, 42	Hong Kong	July 1, 2034	306599369
2. . .		Duality Shanghai	5, 35, 42	Hong Kong	July 1, 2034	306599350
3. . .		Duality Shanghai	5, 35, 42	Hong Kong	July 1, 2034	306599341
4. . .		Duality Suzhou	5	PRC	June 6, 2034	75776197
5. . .		Duality Suzhou	35	PRC	June 6, 2034	75779984
6. . .		Duality Suzhou	42	PRC	June 6, 2034	75776224
7. . .		Duality Suzhou	5	PRC	June 6, 2034	75772443
8. . .		Duality Suzhou	35	PRC	June 6, 2034	75762085
9. . .		Duality Suzhou	42	PRC	June 6, 2034	75759049
10. .		Duality Suzhou	5	PRC	February 6, 2031	46623566
11. .		Duality Suzhou	35	PRC	February 6, 2031	46618058
12. .		Duality Suzhou	42	PRC	January 20, 2031	46614402
13. .		Duality Suzhou	5	PRC	January 27, 2031	46640026
14. .		Duality Suzhou	35	PRC	January 20, 2031	46610249
15. .		Duality Suzhou	42	PRC	January 20, 2031	46612210

(ii) Patents

(a) Registered Patents

As of the Latest Practicable Date, we owned the following registered patents which we consider to be or may be material to our business:

No.	Patent	Type of patent	Place of registration	Patent number	Owner	Expiration date
1.	Anti-tumor Compound and Preparation Method and Application Thereof (一種抗腫瘤化合物及其製備方法和應用)	Invention patent	PRC	CN115925796B	Duality Suzhou	September 28, 2041
2.	Anti-tumor Compound and Preparation Method and Application Thereof (一種抗腫瘤化合物及其製備方法和應用)	Invention patent	PRC	CN116199739B	Duality Suzhou	September 28, 2041
3.	Anti-tumor Compound and Preparation Method and Use Thereof	Invention patent	U.S.	US11685742B2	Duality Suzhou	September 28, 2041
4.	Anti-tumor Compound and Preparation Method and Use Thereof	Invention patent	U.S.	US11607459B1	Duality Suzhou	September 28, 2041

(b) Patents under Application

As of the Latest Practicable Date, we have applied for the following PCT patent applications (which have entered or still have opportunity to enter national phases) which we consider to be or may be material to our business:

No.	Patent	Type of Patent	Place of Registration	Application Number	Applicant	Application Date
1.	Anti-B7H3 and PD-L1 Bispecific Antibody-Drug Conjugate, Preparation Method Therefor, and Use Thereof (抗B7H3和PD-L1的雙特異性抗體藥物偶聯物及其製備方法和用途)	Invention patent	PCT	PCT/CN2023/142481	Duality Suzhou	December 27, 2023
2.	Anti-BDCA2 Antibody-Drug Conjugates and Uses Thereof (抗BDCA2 抗體-藥物偶聯物及其用途)	Invention patent	PCT	PCT/CN2023/142457	Duality Suzhou	December 27, 2023
3.	Anti-B7H3 Antibody-Drug Conjugates and Uses Thereof (抗B7H3抗體-藥物偶聯物及其用途)	Invention patent	PCT	PCT/CN2023/098596	Duality Suzhou	June 6, 2023
4.	HER3 Antibody-Drug Conjugates and Use Thereof (HER3抗體藥物偶聯物及其用途)	Invention patent	PCT	PCT/CN2023/073130	Duality Suzhou	January 19, 2023
5.	Steroid Compound and Conjugate Thereof (一種甾體化合物及其綴合物)	Invention patent	PCT	PCT/CN2022/114855	Duality Suzhou	August 25, 2022
6.	Antitumor Compound, and Preparation Method Therefor and Use Thereof (一種抗腫瘤化合物及其製備方法和應用)	Invention patent	PCT	PCT/CN2021/121721	Duality Suzhou	September 29, 2021

(iii) Domain Name

As of the Latest Practicable Date, we had registered the following internet domain name which we consider to be or may be material to our business:

No.	Domain Name	Owner	Expiry date
1. . .	dualitybiologics.com	Duality Shanghai	April 20, 2025

Save as aforesaid, as of the Latest Practicable Date, there were no other trade or service marks, patents, intellectual or industrial property rights which were material in relation to our Group's business.

C. FURTHER INFORMATION ABOUT OUR DIRECTORS, CHIEF EXECUTIVES AND SUBSTANTIAL SHAREHOLDERS

1. Disclosure of Interest

(i) Interests and Short Positions of the Directors and Chief Executive of Our Company in the Shares, Underlying Shares and Debentures of Our Company and Our Associated Corporation

The following table sets out the interests and short positions of our Directors and chief executive of our Company as of the date of this document and immediately following the completion of the [**REDACTED**] (assuming the [**REDACTED**] is not exercised and the outstanding share options granted under the Pre-[**REDACTED**] Equity Incentive Plan are not exercised) in our Shares, underlying Shares or debentures of our Company or any of our associated corporations (within the meaning of Part XV of the SFO) which will have to be notified to us and the Stock Exchange pursuant to Divisions 7 and 8 of Part XV of the SFO (including interests and short positions in which they are taken or deemed to have under such provisions of the SFO), or which will be required, pursuant to section 352 of the SFO, to be entered in the register referred to therein, or which will be required to be notified to us and the Stock Exchange pursuant to the Model Code for Securities Transactions by Directors of Listed Issuers contained in the Listing Rules:

		As of the date of this document		Immediately after the [REDACTED][(2)]	
Name	Nature of interests	Number of Shares[(1)]	Approximate percentage of interest in our Company	Number of Shares[(1)]	Approximate percentage of interest in our Company
Dr. ZHU Zhongyuan (朱忠遠)	Interests in controlled corporation[(3)]	6,500,000	9.54%	[6,500,000]	[**REDACTED**]%
	Beneficial owner[(4)]	8,622,203	12.66%	[8,622,203]	[**REDACTED**]%
Mr. ZHANG Shaoren (張韶壬)	Beneficial owner[(5)]	392,500	0.58%	[392,500]	[**REDACTED**]%
Ms. SI Wen (司文)	Beneficial owner[(6)]	243,800	0.36%	[243,800]	[**REDACTED**]%

Notes:

(1) All interests stated are long positions.

(2) The calculation is based on the total number of Shares in issue immediately following the completion of the [**REDACTED**] (assuming the [**REDACTED**] is not exercised and the outstanding share options granted under the Pre-[**REDACTED**] Equity Incentive Plan are not exercised).

(3) DualityBio Ltd. directly holds 6,500,000 Shares as beneficial owner. As DualityBio Ltd. is wholly owned by Dr. ZHU Zhongyuan, Dr. ZHU Zhongyuan is deemed to be interested in the Shares held by DualityBio Ltd. by virtue of the SFO. For details, see the section headed "Substantial Shareholders" in this document.

(4) These Shares represent Dr. ZHU Zhongyuan's entitlement to receive up to 8,622,203 Shares pursuant to the exercise of options granted to him under the Pre-[**REDACTED**] Equity Incentive Plan, subject to the terms and conditions of these options.

(5) These Shares represent Mr. ZHANG Shaoren's entitlement to receive up to 392,500 Shares pursuant to the exercise of options granted to him under the Pre-[**REDACTED**] Equity Incentive Plan, subject to the terms and conditions of these options.

(6) These Shares represent Ms. SI Wen's entitlement to receive up to 243,800 Shares pursuant to the exercise of options granted to her under the Pre-[**REDACTED**] Equity Incentive Plan, subject to the terms and conditions of these options.

(ii) Interests of the Substantial Shareholders in the Shares and Underlying Shares of Our Company

Save as disclosed in the section headed "Substantial Shareholders," immediately following the completion of the [**REDACTED**] (assuming the [**REDACTED**] is not exercised and the outstanding share options granted under the Pre-[**REDACTED**] Equity Incentive Plan are not exercised), our Directors are not aware of any other person (not being a Director or chief executive of our Company) who will have an interest or short position in the Shares or the underlying Shares which would fall to be disclosed to us and the Stock Exchange under the provisions of Divisions 2 and 3 of Part XV of the SFO, or who is, directly or indirectly, interested in 10% or more of the voting power of our Company and any other member of our Group.

2. Particulars of Directors' Service Contracts and Letters of Appointment

(i) Executive Directors and Non-executive Directors

We [have entered] into a service contract with each of our executive Director and our non-executive Directors in respect of, among other things, (i) compliance of the Listing Rules and applicable laws; and (ii) observance of the Articles of Association. Such service contracts have terms of three years commencing from the date of 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.

(ii) Independent non-executive Directors

We [have entered] into a letter of appointment with each of independent non-executive Directors in respect of, among other things, (i) compliance of the Listing Rules and applicable laws; and (ii) observance of the Articles of Association. Such letters of appointment have terms of either three years commencing from the [**REDACTED**] 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.

3. Directors' Remuneration

For details of the Directors' remuneration, see "Directors and Senior Management — Directors' and Senior Management's Remuneration" and Note 31 to the Accountant's Report as set out in Appendix I to this document.

Save as disclosed above, none of the Directors has or is proposed to have a service contract with our Company other than contracts expiring or determinable by the employer within one year without the payment of compensation (other than statutory compensation).

4. Directors' Competing Interests

None of our Directors are interested in any business apart from our Group's business which competes or is likely to compete, directly or indirectly, with the business of our Group.

5. 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 or the experts named in the paragraph headed "— E. Other Information — 8. Qualifications and Consents 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;

(iii) save as in connection with the [**REDACTED**] Agreements, none of our Directors nor any of the experts named in the paragraph headed "— E. Other Information — 8. Qualifications and Consents of Experts" in this Appendix is materially interested in any contract or arrangement subsisting at the date of this document which is significant in relation to the business of our Group as a whole;

(iv) 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 the Stock Exchange under the provisions of Divisions 2 and 3 of Part XV 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;

(v) 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 the Stock Exchange pursuant to Divisions 7 and 8 of Part XV 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 section 352 of the SFO, to be entered into the register referred to therein, or will be required, pursuant to the Model Code for Securities Transactions by Directors of Listed Issuers as set out in Appendix C3 to the Listing Rules, to be notified to our Company and the Stock Exchange;

(vi) save in connection with the [**REDACTED**] Agreements, none of the experts named in the paragraph headed "— E. Other Information — 8. Qualifications and Consents of Experts" in this Appendix: (i) is interested legally or beneficially in any of our Shares or any shares in any of our subsidiaries; or (ii) has any right (whether legally enforceable or not) to subscribe for or to nominate persons to subscribe for securities in any member of our Group; and

(vii) none of our Directors or their respective close associates or any Shareholders of our Company (who to the knowledge of our Directors owns more than 5% of the number of our issued shares) has any interest in our five largest suppliers or our five largest customers.

D. SHARE INCENTIVE PLANS

As of the Latest Practicable Date, we had one share incentive scheme, namely the Pre-[**REDACTED**] Equity Incentive Plan, the terms of which are not subject to the provisions of Chapter 17 of the Listing Rules. For the purpose of the [**REDACTED**], our Company [adopted] the Post-[**REDACTED**] Share Incentive Plan on [●], 2025, the terms of which comply with the requirements of Chapter 17 of the Listing Rules. The Post-[**REDACTED**] Share Incentive Plan will take effect upon the [**REDACTED**].

1. Pre-[REDACTED] Equity Incentive Plan

Our Company adopted the Pre-[**REDACTED**] Equity Incentive Plan on February 28, 2021 and amended on June 25, 2023.

A summary of the principal terms of the Pre-[**REDACTED**] Equity Incentive Plan is set out below:

(i) Purpose

The purposes of the Pre-[**REDACTED**] Equity Incentive Plan are to secure and retain the services of the Eligible Individuals (as defined below), provide incentives for such persons to exert maximum efforts for the success of our Group and provide means by which the Eligible Individuals (as defined below) may benefit from increases in value of the Shares.

(ii) Eligible Individuals

The following participants (collectively, the "**Eligible Individuals**") are eligible to participate in the Pre-[**REDACTED**] Equity Incentive Plan:

Employee	any person employed by our Group. However, service solely as a director or as a member of the board of directors of an affiliate, or payment of a fee for such services, will not cause a person to be considered an "Employee" for purposes of the Pre-[**REDACTED**] Equity Incentive Plan
Director	any Director of our Company
Consultant	any person, including an advisor, who is (a) engaged by our Group to render consulting or advisory services and is compensated for such services, or (b) serving as a member of the board of directors of any affiliate and is compensated for such services. However, service solely as a director or as a member of the board of directors of an affiliate, or payment of a fee for such service, will not cause a person to be considered a "consultant" for purposes of the Pre-[**REDACTED**] Equity Incentive Plan. A consultant will not be eligible for the grant of share awards under the Pre-[**REDACTED**] Equity Incentive Plan if, at the time of the grant, either the [**REDACTED**] or sale of our Company's securities to such consultant is not exempt under Rule 701 of the U.S. Securities Act ("**Rule 701**") because of the nature of the services that such consultant is providing to our Company, because the consultant is not a natural person, or because of any other provision of Rule 701, unless our Company determines that such grant need not comply with the requirements of Rule 701 and will satisfy another exemption under the U.S. Securities Act, and it is in due compliance with applicable law

(iii) Administration

The Pre-[**REDACTED**] Equity Incentive Plan shall be subject to the administration of the Board or one or more delegated committees of Directors. All determinations, interpretations and constructions made by the Board in good faith will not be subject to review by any person and will be final, binding and conclusive on all persons.

(iv) Types of Awards

The Pre-[**REDACTED**] Equity Incentive Plan permits (a) options, (b) share appreciation rights, (c) restricted share awards, (d) restricted share unit awards, and (e) other share awards based in whole or in part by reference to the Shares.

(v) Maximum Number of Shares

The maximum number of Shares that may be issued pursuant to the share awards under the Pre-[**REDACTED**] Equity Incentive Plan shall not exceed 22,287,582 Shares in the aggregate.

(vi) Grant of Share Awards

Unless determined otherwise by the Board, corporate action constituting a grant by our Company of a share award to any Eligible Individual will be deemed completed as of the date of such corporate action, regardless of when the instrument, certificate, or letter evidencing the share award is communicated to, or received or accepted by, the Eligible Individual.

(vii) Exercise of Options and Share Appreciation Rights

(a) Exercise period and conditions

The term of each option or share appreciation right shall be specified in the share award agreement but shall not exceed ten (10) years from the date of its grant.

To exercise any outstanding share appreciation right, the Eligible Individual must provide written notice of exercise to our Company in compliance with the provisions of the share award agreement evidencing such share appreciation right.

(b) Exercise price

The exercise price of each option and share appreciation right granted to a U.S. Eligible Individual will be not less than 100% of the fair market value of the Shares subject to the option and share appreciation right on the date of grant, except if such share award is granted pursuant to an assumption of or substitution for another option or share appreciation right pursuant to a corporate transaction, and in due compliance with applicable law. The exercise price of each option and share appreciation right granted to a non-U.S. Eligible Individual shall be determined by the Board, in compliance with applicable laws. No option or share appreciation right may be granted with an exercise or strike price lower than the par value of the Shares.

(c) Early exercise of options

Subject to provisions of the share award agreement, the Eligible Individual may elect at any time before his or her continuous service terminates to exercise the option as to any part or all of the Shares subject to the option prior to the full vesting of the option.

(viii) Subscription Price of Options

The amount payable for the Shares to be subscribed for under an option in the event of the option being exercised may be paid, to the extent permitted by applicable law and as determined by the Board in its sole discretion, by any combination of the methods of payment, including, among others, cash, check, bank draft or money order payable to our Company. Any Shares that are not fully paid will be subject to the forfeiture provisions in the Memorandum and Articles of Association.

(ix) Consideration

Restricted share awards: A restricted share award may be awarded in consideration for (a) cash, check, bank draft or money order payable to our Company, (b) past services to our Company or our affiliates, or (c) any other form of legal consideration (including future services) that may be acceptable to the Board, in its sole discretion, and permissible under applicable law.

Restricted share unit awards: At the time of grant of a restricted share unit award, the Board will determine the consideration, if any, to be paid by the Eligible Individual upon delivery of each Share subject to the restricted share unit award. The consideration to be paid, if any, by the Eligible Individual for such Share may be paid in any form of legal consideration that may be acceptable to the Board, in its sole discretion, and permissible under applicable law.

(x) Vesting of Share Awards

Options and share appreciation rights: At the Board's discretion, the total number of Shares subject to an option or share appreciation right may vest and become exercisable in periodic installments that may or may not be equal, the option or share appreciation right may be subject to such other terms and conditions on the time or times when it may or may not be exercised, and the vesting provisions of individual options or share appreciation rights may vary.

Restricted share awards: The Shares awarded under the restricted share award agreement may be subject to forfeiture to our Company in accordance with a vesting schedule to be determined by the Board.

Restricted share unit awards: At the date of the grant, the Board may impose restrictions on or conditions to the vesting of the restricted share unit award as it, in its sole discretion, deems appropriate.

(xi) Lapse of Share Awards

A share award shall lapse automatically (to the extent not already exercised) immediately upon the earliest of:

(a) the expiry of the option or share appreciation right period;

(b) the expiry of any of the periods for rights on ceasing employment, disability or death;

(c) immediately prior to the completion of dissolution or liquidation of our Company;

(d) subject to the Board's discretion, upon the closing of a corporate transaction;

(e) in the event that the Eligible Individual (i) commits any crime or felony involving fraud, dishonesty, or moral turpitude under the laws of any applicable jurisdiction, (ii) attempts to commit, or participate in fraud or an act of dishonesty against our Company or any of our affiliates, (iii) intentionally and materially violates any contract or agreement between the Eligible Individual and our Company or any of our affiliates or of any statutory duty owed to our Company or any of our affiliates, (iv) commits unauthorized use or disclosure of our Company's or any of our affiliates confidential information or trade secrets, (v) commits gross misconduct; or

(f) the date on which the option or share appreciation right is cancelled by the Board.

(xii) Right of Repurchase or Right of First Refusal

The options or share appreciation rights may include a provision, as specified in the share award agreement, whereby our Company may elect to (a) repurchase all or any part of the vested Shares acquired by the Eligible Individual, or (b) exercise a right of first refusal following receipt of notice from the Eligible Individual of the intent to transfer all or any part of the Shares received, upon the exercise of the options or share appreciation rights. Unless otherwise provided, the repurchase price for vested Shares shall be the exercise purchase price.

(xiii) Transferability

Options and share appreciation rights: The Board may, in its sole discretion, impose limitations on the transferability of options and share appreciation rights. In the absence of such determination by the Board to the contrary, neither an option nor share appreciation right may be transferred for consideration, except through domestic relations orders or a beneficiary designation, subject to the approval of the Board or any duly authorized person designated by our Company and in due compliance with applicable laws.

Restricted share awards: Rights to acquire Shares under the restricted share award agreement will be transferable by the Eligible Individual only upon such terms and conditions as are set forth in the agreement, as the Board will determine in its sole discretion, so long as Shares awarded under the restricted share award agreement remains subject to the terms of the agreement.

(xiv) Cancellation

The Board, in its sole discretion, with the consent of any affected Eligible Individual, may effect the cancellation of any outstanding share award and the grant in substitution therefor of a new consideration.

(xv) Clawback Mechanism

If a share award or any portion thereof (i) expires or otherwise terminates without all of the Shares covered by such share award having been issued or (ii) is settled in cash, such expiration, termination or settlement will not reduce, or otherwise offset, the number of Shares that may be available for issuance under the Pre-[**REDACTED**] Equity Incentive Plan.

If any Share issued pursuant to a share award is forfeited back to or repurchased by our Company because of the failure to meet a contingency or condition required to vest such shares in the Eligible Individual, the aforementioned Shares will revert to and become available for issuance under the Pre-[**REDACTED**] Equity Incentive Plan. Any Shares reacquired by our Company in satisfaction of tax withholding obligations on a share award or as consideration for the exercise or purchase price of a share award will again become available for issuance under the Pre-[**REDACTED**] Equity Incentive Plan.

(xvi) Duration, Alteration, Suspension and Termination

The Pre-[**REDACTED**] Equity Incentive Plan shall be valid and effective for the period of ten (10) years commencing on the adoption date, unless terminated earlier by the Board. Post the duration, no share award shall be granted pursuant to the Pre-[**REDACTED**] Equity Incentive Plan.

The Board may amend the Pre-[**REDACTED**] Equity Incentive Plan in any respect it deems necessary or advisable, in due compliance with applicable law. No amendment shall impair an Eligible Individual's rights under an outstanding share award unless with the written consent of such Eligible Individual or as otherwise provided in the Pre-[**REDACTED**] Equity Incentive Plan.

The Board may at any time suspend or terminate the operation of the Pre-[**REDACTED**] Equity Incentive Plan. Suspension or termination of the Pre-[**REDACTED**] Equity Incentive Plan will not impair the rights and obligations under any share award granted except with the written consent of the affected grantee or as otherwise permitted in the Pre-[**REDACTED**] Equity Incentive Plan.

(xvii) Outstanding Options Granted

Since the adoption of the Pre-[**REDACTED**] Equity Incentive Plan, other than options, no other types of share awards have been awarded by our Company. No further awards will be granted under the Pre-[**REDACTED**] Equity Incentive Plan upon [**REDACTED**].

We have conditionally granted an aggregate of 18,763,423 options (representing the right to subscribe for 18,763,423 Shares) (the "**Outstanding Pre-[REDACTED] Options**") to 102 grantees, who are our current employees or external consultants, under the Pre-[**REDACTED**] Equity Incentive Plan, all of which will remain outstanding as of the [**REDACTED**].

We are supported by a scientific advisory board of world-renowned ADC experts to guide our R&D activities and provide invaluable strategic advice. To ensure consistent, high-quality consulting services and align their interests with the Company's long-term objectives, we have granted options to three key external consultants who serve on this board. These options allow them to subscribe for an aggregate of 300,000 Shares, representing approximately [**REDACTED**]% of the total number of Shares in issue immediately after completion of the [**REDACTED**] (assuming the [**REDACTED**] is not exercised). These consultants have been engaged for a renewable three-year term to provide expert advice on R&D activities, strategic developments, and/or regulatory affairs. To the best of our Company's knowledge, information and belief having made all reasonable enquiries, save for Dr. SU Ling, a venture partner of Lilly Asia Ventures, none of the external consultants have any other past or present relationships with our Shareholders, Directors, senior management members or any of their respective associates.

The number of the Shares underlying the Outstanding Pre-[**REDACTED**] Options amounting to 18,763,423 will only be issued by our Company after the [**REDACTED**] if such Outstanding Pre-[**REDACTED**] Options are fully vested and exercised. Therefore, the Outstanding Pre-[**REDACTED**] Options will have potential dilution effect on the Shares held by our Shareholders as of the [**REDACTED**]. No consideration is paid for grant of the Outstanding Pre-[**REDACTED**] Options.

a. As of the Latest Practicable Date, the Shares underlying the Outstanding Pre-[**REDACTED**] Options (i.e., 18,763,423 Shares) represented approximately 27.55% of the total issued and outstanding Shares of our Company.

b. The Shares underlying the Outstanding Pre-[**REDACTED**] Options (i.e., 18,763,423 Shares) represented approximately [**REDACTED**]% of the total number of Shares in issue immediately after completion of the [**REDACTED**] (assuming the [**REDACTED**] is not exercised).

c. The shareholding of our Shareholders upon completion of the [**REDACTED**] (assuming the [**REDACTED**] is not exercised) will be diluted by approximately [**REDACTED**]% if the Outstanding Pre-[**REDACTED**] Options are fully vested and exercised.

As the Group incurred losses for the nine months ended September 30, 2024, the dilutive potential Ordinary Shares were not included in the calculation of diluted loss per Share as their inclusion would be anti-dilutive. Accordingly, the diluted loss per Share for the nine months ended September 30, 2024 was the same as the basic loss per Share of the same period.

The table below shows the details of options granted to Directors and senior management of our Company under the Pre-[**REDACTED**] Equity Incentive Plan that are outstanding as of the Latest Practicable Date:

Name	Title	Address	Number of Shares underlying the options granted	Date of grant	Exercise period	Vesting Period	Exercise price	Number of Shares underlying the outstanding options granted as of the Latest Practicable Date	Approximate percentage of issued Shares immediately after the [REDACTED][(4)]
							(US$)		
Directors									
Dr. ZHU Zhongyuan (朱忠遠) .	Chairman of the Board, executive Director and chief executive officer	Room 403, Building 10, Lane 1299, Dingxiang Road, Pudong New Area, Shanghai, the PRC	903,920	December 20, 2024	Ten (10) years from date of grant	*Note 3*	1.60	903,920	[REDACTED]%
			451,959	August 10, 2023		*Note 1*	0.90	451,959	[REDACTED]%
			2,280,000	June 5, 2023		*Note 2*	0.90	2,280,000	[REDACTED]%
			1,140,244	June 10, 2022		*Note 1*	0.72	1,140,244	[REDACTED]%
			750,000	January 1, 2022		*Note 2*	0.30	750,000	[REDACTED]%
			831,250	December 15, 2021		*Note 2*	0.30	831,250	[REDACTED]%
			3,168,750	September 30, 2020		*Note 1*	0.30	3,168,750	[REDACTED]%
Subtotal . .			***9,526,123***					***9,526,123***	[REDACTED]**%**
Mr. ZHANG Shaoren (張韶壬) .	Executive Director and vice president of finance	Rooms 201-203, Building 2, Lane 76, Nujiang Road, Putuo District, Shanghai, the PRC	95,000	January 1, 2024	Ten (10) years from date of grant	*Note 2*	0.90	95,000	[REDACTED]%
			127,500	April 16, 2021		*Note 2*	0.72	127,500	[REDACTED]%
			170,000	November 1, 2020		*Note 1*	0.30	170,000	[REDACTED]%
Subtotal . .			***392,500***					***392,500***	[REDACTED]**%**
Ms. SI Wen (司文) . .	Executive Director and executive director (執行總監) of human resources	Room 402, No. 44, Lane 438, Guzong Road, Pudong New Area, Shanghai, the PRC	50,000	December 29, 2023	Ten (10) years from date of grant	*Note 1*	0.90	50,000	[REDACTED]%
			23,800	January 1, 2022		*Note 2*	0.72	23,800	[REDACTED]%
			170,000	April 20, 2021		*Note 1*	0.30	170,000	[REDACTED]%
Subtotal . .			***243,800***					***243,800***	[REDACTED]**%**

Name	Title	Address	Number of Shares underlying the options granted	Date of grant	Exercise period	Vesting Period	Exercise price	Number of Shares underlying the outstanding options granted as of the Latest Practicable Date	Approximate percentage of issued Shares immediately after the [REDACTED][4]
							(US$)		
Senior management members									
Dr. QIU Yang (邱楊) . .	Chief scientific officer	74 Alder Lane, Basking Ridge, NJ 07920, the United States	240,000	December 29, 2023	Ten (10) years from date of grant	*Note 1*	0.90	240,000	[REDACTED]%
			500,000	November 1, 2023		*Note 1*	0.90	500,000	[REDACTED]%
			500,000	July 1, 2023		*Note 1*	0.90	500,000	[REDACTED]%
			280,000	July 1, 2023		*Note 2*	0.90	280,000	[REDACTED]%
			562,500	July 19, 2021		*Note 1*	0.72	562,500	[REDACTED]%
Subtotal . .			***2,082,500***					***2,082,500***	[REDACTED]%
Ms. GU Wei (顧薇) . .	Chief medical officer	6D, No. 3, Lane 888, South Shaanxi Road, Xuhui District, Shanghai, the PRC	1,000,000	July 18, 2022	Ten (10) years from date of grant	*Note 1*	0.72	1,000,000	[REDACTED]%
Dr. HUA Haiqing (花海清) .	Senior vice president and head of drug discovery	Room 601, No. 6, Lane 498, Bohua Road, Pudong New Area, Shanghai, the PRC	112,500	January 1, 2024	Ten (10) years from date of grant	*Note 2*	0.90	112,500	[REDACTED]%
			375,000	January 1, 2022		*Note 1*	0.72	375,000	[REDACTED]%
Subtotal . .			***487,500***					***487,500***	[REDACTED]%
Mr. WANG Xin (王昕) . .	Senior vice president of strategy and business development	16 Jersey Avenue, Edison, NJ 08820, the United States	375,000	December 27, 2022	Ten (10) years from date of grant	*Note 1*	0.90	375,000	[REDACTED]%
Mr. YU Xin (于鑫) . .	Vice president and head of regulatory affairs	Room 203, Building 6, Guang'an Men Wai Street, Xicheng District, Beijing, the PRC	80,000	January 1, 2024	Ten (10) years from date of grant	*Note 2*	0.90	80,000	[REDACTED]%
			187,500	January 1, 2022		*Note 1*	0.72	187,500	[REDACTED]%
Subtotal . .			***267,500***					***267,500***	[REDACTED]%

Name	Title	Address	Number of Shares underlying the options granted	Date of grant	Exercise period	Vesting Period	Exercise price	Number of Shares underlying the outstanding options granted as of the Latest Practicable Date	Approximate percentage of issued Shares immediately after the [REDACTED][4]
							(US$)		
Dr. SHI Rong (施榕) . .	Vice president of development science	422 Wendover Dr, Princeton, NJ 08540, the United States	187,500	August 24, 2022	Ten (10) years from date of grant	*Note 1*	0.72	187,500	[REDACTED]%
Dr. CHU Ruiyin (儲瑞銀) .	Vice president of translational medicine	8 Comstock Lane, Skillman, NJ08558, the United States	180,000	January 24, 2024	Ten (10) years from date of grant	*Note 1*	0.90	180,000	[REDACTED]%
Ms. ZHOU Lan (周嵐) . .	Vice president of commercial strategy	Room 1002, 7 Lane 1398, Gubei Road, Changning District, Shanghai, the PRC	60,000	November 1, 2024	Ten (10) years from date of grant	*Note 1*	0.90	60,000	[REDACTED]%
Total . . .			**14,802,423**					**14,802,423**	[REDACTED]%

The table below shows the details of options granted to external consultants under the Pre-[**REDACTED**] Equity Incentive Plan that are outstanding as of the Latest Practicable Date:

Name	Address	Number of Shares underlying the options granted	Date of grant	Exercise period	Vesting Period	Exercise price	Number of Shares underlying the outstanding options granted as of the Latest Practicable Date	Approximate percentage of issued Shares immediately after the [REDACTED][4]
						(US$)		
Antoine Yver. . . .	42 Washington St Rocky Hill, NJ 08553, the United States	200,000	June 1, 2022	Ten (10) years from date of grant	*Note 2*	0.72	200,000	[REDACTED]%
Pasi A. Janne . . .	9 Savoy Road, Needham, MA 02492, the United States	50,000	November 1, 2022	Ten (10) years from date of grant	*Note 2*	0.90	50,000	[REDACTED]%

Name	Address	Number of Shares underlying the options granted	Date of grant	Exercise period	Vesting Period	Exercise price	Number of Shares underlying the outstanding options granted as of the Latest Practicable Date	Approximate percentage of issued Shares immediately after the [REDACTED][4]
						(US$)		
SU Ling	Room 502, No. 477, Yongjia Road, Xuhui District, Shanghai, the PRC	50,000	April 22, 2024	Ten (10) years from date of grant	*Note 2*	0.90	50,000	[**REDACTED**]%
Total		**300,000**					**300,000**	[REDACTED]%

The table below sets out the details of the share options granted to other grantees that are not set out above under the Pre-[**REDACTED**] Equity Incentive Plan as of the Latest Practicable Date:

Range of Shares underlying the options granted	Total number of grantees	Date of grant	Vesting Period	Exercise price	Number of Shares underlying the outstanding options as of the Latest Practicable Date	Approximate percentage of issued Shares immediately after the [REDACTED][4]
				(US$)		
100,000 – 216,000 .	11	January 13, 2021 – February 1, 2024	*Note 1, Note 2*	0.30 – 0.90	1,386,000	[**REDACTED**]%
50,000 – 99,999 . .	24	January 1, 2022 – December 24, 2024	*Note 1, Note 2*	0.72 – 0.90	1,300,000	[**REDACTED**]%
5,000 – 49,999 . . .	53	February 4, 2022 – January 29, 2025	*Note 1*	0.72 – 0.90	975,000	[**REDACTED**]%
Total	**88**				**3,661,000**	[REDACTED]%

Notes:

(1) 25% of the options granted to such grantee will be vested at the first-year anniversary of the date of grant, the remaining will be vested during the three years thereafter, with 1/48 of the total number of options vested each month.

(2) 33% of the options granted to such grantee will be vested during the first year from the date of grant, 33% will be vested during the second year and the remaining 34% will be vested during the third year.

(3) 1/3 of the options granted to such grantee will be vested on the date of completion of applicable milestones (the "**Milestone Options Vesting Date**"), 1/3 will be vested on the first anniversary of the Milestone Options Vesting Date and the remaining 1/3 will be vested on the second anniversary of the Milestone Options Vesting Date.

(4) Assuming the [**REDACTED**] is not exercised.

We have applied for, and [have been granted] (i) a waiver from the Stock Exchange from strict compliance with the requirements under Rule 17.02(1)(b) of the Listing Rules and paragraph 27 of Appendix D1A to the Listing Rules; and (ii) a certificate of exemption from the SFC from strict compliance with paragraph 10(d) of Part I of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance pursuant to section 342A of the Companies (Winding Up and Miscellaneous Provisions) Ordinance. For details, see "Waivers from Strict Compliance with the Listing Rules and Exemptions from the Companies (Winding Up and Miscellaneous Provisions) Ordinance" in this document.

2. Post-[REDACTED] Share Incentive Plan

The Post-[**REDACTED**] Share Incentive Plan has been approved and adopted by our Company on [●], 2025 in compliance with the provisions of Chapter 17 of the Listing Rules, with effect upon [**REDACTED**].

A summary of the principal terms of the Post-[**REDACTED**] Share Incentive Plan is set out below:

(i) Purpose

The purpose of the Post-[**REDACTED**] Share Incentive Plan is to: (a) provide our Company with a flexible means of attracting, remunerating, incentivising, retaining, rewarding, compensating and/or providing benefits to Eligible Participants (as defined below); (b) align the interests of Eligible Participants (as defined below) with those of our Company and Shareholders by providing such Eligible Participants (as defined below) with the opportunity to acquire proprietary interests in our Company and become Shareholders; and (c) encourage Eligible Participants (as defined below) to contribute to the long-term growth, performance and profits of our Company and to enhance the value of our Company and our Shares for the benefit of our Company and Shareholders as a whole.

(ii) Eligible Participants

The following participants are eligible to participate in the Post-[**REDACTED**] Share Incentive Plan ("**Eligible Participants**"):

For Awards over New Shares

Service provider participants shall include the following categories of service provider:

Employee Participant	A director, officer or employee of our Group on the grant date.
Related Entity Participant . .	A director, officer or employee of: (i) our holding company (if any); (ii) subsidiaries of our holding company other than our Group (if any); and (iii) associate companies of our Company.
Service Provider Participant	Persons providing services to our Group on a continuing basis in its ordinary and usual course of business that are in the interests of the long-term growth of our Group, as determined by the scheme administrator (as defined below), pursuant to the criteria set out in the Post-[**REDACTED**] Share Incentive Plan, and: (a) includes consultants, suppliers and service providers, in the industries of healthcare, biomedicine and health sciences, pharmaceutical services, technology, e-commerce or other business industries in which our Group operates from time to time, that is, or is anticipated to be going forward, a significant business partner or otherwise significant to our business, with reference to, among other metrics, consulting and advisory services and contribution, research and development, technical contribution, manufacturing or sourcing or distribution of products provided by our Group, or financial or business significance, based on qualitative and quantitative performance indicators to be determined by the scheme administrator (as defined below) on a case-by-case basis; but

(b) does not include: (i) placing agents or financial advisors providing advisory services for fundraising, mergers or acquisitions; or (ii) professional service providers such as auditors or valuers who provide assurance or are required to perform their services with impartiality and objectivity.

For Awards over Existing Shares

Eligible Participants who are eligible to receive awards over Existing Shares (as defined below) are any person who the scheme administrator (as defined below) determines eligible to be granted awards over Existing Shares (as defined below) (the "**Non-diluting Participants**"), and which may include, but is not limited to, employee participants, related entity participants and service provider participants.

(iii) Awards and Scheme limits

We may grant share options (the "**Share Options**") and share awards (the "**Share Awards**", together with Share Options, the "**awards**"), which may take the form of (i) Shares to be allotted and issued by our Company and that are already recorded on the register of members of our Company as at the date of this document (the "**New Shares**"); or (ii) Shares that have already been allotted and issued by our Company at an earlier date and are already recorded on the register of members of our Company (the "**Existing Shares**"), or an equivalent value determined at the prevailing market rate, under the Post-[**REDACTED**] Share Incentive Plan.

For Awards over New Shares

Scheme Limits

The Post-[**REDACTED**] Share Incentive Plan shall have the following scheme limits:

Scheme Mandate Limit. . . . . The total number of New Shares which may be issued pursuant to all Awards to be granted under the Post-[**REDACTED**] Share Incentive Plan shall not exceed [**REDACTED**]% of the share capital of our Company immediately after completion of the [**REDACTED**] (assuming the [**REDACTED**] is not exercised and the outstanding share options granted under the Pre-[**REDACTED**] Equity Incentive Plan are not exercised), being [**REDACTED**] Shares (the "**Scheme Mandate Limit**").

Service Provider Sublimit . . The total number of New Shares which may be issued pursuant to Awards to be granted to Service Provider Participants under the Post-[**REDACTED**] Share Incentive Plan shall not exceed [**REDACTED**]% of the Scheme Mandate Limit (the "**Service Provider Sublimit**").

Refreshing Scheme Limits

The above Scheme Limit and Service Provider Limit may be refreshed by Shareholders at general meeting in accordance with Rule 17.03C of Chapter 17 of the Listing Rules.

For Awards over Existing Shares

The award shares underlying awards over Existing Shares that may be granted under the Post-[**REDACTED**] Share Incentive Plan shall not exceed [**REDACTED**]% of the Shares in issue on the [**REDACTED**], *provided that* this percentage shall automatically refresh on January 1 of each year to equal [**REDACTED**]% of the Shares in issue on December 31 of the previous year (the "**Non-diluting Scheme Mandate Limit**"). The Board may adjust the Non-diluting Scheme Mandate Limit at any time and from time to time.

For Awards over New Shares

Individual Grant Limits and Additional Approvals

Each Eligible Participant receiving awards over New Shares shall be subject to an individual grant limit and additional approval requirements, (a) with respect to a Director, chief executive or substantial shareholder of our Company, or their respective associates, as specified in Rule 17.04 of Chapter 17 of the Listing Rules; and (b) with respect to any Eligible Participant, as specified in Rule 17.03D of Chapter 17 of the Listing Rules.

Ranking of Award Shares

Shares issued pursuant to settlement of a share option or share award under the Post-[**REDACTED**] Share Incentive Plan, if settled by New Shares, shall be identical to all other Existing Shares and rank pari passu with all other fully paid Shares in issue on the date the name of the grantee is registered on the register of members of our Company, save that the grantee shall not have any voting rights, or rights to participate in any dividends or distributions (including those arising on a liquidation of our Company) declared or recommended or resolved to be paid to the Shareholders on the register on a date prior to such registration.

(iv) Administration and Implementation by Trust

The Post-[**REDACTED**] Share Incentive Plan shall be administered by our Board, which may establish a committee and appoint person(s) to administer and implement the Post-[**REDACTED**] Share Incentive Plan (collectively, the "**scheme administrator**"). The scheme administrator will be responsible for administering and implementing the Post-[**REDACTED**] Share Incentive Plan, including making grants, determining conditions attachment to awards, acting on behalf of our Company to settle awards. Our Company may establish a trust and appoint a trustee to hold Shares and other trust property under the trust for the purpose of implementing and administering the Post-[**REDACTED**] Share Incentive Plan, and unless otherwise agreed between our Company and the trustee, the trustee shall be instructed by the scheme administrator and the trustee holding unvested shares do not have voting rights with respect to those unvested shares.

(v) Grant and Accept of Awards

Grants of awards shall be determined by the scheme administrator and shall be made to Eligible Participants only. No awards over New Shares shall be made in contravention of the Model Code set out in Appendix C3 to the Listing Rules and where our Company is in possession of inside information and until (and including) one full trading day after the date that such information is announced, including within the one month prior to the earlier of our Board approving any annual, half-year or quarterly results, or the deadline for our Company announcing such results under the Listing Rules.

The scheme administrator shall determine the period within which a grant may be valid for acceptance by the grantee, and the method of and purchase price (if any) payable with acceptance, which shall be set out in the award letter. However, if not otherwise specified in the award letter, a grantee shall have ten business days from the grant date to accept the award. Any awards not accepted by the grantee within the acceptance period (in the manner specified) shall be deemed as declined and automatically lapse.

(vi) Vesting period

The scheme administrator may set a vesting period and specify this in the award letter. However, the vesting period may not be for a period less than 12 months from the grant date, except for awards over New Shares granted to Employee Participants in the following circumstances:

(a) grants of "make whole" awards over New Shares to a new Employee Participant to replace award shares that the Employee Participant forfeited when leaving their previous employers;

(b) grants to an Employee Participant whose employment is terminated due to death or disability or event of force majeure;

(c) grants of awards over New Shares with performance-based vesting conditions in lieu of time-based vesting criteria;

(d) grants of awards over New Shares the timing of which is determined by administrative or compliance requirements not connected with the performance of the relevant Employee Participant, in which case the vesting date may be adjusted to take account of the time from which the award would have been granted if not for such administrative or compliance requirements;

(e) grants of awards over New Shares with a mixed vesting schedule such that the awards vest evenly over a period of 12 months; or

(f) grants of awards over New Shares with a total vesting and holding period of more than 12 months.

The Board (and the Remuneration Committee) believes that it is in the best interests of our Company to retain the flexibility to impose appropriate conditions in light of the particular circumstances of each grant, which would act as a more meaningful reward for the unique Employee Participant in that Employee Participant's unique circumstances. By having the flexibility of having a shorter vesting period than 12 months in appropriate circumstances, the Board (and the Remuneration Committee) considers that our Group will be in a better position to attract and retain suitable Employee Participants to continue serving our Group whilst at the same time providing them with incentives towards achieving the business/financial goals of our Group, and thereby towards achieving, and aligned with achieving, the purpose of the Post-[**REDACTED**] Share Incentive Plan.

(vii) Performance Targets and Other Conditions for Vesting

The scheme administrator may set vesting conditions on awards, which shall be specified in the award letter. These include performance targets, criteria or conditions to be satisfied in order for the relevant award to vest and be settled by our Company, and may be based on, among other criteria, performance appraisals within a specified period, business/financial/transactional/performance milestones, current and anticipated future contribution to our Group and business, minimum service period, upon reaching other specified targets. The Board believes that imposing performance targets and other conditions, on case-by-case basis in the award letters of individual Eligible Participants, not only provides our Company with flexibility to set specific conditions that are relevant to that individual Eligible Participant and in light of the goals that our Company would like that individual Eligible Participant to achieve to benefit our Group, but also provides Eligible Participants with tailored and specific identifiable targets/metrics that they can work towards that would directly tie into and benefit our Group once achieved, which is in line with the purpose of the Post-[**REDACTED**] Share Incentive Plan.

Where awards are granted to Directors or members of the senior management of our Company with a vesting period shorter than 12 months, the views of the Remuneration Committee on why a shorter vesting period is appropriate, and where such awards are without performance targets, the views of the Remuneration Committee on why performance targets are not necessary and how the grants align with the purpose of the Post-[**REDACTED**] Share Incentive Plan, will be included in the announcement to be issued upon any grant of awards as required by the Listing Rules.

(viii) Exercise Price and Issue Price

For Awards over New Shares

The scheme administrator shall determine the exercise price for a share option over New Shares and issue price for a share award over New Shares, which shall be specified in the award agreement, provided that: (i) the exercise price shall be the higher of: (a) closing price of the Shares as stated in the daily quotations sheet issued by the Stock Exchange on the grant date; and (b) the average closing price of the Shares as stated in the daily quotations sheets issued by the Stock Exchange for the five business days immediately preceding the grant date; and (ii) the scheme administrator has absolute discretion to determine the issue price for the exercise of each share award, which may be for nil consideration or such other number specified in the award agreement.

For Awards over Existing Shares

For awards over Existing Shares, whether taking the form of share awards or share options, the issue price or exercise price, as the case may be, for the exercise of such awards shall be such price determined by the scheme administrator in their absolute discretion and notified to the grantee in the award letter. For the avoidance of doubt, the scheme administrator may determine the issue price or the exercise price, as the case may be, to be nil.

(ix) Exercise Period

For Awards over New Shares

The exercise period for a share option and a share award over New Shares shall be determined by the scheme administrator in their absolute discretion and specified in the award agreement. In particular: (i) the exercise period for a share option over New Shares being the period within which the grantee may exercise a vested share option granted to them) shall not be longer than ten (10) years from the grant date; and (ii) the exercise period for a share award over New Shares (being the period within which the grantee may request a vested share award granted to them to be settled and satisfied by or on behalf of our Company) shall be such period determined by the scheme administrator, and for the

avoid of doubt, may be determined by the share administrator to be not applicable (in which case, the underlying award shares shall fall to be settled upon the vesting date without further action by the grantee).

For Awards over Existing Shares

The exercise period for any grant of awards over Existing Shares, whether taking the form of share options or share awards, shall be such period determined by the scheme administrator in their absolute discretion and notified to the Eligible Participant in the award letter. For the avoidance of doubt, the scheme administrator may determine the exercise period of an award to be not applicable and determine that the award shares shall fall to be settled upon the vesting date without further action by the grantee.

(x) Voting and Dividend Rights

Awards do not carry any right to vote at general meetings of our Company, nor any right to dividends, transfer or other rights. No grantee shall enjoy any of the rights of a Shareholder by virtue of being granted an award unless and until the Shares underlying an award are delivered to the grantee pursuant to the vesting and exercise of such award.

(xi) Other Terms and Conditions of Awards over New Shares

Transferability

Awards over New Shares are personal to the grantee and shall not be assignable or transferrable, except where a waiver has been granted by the Stock Exchange with respect to the proposed transfer, and such transfer has been made in compliance with the Listing Rules and with the consent of our Company. Following such transfer, the transferee shall be bound by the plan rules and award letter as if the transferee were the grantee.

Clawback

Where certain events specified in the plan arise, our Board may determine that, with respect to a grantee, awards granted but not yet exercised shall immediately lapse, and with respect to any Shares delivered or amount paid to the grantee, the grantee be required to transfer the same value, whether in Shares and/or cash, back to our Company (or nominee). These circumstances are:

(a) the grantee ceasing to be an Eligible Participant by reason of termination for cause or without notice, or the result of being charged/penalized/convicted of an offence involving the grantee's integrity or honesty;

(b) the grantee commits a serious misconduct or breach, including with respect to a policy or code of or other agreement with our Group, which is considered to be material; or

(c) the award is no longer determined to be appropriate and aligned with the purpose of the Post-[**REDACTED**] Share Incentive Plan.

The Board believes that making grants that are subject to a clawback mechanism allows our Company to retain the flexibility to re-evaluate and re-assess the circumstances of each grantee from time to time after the grant is made in order to determine whether it would still be appropriate to grant awards (or allow the grantee to be entitled to award shares) under the Post-[**REDACTED**] Share Incentive Plan in circumstances that suggest the grant (or entitlement to award shares) would no longer be aligned with the purpose of the Post-[**REDACTED**] Share Incentive Plan or where it may be regarded as inequitable for the awards (or award shares) to be retained by the grantee.

Lapsed and Cancelled Awards

The scheme administrator may cancel an award with the prior consent of the grantee. Award shares over New Shares underlying cancelled awards shall be treated in the manner required under the Listing Rules. In particular, where our Company cancels an award over New Shares granted to a participant and subsequently makes a new grant over New Shares to that same participant, such new grant may only be made under the Post-[**REDACTED**] Share Incentive Plan where there is available Scheme Mandate Limit, and awards cancelled will be regarded as utilised for the purpose of calculating the Scheme Mandate limit (and the Service Provider Sublimit).

Awards shall automatically lapse upon the following events. Lapsed awards shall not be counted for the purpose of calculating the Scheme Mandate limit (and the Service Provider Sublimit).

(a) the award has not been accepted by the grantee (in the manner specified) within the acceptance period;

(b) expiry of the exercise price;

(c) the clawback mechanism being triggered;

(d) following the grantee's death or permanent incapacity, bankruptcy, or where the grantee ceases to be an Eligible Participant or terminates their employment or contractual engagement with our Group for reasons other than as already provided for in the Post-[**REDACTED**] Share Incentive Plan, or where the grantee's employment or contractual engagement has been suspended, or the grantee's position in or with respect to our Group has been vacated, for more than six months;

(e) forfeiture of the award by the grantee; or

(f) the grantee transfers the award in breach of the transferability provisions specified in the plan.

Duration, Amendment and Termination

Subject to any early termination as determined by our Board, the Post-[**REDACTED**] Share Incentive Plan shall have a plan life of ten (10) years from the adoption date.

The scheme administrator may, in their sole discretion, amend the Post-[**REDACTED**] Share Incentive Plan or an award provided that:

(a) the amendments, and the amended plan or award, shall comply with the relevant requirements under Chapter 17 of the Listing Rules;

(b) Shareholders' approval at general meeting is required for the following: (a) any amendment or alteration to the terms of the plan that is of a material nature or any amendment or alteration to those provisions that relate to the matters set out in Rule 17.03 of the Listing Rules to the advantage of Eligible Participants; (b) any change to the authority of the Board or the scheme administrator to alter the terms of the Post-[**REDACTED**] Share Incentive Plan; and

(c) any amendment or alteration to the terms of an award the grant of which was subject to the approval of a particular body shall be subject to approval by that same body, provided that this requirement does not apply where the relevant alteration takes effect automatically under existing terms of the Post-[**REDACTED**] Share Incentive Plan.

No grants may be made after termination of the Post-[**REDACTED**] Share Incentive Plan. Notwithstanding termination of the Post-[**REDACTED**] Share Incentive Plan, the Post-[**REDACTED**] Share Incentive Plan and its rules shall continue to be valid and effective to the extent necessary to give effect to the vesting and exercise of awards granted prior to termination, and the termination shall not affect any subsisting rights already granted to a grantee. For the avoidance of doubt, awards granted during the plan life but that remain unexercised or unexpired prior to the termination shall continue to be valid and exercisable in accordance with the Post-[**REDACTED**] Share Incentive Plan and the relevant award letter.

E. OTHER INFORMATION

1. Estate Duty

Our Directors have been advised that no material liability for estate duty is likely to impose on our Company or any of the subsidiaries of our Company.

2. Litigation

As of the Latest Practicable Date, no member of our Group was involved in any litigation, arbitration, administrative proceedings or claims of material importance, and, so far as we are aware, no litigation, arbitration, administrative proceedings or claims of material importance are pending or threatened against any member of our Group.

3. Joint Sponsors

The Joint Sponsors satisfy the independence criteria applicable to sponsors set out in Rule 3A.07 of the Listing Rules. Each of the Joint Sponsors will receive a fee of US$500,000 to act as a sponsor to our Company in connection with the [**REDACTED**]. The Joint Sponsors have made an [**REDACTED**] on our Company's behalf to the Listing Committee of the Stock Exchange for the granting of the approval for the [**REDACTED**] of, and permission to [**REDACTED**], all the Shares in issue and to be issued as mentioned in this document. All necessary arrangements [have been made] for the Shares to be admitted into [**REDACTED**].

4. Preliminary Expenses

As of the Latest Practicable Date, our Company has not incurred any material preliminary expenses.

5. No Material Adverse Change

Our Directors confirm that there has been no material adverse change in the financial or trading position or prospects of our Group since September 30, 2024 (being the date to which the latest audited historical financial information of our Group were prepared).

6. Promoters

Our Company has no promoter for the purpose of the [**REDACTED**]. 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.

7. Agency Fees or Commissions Received

Save as disclosed in the section headed "[**REDACTED**] — [**REDACTED**] Arrangements and Expenses" in this document, within the two years immediately preceding the date of this document, no commissions, discounts, brokerages or other special terms have been granted in connection with the issue or sale of any share or loan capital of our Company or any of our subsidiaries.Within the two years preceding the date of this document, no commission has been paid or is payable for subscribing or agreeing to subscribe, or procuring or agreeing to procure the subscriptions, for any Shares in our Company.

8. Qualifications and Consents of Experts

The following are the qualifications of the experts who have given opinions or advice which are contained in this document:

Name	Qualification
Morgan Stanley Asia Limited . .	A licensed corporation to conduct Type 1 (dealing in securities), Type 4 (advising on securities), Type 5 (advising on futures contracts), Type 6 (advising on corporate finance) and Type 9 (asset management) regulated activities under the SFO
Jefferies Hong Kong Limited* .	A licensed corporation to conduct Type 1 (dealing in securities), Type 4 (advising on securities) and Type 6 (advising on corporate finance) regulated activities under the SFO
CITIC Securities (Hong Kong) Limited*	a licensed corporation to conduct Type 4 (advising on securities) and Type 6 (advising on corporate finance) regulated activities under the SFO
CM Law Firm	Legal advisors to our Company as to PRC laws
JunHe LLP	Legal advisors to our Company as to PRC intellectual property laws
Jun He Law Offices P.C.	Legal advisors to our Company as to intellectual property laws of the United States
Harney Westwood & Riegels . . .	Legal advisors to our Company as to Cayman Islands laws
PricewaterhouseCoopers	Certified Public Accountants under Professional Accountants Ordinance (Chapter 50 of the Laws of Hong Kong) and Registered Public Interest Entity Auditor under Accounting and Financial Reporting Council Ordinance (Chapter 588 of the Laws of Hong Kong)
Frost & Sullivan (Beijing) Inc., Shanghai Branch Co.	Independent industry consultant

(in no particular order)*

Each of the experts named above has given and has not withdrawn its consent to the issue of this document with the inclusion of its report, letter, summary of valuations, valuation certificates and/or legal opinion (as the case may be) and references to its name included in the form and context in which it respectively appears.

None of the experts named above has any shareholding interests 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 our Company or any of our subsidiaries.

9. Binding Effect

This document shall have the effect, if any application is made pursuant hereto, of rendering all persons concerned bound by all the provisions (other than the penal provisions) of sections 44A and 44B of the Companies (Winding Up and Miscellaneous Provisions) Ordinance so far as applicable.

10. Bilingual Document

The English language and Chinese language versions of this document are being published separately, in reliance upon the exemption provided by section 4 of the Companies Ordinance (Exemption of Companies and Prospectuses from Compliance with Provisions) Notice (Chapter 32L of the Laws of Hong Kong). In case of any discrepancies between the English language version and Chinese language version of this document, the English language version shall prevail.

11. Miscellaneous

(i) Save as disclosed in "History and Corporate Structure" and in connection with the [**REDACTED**] Agreements, within the two years immediately preceding the date of this document:

(a) no share or loan capital of our Company or any of its subsidiaries has been issued nor agreed to be issued fully or partly paid either for cash or for a consideration other than cash;

(b) no commissions, discounts, brokerage fee or other special terms have been granted in connection with the issue or sale of any Share or loan capital of our Company or any of our subsidiaries;

(c) no Share or loan capital of our Company is under option or is agreed conditionally or unconditionally to be put under option; and

(d) no commission has been paid or is payable for subscribing or agreeing to subscribe, or procuring or agreeing to procure the subscriptions of any share in our Company or any of our subsidiaries;

(ii) we have not issued nor agreed to issue any founder shares, management shares or deferred shares;

(iii) there are no arrangements under which future dividends are waived or agreed to be waived;

(iv) there are no procedures for the exercise of any right of pre-emption or transferability of subscription rights;

(v) there have been no interruptions in our business which may have or have had a significant effect on our financial position in the last 12 months;

(vi) there are no restrictions affecting the remittance of profits or repatriation of capital by us into Hong Kong from outside Hong Kong;

(vii) no part of the equity or debt securities of our Company, if any, is currently [**REDACTED**] on or [**REDACTED**] in on any stock exchange or trading system, and no such [**REDACTED**] or permission to [**REDACTED**] on any stock exchange other than the [**REDACTED**] is currently being or agreed to be [**REDACTED**]; and

(viii) our Company has no outstanding convertible debt securities or debentures.

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, among other documents:

(a) the written consents referred to in "Appendix IV — Statutory and General Information — E. Other Information — 8. Qualifications and Consents of Experts;" and

(b) a copy of the material contract referred to in "Appendix IV — Statutory and General Information — B. Further Information about Our Business — 1. Summary of Material Contract."

DOCUMENTS AVAILABLE ON DISPLAY

Copies of the following documents will be available on display on the Stock Exchange's website at **www.hkexnews.hk** and our Company's website at **www.dualitybiologics.com** during a period of 14 days from the date of this document:

(a) the Memorandum of Association and Articles of Association;

(b) the Accountant's Report for the two years ended December 31, 2023 and [2024] from PricewaterhouseCoopers, the text of which is set out in Appendix I to this document;

(c) the audited historical financial information of our Group for the two years ended December 31, 2023 and [2024];

(d) the report on unaudited [**REDACTED**] financial information of our Group from PricewaterhouseCoopers, the text of which is set out in Appendix II to this document;

(e) the legal opinions issued by CM Law Firm, our PRC Legal Advisor in respect of general matters and property interests of our Group in the PRC;

(f) the industry report prepared by Frost & Sullivan, the summary of which is set forth in "Industry Overview;"

(g) the letter of advice prepared by Harney Westwood & Riegels, our legal advisors as to the laws of the Cayman Islands, summarizing certain aspects of the Cayman Companies Act as referred to in Appendix III to this document;

(h) the Cayman Companies Act;

(i) the material contract referred to in "Appendix IV — Statutory and General Information — B. Further Information about Our Business — 1. Summary of Material Contract;"

(j) the written consents referred to in "Appendix IV — Statutory and General Information — E. Other Information — 8. Qualifications and Consents of Experts;"

(k) the service contracts or letters of appointment referred to in "Appendix IV — Statutory and General Information — C. Further Information about Our Directors, Chief Executives and Substantial Shareholders — 2. Particulars of Directors' Service Contracts and Letters of Appointment;"

(l) the terms of the Pre-[**REDACTED**] Equity Incentive Plan; and

(m) the terms of the Post-[**REDACTED**] Share Incentive Plan.

DOCUMENTS AVAILABLE FOR INSPECTION

A copy of the full list of all the grantees under the Pre-[**REDACTED**] Equity Incentive Plan, containing all the details as required under Rule 17.02(1)(b) of and paragraph 27 of Appendix D1A to the Listing Rules and paragraph 10 of Part I of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance, will be available for inspection at the office of Kirkland & Ellis, 26/F, Gloucester Tower, The Landmark, 15 Queen's Road Central, Hong Kong during normal business hours up to and including the date which is 14 days from the date of this document.