

## SUMMARY

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

## OVERVIEW

We are a biopharmaceutical company committed to the discovery, development and commercialization of first-in-class/best-in-class biologics that regulate immune microenvironment by directly modulating both the innate and adaptive immune systems. Leveraging our deep understanding of immunology, we have developed various types of immunotherapies including immunocytokines to treat cancers and autoimmune diseases. We stand out as one of the world’s leading companies in developing immunocytokine products, and are among the few early movers with the most clinically advanced immunocytokine candidates, according to Frost & Sullivan. We aim to develop innovative therapies that overcome disadvantages of currently available treatments, including low response rates and drug resistance, and to bring perceivable benefits and affordable medicine to patients worldwide.

Since our inception in 2018, we have built fully-integrated, end-to-end, in-house R&D capabilities encompassing all the key biological drug development functionalities, including discovery, antibody and protein engineering, process development, preclinical pharmacology studies, clinical development, and good manufacturing practice (“GMP”)-compliant manufacturing. Through our proprietary technology platforms, we have identified and developed a pipeline of nine products, with six of them in clinical stage, among which three are identified as Core Products, i.e. IAP0971, IAE0972 and IAH0968. As a leading company in exploring antibody-cytokine fusion protein based drugs, we implement a global strategy for our immunocytokine products, and have obtained investigational new drug (“IND”) approvals for conducting clinical trials of all three immunocytokines, namely IAP0971, IAE0972 and IBB0979, from regulatory authorities of both China and the U.S. According to Frost & Sullivan, as of the Latest Practicable Date, these three candidates were among the most clinically advanced immunocytokines in treating cancer patients in the world.

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

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

We have received IND approvals for conducting Phase I/II clinical trials for our Core Products IAP0971 and IAE0972 in patients with advanced solid tumors from both the NMPA and the U.S. Food and Drug Administration (“**FDA**”), and completed the Phase I clinical trials in July 2023. Phase I clinical data showed that our core immunocytokine products IAP0971 and IAE0972 were well tolerated and demonstrated encouraging preliminary anti-tumor activities as monotherapy in heavily pretreated patients who have failed chemotherapy, targeted therapy, immunotherapy, and/or their combination.

In addition to immunocytokines, our R&D capabilities also cover development of candidates in forms of monoclonal antibodies (“**mAbs**”), bispecific antibodies (“**bsAbs**”), and fusion proteins, some of which extend indications into treatment areas beyond oncology. Our Core Product IAH0968 is an antibody-dependent cell-mediated cytotoxicity (“**ADCC**”) enhanced mAb targeting human epidermal growth factor receptor 2 (“**HER2**”) with 100% fucose knock out, which greatly enhances the binding affinity of its fragment crystallizable (“**Fc**”) to its receptor FcγRIIIa. Data from preclinical study showed that IAH0968 increased the binding affinity up to 20-fold comparing to trastuzumab or Herceptin, an anti-HER2 antibody without enhanced ADCC activity. The Phase I clinical data demonstrated a 40% objective response rate (“**ORR**”), and an 80% disease control rate (“**DCR**”) using IAH0968 as monotherapy for heavily pretreated metastatic biliary tract carcinoma (“**BTC**”), and colorectal cancer (“**CRC**”) patients who had failed all previous therapies. Currently, we are conducting Phase II clinical trials in patients with inoperable HER2+ advanced or metastatic BTC and HER2+ metastatic CRC as first-line treatments.

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In addition to our Core Products mentioned above, we are developing six other product candidates: clinical stage products IBB0979, IBC0966 and IBD0333, and preclinical stage products IAN0982, ISH0988 and ISH0613.

- IBB0979, another immunocytokine developed by us based on AIC<sup>TM</sup> Platform, received IND approvals from both the FDA and the NMPA for conducting clinical trials for B7H3-high expressing solid tumors. It is a potential first-in-class, anti-B7 homolog 3 protein (“**B7H3**”) antibody-IL-10 homodimer bifunctional fusion protein for immune cell activation. It is designed to bind to B7H3 and trigger blockage of downstream signaling pathways that participate in TME shaping and development, and deliver IL-10 to activate CD8+ T cells in the TME.
- IBC0966 is a clinical stage anti-PD-L1 antibody-signal regulatory protein  $\alpha$  (“**SIRP $\alpha$** ”) bifunctional fusion protein. It is a potential first-in-class PD-L1/SIRP $\alpha$  dual-target therapy that stimulates both innate and adaptive immunity, leading to strong synergistic effects and long-lasting tumor-specific immune responses.
- IBD0333 also received IND approvals from both the FDA and the NMPA. It is a 4-1BB/CD24 bsAb, which simultaneously targets CD24 over expressed tumor cells and activates the stimulatory signal of 4-1BB in CD8+ T cells to induce T cell mediated antitumor immunity at the targeted tumor tissue.
- The remaining candidates, namely IAN0982, ISH0988 and ISH0613, are currently in the IND enabling stage. IAN0982 is being developed for oncology, while ISH0988 and ISH0613 are immunosuppressors focused on autoimmune diseases.

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

We have built our GMP-compliant manufacturing facilities, which enhance quality assurance and control of our products and fulfill clinical and potential commercial demands for our product candidates in a cost efficient way. Our drug substance production facility is currently equipped with four production lines for a total bioreactor capacity of 1,600L. We have completed the installation of a production line for 5,000L bioreactor capacity, which is currently under qualification. Our drug product facility includes one liquid injection filling production line and one lyophilized powder production line, which enables us to prepare

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biological products into various dosage forms according to different needs in both clinical and commercial stages. Leveraging our rich experience and understanding of GMP-compliant manufacturing, as of the Latest Practicable Date, we had successfully completed at least 30 batches with a success rate of 100%.

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

### **Our Business Model**

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

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### Our Pipeline

Our pipeline includes three Core Products: two immunocytokines and one ADCC enhanced mAb. The two immunocytokines, IAP0971 and IAE0972, were developed based on our AIC<sup>TM</sup> platform. The ADCC enhanced mAb, IAH0968, was developed based on our AEA<sup>TM</sup> Platform. The following chart summarizes the development status of our Core Products and other selected product candidates as of the Latest Practicable Date.

	Candidate	MoA	Platform	Indication	Preclinical	IND Enabling	Phase I	Phase II	Phase III	Commercial rights	Upcoming milestone
Cancer Immunotherapy	★ IAP0971	PD-1/IL-15 (Antibody-cytokine fusion protein)	AIC <sup>TM</sup>	Lung cancer, cervical cancer, and HNSCC						Global	Enter Phase II in Q4 2023
				NMIBC							Start Pivotal Trial in Q3 2024
	★ IAE0972	EGFR/IL-10 (Antibody-cytokine fusion protein)	AIC <sup>TM</sup>	EGFR-high expressing solid tumors						Global	Enter Phase II in Q4 2023
	IBB0979	B7H3/IL-10 (Antibody-cytokine fusion protein)	AIC <sup>TM</sup>	B7H3-high expressing solid tumors						Global	Enter Phase II in Q3 2024
	★ IAH0968	HER2 (ADCC enhanced mAb)	AEA <sup>TM</sup>	BTC						Global	Complete Phase II recruitment in Q4 2023
				CRC							Complete Phase II recruitment in Q4 2023
	IBC0966	PD-L1/SIRPα (Bispecific antibody fusion protein)	bsFp platform	Non-Hodgkin Lymphoma and solid tumors						Greater China*	Enter Phase II in Q1 2024
Autoimmune Diseases	IBD0333	4-1BB/CD24 (Bispecific immune modulatory antibody)	bsAb platform	Solid tumors						Global	Complete Phase I in Q4 2024
	IAN0982	Confidential (Multispecific innate effector activator)	AIM <sup>TM</sup>	Solid tumors						Global	IND filing in Q2 2024
	ISH0988	Confidential (Anti-inflammatory and tissue-protective)	AIC <sup>TM</sup>	IBD						Global	IND filing in Q2 2024
	ISH0613	Confidential (Inhibit B cell activation and IPN secretion)	AIC <sup>TM</sup>	SLE						Global	IND filing in Q2 2024

★ Core Product
 NMPA
 FDA
 Preclinical Study

Abbreviations: HNSCC = head and neck squamous cell carcinoma; NMIBC = non-muscle invasive bladder cancer; BTC = biliary tract carcinoma; CRC = colorectal cancer; ADCC = antibody-dependent cell-mediated cytotoxicity; IBD = inflammatory bowel disease; SLE = systemic lupus erythematosus; mAb = monoclonal antibody; bsAb = bispecific antibody; bsFp = bispecific fusion protein; AIC<sup>TM</sup> = Armed ImmunoCytokine Platform; AEA<sup>TM</sup> = ADCC Enhanced Antibody Platform; AIM<sup>TM</sup> = Armed Innate Effector Multispecific Platform.

*Note:*

- \* We acquired exclusive rights from ImmuneOnco Biopharmaceuticals (Shanghai) Inc. to develop, manufacture and commercialize IBC0966 in Greater China including mainland China, Hong Kong, Macau and Taiwan, as well as a single-digit percentage of interests in the overseas rights of IBC0966. For more information, please see “Business — Collaboration Agreement — Collaboration Agreement With ImmuneOnco in Relation to the Development of IBC0966”.

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### OUR PRODUCT CANDIDATES

#### **Core Product IAP0971 – Potential First-in-Class, Anti-PD-1 Antibody-IL-15/IL-15R $\alpha$ Heterodimer Fusion Protein**

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

The selection of IL-15 payload and PD-1 target was based on favorable individual features and the potential for great cis-synergy when combined. IL-15 is deemed a promising candidate for developing immunotherapy that could cure cancers. It can promote activation and proliferation of CD8+ T cells and NK cells, and in the meantime it does not induce regulatory T cell (“**Treg**”)—related immune response suppression that is often observed for IL-2 based cytokine drugs. Also, IL-15 inhibits IL-2-induced T cell death. As such, IL-15 can stimulate CD8+ cells and NK cells for a longer term and induce more rapid and robust immune responses without activating Tregs or inducing apoptosis of activated T cells, which are common side effects of IL-2-based therapies.

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

Structure of IAP0971 is also optimized to improve biological activities, developability and productivities. The cytokine moiety of IAP0971 is designed to adopt a structure of IL-15 combining with its receptor IL-15R $\alpha$  to form a heterodimer that resembles its natural state. On the one hand, the natural high affinity between IL-15 and IL-15R $\alpha$  avoids the formation of IL-15 homodimer and half antibody fragment, and reduces the mismatch of two different heavy chains of the anti-PD-1 antibody, which improves the productivity of IAP0971. On the other hand, the IL-15/IL-15R $\alpha$  complex adopted in IAP0971 is reported to be more active than IL-15 alone in stimulating proliferation and survival of memory phenotype CD8+ T cells. In addition, the spatial structure of IAP0971 is also optimized by embedding the IL-15/IL-15R $\alpha$  heterodimer in the “hinge” region of the anti-PD-1 antibody. This structure can balance the dose of IL-15 cytokine with that of the PD-1 antibody, as well as prevent degradation of IL-15, thereby prolonging the half-life of IL-15. For more details on the competitive advantages of IAP0971, see “Business — Drug Candidates — Core Product: IAP0971 (PD-1/IL-15 antibody-cytokine fusion protein) — Competitive Advantages” in this document.



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Preclinical data showed that IAP0971 was well tolerated up to 1.0 mg/kg when subcutaneously administered in MC38 syngeneic mouse model. In the repeated-dose toxicity study in cynomolgus monkeys, IAP0971 showed a favorable safety profile even at 1.2 mg/kg, around 40-fold higher than an IL-15-Fc fusion protein. Furthermore, in pharmacokinetic analysis, IAP0971 showed a half-life of 15.7 hours, which is approximately 15-fold longer than that of recombinant IL-15, and approximately 2-fold longer than that of an IL-15-Fc fusion protein. In addition, IAP0971 achieved superior tumor inhibition rate (110.47% when treated with 0.5mg/kg of IAP0971 vs. 74% when treated with 0.5mg/kg of anti-PD-1 antibody) and complete tumor regression rate (90% when treated with 0.5mg/kg of IAP0971 vs. 50% when treated with 0.5mg/kg of anti-PD-1 antibody) in our preclinical study.

According to Frost & Sullivan, currently, there is no IL-15-based immunotherapy indicated for the treatment of cancer approved for marketing worldwide. Outside of China, there are eleven products under clinical development. Among these products, IAP0971 and the other six product candidates are IL-15 based immunocytokines. Being in the clinical stage of Phase I/II, IAP0971 is one of the most clinically advanced immunocytokines in the world. In China, there are five products currently under clinical development, with the most clinically advanced products in Phase I/II stage. Only two products including IAP0971 are IL-15 based immunocytokines, and IAP0971 is the most clinically advanced immunocytokine in China.

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

In January 2022 and December 2021, we obtained IND clearance from both the NMPA and the FDA for conducting Phase I/II clinical trials in patients with advanced malignant tumors, respectively. In July 2023, we completed the Phase I clinical trial. As of the Latest Practicable Date, we have not received any concerns or objections from the NMPA related to the commencement of a Phase II clinical trial. We plan to initiate a Phase II clinical trial for IAP0971 in China in the fourth quarter of 2023. For more details on the clinical development plan of IAP0971, see “Business — Drug Candidates — Core Product: IAP0971 (PD-1/IL-15 antibodycytokine fusion protein) — Clinical Development Plan” in this document.

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### **Core Product IAE0972 – Potential First-in-Class, Anti-EGFR Antibody-IL-10 Homodimer Bifunctional Fusion Protein**

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

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

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

*In vivo* data of the preclinical study showed that IAE0972 was well tolerated up to 6 mg/kg in cynomolgus monkeys, which is 300 times the safe dosage of IL-10 cytokine therapy. Also, no obvious EGFR-related skin toxicity, no significant organ changes for liver, thymus, adrenal gland and thyroid gland, as well as no significant changes for levels of IL-2, tumor necrosis factor-alpha (“TNF $\alpha$ ”) and Interferon-gamma (“IFN $\gamma$ ”) were observed in the cynomolgus monkey repeated-dose toxicity studies. Studies showed that IAE0972 had a tumor growth inhibition (“TGI”) rate of 83% in a MC38-hEGFR syngeneic mice model, which rate is significantly higher than that of an anti-EGFR antibody.



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In our Phase I clinical trial, we recruited 14 patients with advanced esophageal squamous cell carcinoma, rectal cancer, gastric cancer, pancreatic cancer, SCLC or NSCLC who progressed from at least one line of treatment. We completed dose escalation for 1 µg/kg, 10 µg/kg, 100 µg/kg, 0.3mg/kg, 1.0mg/kg and 2.5mg/kg of IAE0972, and only observed one Grade 3 adverse events. Preliminary efficacy was observed in multiple heavily pretreated patients who failed all previous therapies. A CRC patient complicated by lung metastasis, who has received multiple lines of prior treatments including standard mFOLFOX6 (5-fluorouracil, leucovorin and oxaliplatin) and CapeOX (capecitabine and oxaliplatin) regimens, achieved SD after given 10µg/kg of IAE0972 for two treatment cycles. Another patient with rectal cancer and lung metastasis and lymph node metastasis, who had experienced recurrence after received two resections, achieved SD after receiving 1.0mg/kg of IAE0972 monotherapy for two cycles.

Currently, there are no approved IL-10 based immunotherapies indicated for the treatment of cancer according to Frost & Sullivan. Outside of China, our IAE0972 and IBB0979 are the only IL-10 based immunocytokines under clinical development for cancer treatment. In China, three IL-10 based immunotherapies are currently under clinical development with two of them from us, i.e. IAE0972 and IBB0979. As of the Latest Practicable Date, our IAE0972 and IBB0979 are in Phase I/II clinical stage, which are the most clinically advanced IL-10 based immunocytokines in China.

We obtained the approval for conducting Phase I/II clinical trials in patients with locally-advanced or metastatic solid tumors from the FDA and the NMPA in December 2021 and January 2022, respectively, and completed the Phase I clinical trial in July 2023. As of the Latest Practicable Date, we have not received any concerns or objections from the NMPA related to the commencement of Phase II clinical trials for IAE0972, and expect to initiate the Phase II clinical trial in the fourth quarter of 2023 in China. For more details on the clinical development plan of IAE0972, see “Business — Drug Candidates — Core Product: IAE0972 (EGFR/IL-10 antibody-cytokine fusion protein) — Clinical Development Plan” in this document.

### **Core Product IAH0968 – Potential Best-in-Class, ADCC Enhanced Anti-HER2 mAb**

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

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We addressed this technical difficulty through constructing a new cell line with mutated FUT8 gene, which encodes an enzyme that catalyzes the transfer of fucose residue from its donor to its target. After genetic manipulation, the new cell line is not able to attach fucose to any protein it produced. In such way, we have successfully generated potentially the first anti-HER2 antibody with 100% removal of fucose from its Fc region, i.e. IAH0968. Such achievement has been verified through glycoprotein detection and glycosylation quantification. For more details on the competitive advantages of IAH0968, see “Business — Drug Candidates — Core Product: IAH0968 (ADCC enhanced anti-HER2 mAb) — Competitive Advantages” in this document.

Produced through our AEA<sup>TM</sup> Platform, IAH0968 showed an affinity between IAH0968 and its Fc receptor five to 20 times higher than unmodified or other ADCC enhanced anti-HER2 antibodies in preclinical studies (especially for the FcγRIIIa, 158F polymorphism). *In vitro* assays demonstrated that IAH0968 mediated stronger ADCC killing toxicity against HER2+ tumor cells SKBR3, BT474 and SKOV2 than trastuzumab. Moreover, IAH0968 showed 100% TGI in a BT474 tumor cell subcutaneous murine model, superior to trastuzumab. In cynomolgus monkeys, IAH0968 showed an excellent safety profile, with no observed adverse effect at a dosage over 100mg/kg.

The Phase I clinical trial showed that IAH0968 was well tolerated and exhibited antitumor activities in patients with advanced HER2+ malignant solid tumors including breast cancers, gastric cancers, CRC and BTC with drug resistance to trastuzumab, pertuzumab, cetuximab, docetaxel, oxaliplatin, capecitabine, irinotecan, nab-paclitaxel and apatinib, or PD1 mAbs. Data showed that only one DLT was found at dosage 10mg/kg, and no MTD was reached. While no head-to-head study was conducted, the Phase I clinical data showed that IAH0968 achieved significantly improved ORR and DCR in heavily pretreated metastatic CRC and BTC patients, when compared to the historical data of current treatments. For heavily pretreated metastatic CRC and BTC patients, the ORR was 40%, and DCR was 80%.

According to Frost & Sullivan, there are three anti-HER2 mAbs in clinical development for cancer treatment outside of China. Among them, the most advanced product is in Phase II/III clinical trial. In China, there are four products in clinical development, with the most advanced ones also in Phase II/III stage. IAH0968 stands out as the most clinically advanced ADCC-enhanced anti-HER2 mAb in China and rest of the world, which is currently in Phase II/III clinical stage.

Based on the encouraging clinical data from the Phase I trial, we obtained IND clearance from the NMPA to proceed with Phase II/III clinical trials of using IAH0968 in combination with chemotherapy for first-line treatment of inoperable HER2+ advanced or metastatic CRC and HER2+ metastatic BTC patients in September 2022. We have dosed the first CRC patient of the Phase II trial in May 2023, and expect to dose the first patient of the Phase II clinical trial for BTC in the third quarter of 2023. For more details on the clinical development plan of IAH0968, see “Business — Drug Candidates — Core Product: IAH0968 (ADCC enhanced anti-HER2 mAb) — Clinical Development Plan” in this document.

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### **IBB0979 – Potential First-in-Class, Anti-B7H3 Antibody-IL-10 Homodimer Bifunctional Fusion Protein**

IBB0979, another immunocytokine developed by us, is a clinical stage, potential first-in-class, anti-B7H3 antibody-IL-10 homodimer bifunctional fusion protein for immune cell activation. It is designed to bind to B7H3 and trigger blockage of downstream signaling pathways that participate in TME shaping and development, and deliver IL-10 to activate CD8+ T cells to fight against tumors. Preclinical study showed that IBB0979 has high affinity to both targets and exhibited potent TGI in C57BL/6J mice bearing MC38-hB7H3 cell line, with TGI of 100% at 0.3mg/kg, 1mg/kg and 3mg/kg respectively. An *in vivo* study in cynomolgus monkeys showed that after intravenously administered with 1 mg/kg, 2 mg/kg and 6 mg/kg of IBB0979 once a week for 29 days (5 times in total, given in days 1, 8, 15, 22 and 29), MTD was not reached up to 6 mg/kg. There was no administration-related mortality, and no donor-related changes observed.

According to Frost & Sullivan, there are currently no approved B7H3-targeted immunotherapies indicated for the treatment of cancer. Outside of China, there are twelve products in various stages of clinical development, with the most advanced candidates undergoing Phase II clinical trials. In China, six products targeting B7H3 are currently under clinical development, with the most advanced product in Phase II. Globally, among all product candidates targeting B7H3, the Company’s product IBB0979 stands out as the only immunocytokine currently undergoing investigation in clinical trials.

We obtained the approval for conducting Phase I/II clinical trials in patients with locally-advanced or metastatic solid tumors from the FDA and the NMPA in October 2022 and November 2022, respectively. The Phase I/II clinical trial is currently on-going, with the first patient dosed in July 2023. Since B7H3 is overexpressed in a wide range of cancers including glioma, thyroid, lung, head and neck, rectal, prostate, breast, skin, renal cell, and ovarian cancers, it has the potential to become a next-generation therapy for resolving T cell exhaustion in cancer patients.

For more details on IBB0979, see “Business — Drug Candidates — Clinical-Stage Product IBB0979 (B7H3/IL-10 antibody-cytokine fusion protein)” in this document.

### **Other Pipeline Products**

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

- **IBC0966:** IBC0966 is a clinical stage, potential first-in-class, anti-PD-L1 antibody-SIRPα bifunctional fusion protein that simultaneously stimulates both innate and adaptive immunity to achieve strong synergistic effects and induce long-lasting tumor-specific immune responses. It is designed to bind to PD-L1 and trigger blockage of the PD-1/PD-L1 signaling pathway to enable T cells to recognize

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## SUMMARY

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and kill targeted cancer cells, and in the meantime deliver SIRP $\alpha$  to the targeted TME to interact with CD47 to block the “don’t eat me” signal of macrophages for tumor cell killing. In March 2021, we obtained the IND approval from the NMPA for conducting clinical trials of IBC0966. As of the Latest Practicable Date, IBC0966 was under Phase I/II clinical trials as a monotherapy for solid tumors. We expect to complete the Phase I clinical trial and enter Phase II clinical trial in the first quarter of 2024. We acquired exclusive rights from ImmuneOnco Biopharmaceuticals (Shanghai) Inc. to develop, manufacture and commercialize IBC0966 in Greater China including mainland China, Hong Kong, Macau, and Taiwan, as well as a single-digit percentage of interests in the overseas rights of IBC0966. For more information, see “Business – Collaboration Agreement – Collaboration Agreement With ImmuneOnco in Relation to the Development of IBC0966” in this document.

- **IBD0333:** IBD0333 is a clinical stage, potential first-in-class, 4-1BB and CD24 bsAb that simultaneously stimulates both innate and adaptive immunity to achieve strong synergistic effects with reduced hepatotoxicity. It is designed to bind to 4-1BB, a robust immune cell activator expressed by CD8+ T cells as well as DC cells, monocytes, B cells, mast cells, NK cells and neutrophils, and CD24, a promising target that plays a key role in tumor evasion in CD24-sialic-acid-binding Ig-like lectin 10 (“**Siglec-10**”) axis and thus is highly expressed in many cancer types. We have obtained IND approvals from the FDA in June 2023 and from the NMPA in July 2023. We plan to initiate a Phase I/II clinical study in the fourth quarter of 2023 in patients with locally advanced/metastatic solid tumors, with the Phase I study to be completed in the fourth quarter of 2024.
- **IAN0982:** IAN0982 is an internally developed innovative multi-specific innate effector activator based on our AIM<sup>TM</sup> platform. We are developing IAN0982 as a monotherapy or in combination with other therapeutics including chemotherapy, immunotherapy, and cell therapy for the treatment of advanced solid tumors. Our IND application for IAN0982 is expected to be submitted to the NMPA and the FDA in the second quarter of 2024.
- **ISH0988:** ISH0988 is an internally developed innovative anti-inflammatory and tissue-protective bifunctional fusion protein based on our AIC<sup>TM</sup> platform. We are developing ISH0988 as a monotherapy for the treatment of inflammatory bowel disease. Our IND application for ISH0988 is expected to be submitted to the NMPA and the FDA in the second quarter of 2024.
- **ISH0613:** ISH0613 is an internally developed innovative bifunctional antibody fusion protein that simultaneously inhibits B cell activation and IFN $\alpha$  secretion based on our AIC<sup>TM</sup> platform. We are developing ISH0613 as a monotherapy for the treatment of systemic lupus erythematosus (“**SLE**”). Our IND application for ISH0613 is expected to be submitted to the NMPA and the FDA in the second quarter of 2024.

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## SUMMARY

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### OUR PLATFORMS

#### AIC™ Platform

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

Our AIC™ Platform successfully addresses technical difficulties for developing immunocytokines. These difficulties range from antibody and cytokine selection and optimization, to final drug production.

- Antibody/cytokine selection. Due to different spatial structure, different types of cytokines behave largely different when fused with antibodies targeting different antigens.
- Structural design. Dose ratio and activity between the selected antibody and cytokine is needed to be balanced to achieve the desired mechanism of actions (“MoA”) and synergistic effects.
- Manufacturing capabilities. It is challenging for developing and manufacturing immunocytokine molecules, because they are structurally complicated, especially considering the degradation vulnerability of cytokines.

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

- MoA-based antibody-cytokine selection is the cornerstone to achieve desired synergistic effects between antibody and cytokine. For example, selection of anti-PD1 antibody and IL-15 cytokine for developing IAP0971 is grounded on their shared action site on the same T/NK cells, leading to great *cis*-synergy. The combination of anti-EGFR antibody and IL-10 is selected based on the potential engager effects it can produce. Specifically, IAE0972 can engage CD8+ T cells through IL-10 while simultaneously targeting tumor cells through the EGFR antibody moiety.

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- Structural design and protein engineering module enables us to structurally design and modify our products to achieve improved safety and efficacy profile while reducing manufacturing cost and enhancing product quality manageability. Structural modifications that we are capable to perform through our AIC™ Platform include antibody and cytokine engineering, deglycosylation, linker/spacer design and optimization, and tertiary structure alteration. Especially, developed through the AIC™ Platform, IAP0971 employs the natural pairing of IL-15/IL-15R $\alpha$ , which leads to more efficient dimerization and eliminates the formation of IL-15 homodimer and half antibody fragments. Additionally, a knobs-into-holes structure is introduced in the Fc region of the anti-PD-1 antibody, reducing the mismatch of two different heavy chains. These structural designs result in improved productivity of IAP0971. Furthermore, IAP0971 is also modified by engineering the IL-15/IL-15R $\alpha$  heterodimers partially embedded into the “hinge” region in the anti-PD-1 antibody. Our drug candidate is the first of this structure to enter into clinical trial, according to Frost & Sullivan. It can increase the stability of cytokine by “hiding” a substantial portion of cytokine within antibody to protect it from hydrolysis by proteases, as well as balance the activity of cytokine versus antibody by introducing steric hindrance to the cytokine, and in the meantime retain the specificity and affinity of cytokine to bind to its receptor and allow it to mediate immune responses.
- Production through customized cell lines is another important function performed by our AIC™ Platform. The cell lines we constructed for producing immunocytokines and other bifunctional fusion proteins are obtained after undergoing multiple rounds of metabolic and growth optimization and are of high expression capacity and excellent purification yield. Coupled with unique cytokine-specific codon optimization, stably expressed vehicles with optimized expression cassettes and our high-throughput screening system, it is able to reach an expression level of 3-5g/L and one-step affinity chromatography purity of 90%, which is at the top level among rivals both at home and abroad, according to Frost & Sullivan.

### AEA™ Platform

Our AEA™ Platform is a genetically manipulated Chinese hamster ovary (“CHO”) cell line with the FUT8 gene knocked-out from its genome to generate antibodies with enhanced ADCC and improved anti-tumor activities. Through this genome modification, the CHO cell line will not be able to catalyze the transfer of fucose residue from its donor to its target, and thus is not able to produce any antibody that carries fucose. Because absence of core fucose on the Fc region has been shown to increase the Fc region’s binding affinity (up to 100 times) to its receptor Fc $\gamma$ RIIIa present on immune effector cells, fucose-negative antibodies are expected to have enhanced ADCC activities through better activating immune effector cells.



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## SUMMARY

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

Feasibility and advantages of AEA<sup>TM</sup> Platform have been demonstrated by IAH0968, the potential first complete fucose-removal anti-HER2-antibody in clinical stage developed through this platform. We have verified through glycoprotein detection and glycosylation quantification that IAH0968 does not contain any fucose. In addition, *in vitro* and *in vivo* tests showed that the affinity between IAH0968 and its Fc receptor was five to 20 times higher than unmodified or other ADCC enhanced anti-HER2 antibodies, resulting in greater enhanced ADCC activity and anti-tumor efficacy.

### AIM<sup>TM</sup> Platform

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

By targeting innate immunity stimulators instead of adaptive immunity stimulators, which is considered more cytotoxic and easily restrained by immune escape of tumors and the immunosuppressive TME, products developed from our AIM<sup>TM</sup> Platform are expected to achieve desired clinical safety and efficacy profiles. Our preclinical product IAN0982 was developed based on the AIM<sup>TM</sup> Platform.

### OUR STRENGTHS

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

- Internally developed pipeline of immunocytokines with first-in-class potentials;
- Differentiated products with first-in-class/best-in-class potentials developed leveraging our deep understanding of immunology and antibody engineering;

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## SUMMARY

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- Proprietary platforms aimed to addressing bottlenecks of current immunotherapies continue fueling the development of innovative and differentiated biological products;
- Fully integrated, end-to-end, in-house drug development capabilities encompassing all key biologic drug development functionalities;
- Seasoned management team of industry veterans with a proven record of success.

## OUR STRATEGIES

We aspire to be a leading global biopharmaceutical company with a focus on antibody and cytokine-based therapeutics. Our mission is to bring perceivable benefits and affordable medicine to patients both in China and globally. We intend to execute the following strategies to achieve our aspiration and mission:

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

## RESEARCH AND DEVELOPMENT

We consistently devote resources to research and development to pave for long-term growth. We believe the diversification and expansion of our product pipeline through both in-house research and development and through external collaboration are critical to our long-term competitiveness and success. Our fully-integrated biological therapeutic platform encompasses all the key biologic drug development functionalities, enabling us to identify and address potential clinical and manufacturing needs early in the development process, so we can direct our efforts towards biologics with best potential. Our platform spans from the early phase of identifying demand, developing core technologies, managing clinical trials, to the manufacturing of products. We believe that our integrated capabilities give us the agility to formulate our innovation, registration, commercialization and product optimization strategies that can navigate us through rapidly changing market needs, enable us to improve pipeline viability and expedite product development cycle at lower cost. See “Business — Research and Development — R&D Platforms” in this document for details.

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## SUMMARY

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

Our research and development expenses amounted to RMB64.0 million and RMB53.2 million and RMB14.6 million in 2021, 2022 and the three months ended March 31, 2023, respectively. During the Track Record Period, our research and development expenses consisted of (i) contract research expenses in relation to the engagement of CROs for preclinical and clinical research services; (ii) staff costs incurred by our research and development personnel; (iii) depreciation and amortization expenses in relation to our research and development machinery and equipment; (iv) material consumed in the course of our research and development activities; (v) application fees for our patent and IND applications, (vi) share-based compensation, and (vii) other research and development expenses.

## COLLABORATION ARRANGEMENT

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

Pursuant to the IBC0966 Agreement, ImmuneOnco transferred to us (i) all of its rights and interests, including but not limited to development, production, regulatory filings and commercialization, in relation to IBC0966 in mainland China, Hong Kong, Macau and Taiwan (the “**Territory**”); (ii) all related patents, if applicable, registered in the Territory; (iii) all technical data and analytical methods relating to the development of IBC0966; and it also granted us a single-digit percentage of interest in the overseas rights of IBC0966. In exchange of our rights, we are obligated to pay RMB20.0 million assignment fee by installments. As of the Latest Practicable Date, the rights and interests of IBC0966 as well as the related documents and materials had been duly transferred to us and we had paid ImmuneOnco an assignment fee of RMB10.0 million. The remaining RMB10.0 million will be payable upon our obtainment of the marketing approval of IBC0966 from the NMPA. In addition, ImmuneOnco is entitled to single-digit percentage royalties based on the annual net sales of IBC0966 in the Territory until the earlier of the tenth year after the initial launch of IBC0966 or the expiration of the patents for IBC0966 molecule sequences. As of the Latest Practicable Date, we did not owe any royalties to ImmuneOnco.

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## SUMMARY

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### RELATIONSHIP WITH CROS AND CONTRACT SERVICE PROVIDERS

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

### INTELLECTUAL PROPERTY RIGHTS

As of the Latest Practicable Date, we owned four issued patents and 102 patent applications, including 49 patent applications in China, one patent application in the U.S., and 52 patent applications under the Patent Cooperation Treaty (“PCT”), relating to certain of our product candidates and technologies. As of the Latest Practicable Date, the material patent and patent applications for our Core Products included (i) one patent and six patent applications in China, one patent application in the U.S., and one patent application under PCT for IAP0971; (ii) five patent applications in China, and one patent application under PCT for IAE0972; and (iii) five patent applications in China, and two patent applications under PCT for IAH0968. In addition, we had five material patent applications under PCT for AIM<sup>TM</sup> Platform, four material patent applications in China for AIC<sup>TM</sup> Platform, and one material patent application in China for AEA<sup>TM</sup> Platform. For further details on our intellectual property rights, see “Business — Intellectual Property” in this document.

### MANUFACTURING

We have established our own global GMP-compliant manufacturing facilities, which meet both clinical and commercial production demands to quantity, quality and dosage form of our product candidates. We currently have four active drug substance production lines up to a total capacity of 1,600L, including three 200L and one 1,000L disposable bioreactors. We have successfully completed over 30 production batches of immunocytokines, mAbs, bsAbs and fusion proteins, which fulfilled the needs for performing preclinical studies, pilot production of antibody drugs and conducting early phase clinical trials. We have completed the installation of a production line for 5,000L bioreactor capacity, which is currently under qualification. When putting into operation, it will enable us to manufacture our drug candidates for Phase III clinical trials and commercialization in-house. Our drug product facility includes one commercial-scale liquid injection filling production line and one commercial scale lyophilized powder production line, which enables us to prepare biological products into various dosage forms according to different needs.

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## SUMMARY

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### SUPPLIERS

During the Track Record Period, our purchases mainly include third-party contract services for preclinical evaluation and clinical trials of our product candidates, premise leases, equipment procurement and others. In 2021, 2022 and the three months ended March 31, 2023, our purchases from our five largest suppliers amounted to RMB56.6 million, RMB17.0 million and RMB7.1 million, respectively, representing 75.4%, 54.1% and 76.1% of our total purchases for the same periods, respectively. In 2021, 2022 and the three months ended March 31, 2023, our purchases from our largest supplier amounted RMB34.4 million, RMB11.1 million and RMB2.7 million, respectively, representing 45.9%, 35.2% and 29.2% of our total purchases for the same periods, respectively.

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

### OUR CONTROLLING SHAREHOLDERS

As of the Latest Practicable Date, Mr. Zhang is able to exercise approximately 85.11% voting rights in our Company through Sunho Fortune, Innovalue Investments, Sunho Wisdom, No5XJR and Sunho Stellar. Immediately upon completion of the Share Subdivision and the [REDACTED] (assuming the [REDACTED] is not exercised), Mr. Zhang will be able to exercise approximately [REDACTED]% voting rights in our Company. Therefore, Mr. Zhang, Sunho Fortune, Innovalue Investments, Sunho Wisdom, No5XJR and Sunho Stellar will be considered as a group of Controlling Shareholders under the Listing Rules.

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

### PRE-[REDACTED] INVESTORS

We received the Pre-[REDACTED] Investments from the Pre-[REDACTED] Investors which are venture capital funds with an investment focus on the biomedicine industry. Efung Capital is our sophisticated investor under Guidance Letter HKEX-GL92-18 issued by the Stock Exchange. Upon completion of the Share Subdivision and the [REDACTED] (assuming the [REDACTED] is not exercised), Efung Capital, through its affiliates, will hold approximately [REDACTED]% of the total issued Shares. For details, see “History, Reorganization and Corporate Structure — Pre-[REDACTED] Investments” in this document.

## SUMMARY

### SUMMARY HISTORICAL FINANCIAL INFORMATION

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

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

	Year Ended December 31,		Three Months Ended March 31,	
	2021	2022	2022	2023
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
			<i>(unaudited)</i>	
Other income	3,224	13,795	11,951	6,027
Other expenses	–	(1,258)	–	–
Other gains and losses, net	150	97	33	(4)
Research and development expenses	(64,033)	(53,171)	(12,007)	(14,561)
Administrative expenses	(5,799)	(5,558)	(1,566)	(2,139)
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Finance costs	(4,174)	(5,074)	(1,187)	(41)
Loss before tax	(70,632)	(51,988)	(2,776)	(15,311)
Income tax expense	–	–	–	–
Loss and total comprehensive expense for the year/period	<u>(70,632)</u>	<u>(51,988)</u>	<u>(2,776)</u>	<u>(15,311)</u>

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



## SUMMARY

### Selected Items of Our Consolidated Statements of Financial Position

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

	As of December 31,		As of
	2021	2022	March 31,
	RMB'000	RMB'000	2023
			RMB'000
Total non-current assets	63,556	56,229	65,353
Total current assets	21,399	14,632	13,542
<b>Total assets</b>	<b>84,955</b>	<b>70,861</b>	<b>78,895</b>
Total current liabilities	58,096	66,154	76,449
<b>Net current liabilities</b>	<b>(36,697)</b>	<b>(51,522)</b>	<b>(62,907)</b>
Total non-current liabilities	158,409	6,206	19,029
<b>Total liabilities</b>	<b>216,505</b>	<b>72,360</b>	<b>95,478</b>
<b>Net liabilities</b>	<b>(131,550)</b>	<b>(1,499)</b>	<b>(16,583)</b>
<b>Capital and reserves</b>			
Share capital	322	322	322
Treasury stock	(29)	(29)	(29)
Reserves	(131,843)	(1,792)	(16,876)
<b>Total deficit</b>	<b>(131,550)</b>	<b>(1,499)</b>	<b>(16,583)</b>

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

## SUMMARY

### Summary Consolidated Statements of Cash Flows

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

	Year Ended December 31,		Three Months Ended March 31,	
	2021	2022	2022	2023
	RMB'000	RMB'000	RMB'000	RMB'000
			<i>(unaudited)</i>	
Cash (used in)/generated from operations before movements in working capital	(52,239)	(36,171)	1,088	(12,854)
Changes in working capital	(413)	1,585	(10,432)	6,465
Net cash flows used in operating activities	(52,652)	(34,586)	(9,344)	(6,389)
Net cash flows used in investing activities	(10,361)	(1,362)	(5,062)	(65)
Net cash flows generated from financing activities	64,980	27,104	8,260	4,808
Net increase (decrease) in cash and cash equivalents	1,967	(8,844)	(6,146)	(1,646)
Cash and cash equivalents at beginning of the year/period	8,698	10,665	10,665	1,821
<b>Cash and cash equivalents at end of the year/period</b>	<b>10,665</b>	<b>1,821</b>	<b>4,519</b>	<b>175</b>

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

Our Directors are of the opinion that, taking into account the financial resources available to our Group, including cash and cash equivalents, the Pre-[REDACTED] Investments and the estimated net [REDACTED] from the [REDACTED], as well as cash burn rate, we have available sufficient working capital to cover at least 125% of the Group’s costs, including general, administrative and operating costs (including any production costs), and research and development costs, for at least the next 12 months from the date of this document.

Our cash burn rate refers to the average monthly amount of net cash used in operating activities, capital expenditures, and other scheduled cash payment. Assuming an average cash burn rate going forward of [REDACTED] the level in 2022, taking into account the Pre-[REDACTED] Investment and scheduled payment of indebtedness, we estimate that our

## SUMMARY

cash at bank and on hand as of March 31, 2023 will be able to maintain our financial viability for [REDACTED], or, if we also take into account the estimated net [REDACTED] (based on the [REDACTED] of HK\$[REDACTED] per Share, being the mid-point of the indicative [REDACTED]), [REDACTED]. Our Directors and our management team will continue to monitor our working capital, cash flows, and our business development progress.

### KEY FINANCIAL RATIO

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

	As of December 31,		As of
	2021	2022	March 31, 2023
Current ratio <sup>(1)</sup>	0.4	0.2	0.2

*Note:*

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

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

### SUMMARY OF MATERIAL RISK FACTORS

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

- Our business and financial prospects depend substantially on the success of our clinical stage and preclinical stage drug candidates. In particular, among our product candidates, IAP0971, IAE0972 and IBB0979 are with first-in-class potential, and IAH0968 is with best-in-class potential. However, if we are unable to successfully complete their clinical development, obtain their regulatory approvals and achieve their commercialization, or if we experience significant delays in doing any of the foregoing, our business will be materially harmed;
- We invest substantial resources in research and development in order to develop, enhance or adapt to new technologies and methodologies, which may not be successful attempts;

## SUMMARY

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- We face intense competition and our competitors may discover, develop or commercialize competing drugs faster or more successfully than we do, which may adversely affect our ability to successfully commercialize our drug candidates;
- If we are unable to obtain and maintain adequate patent and other intellectual property protection for our drug candidates throughout the selected markets in the world, or if the scope of such intellectual property rights obtained is not sufficiently broad, third parties could develop and commercialize drug candidates and technologies similar or identical to ours and compete directly against us, and our ability to successfully develop and commercialize any of our drug candidates or technologies would be materially and adversely affected;
- We have limited experience in manufacturing therapeutic biologic products on a large commercial scale, and our business could be materially and adversely affected if we encounter problems in manufacturing our future drug products;
- If we are unable to build and manage sales network, or maintain sufficient sales and marketing capabilities, either by ourselves or through third parties, we may not be able to successfully create or increase market awareness of our products or sell our products, which will materially affect our ability to generate product sales revenue;
- We have a limited operating history and have incurred net losses since inception. We expect to continue to incur net losses for the foreseeable future and may not be able to generate sufficient revenue to achieve or maintain profitability;
- We may need to obtain additional financing to fund our operations even if we consummate the [REDACTED], and if we fail to obtain such financing, we may be unable to complete the development and commercialization of our primary drug candidates; and
- There has been no prior [REDACTED] market for our Shares and there can be no assurance that an active market would develop, especially taking into account that certain of our existing shareholders may be subject to a lock-up period, and the [REDACTED] and [REDACTED] of our Shares may be volatile.

For more details, see “Risk Factors” in this document.

## SUMMARY

### [REDACTED] STATISTICS

The [REDACTED] consists of:

- the [REDACTED] of initially [REDACTED], for [REDACTED] by the [REDACTED] in Hong Kong, referred to in this document as the [REDACTED]; and
- the [REDACTED] of initially [REDACTED], outside the U.S. (including to professional, institutional and other [REDACTED] within Hong Kong) in off shore transactions in reliance on Regulation S and in the U.S. to QIBs in reliance on Rule144A or another exemption from the registration requirements under the U.S. Securities Act, referred to in this document as the [REDACTED].

	Based on the [REDACTED] of HK\$[REDACTED]	Based on the [REDACTED] of HK\$[REDACTED]
[REDACTED] of our Shares <sup>(1)</sup>	<u>HK\$[REDACTED]</u>	<u>HK\$[REDACTED]</u>
Unaudited pro forma adjusted net tangible assets per Share <sup>(2)</sup>	<u>HK\$[REDACTED]</u>	<u>HK\$[REDACTED]</u>

*Notes:*

- \* All statistics in this table are on the assumption that the [REDACTED] is not exercised.
- (1) The calculation of [REDACTED] is based on [REDACTED] Shares expected to be in issue taking into account of the Share Subdivision and immediately upon completion of the [REDACTED] (assuming the [REDACTED] is not exercised).
- (2) The unaudited pro forma adjusted net tangible assets per Share is calculated after making the adjustments (after taking into consideration of Share Subdivision) referred to in “Financial Information – Unaudited Pro Forma Statement of Adjusted Consolidated Net Tangible Assets” in this document.

### LOSS ESTIMATE FOR THE YEAR [ENDED] DECEMBER 31, 2023

[REDACTED]

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## SUMMARY

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### DIVIDENDS

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

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

### USE OF [REDACTED]

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

- [65.4]%, or approximately HK\$[REDACTED], will be primarily used for the research and development of our Core Products, namely IAP0971, IAE0972 and IAH0968;
- [21.4]%, or approximately HK\$[REDACTED], will be primarily used for the research and development of our other clinical pipeline product candidates, namely IBB0979, IBC0966 and IBD0333;
- [3.2]%, or approximately HK\$[REDACTED], will be used for preclinical and planned clinical trials of our other preclinical pipeline product candidates; and
- [10.0]%, or approximately HK\$[REDACTED], will be used for our general corporate and working capital purposes.

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



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## SUMMARY

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[REDACTED]

[REDACTED] to be borne by us are estimated to be approximately HK\$[REDACTED] (assuming an [REDACTED] of HK\$[REDACTED] per Share, being the mid-point of the indicative [REDACTED] of HK\$[REDACTED] to HK\$[REDACTED] per Share), representing approximately [REDACTED]% of the estimated gross [REDACTED] from the [REDACTED] assuming no Shares are [REDACTED] pursuant to the [REDACTED]. The [REDACTED] consist of (i) [REDACTED] expenses, including [REDACTED] commission, of approximately HK\$[REDACTED] (representing approximately [REDACTED]% of the estimated gross [REDACTED] from the [REDACTED]), and (ii) [REDACTED] expenses of approximately HK\$[REDACTED], comprising (a) fees and expenses of our legal advisors and reporting accountants of approximately HK\$[REDACTED], and (b) other fees and expenses of approximately HK\$[REDACTED]. During the Track Record Period, the [REDACTED] charged to our consolidated statements of profit or loss were RMB[REDACTED] (HK\$[REDACTED]) and the [REDACTED] costs, which was recognized as prepayments and are expected to be deducted from equity upon the [REDACTED], were RMB[REDACTED] (HK\$[REDACTED]). After the Track Record Period, approximately HK\$[REDACTED] is expected to be charged to our consolidated statements of profit or loss, and approximately HK\$[REDACTED] is expected to be accounted for as a deduction from equity upon the [REDACTED]. We do not believe any of the above fees or expenses are material or are unusually high to our Group. The [REDACTED] above are the latest practicable estimate for reference only, and the actual amount may differ from this estimate. Our Directors do not expect such [REDACTED] to have a material adverse impact on our results of operations for the year [ended] December 31, 2023.

## RECENT DEVELOPMENTS AND NO MATERIAL ADVERSE CHANGE

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

1. In May 2023, we obtained the IND approval from the NMPA to conduct Phase I/II trials using IAP0971 monotherapy or in combination with Bacillus Calmette-Guerin (“BCG”) for high-risk non-BCG responsive non-muscle invasive bladder cancer.
2. In May 2023, we dosed the first patient of the Phase II/III clinical trial to evaluate the combination of IAH0968 with CapeOX as first-line therapy in HER2+ advanced CRC.
3. In June 2023, we obtained the IND approval from the FDA for conducting Phase I/II clinical trials of IBD0333 for locally advanced or metastatic solid tumors. In July 2023, we also obtained the IND approval from the NMPA for conducting Phase I/II clinical trials of IBD0333 for locally advanced or metastatic solid tumors.
4. In July 2023, we enrolled the first patient in the Phase I/II clinical trial of IBB0979 for locally advanced or metastatic solid tumors.
5. In July 2023, we completed Phase I clinical trials of IAP0971 and IAE0972 for locally advanced or metastatic solid tumors.

## SUMMARY

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In addition, we completed the Pre-[REDACTED] Investments and raised RMB210 million. For details, see “History, Reorganization and Corporate Structure — Pre-[REDACTED] Investments” in this document.

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

## REGULATORY DEVELOPMENTS ON OVERSEAS LISTING

On February 17, 2023, the CSRC published the new regulations for the filing-based administration for overseas securities offerings and listings by domestic companies, which came into effect on March 31, 2023. The newly released set of regulations consists of Overseas Listing Trial Measures and relevant guidelines. As advised by our PRC Legal Adviser, our proposed [REDACTED] and [REDACTED] falls within the scope of indirect overseas [REDACTED] of PRC domestic companies as provided for in the Overseas Listing Trial Measures, and therefore we will be subject to the filing procedures with the CSRC.